Final report on the updated assessment of the Geographical BSE-Risk (GBR) of BRAZIL - 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 information available was suitable to carry out a qualitative assessment of the GBR. Nevertheless, this report is based on reasonable worst case assumptions, in cases where data are not complete.

Sources of data

• Country dossier (CD) consisting of information provided from the country's authorities in 2000-2003

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 1980-2001.
- 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.
- FVO Report of Mission carried out in Brazil (10-19 April 2002) in order to evaluate measures concerning BSE.

2. EXTERNAL CHALLENGES

2.1 Import of cattle from BSE-Risk¹ countries

Table 1 provides an overview of the data on live cattle imports, as provided in the country dossier (CD) and the corresponding data on relevant exports as available from BSE risk countries (Eurostat and other data) that exported to Brazil. Only data from risk periods are indicated, i.e. those periods when exports from a BSE risk country already represented, according to the SSC opinion on the GBR method of January 2002, an external challenge.

- According to the CD, Brazil imported 254 live bovine animals from the UK in the period 1980-2000.
- According to Eurostat and other data 486 live bovine animals were exported from the UK to Brazil in the same period.

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

Report on the updated assessment of the Geographical BSE-risk of Brazil April 2003

		Live impo		cattle																				
Country:	Data	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	00	01	Total
Austria	CD					2		10			11			4		153	345							525
	Other																21							21
Belgium	CD															14								14
	Other															14								14
Denmark	CD															36	20							56
	Other															116								116
France	CD	85		9	25	5	5	13	1			10	14	1	188			29						1108
	Other	14		199	75	4	55	4	10			65			256		143	16						1258
Germany	CD	14			4						1	9	334	93	924		968	3						4464
	Other											12	280	132	1086	2130	760							4400
Hungary	CD																70							70
	Other																84							84
Italy	CD	102									8	27	9					23						169
	Other										8	26	9					36						79
Luxembourg	CD															10								10
	Other																							0
Netherlands	CD	22									27							8						57 15
	Other		_				_					5							10					15
Switzerland	CD	18	8	2			1				8					34	7	5						83
	Other	17	19				7									18	4	6						71
UK	CD	23	28	2	17			5			119	60												254
	Other	27	12	195				40	33		119	60												486
ALL TOTALS																								
non UK	CD	241	8	11	29	7	6	23	1	0		46	357	98	1112		1647	68	0	v	0	0	0	
	Other	31	19	199	75	4	62	4	10			108	289	132	1342	2695	1012	58	10	0	0	0	0	6058
UK	CD	23	28	2	17	0	0	5	0	Ů		60	0	0	0		0	0	0	0	0	0	0	254
	Other	27	12	195	0	0	0	40	33	0	119	60	0	0	0	0	0	0	0	0	0	0	0	486

<u>Table 1</u>: Live cattle imports into Brazil (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 (grey shaded) are taken into account for assessing the external challenge. Risk periods are defined according to the SSC opinion of 2000 as amended in 2002.

- According to the CD, Brazil imported 6,556 live bovine animals from non-UK BSE risk countries in the period 1980-2000, mainly from Germany (4,464), France (1,108) and Austria (525), but also from Italy (169), Switzerland (83), Hungary (70), the Netherlands (57), Denmark (56), Belgium (14) and Luxembourg (10).
- Eurostat and other data have registered also 6,058 live cattle exported from non-UK BSE-risk countries.

The import data provided by Brazil are largely compatible with the export data provided by Eurostat and other data. However, some differences between the CD and Eurostat data on the exports/imports of live cattle from the UK are relevant. Eurostat registered the export of 195 live cattle from the UK to Brazil in 1982. The UK authorities stated that there are no official records of exports from the UK to Brazil in the period 1980-1987, and the Brazil authorities provided evidence that only 2 live bovines were imported from the UK in 1982. Brazilian authorities informed that imports are only allowed if import permits were granted. They also stated that, due to sanitary and economical reasons, the effective number of animals imported could be inferior to the prior authorised.

