Scientific Report of the European Food Safety Authority on the Assessment of the Geographical BSE-Risk (GBR) of AUSTRALIA.

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 **G**eographical **B**ovine Spongiform Encephalopathy (BSE) **R**isk **(GBR)** were asked by the European Commission (EC) to provide an up-to-date scientific report on the GBR in Australia, i.e. the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, in Australia. This scientific report addresses the GBR of Australia as assessed in 2004 based on data covering the period 1980-2003.

In the case of Australia, an extremely or very unstable system was exposed to a very low or negligible challenge through the import of cattle. Under these conditions, it is highly unlikely that any internal challenge occurred. Given the negligible level of external challenge through meat and bone meal (MBM), it is highly unlikely that any internal challenge occurred.

The risk that BSE-infected cattle entered processing in Australia and were, at least partly, rendered for feed, due to imported cattle from BSE-risk countries has been very low to negligible throughout the considered period. Some imports of cattle in the early 80s from the UK and from the mid-80s onwards from USA, Canada and European countries increased the risk of BSE infectivity entering the feed chain. However, the probability that BSE contaminated material entered processing is seen as being very low.

EFSA concludes that **the current GBR level of Australia is I** *i.e., it is highly unlikely* that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent. As long as the possibility of cross-contamination exists and there are no serious changes in rendering, the system will continue to be very unstable. Thus, the possibility of cattle being (pre-clinically or clinically) infected with the BSE-agent will remain at a low level.

Key words: BSE, geographical risk assessment, GBR, Australia, 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[1] 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 Australia.

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.

[1] 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.

External Challenge

Australia was exposed to a **very low external challenge** for the period 1980-1985, a **negligible external challenge** for the period 1986-1995, a **very low external challenge** for period 1996-2000, and a negligible external challenge for the period 2001-2003.

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. Taking the above-summarised discussion of the most relevant stability factors into account, it is concluded that the BSE/cattle system of the Australia was **extremely unstable** at least until 2001, and slightly improved since then, to **very unstable**.

Feeding

Until October 1997, ruminant Meat and Bone Meal (ruminant-MBM) was legally fed to cattle. Feeding was therefore **"not OK"**. In October 1997, a ruminant MBM-ban was introduced but feeding of non-ruminant mammalian MBM to cattle remained legal as well as feeding of ruminant-MBM to non-ruminant animals (farm animals and pets). This made control of the feed ban very difficult because analytical differentiation between ruminant and non-ruminant MBM is difficult if not impossible. The ban was further strengthened in 1999 and a comprehensive ban on the feeding of vertebrate MBM to ruminants was put in place in 2001. Given that procedures for auditing and enforcing the ban were also in place by that time, it is assumed that the stability of the system in relation to feeding has been "**reasonably OK"** since 2001, i.e., voluntary feeding is unlikely but cross contamination cannot be excluded**.**

Rendering

The rendering industry is operating processes that are not tested with regard to their capacity to reduce BSE-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

- From 1990 to 1997 BSE surveillance remained insufficient, even if a TSE-surveillance program was introduced.
- In 1998, the surveillance system became able to detect BSE to the level set out in the OIE code as a result of the introduction of the NTSESP.

Conclusions

The European Food Safety Authority concludes:

1. In the case of Australia, an extremely or very unstable system was exposed to a very low or negligible challenge through the import of cattle. Under these conditions, it is highly unlikely that any internal challenge occurred. Given the negligible level of

external challenge through MBM, it is highly unlikely that any internal challenge occurred.

2. The risk that BSE-infected cattle entered processing in Australia, and were at least partly rendered for feed, due to imported cattle from BSE-risk countries has been very low to negligible throughout the considered period. Some imports of cattle in the early 80s from the UK and from the mid-80s onwards from USA, Canada and European countries increased the risk of BSE infectivity entering the feed chain. However, the probability that BSE contaminated material entered processing is seen as being very low.

3. The current geographical BSE-risk (GBR) level is I, i.e., it is highly unlikely that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

Expected development of the GBR

As long as the possibility of cross-contamination exists and there are no serious changes in rendering, the system will continue to be very unstable. Thus, the possibility of cattle being (pre-clinically or clinically) infected with the BSE-agent will remain at a low level.

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.
- 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

Members of the EFSA Scientific Expert Working Group on GBR are acknowledged for their valuable contribution to this mandate. The members are: Didier Calavas, Aline De Koeijer, Michael Gravenor, John Griffin, Dagmar Heim, Matthias Kramer, Riitta Maijala, Mo Salman, Vittorio Silano, Emmanuel Vanopdenbosch, and Stig Widell.

