Final report on the updated assessment of the Geographical BSE-Risk (GBR) of URUGUAY- 2003

10 April 2003

NOTE TO THE READER

Independent experts 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 SSC on "the Geographical Risk of Bovine Spongiform Encephalopathy (GBR)", 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>

This report, and the opinion of the SSC based on it, is now serving as the risk assessment required by the TSE-Regulation EU/999/2001 for the categorisation of countries with regard to their BSE-status. The final BSE-status categorisation depends also on other conditions as stipulated in annex II to that TSE-Regulation.

1. Data

- The available information was sufficient to carry out the qualitative assessment of the GBR.

Sources of data

- Country dossier (CD) consisting of information provided by the country's authorities between 1998 and 2002.

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 2001.
- UK-export data (UK) on "live bovine animals" (1980-1996) and on "Mammalian Flours, Meals and Pellets", 1988-1996. As it was illegal to export mammalian meat meal, bone meal and MBM from UK since 27/03/1996, exports indicated after that date under customs code 230110 should only have included non-mammalian MBM.
- Export data from Cyprus, the Czech Republic, Estonia, Hungary, Lithuania, Romania, Slovenia and Switzerland.

2. EXTERNAL CHALLENGES

2.1 Import of cattle from BSE-Risk[1] countries

- According to the CD, Uruguay imported 9 cattle from the UK (7 in 1980, 2 in 1988). All were pedigree Hereford cattle. They all died and were destroyed on the farm, none of them was sent for slaughter. The four farms of destination of the animals were inspected several times by staff from the Division of Animal Health. Clinical symptoms that could rise suspicion for BSE were never observed in these farms.
- According to Eurostat and other data, 10 cattle were imported from the UK (3 in 1980, 5 in 1981 and 2 in 1989). According to the CD, one of the animals imported in 1980 died during the quarantine, therefore it was not officially registered.
- According to Eurostat and other data 272 cattle were imported from France (271 in 1988 and one in 1994). However, after consultation of French export statistics and contacts with the French authorities, it was confirmed that these data are not correct and no imports have taken place.
- Also the Uruguay veterinary services have not found any reference to these imports in their statistics (two sources checked: Uruguayan Rural Society (ARY) and the Animal Health Division DSA).

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

2.2 Import of MBM[2] or MBM-containing feedstuffs from BSE-Risk countries

- According to the CD and to Eurostat and other data, no imports/exports of MBM or MBM-containing feedstuffs neither from UK or any other BSE risk country have occurred in the reference period.

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 2001, 10 live cattle (Eurostat and other data) all from the UK. Broken down to 5-years periods the resulting external challenge is as given in table 1.

- MBM imports:

The country imported over the period 1980-2001 no MBM (Eurostat and other data and CD) from BSE-risk countries.

External Challenge experienced by URUGUAY				
External challenge		*Reason for this external challenge*		
Period	**Overall Level**	**Cattle imports**	**MBM imports**	**Comment**
1980 – 1985	**Negligible**	**Negligible**	**Negligible**	
1986 – 1990				
1991 – 1995				
1996 – 2000				

Table 1: 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 the table above.

[2] 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".

3. STABILITY

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

Feeding

- The general husbandry system for Uruguay cattle is utilising the extensive pasture.
- In 2002, a total of 148 feed mills were registered in Uruguay. Of those, 59 were producing feed for more than one species, 39 produced poultry feed only, 22 ruminant feed only, 15 petfood only, 7 pig feed only and 6 produced other feed.
- 90% of the industrial poultry production and 60% of the swine production are vertically integrated.
- According to the CD, 85 % of the supplementary feed produced for the dairy industry is produced by a single co-operative, which is not producing non-ruminant feed. As protein sources wheat by-products, cotton seed, sunflower meal, soy meal, gluten meal, gluten feed and other products of plant origin are used.

Use of MBM in cattle feed

- According to the CD for dairy cattle an average of 193g of concentrate per kg of milk produced were used in 1997.
- It is argued that for dairy cattle, production costs must be kept low in order to compete and that in no case high production is a goal and that the necessary protein content for dairy rations can be easily achieved using pasture and plant origin concentrates.
- Concerning the protein containing commodities, prices per ton were provided and these showed that MBM was significantly more expensive than sunflower or wheat bran proteins since 1984 (Table 2). However, if protein content is taken into account, the MBM commodity might have been competitive with vegetal protein sources.
- In view of the explained need for protein, it can be assumed that there is no real need to feed MBM to cattle.