For imports from UK the following was found:

- It is assumed that 75 live cattle were imported from the UK in the period 1980-1987. The Brazilian authorities provided data on their origin and fate. All animals were born between 1976 and 1983 and were from high genetic value breeds. According to the CD, the animals were followed and monitored for any BSE related symptoms. After the animals died, they were all buried on the farm where they were kept (detailed data on all animals were provided). None of them was suspicious for BSE.
- In 1989 and 1990, 179 cattle were imported from the UK. Since the importation, all animals and their offspring are monitored. So far (as of February 2003), 82 out of these 179 animals died of different causes; all were buried on the farms and 10 were submitted for BSE laboratory diagnosis because of neurological symptoms, with negative results. The remaining 97 animals are still alive and are monitored by the veterinary services. None has shown neurological signs so far. Individual details on all imported animals were provided in the country dossier. These animals are now also excluded from entering the food and feed chain in Brazil.

For imports from other BSE risk countries the following was found:

- According to the CD, these imports are under surveillance by the official veterinary service and no BSE signs have been detected so far.
- All animals were imported because of their high genetic value, for improving the genetic make-up of beef (85%) and dairy (15%) herds.
- According to the CD, the Brazilian Animal Health Authorities carried out a
 tracing exercise and it was possible to trace back most (6,473 out of 6,556) of the
 cattle imported from non-UK BSE risk countries and to establish their fate. This
 tracing exercise was based on the information recorded in the Brazilian import
 control system, which has been thoroughly described in the CD, the information
 provided by the National Breeding Associations and the inspections and audits

carried out "in situ" by the official veterinary service of the Department of Animal Health. Detailed information, including written evidences and field examples are available to support the tracing exercise.

Country of		IMPORTE	TRACEABILITY			
Origin	Imported	Alive	Slaughtered	Dead	Completed	Undergoing
Austria	525	267	43	215	525	0
Germany	4464	2179	317	1885	4381	83
France	1108	643	99	366	1108	0
Hungary	70	30	7	33	70	0
Italy	169	5	24	140	169	0
Switzerland	83	28	12	43	83	0
Belgium	14	4	1	9	14	0
The Netherlands	57	15	0	42	57	0
Denmark	56	27	2	27	56	0
Luxembourg	10	1	0	9	10	0
TOTAL	6556	3199	505	2769	6473	83

<u>Table 2</u>: Summary of traceability data concerning cattle imported in Brazil from non-UK BSE risk countries (data as of February 2003).

• Out of 6,473 cattle with complete information 3,199 are still alive. Of these, most are 8 years of age or older. A total of 2,769 cattle died of diseases or accidents. The most common causes of death were babesiosis and anaplasmosis, accidents, bacterial and viral diseases and intoxication. It was explained that tick-borne diseases, such as babesiosis and anaplasmosis, were the cause of death of many cattle imported from Europe, shortly after arriving in the country; some died during the quarantine period. It was further explained that many animals were bought relatively cheap, thanks to favourable exchange rates during a certain period in the 90s, which made prevention and/or treatment not worthwhile. The high percentage of accidents is explained by the extensive free ranging of cattle, which makes them more susceptible to accidents. According to the country dossier, all 2,769 bovines that died were destroyed and buried on farm. In no cases symptoms pointing to BSE were apparent.

According to the CD, 505 (8% of all traced import cattle) were slaughtered. Details on the age distribution of the slaughtered animals and on the reasons for slaughter are given in table 3.

Reason for slaughter	<u>≤</u> 2	3 to 7	<u>≥</u> 8	TOTAL
Slaughter at the farm for own consumption	4	8	28	40
Slaughter due to close down of cattle production	0	18	17	35
Reproductive problems	5	237	78	320
Chronic Mastitis	0	32	14	46
Lameness	0	36	18	54
Trauma	6	3	1	10
TOTAL	15	334	156	505

Table 3: Reason for slaughter per age category.

Year of	Country of Origin								
Import	Austria	Hungary	Belgium	Denmark	France	Germany	Italy	Switzerland	Total
1980					8	5		1	14
1981								8	8
1982					6				6
1983					6				6
1984	2								2
1986					1				1
1987					1				1
1989	3								3
1990						3	14		17
1991					2	29	2		33
1992						2			2
1993					36	63			99
1994	5		1	2	17	112		3	140
1995	12	7			20	84			123
1996					2		8		10
Total	22	7	1	2	99	298	24	12	465

Table 4: Animals slaughtered per country and year of import. Animals slaughtered at the farm for own consumption are excluded.