Annex

Details of the assessment are presented in the report as prepared by the EFSA GBR Expert Working Group:
http://www.efsa.eu.int/science/efsa_scientific_reports/gbr_assessments/scr_annexes/562_en.html

Australia, Summary of the GBR-Assessment, July 2004						GBR Level : I**
EXTERNAL CHALLENGE		**STABILITY**				**INTERACTION of EXTERNAL CHALLENGE and STABILITY**
1980-1985: Very low 1986-1995: Negligible 1996-2000: Very low 2001-2003: Negligible		1980-2000: Extremely unstable 2001-2003: Very unstable				Any external challenge would have met the extremely unstable or very unstable system and infectivity would have been recycled.
Live Cattle imports	***MBM imports***	***Feeding***	***Rendering***	***SRM-removal***	***BSE surveillance***	
From UK: 204 (CD*) or 194 (other sources of data) From other BSE risk countries: 1044 (CD) or 2.044 (other sources of data). *CD: country dossier	From UK: 21 tons (CD) or 0 ton (other sources of data) From other BSE risk countries: 16 tons (CD) or 2.844 tons (other sources of data)	1980-2000: Not OK. 2001-2003: Reasonably OK Feeding of ruminant MBM to cattle legally possible until October 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.	1980-2000: Mainly passive. 2001-2003: Improving with some active testing	**INTERNAL CHALLENGE** An internal challenge was highly unlikely from 1980 to 2003 **EXPECTED DEVELOPMENT OF THE GBR** As long as the possibility of cross-contamination exists and there are no serious changes in rendering, the system will continue to be very unstable. Thus, the possibility of cattle being (pre-clinically or clinically) infected with the BSE-agent will remain at a low level.

** GBR level I: 'it is highly unlikely' that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

European Food Safety Authority

Scientific Expert Working Group on GBR

Working Group Report on

the Assessment of the Geographical BSE-Risk (GBR) of

AUSTRALIA

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>

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 were the available information was not fully complete.

Sources of data

- Country dossier (CD) consisting of information provided from the country's authorities in 1999, 2001/2002 and 2004.

- 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 1980-2003.

- UK-export data (UK) on "live bovine animals" (1980-1996) and on "Mammalian Flours, Meals and Pellets" (MBM[1]) (1980-1996).

- Available export data BSE-risk countries.

- Food veterinary office (FVO) mission report of November 11 to 23, 1999 relating to the production of fresh bovine meat for export to the European Union.

- Food veterinary office (FVO) mission report of 30 March- 2 April 1998 relating to the fresh meat establishments.

2. EXTERNAL CHALLENGES

2.1 Import of cattle from BSE-Risk[2] 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 Australia. 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 CD, the import of live cattle has been prohibited from the UK and Ireland since 1988 and from all other countries other than New Zealand, New Caledonia, Canada and the USA since 1991. However, consignments of 42

[1] 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".

[2] BSE-Risk countries are all countries already assessed as GBR III or IV or with at least one confirmed domestic BSE case.

buffalo and 24 buffalo from Denmark were recorded in Australia's import statistics for 1995 and 1996, respectively. The Australian authorities stated that the animals imported in 1995 originated in Italy and that the animals imported in 1996 originated in Bulgaria. Imports from New Caledonia were suspended in 1995.

- The CD states that 204 live cattle were imported for breeding purposes from the UK between 1980 and 1988. According to EUROSTAT, however, 194 cattle were imported during the same period.
- A detailed risk assessment was carried out by the Australian authorities on the cattle that were imported from the United Kingdom. Sixty-two of the imported animals were dairy cattle and nine were dual-purpose animals. Details were provided in the CD in relation to the fate of the imported animals. According to the Australian authorities, 127 of these died and were not rendered. Seven animals remain alive. The remaining seventy animals were slaughtered and presumably entered the food and feed chains.
- In addition to cattle imported from the UK, Australia also imported cattle from other BSE risk countries. According to the CD, Australia imported cattle from Canada (31), Denmark (128), France (185), Ireland (1), Japan (24), and the USA (675). Most of these imports occurred between 1988 and 2003.
- The Eurostat figures are reasonably consistent with those of the CD for Denmark, France and Ireland. However, they indicate that cattle were also imported from Austria (33), Cyprus (1), Germany (86), Hungary (35), Netherlands (124) and Switzerland (9) between 1986 and 2002.
- A detailed risk assessment was carried out by Australian authorities on the imports from European countries other than the UK. This assessment indicates lower numbers of imports from European countries than indicated in the Eurostat data, which are currently being cross-checked by the Australian authorities.
- Information from the Austrian authorities indicated that the export of 33 cattle to Australia from Austria did not, in fact, occur; the country of destination was wrongly coded as AU (Australia) rather than UA (Ukraine), the actual destination of the cattle.
- According to the CD, imports from the Netherlands and Hungary did not occur. However, evidence could not be provided.
- The official USA export figures indicate that a total of 1,441 cattle were exported to Australia from the USA during the period 1993 and 2001. However, information subsequently provided by the only pre-USA export quarantine station that was approved during the time period in question indicated that only 493 cattle were exported to the Australia from the USA during that period. According to the Australian authorities, 190 of the animals imported into Australia between 1996 and 2003 were still alive in early 2004. A further 11 of these animals had died but did not enter the rendering system.
- Official export data were not available for Canada. According to the Australian authorities, 16 of the 21 animals imported from Canada between 1996 and 2003 were still alive in early 2004.
- Official export data were not available for Japan. According to the Australian authorities, 22 of the 24 animals imported from Japan in 1988 were still alive in early 2001 and placed in lifetime quarantine and 2 died on farm and did not enter the rendering system.