Year	MBM (1) 45/50	SM 37/42	Relation MBM/SM	WB 12/14	Relation MBM/WB
1984	253,8	155,6	1,63	74,1	3,43
1985	126,9	87,8	1,45	58,2	2,18
1990	191,2	117,4	1,63	65,2	2,93
1995	244,1	104,6	2,33	91,9	2,66
1996	280,0	148,8	1,88	120,0	2,33
1997	281,0	144,2	1,95	93,7	3,00
1998	257,2	114,7	2,24	69,8	3,68
1999	252,1	97,6	2,58	73,9	3,41
2000	265,7	115,0	2,31	102,5	2,59
Average	***230,8***	***125,1***	***1,88***	***82,2***	***2,85***

Note: Data not available before 1984
(1) Percentage of protein
FROM: C. M. P. P.

Table 2: Prices of meat and bone meal (MBM), sunflower meal (SM) and wheat bran (WB) in June of each year (USD/Ton).

Feed bans

- Since April 1996 feeding of MMBM to ruminants is prohibited in Uruguay (Decree 139/996). Mineral concentrates derived from calcinated bones are allowed.
- Already before the ban, according to the CD, the use of protein concentrates for ruminants was exceptional. Beef and dairy cattle feed is only supplemented by hay, silage or straw treated with non-protein nitrogen sources or protein supplements of plant origin. The CD states: "The fattening in feedlots is minimum, approximately 30,000 steers per year. Preserved roughage and concentrates made with grains is used when the economic equation so enables."

Potential for cross-contamination and measures taken against

- According to the CD, the feed mills processing feeds for different species do not have separate lines. To avoid cross contamination thorough cleaning between lots is performed, using grain, which is passed through several times (flushing). This grain is separated, individualised and used as feed for non-ruminants.
- According to the CD, cross-contamination during transportation is very unlikely since only poultry feeds are transported in bulk, feed for all other species is transported in bags.
- The legal regulations in force establish obligatory labelling of all animal feeds, specifying the animal species of destination.

Control of Feed bans and cross-contamination

- According to the CD, feed controls and inspections are carried out by the General Direction of Agricultural Services (DGSA) both on domestic production and on imported goods.
- From 1996 until 1999, controls were put in place to enforce the feed ban. The controls comprise documentary checks at the feed mills and sampling and analysing of feed for the presence/absence of MBM in feed. The control programme was suspended in the end of 1999, because the analytical methods used were found not to be reliable.
- Analytical methods used are microscopy techniques and an Elisa method. No details are provided on the sensitivity and specificity of the tests used. It is not clear whether the Elisa test used performs well if MBM included in samples tested was heat treated according to the $133°C/3^{bar}/20^{min}$ standard.
- The control over imported products is 100% upon entrance and domestic products were sampled as well. The sampling scheme was provided, which establishes how many samples have to be taken in relation to the lot to be checked. Results of controls are shown in Table 3. However, it is not clear which analytical method was used for the different samples.
- When the presence of MBM is confirmed, the feed mill or the importer must either destroy the products or re-export it. The percentage of positive samples was very low since the beginning and positives were only detected in imported material. The affected lots were either destroyed or re-exported. No positive samples were found in domestically produced feedstuffs.

	1996		1997		1998		1999	
	domestic production	imports	domestic production	imports	domestic production	imports	Domestic production	imports
Samples analysed	374	1,443	467	1,762	465	2,281	403	2,414
Positive	0	14	0	2	0	0	0	0

Table 3: Number of samples analysed and results.

- Since only a small part of the cattle population is fed with supplementary feed, cross-contaminated feed would only reach this small part. Because controls were in place until 1999 and cross-contamination during transport is almost excluded, cross-contamination can be regarded as limited, but can still occur in the multi-species feed mills.

Rendering

- According to the CD, raw material for rendering consists of bones, fat trimmings and cuts derived from slaughter lines and de-boning activities, derived only from animals approved for human consumption.
- All raw material is species specific, i.e. not consisting of different species as different species are never slaughtered at the same time.
- Rendering plants are either attached to slaughterhouses or are stand alone plants.
- The raw material is first ground to a maximum size of 1 cm and then subjected to a thermal process. The pressure of the steam injected into the jacket is 6-7 kg/cm^2, equivalent to a temperature of 165-170°C. Depending on the gradient, the batch is cooked at temperatures of 135-140°C for 2 to 3 hours. Since the rendering process occurs under atmospheric pressure, it is regarded to be not equivalent with the $133°C/20^{min}/3^{bar}$ standard. Temperature records are not available in the country.
- The domestic yearly MBM production (40,000 tons per year) is intended either for export to mainly Brazil and Japan, or domestically used as protein concentrates for swine, poultry and petfood.
- Fallen bovines which died on pasture are destroyed (burned or buried) on the spot.
- Bovines which died in the holding pens of the slaughterhouses and condemned material are sterilised (133°C, 2 hours) using steam with a pressure of 2 kg/cm^2 in a sanitary tank (digester). The final product is used as fertiliser.