- Most of the animals imported after 1990 are still alive (3,199 in total). A tracing system dealing with cattle imported from all European countries with a BSE risk has been installed since February 2002. It aims to gather data on age, gender, breed and production purpose, as well as on the date and cause of death, and fate of animals disposed of.
- The above reported data should be considered in the light of the limitations of the bovine traceability system in Brazil pointed out in the latest FVO report (mission in Brazil, April 2002).
- For the calculation of the external challenge all animals which ended up or might have ended up in rendering plants were used (505 slaughtered cattle and 83 cattle not traced). This includes also the cattle which have been, according to the CD, slaughtered on the farm for own consumption (40 cattle) were, based on a worst case assumption seen as potential external challenge. This is mainly due to the FVO report.

2.2 Import of MBM² from BSE-Risk countries

 According to Eurostat and other data, only negligible amounts of MBM were exported to Brazil in the period 1980-2001: 200 kg from France in 1992. According to the CD, no MBM imports took place.

- 6 -

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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".

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 2002).

• <u>Live cattle imports</u>:

It is assumed that in total the country imported 6,810 live cattle (CD data) from BSE risk countries, of which 254 came from the UK. Together these imports represent a high external challenge. However, according to the information available on the fate of the imported cattle, provided in chapter 2.1, only a portion of these cattle entered the Brazilian rendering system.

Broken down to 5 year periods the resulting external challenge is as given in table 5.

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. Obviously, this assessment depends fully on the information about the fate of animals imported from the UK and other BSE-risk countries that was provided by the Brazilian authorities.

• MBM imports:

In total the country imported 200 kg MBM from France in 1992 (Eurostat data). Together these imports represent a negligible external challenge. Broken down to 5 year periods the resulting external challenge is as given in table 5.

External Challenge experienced by BRAZIL							
Externa	ıl challenge	Reason for this external challenge					
Period	Overall Level	Cattle imports	MBM imports	Comment			
1980 to 1990	Negligible	Negligible	Negligible				
1991 to 1995	Very Low	Very Low	Negligible				
1996 to 2000	Negligible	Negligible	Negligible				

<u>Table 5</u>: 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 2002).

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

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

According to the CD, the general husbandry system for Brazilian cattle is extensive pasture. The climate and soil conditions make it possible to maintain cattle on native or on, sometimes, cultivated pastures almost throughout the whole year across the country, both for beef and dairy herds. Only in improved beef production systems (about 1,5 million heads) and in higher yielding cows (0,5 million heads) supplementary feeding, all of vegetal origin, is used. To compose the cattle rations, fats from vegetable or fish origin are added as well as minerals. This population is seen to be most at risk of accidentally receiving feed contaminated with ruminant derived materials.

The exclusive use of vegetable protein in ruminant feed is justified on the following reasons:

- Vegetal protein compares favourably in terms of feed conversion and cost (Information on the prices in Brazil for one ton of the main components of feed stuffs for animals is provided in the CD).
- Brazil is a major soy producer and exporter.
- The low milk price makes it largely uneconomic to use protein enriched rations in dairy production.

The CD provides details on feeding practices indicating that MBM are not and were not voluntarily fed to cattle.

Feed bans

A ruminant MBM-to-ruminants feed ban was installed in 1996 by Directive 365 of 3/7/96

Since 1st February 2001, a mammalian MBM-to-ruminants feed ban exists. It was installed by Normative Instruction n° 6, which bans the production, importation, commercialisation and use of mammalian-derived protein and fat to be used as ruminant feed.

According to the CD, on 17 July 2001, the mammalian MBM-to-ruminants feed ban was further amended by Normative Instruction SDA n° 15. It extended the ban to poultry MBM and to any ingredient or raw material containing offal of animals fed with ruminant protein or fat. .

Potential for cross-contamination and measures taken against

Due to the legislation in force (Law n° 76.986/76), all the companies that produce, import and commercialise products for animal feed must be registered. The companies must request their registry at the competent Brazilian Authorities. After the completion of all the legal requirements a final audit of the plant is carried out and, if legislation in place is being correctly followed, a registry certificate is issued.