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																									0
	other																						33			33
Canada	CD															10		3	10		1		7			31
	other																						0			0
Cyprus	CD																									0
	other																							1		1
Denmark	CD										33		29				42	24								128
	other										33		28				42	24								127
France	CD									78		79	28													185
	other								40			120	28													188
Germany	CD																									0
	other								32		49	4					1									86
Hungary	CD																									0
	other																	35								35
Ireland	CD									1																1
	other																									0
Japan	CD									24																24
	other																									0
Netherlands	CD																									0
	other							90					34													124
Switzerland	CD																									0
	other								7		2															9
USA	CD														167	21	113	35	97	83	81	4	12	39	23	675
	other														113	464	75	393	13	119	81	171	12			1441
UK	CD	59	7	61	0	25	5	16	17	14																
	other	16		103		23	5	15	17	15																
ALL TOTALS																										
non UK	CD	0	0	0	0	0	0	0	0	103	33	79	57	0	167	31	155	62	107	83	82	4	19	39	23	1044
	other	0	0	0	0	0	0	90	79	0	84	124	90	0	113	464	118	452	13	119	81	171	45	1	0	2044
UK	CD	59	7	61	0	25	5	16	17	14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	204
	other	16	0	103	0	23	5	15	17	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	194

Table 1: Live cattle imports into Australia (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 Australia. 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 CD, Australia has imported no MBM from any BSE risk country between 1980 to 2001, as the import of MBM from all countries except New Zealand has been prohibited since 1966. The official import records show that 18 tons of MBM material was imported into Australia from the UK in 1988 and 3 tons in 1994 under the customs code 230110. An investigation by the Australian authorities showed that these imports were fishmeal and packaged dog food. The official import records also show that 7 tons of MBM material was imported into Australia from the USA in 1999 and 9 tons in 2001 under the customs code 230110. An investigation by the Australian authorities showed that the figure for 1999 referred to dried bio-flavour and that the figure for 2001 referred to prepared and packaged dog food for market testing.
- According to Eurostat and other data, Australia has imported no MBM from the UK but has imported 1,824 tons of similar material from other BSE risk countries in Europe. Of these, 43 tons were imported from Denmark in 1996 and 1997, 1,615 tons were imported from France between 1983 and 1985, 22 tons were imported from Germany in 2002, 143 tons were imported from Ireland in 1994 and 1 ton was imported from Italy in 1995.
- The official export figures from the USA showed that 857 tons of MBM was exported to Australia between 1996 and 2001. The official export figures from Canada showed that 163 tons of MBM was exported to Australia in 1998.
- According to the CD, the imports of MBM from Denmark did not take place; however, conclusive evidence was not provided.
- The Australian authorities indicated that coding errors were the most likely reason for these discrepancies. This conclusion was supported by information received from the countries of origin. Such coding errors could include misrepresenting Austria (AUT) as Australia (AUS) or misrepresenting fishmeal and pet food flavourings as meat and bone meal. They pointed out that custom code 230110 may also have been mistakenly used instead of custom code 230910; the latter refers to “dog/cat food put up for retail sale”. Another possibility is that the consignments were refused entry into Australia and were therefore diverted to other markets.