SRM and fallen stock

- A SRM-ban does not exist.
- Brain and spinal cord derived from animals declared fit for human consumption are processed and destined for human consumption, both for the domestic market and for export. SRM from condemned animals are sterilised in the digester.
- Fallen stock, which died on farm/pasture is not rendered.

Conclusion on the ability to avoid recycling

In light of the above-discussed information it has to be assumed that the BSE agent, should it have entered the Uruguay territory could have been recycled and amplified.

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

		Average number of cattle ≥ 2 years (*1000)						
	Total (all ages) (*1000)	male		female			Total stock ≥ 2 years	% of total stock
Period		meat	reproduction	meat	dairy	reproduction		
1980-84	10,519	1,788	175	896	368	3,489	6,641	63.1
1985-89	9,678	1,587	151	791	382	3,061	5,972	61.7
1990-94	9,618	1,627	139	704	397	3,212	5,999	62.4
1995-99	10,457	1,607	148	546	428	3,686	6,415	61.3

Table 4: Key data on the bovine cattle population.

- Data were provided for cattle, sheep and goats with breakdown for the first one in age-groups, sex and purpose (beef or dairy). Data are available since 1980 and lie in the range of about 10.000 million cattle in total of which about 3.4 million are breeding cows, 0.7 fattening cows and 2.1 million steers and heifers over 2 years of age; 0.4 million are dairy cattle over 2 years; 6.257 million cattle are older than two years.
- Bulls are slaughtered at an average age of 5 years or more. For cows, the average age at slaughter is at least 6 years and for dairy cows at least 7 years. This implies that the animals could reach the age of showing symptoms of BSE. The average age at slaughter of steers is below 4 years.
- Co-farming is normally not performed on large farms, but it can occur on smaller farms, intended for local production. If so, pigs are usually raised in paddocks, mainly grazing and eating bovine or ovine offal, from animals slaughtered on the farm. Pigs are given grain supplements for final fattening and sometimes kitchen leftovers. Poultry is usually kept in independent paddocks and are fed mainly kitchen leftovers and grain.
- According to this information, it can be concluded that accidental feeding of bovines with animal protein supplemented feed on farms where co-farming exists, cannot be excluded, albeit deliberate cross-feeding seems to be unlikely.

BSE surveillance

- Compensation is covering the full market value of sacrificed animals as described in Law 16.082 dated 18 October 1989.
- Notification of BSE became compulsory in 1994.
- According to the CD, since December 2001 immuno-histochemistry has been included in laboratory methods.

Passive surveillance

- According to the CD, in 1992 a "programme for the Active Epidemiological Surveillance so as to assist all those cases with a central nervous problem was established." In this, a sampling protocol and basic elements of biological security were approved. However, as no further information was present in the dossier, it is assumed that it concerns general guidance whenever any central nervous problem occurs. No description is given for a BSE-suspect, but a resolution of the General Direction of Livestock Services on a surveillance system of TSE (dated 15/01/1996) specifies that all animals with nervous symptoms or locomotion disorders of central origin have to be reported as these will be systematically examined for BSE.
- Since 1994, a passive surveillance system has been installed and cattle brains have been examined for BSE, without any lesions compatible with TSE being observed (Table 5).
- Moreover, in 1995 a retrospective survey of brains of cattle with pathologies of the CNS was carried out going back until 1972 (Table 5). Of a total of 433 cattle brains examined none showed lesions compatible with BSE. Data are provided in the CD for 1988 (37 animals examined) as an example and they show that animals of all ages were included in this study, although most of them are more than 2 years old. Samples are examined according to the provisions of the Manual of Standards for Diagnosis tests and vaccines of the OIE.
- Since January 1996 an official system of TSE Surveillance was developed, according to the resolution adopted by the general meeting of the OIE. In this, instructions and forms were established for the different participants.

Active surveillance

- For 1998 an active surveillance with random sampling of at least 5-year old bovines was programmed. Samples were taken at slaughterhouses inspected by the Animal Industry Division. Cattle were selected which showed one of the following: traumatic problems, changes in behaviour, cachexia, confiscation of heads due to tumoral or infectious problems, animals dead during transportation to the slaughtering plants, animals fallen in ante mortem observation yards and all animals older than 8 years with or without clinical symptoms. Results are given in Table 5. Additionally also other animal species are examined in this surveillance programme.
- The following differential diagnoses were most common: bacterial encephalitis, hepato-encephalopathies due to poisoning, poly-encephalomacia, babesiosis, metabolic disorders, traumatisms and tumoral and parasitic pathologies.