According to the CD, 1258 feed mills are registered in Brazil. The annual production of feed stuffs, in tons, is 21,4 million for poultry; 10,6 million for pigs and 3,9 million for ruminants. Ruminant feed is produced in 888 establishments, mainly in mono-line feed mills producing for both ruminant and non-ruminant.

Domestically produced animal meals are used for non-ruminant feeds, some of it produced in the same feed mills and in the same production lines as cattle feed. As no feed controls were carried out it is therefore assumed that cross-contamination of cattle feed with MBM is likely to have occurred. This likelihood was higher before July 1996, i.e. before the first ruminant MBM-ban because until then there was no legal obligation to undertake specific efforts to minimise cross-contamination.

It is therefore assumed that intensively managed dairy and beef cattle (about 2 million animals) might have occasionally received ruminant proteins until July 1996 and still thereafter, due to the lack of controls on the finished product.

Since the new Instruction of the 1st February 2001 came into force, it can be assumed, pending on the outcome of controls performed, that MBM is no longer intentionally fed to cattle.

There are 40 abattoirs where both cattle and pigs are slaughtered, and these have dedicated/separated rendering facilities for each species. Hence, according to the CD, the resulting MBM is normally composed of one single species. At the rendering plants, MBM is produced under permanent veterinary inspection. Non-ruminant MBM was allowed for ruminant feed until 01/02/2001 and except for the separation of the production lines no measures against cross-contamination of non-ruminant MBM with ruminant material have been described.

In order to avoid cross-contamination in feed mills, the process, as well as the installations, are inspected by the official services during production. Moreover, the daily production starts with the production of rations destined for horses, bovines, sheep and goats, which do not receive ingredients from animal origin. Rations for monogastric animals (poultry, swine) are produced thereafter. They normally include animal proteins. Finally, wheat bran is passed-through to flush the whole system. The resulting feed is prohibited as feed for horses, cattle, sheep and goats. These controlling procedures have been adopted since 1976 (Ministerial Decree 76.986 of 6 January 1976). This Decree also foresees that products destined for animal feeding are registered.

According to the CD, the feed producers have invested in the development and improvement of procedures to avoid cross-contamination between feeds for different animal species in order to reduce the intoxication risk resulting from the incompatibility of some additives and some species. Official controls on cross-contamination were carried out at feed mills, but the feeds themselves were not analysed.

Since July 1997, labelling of cattle and pig feed is required and official controls are carried out on these labels, but not on the feed itself. It is assumed that these labels reduce the risk of cross feeding to some extent.

Control of Feed bans and cross-contamination

From 1st February 2001 onwards, together with a generalised MBM-ban, a system of laboratory feed testing has been installed (microscopic method). It aims to ensure that no animal protein is present in feed stuffs declared to be made from plant material alone and hence to prevent cross-contamination of ruminant feed. Tests are carried out in an accredited laboratory of the Ministry of Agriculture and Food Supply (minimum 100 tests per week). Feed mills have already submitted samples to testing and out of the 180 tests carried out until the end of March 2001, none were found positive for animal protein. The system will be developed towards a systematic sampling at feed mills.

Very few farms in Brazil are engaged in co-farming of intensive cattle production and intensive pig or poultry production. The latter are traditionally carried out in specialised systems under which farmers are not allowed to keep more than one species on-farm. The possibility that a cattle producer would use animal meals intended for pigs or poultry of the same farm is therefore, according to the CD, regarded to be negligible. However, the existence of small-scale multi species farms cannot be excluded and hence neither the potential of accidental access of cattle to MBM containing pig/poultry feed.

It is concluded that cross-contamination of ruminant feed with ruminant (or other animal) protein might have occurred in the past, before and after the 1996 RMBM-ban. Subject to the verification by the planned systematic feed sampling, at present cross-contamination seems to be much less likely than until end of January 2001.

Rendering

The rendering process used in Brazil is an open (atmospheric pressure) batch-type rendering at 140°C for 180-240 minutes. The steam used to heat the system has a pressure of 3-4 bars. Particles entering the digester are ground to a size of 5-10 cm³. This process doesn't appear to meet the EU standard of 133°C/20min/3bar.