MBM 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)
Canada	CD																									0
	other																			163						163
Denmark	CD																									0
	other																	23	20							43
France	CD																									0
	other				15	412	1188																			1615
Germany	CD																									0
	other																							22		22
Ireland	CD																									0
	other															143										143
Italy	CD																									0
	other																1									1
USA	CD																				7		9			16
	other																	13	286	492	55		11			857
UK	CD									18						3										
	other																									
ALL TOTALS																										
non UK	CD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	0	9	0	0	16
	other	0	0	0	15	412	1188	0	0	0	0	0	0	0	0	143	1	36	306	655	55	0	11	22	0	2844
UK	CD	0	0	0	0	0	0	0	0	18	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	21
	other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2: MBM imports into Australia (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

2.3 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 over the period 1980 to 2003, 1,248 live cattle from BSE-risk countries, of which 204 came from the UK according to the CD or 2,238 live cattle from BSE-risk countries, of which 194 came from the UK according to other sources. 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-years periods the resulting external challenge is as given in **table 3**. This assessment takes into account the different aspects discussed above that allow us to assume that certain imported cattle did not enter the domestic BSE/cattle system, i.e. were not rendered into feed. Following a review of the Australian data, it was decided to exclude all animals imported from the UK that were born before June 1976 or were still alive. Imported animals that died on farm were also excluded on the basis of an assurance from the Australian authorities that these animals were placed in lifetime quarantine and, consequently, did not enter the feed chain. A trace back by the Australian authorities showed that some of the animals that were imported from the UK were over 10 years of age at the time of slaughter or death. The Australians considered that the likelihood of these animals contaminating the feed chain with the BSE agent was very low. However, such animals were not excluded from the current assessment because of the fact that many BSE cases have been confirmed in animals over ten years of age in Europe. The Australian risk analysis also took into account the history of the UK farm of origin. Animals from herds of origin in which no cases of BSE were recorded were considered to present no risk. For many of the animals from farms in the UK that did subsequently disclose cases of BSE, the Australian authorities considered that the risk was low because there was a long interval between the data of birth of the imported animals and the date of birth of the cases in the herds of origin. However, such animals were not excluded from the current risk assessment, as per the general procedure of this process, because of the possibility of unreported cases in the herds of origin and the fact that the imported animals could have been the only animals infected with the BSE agent in the herd of origin.

The level of the external challenge as a result of animals imported to Australia from the USA was changed from 1,441 to 493 on the basis of data received from the pre-US export quarantine station. In addition, animals that were still alive or that had been slaughtered but not rendered were removed from the external challenge. Sixteen of the twenty-one animals imported from Canada in 1996 to 2001 were excluded from the external challenge on the basis of information received from the Australian authorities that they were still alive in early 2004. Likewise, the animals imported from Austria in 2001 were excluded from the external challenge on the basis of the explanation from the Austrian authorities that these animals were, in fact, exported to the Ukraine rather than Australia.

MBM imports:

In total the country imported, over the period 1980-2003, 37 tons under the import code 230110 from BSE-risk countries, of which 21 tons came from the UK according to the CD. Other sources, such as EUROSTAT, indicate that the total import of MBM was 2,844 tons none of which came from the UK. 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 us to assume that certain imported MBM did not enter the domestic BSE/cattle system or did not represent an external challenge for other reasons. Following a review of the Australian data, the 22 tons said to have been exported from Germany in 2002 was excluded from the external challenge because the export of processed animal proteins was prohibited from European Union countries from 2001 unless a letter agreement was signed by both countries and the Australians claim (letter dated 21 April 2004) that this was not the case. The 21 tons said to have been exported from the UK in 1988 and 1994 were excluded from the external challenge on the basis of evidence from the Australian authorities that these consignments consisted of fishmeal or dog food. The 143 tons said to have been exported from Ireland in 1994 were excluded from the external challenge on the basis of an assurance from the Irish Chief Veterinary Officer that there was no trade of MBM between Ireland and Australia during the relevant period. All of the imports from Canada, France and the USA were also excluded on the basis of similar assurances from the Chief Veterinary Officer from those countries.

<table>
<tr><th colspan="5">External Challenge experienced by AUSTRALIA</th></tr>
<tr><th colspan="2">External challenge</th><th colspan="3">Reason for this external challenge</th></tr>
<tr><th>Period</th><th>Overall Level</th><th>Cattle imports</th><th>MBM imports</th><th>Comment</th></tr>
<tr><td>1980 to 1985</td><td>Very low</td><td>Very low</td><td>Negligible</td><td></td></tr>
<tr><td>1986 to 1990</td><td rowspan="2">Negligible</td><td rowspan="4">Negligible</td><td rowspan="4">Negligible</td><td rowspan="2"></td></tr>
<tr><td>1991 to 1995</td></tr>
<tr><td>1996 to 2000</td><td>Very low</td><td>The combination of the negligible cattle and negligible MBM imports gave a very low overall challenge</td></tr>
<tr><td>2001 to 2003</td><td>Negligible</td><td></td></tr>
</table>

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** above.