Examination of cattle brains for BSE in Uruguay								
Year	**N° of cattle brains examined for BSE**	**Results**	**Year**	**N° of cattle brains examined for BSE**	**Results**	**Year**	**N° of cattle brains examined for BSE**	**Results**
1972	**15**	Negative	**1983**	**35**	Negative	**1994**	**6***	Negative
1973	**9**	Negative	**1984**	**47**	Negative	**1995**	**17***	Negative
1974	**4**	Negative	**1985**	**34**	Negative	**1996**	**6***	Negative
1975	**5**	Negative	**1986**	**25**	Negative	**1997**	**24***	Negative
1976	**15**	Negative	**1987**	**37**	Negative	**1998**	**33* +499#**	Negative
1977	**12**	Negative	**1988**	**37**	Negative	**1999**	**58* + 263#**	Negative
1978	**7**	Negative	**1989**	**25**	Negative	**2000**	**8*+90#**	Negative
1979	**18**	Negative	**1990**	**22**	Negative	**2001**	**6*+55#**	Negative
1980	**19**	Negative	**1991**	**12**	Negative	**2002**	**7*+375#**	Negative
1981	**9**	Negative	**1992**	**14**	Negative			
1982	**5**	Negative	**1993**	**27**	Negative			

Table 5: Examination of cattle brains for BSE in Uruguay. 1972-1993: Retrospective examination of CNS-cattle brains, carried out in 1995. 1994-1999: Brains from cattle notified as CNS-suspects*. 1998-2002: Brains from cattle notified as CNS-suspects* plus cattle >5 years sampled at slaughter ("active surveillance")#

- The number of bovine brains to be examined according to the OIE would be 300 to 336 annually based on the stock analysis. This number was not reached until 1998.

- According to the CD, the reduction in the number of brains processed during 2000 and 2001 was caused by the restrictions in slaughter activities, due to a FMD outbreak.

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 is applied.

Feeding

Feeding of MMBM to cattle was legally possible until 1996, even if apparently uncommon before that date. Therefore feeding is assessed **"not OK"** from 1980 until 1995. Since 1996 a mammalian MBM to ruminant feed ban is in force and a control program was installed, which was applied until the end of 1999. Due to the fact that the authorities themselves do not consider the analytical methods used to have been reliable for the monitoring of the feed ban, feeding is assessed as **"reasonably OK"** since 1996 until today.

Rendering

The rendering systems do not appear to meet the 133°C/20^{min}/3^{bar} standard. Therefore is assumed to be **"not OK"** throughout the reference period.

SRM-removal

As SRM from cattle fit for human consumption are eaten, this factor can be considered to be **"reasonably OK"**. SRM from condemned or fallen stock is digested and buried or sent to a landfill and it is unlikely that it could reach cattle.

BSE surveillance

Regarding the surveillance system, Uruguay would probably not be able to detect small numbers of clinical BSE-cases.

Stability of the BSE/cattle system in URUGUAY over time					
Stability		Reasons			
Period	Level	Feeding	Rendering	SRM removal	BSE surveillance
1980 - 1995	Very unstable	not OK	Not OK	reasonably OK	↓
1996 - 2000	Unstable	reasonably OK			
2001 -					

Table 6: 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 amended in 2002.

On the basis of the available information it has to be concluded that the country's BSE/cattle system was very unstable from 1980 until 1995 and is unstable since 1996.

4. CONCLUSION ON THE RESULTING RISKS

4.1 Interaction of stability and challenges

In conclusion, the stability of the Uruguay BSE/cattle system in the past and the external challenges the system has coped with are summarised in the table 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 that had to be met by the system, in addition to the external challenges that occurred.

INTERACTION OF STABILITY AND EXTERNAL CHALLENGE IN URUGUAY			
Period	Stability	External Challenge	Internal challenge
1980 - 1995	Very unstable	Negligible	Highly unlikely
1996 – 2000	Unstable		

Table 7: 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.

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

Given the small number of animals imported, in the case of Uruguay this implies that a very unstable or an unstable system was exposed to a negligible challenge.

Given the negligible level of the external challenge, it is very unlikely that an internal challenge occurred.

4.2 Risk that BSE infectivity entered processing

- Given the negligible risk that BSE-infectivity has been imported into Uruguay, the processing risk was always negligible.

4.3 Risk that BSE infectivity was recycled and propagated

- Given the negligible risk that BSE-infectivity entered the country there was no risk that BSE-infectivity was recycled or propagated.

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 external challenge remains negligible, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent will remain very low.
- Due to the current unstable system, any external challenge could lead to an increasing GBR.

5.3 Recommendations for influencing the future GBR

- In order to ensure that the GBR remains as low as at present it is recommended that, in addition to minimising the external challenge, additional efforts are made to enhance the stability of the system.