3. STABILITY

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

Feeding

- In the financial year 2000/2001, the domestic production consisted of 516,000 tons of MBM, including 46,000 tons of poultry meal. About 260,000 tons was of bovine/ovine origin.
- Between 1992 and 2001, between 30 and 45% of Australian MBM was exported.

Use of MBM in cattle feed

- The ruminant livestock industry in Australia is based in the main on pasture feeding of animals. Cereal grains and legume and oilseeds are used for supplementary feeding. Historically, MBM has never been a favoured feedingstuff.
- MBM has primarily been used in pigs and poultry rations although prior to the ban on the feeding of ruminant derived meat-and-bone meal to ruminants in 1997 it was used in adult dairy cattle rations and in the beef feedlots.
- The usage of MBM in dairy cattle feed increased between 1988 and 1994. The peak usage was in 1994 at 29,000 tons. After this time there was a sharp decline until the formal ban in 1997. According to the country experts, however, the use of MBM always remained at low levels.

Feed bans

- In May 1996 the Australian livestock industries adopted a voluntary ban on the feeding of ruminant derived meat-and-bone meal to ruminants (RMBM-ban).
- By October 1997, legislation was in place enforcing a compulsory ban on the feeding of ruminant-derived protein to ruminants (RMBM-ban) in all States and Territories.
- By June 1999, amendments to State/Territory statutory law extended the feed ban to MBM from all mammals except horses, pigs and macropods (mainly kangaroos).
- In 2001 the range of vertebrate materials that could not be fed to ruminants in Australia was further extended. The extension covered 'meat-and-bone meals containing only porcine, equine, or macropod materials, blood and blood products, inspected meat products (that have been cooked and offered for human food and further heat processed into animal feed) and poultry (offal and feather) meals and fish meals'. This feed ban is not equivalent to the total feed ban currently in force within the EU which is also aiming to prevent cross contamination.

Potential for cross-contamination and measures taken against

- Cross-contamination is possible at rendering as low-risk material (i.e. non-ruminant material, ruminant material other than specified risk material (SRM)) is rendered together with high-risk material (SRM, fallen-stock).
- Forty-one of the 117 feed mills that were operating in 2003 were mixed mills, i.e. they produced feed for bovines and other farmed animals. The remainder were

dedicated to producing feeds for particular species. In view of the presence of these mixed mills, a potential for cross-contamination of cattle feed with (potentially contaminated) RMBM cannot be excluded.

- Cross-contamination during transport and on-farm is possible. The latter seems to be under control if the (small) sample of farms that were controlled in this respect is representative (see below).

Control of feed bans and cross-contamination

- Australia's Commonwealth Government conducted three countrywide audits in collaboration with State and Territory authorities between 1998 and 2001 to assess the level of compliance with the feed ban. They consisted of visual inspection of premises and completion of questionnaires. Audits were conducted on samples from each sector of the ruminant livestock industry. A statistically based random selection process was employed and was designed to detect a 10% non-compliance rate at the 95% confidence level. The sample included farms (dairy farms, sheep feedlots and beef feedlots), rendering establishments, stockfeed manufacturers and stockfeed resellers.
- Since 2001, comprehensive, risk-based compliance inspection/audit programs have been undertaken by State and Territory authorities that target all sectors of the livestock feed chain. This involves inspection/auditing of all known renderers and stock food manufacturers and a random selection of retailers. Audits are carried out at a frequency of between 12 and 24 months using a risk-based approach. On-farm audits are also carried out at a level that is claimed to detect a 1% level of non-compliance with 95% confidence. The sample size required to achieve this target is 308 farms per 2 years.
- The Australian authorities provided detailed results of audits carried out between 2001 and 2003. These showed a high level of compliance with the ban. Generally this was over 90% for all of the sectors.
- The Australian Government Analytical Laboratories (AGAL) has developed a test capable of detecting low levels of ruminant DNA in animal feeds. The test is based on PCR. According to the Australian authorities, validation studies indicate that ruminant material, including that which has been denatured by heat during rendering processes, can be consistently detected in animal feed at an adulteration level as low as 0.5% weight for weight. Final validation of the test is currently underway. A commercially available test (Neogen ®) for ruminant materials in feeds is also being assessed as a possible screening test.
- A Code of Good Manufacturing Practice for home-mixed feeds, the feed-milling industry and stock–feed premises is in place to prevent cross-contamination risk. The code requires physical cleaning, flushing with feed materials and sequencing. In sequencing, a feed for a non-ruminant species without meat meal as an ingredient is passed through the mill before the preparation of ruminant feeds. According to the Australian authorities, these measures have proven effective with highly sensitive tests failing to detect even very low levels of medications in feeds for non-target species. The European experience indicates that such a procedure does not guarantee absence of cross contamination. Currently the only testing for evidence of cross-contamination of feeds is done for the presence of medication added in certain rations produced on a single line. It is not done specifically for cross-contamination of mammalian protein. However, as described above, a PCR

test is being developed to test for evidence of cross-contamination and has been used on a trial basis.

Rendering

Raw material used for rendering

- Animal by-products, including SRM, fallen stock etc. are used for rendering.
- Between 1999 and 2003, the average number of cattle slaughtered annually was 8,868,000. Of these 7.8 million were over 12 months of age at the time of slaughter. The Australian authorities estimate that approximately 8,000 of these were emergency slaughter animals. Animal welfare considerations prevent the transport of sick cattle to abattoirs in Australia and emergency slaughter cattle are those that suffer misadventure during transport.
- Materials derived from cattle dead at arrival at abattoirs, or condemned at ante mortem inspection, or material condemned at post mortem inspection, may be used for various inedible purposes including rendering or used as pet food, depending on its suitability for these purposes and subject to appropriate controls.

Rendering processes

- In the financial year 2000/2001 there were 114 rendering plants in the country. Forty-three of the plants processed mixed mammalian material including bovine material. A further 19 plants processed material from a number of species including mammalian, fish and poultry. The remaining plants were dedicated to processing material from a particular species; these included 35 plants that were dedicated to bovine material. There are two distinct types of renderers, those associated with abattoirs and those specialising in rendering. The majority of MBM production comes from abattoir-associated renderers, with other renderers contributing about 24% of the total in the early 1990s.
- Detailed information was not provided on the rendering processes in 2000/2001 but it is likely that the processes were similar to those described in the 1999 CD. According to 1999 CD:
  * 60 establishments use batch dry rendering with different condition according to the type of material being processed(i.e. lowest T is 120°C and highest T 145°C for mixed raw material including soft material).
  * 40 establishments operate continuous dry rendering with different conditions according to the type of material being processed (i.e. lowest T is 125°C and highest T 136°C for mixed raw material including soft material).
  * 19 establishments operate continuous different wet rendering systems.
- According to the 2004 CD, there are two plants that can transform ruminant material into MBM under batch conditions at 133°C, 3bar, 20min. These plants are dedicated to processing ovine material.
- Major initiatives have been undertaken in relation to the quality of MBM. These included the implementation of a code of practice and an accreditation scheme developed by the Australian Renderers' Association. A national standard for the production of MBM was also put in place.

SRM and fallen stock

- There is no SRM-ban in place in Australia.

- According to the CD, fallen stock that are dead on farm are claimed to be generally buried or burned on farm. In Victoria, it is permissible to process dead stock in knackeries and render the residue. This happens to a lesser degree in some other States of Australia.

Conclusion on the ability to avoid recycling

The Australian System was and is unable to avoid recycling of the BSE-agent, should it enter the system.

- In the 1980s, and increasingly between 1988 and 1994, MBM was fed to cattle.
- Since 1995 the practice of feeding MBM to ruminants declined.
- In October 1997 a mandatory ruminant to ruminant ban was put in place. The ban was further strengthened in 1999 and the range of vertebrate materials that could not be fed to ruminants in Australia was further extended in 2001. In addition, comprehensive auditing procedures have been put in place; these indicate a high level of compliance with the ban. However, the auditing procedures do not include a validated test for detecting the presence of MBM in feed and there is still considerable potential for cross-contamination.
- The Australian rendering system is not able to inactivate TSE agents.
- SRMs are rendered for feed.

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 Australia in 2002 was approximately 28 million with beef animals accounting for approximately 24 million and dairy animals for the remainder.
- The number of beef cattle increased by 13% between 1988 and 1998.
- In the same period the number of dairy cattle increased by 14%. However, the number of dairy farms has halved over the past two decades, from 22,000 in 1980 to fewer than 11,000 in 2003. Average herd size has increased from 85 cows in 1980 to an estimated 195 in 2002/03.

Age distribution of cattle alive and at slaughter

- Age of beef cattle at slaughter: 14-16.5 months of age (domestic market: less than 40%); 22-24 months of age (Japanese market: 10-15%). The age of the remaining 45 to 50% was not provided.
- The average age of slaughter for dairy cattle is estimated to be approximately 5 years.

Husbandry systems

- Across northern Australia beef cattle are produced on large extensive cattle holdings, grazing native pasture at low stocking rates. In southern Australia, beef cattle are produced on smaller holdings, grazing largely on improved pastures. Cattle are produced in a range of farms, ranging from farms specialised on

extensive large-scale beef or dairy production to mixed farm operations that include sheep and/or cropping with beef or dairy.

- There are some beef feedlots that are intensively managed.
- Dairy cattle:
  - Victoria has some 56% of dairy farms and accounts for 61% of the milk produced followed by New South Wales (15% of farms and 13% of milk production) and Queensland (13% of farms and 10% of production).
  - The dairy operations are for the most part intensively managed, i.e. the dairy cattle receive additional compound feed.
- Poultry operations are mostly located near the population centres.
- Both dairy and hog operations are common in New South Wales.

Cattle identification and monitoring system

- The tail tag system was commenced in the late 1960's. The identification is applied when an animal leaves the premise of origin. If there are subsequent movements the animals are to be re-identified with the new premise ID and records maintained to indicate the movement. This identification system is maintained under State and Territory legislation and State/Territory Agriculture Department maintain and check the database. The system was utilized in the effective eradication of brucellosis and tuberculosis.
- In 1997, a national system of identifying and registering cattle (NLIS) was agreed to by ARMCANZ and the red meat industry. The new system applies radio-tags. It is being progressively implemented.
- The FVO-mission report of November 1999 stated that the "Australian system for animal identification and traceback does not enable the competent authority to determine the origin and movement history of each animal presented for slaughter".

BSE surveillance

- Since 1994 BSE is compulsory notifiable.
- Between January 1990 and December 1997, a total of 3,319 brains were examined for BSE. All were negative.
- In September 1997, a National TSE Surveillance Program (NTSESP) was implemented. One of the components was a monetary incentive for farmers and veterinarians to report cases where there was a suspicion of a TSE on the basis of clinical signs. As no information was available on this issue for the period before 1998, it is assumed that no compensation payment existed prior to this date. Following the introduction of the NTSESP, a total 2,792 brains were examined between 1998 and 2003. 938 (34%) of these were from two or three-year-old animals. The number of cattle brains examined annually has varied from 335 to 547. These figures generally comply with the number recommended by the OIE, i.e. 400 brains in the case of Australia. No evidence of BSE was detected.
- Field veterinarians have been trained in the recognition and diagnosis of animal TSEs. Information has been distributed to State and Federal veterinarians, private practitioners, the cattle and other (related) industries. Videotapes showing the importance of surveillance for BSE as well as the typical clinical signs have been produced and distributed.

- State laboratory personnel have been trained in TSE histopathology. National Veterinary Laboratory staff has also been trained in ancillary tests such as immunohistochemistry, scrapie-associated fibril (SAF) examination, immuno-blotting and mouse inoculation. Currently (it is not clear since when but probably since 1998) tests which supplement histopathology are run on samples that are inconclusive or would be considered positive on histopathology.
- In regards to surveillance at slaughter, approximately 78% of the cattle receive veterinary ante and post mortem inspections. These inspections are undertaken in the plants that slaughter animals for export. The FVO mission report of March/April 1998 indicated significant shortcomings in the visited plants. However, corrective actions were taken which was documented in the FVO mission report of 1999. The animals slaughtered for domestic consumption, of which the vast majority is less than 2 years of age, are inspected by non-veterinarian meat inspectors, which are specifically trained in recognition of cattle diseases. If there is suspicion of disease a veterinarian is brought in to determine the disposition of the animal.
- Cases of cattle displaying evidence of neurological disease at slaughter are identified as suspects and slaughtered at the end of the production line for a more detailed examination. Samples are collected for laboratory analysis. As it is not specified since when, it is assumed that this was introduced in 1998.
- A field trial using the Prionics rapid test was undertaken between 2001 and 2003. Over 2,000 cattle samples were tested from clinically normal animals (407), fallen and emergency slaughter animals (1,321) and from animals selected under the National TSE Surveillance Program (362). All were negative

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 January 2002) is applied.

Feeding

Until October 1997, RMBM was legally fed to cattle. Feeding was therefore **"not OK"** for the period 1980-2000. In October 1997 an RMBM-ban was introduced but feeding of non-ruminant Mammalian MBM to cattle remained legal as well as feeding of RMBM to non-ruminant animals (farm animals and pets). This made control of the feed ban very difficult because analytical differentiation between ruminant and non-ruminant MBM is difficult if not impossible. The ban was further strengthened in 1999 and a comprehensive ban on the feeding of vertebrate MBM to ruminants was put in place in 2001. Given that procedures for auditing and enforcing the ban were also in place by that time, it is assumed that the stability of the system in relation to feeding has been '**reasonably OK'** since 2001, i.e., voluntary feeding is unlikely but cross contamination cannot be excluded**.**

Rendering

The rendering industry is operating processes that are not tested with regard to their capacity to reduce BSE-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

- From 1990 to 1997 BSE surveillance remained insufficient, even if a TSE-surveillance program was introduced.
- In 1998, the surveillance system became able to detect BSE to the level set out in the OIE code as a result of the introduction of the NTSESP.

Stability of the BSE/cattle system in AUSTRALIA over time					
Stability		Reasons			
Period	Level	Feeding	Rendering	SRM removal	BSE surveillance
1980 to 1985	Extremely unstable	Not OK	Not OK	Not OK	Mainly passive
1986 to 1990					
1991 to 1995					
1996 to 2000					
2001 to 2003	Very unstable	Reasonably OK			Improving with some active testing

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).

Taking the above-summarised discussion of the most relevant stability factors into account, it is concluded that the BSE/cattle system of the Australia was extremely unstable at least until 2001, and slightly improved since then, to very unstable (**Table 4**).

Should the BSE agent have entered the feed cycle the probability that it reached domestic cattle is very high. Even today, it is likely that this would happen, given that SRM are rendered, that MBM is produced under inappropriate conditions, and that MBM (incl. RMBM) is legally fed to non-ruminant animals. Cross-contamination, under these circumstances according to European experience, is unavoidable.

4. CONCLUSION ON THE RESULTING RISKS

4.1 Interaction of stability and challenges

In conclusion, the stability of the Australian BSE/cattle system in the past and the external challenges 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.

INTERACTION OF STABILITY AND EXTERNAL CHALLENGE IN AUSTRALIA			
Period	**Stability**	**External Challenge**	**Internal challenge**
1980 to 1985	**Extremely unstable**	Very low	**Highly unlikely**
1986 to 1990		Negligible	
1991 to 1995		Negligible	
1996 to 2000		Very low	
2001 to 2003	**Very unstable**	Negligible	

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 imports 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 large amounts 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, as they are 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 breeding cattle (that are normally imported at 20-24 months of age) that could have been infected prior to import. In the case of Australia, an extremely or very unstable system was exposed to a very low (1980 – 1985) or negligible (1986 – 2003), challenge through the import of cattle. (Note: the combination of the negligible cattle imports and negligible MBM imports gave a very low overall challenge in the period 1996-2000.) Under these conditions, it is highly unlikely that any internal challenge occurred.

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 feedstuffs reached cattle, such imports might not lead to an internal challenge at all. In the case of Australia, given the negligible level of the external challenge through MBM, it is highly unlikely that any internal challenge occurred.

Although the system was extremely unstable in Australia from the early 1980s until 2000 and very unstable thereafter, the occurrence of an internal challenge is considered highly unlikely due to a very low to negligible external challenge.

4.2 Risk that BSE infectivity entered processing

- The risk that BSE-infected cattle entered processing in Australia, and were at least partly rendered for feed, due to imported cattle from BSE-risk countries has been very low to negligible throughout the considered period. Some imports of cattle in the early 80s from the UK and from the mid-80s onwards from USA, Canada and

European countries increased the risk of BSE infectivity entering the feed chain. However, the probability that BSE contaminated material entered processing is seen as being very low.

4.3 Risk that BSE infectivity was recycled and propagated

- If BSE-infected animals would have been processed, the BSE-infectivity would have been recycled and the disease could have been propagated and amplified by the extremely to very unstable system.
- However, during the period when imported cattle could have been slaughtered and processed this risk was very low, given the small number of imported animals that could possibly have had this fate.

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 *I, i.e., it is highly unlikely* that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

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

- As long as the possibility of cross-contamination exists and there are no serious changes in rendering, the system will continue to be very unstable. Thus, the possibility of cattle being (pre-clinically or clinically) infected with the BSE-agent will remain at a low level.

5.3 Recommendations for influencing the future GBR

- Measures that improve the stability of the system, will, over time, reduce the probability that cattle get infected with the BSE-agent. Possible actions include
  - removal of SRM and/or fallen stock from rendering,
  - pressurised rendering processes,
  - significant improvement of the ban on the use of vertebrate MBM in cattle feed, supported by regular sampling of feed for the occurrence of such MBM.
  - Improved 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 the monitoring of the efficiency of the 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).
- SSC, January 2002. Updated opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).

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