Bovine raw materials, including bovine brains and spinal cord, non-edible and rejected edible offal, condemned materials, blood and bones derived from animals declared fit for human consumption are rendered for feed.

The national annual production of MBM is about 140,000 to 150,000 tons. All rendering material comes from animals that have passed the ante mortem inspection and are slaughtered in approved and controlled slaughterhouses. Animals that are assessed in ante mortem inspections as not being fit for human consumption, or animals submitted to emergency slaughter are slaughtered in separate plants and incinerated afterwards.

Rendering plants are located close to slaughterhouses. They are subject to the same Federal Inspection Service rules that apply for the abattoirs. In Brazil there are 78 slaughterhouses authorised for pigs and bovines slaughter, about 40 of them slaughter both. Some equipment may be shared but thorough cleaning and disinfecting are carried out between different slaughter cycles.

Domestic rendering production is often processing only one species: either cattle or pig. Separated processing lines ensure complete segregation. In the case of slaughterhouses processing both species, cattle and pig raw material is rendered in separated/dedicated plants within the abattoir. Until 1/2/2001 it was legal to include non-ruminant MBM in ruminant feed. If there were no such separate lines, the

produced meals could not be used in rations for ruminants. Since 1/2/2001 the production and use of mammalian protein for ruminant feed has been prohibited.

SRM and fallen stock

There is no SRM-ban and SRM have always been and are rendered together with other slaughterhouse offal from animals fit for human consumption.

Fallen bovine stock is destroyed by burial on the farm. Materials condemned in the post-mortem inspection at slaughterhouses are rendered. Animals that died during transport and at the slaughterhouse are examined (autopsy) and, if necessary, sampled (according to the Regulation of Sanitary and Industrial Inspection of Animal Origin Products). If contagious diseases are diagnosed, these animals are incinerated or "sterilised" (by heat treatment).

Conclusion on the ability to avoid recycling

Supplementary feed that could be cross-contaminated with (ruminant) animal protein, which in turn is produced by rendering processes not able to significantly reduce BSE infectivity. It is therefore likely that the BSE-agent should it have entered rendering, would have been recycled and over time, propagated.

In light of the recent improvements concerning the feed-ban and its controls, it may be assumed that in the future the risk of recycling would decrease.

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

According to the CD, in 2001 the total cattle population of Brazil was about 159 million heads of which about 44 million were dairy cows, the remaining being dual-purpose or beef cattle. The total population over 24 months was about 83 million heads.

The specialised beef herd (e.g. industrial cross-breeding) is estimated at about 20 million cattle of which 1.5 million are reared in intensive and confined production systems, where additional feeding is provided.

About 500,000 cows are intensively managed for higher milk yield. The national average production of milk is 4,9 litres per animal/day

The average age at slaughter of beef cattle is 3-4 years, of dairy cattle 7-9 years and of breeding cattle between 12-15 years.

BSE surveillance

Notification of BSE has been compulsory since 1997 ("Portaria Ministerial" n°516 of 9/12/97).

No legal definition for a BSE-suspect existed in Brazil until very recently (September 2002). Until 2001, surveillance of CNS disease symptoms was carried out under the rabies surveillance system. Since 1990 until 2000, 3152 animals were tested for BSE

out of 9,551 animals that tested negative for rabies, in most cases because they showed signs of neurological disease (Table 6). No details on their age distribution were provided. None of them were diagnosed as a BSE case. The material was collected and sent to the laboratory in compliance with procedures laid down in a purpose-developed manual (the detailed sampling procedure is provided in the CD). Not all samples that tested negative for rabies could be submitted for BSE examination because of insufficient quantity of test material or its improper condition, or because another diagnosis was confirmed in the herd. This points to a certain risk that BSE positive samples could have been included in the brains that were not tested for BSE.

Since 1991 cattle imported from UK have been submitted to a histopathological examination for BSE whenever neurological signs arise and the cause of death has not been established.

Awareness/training measures were in place but all in the context of the rabies awareness programme.

Compensation was and is foreseen for all exotic notifiable disease. This is regulated in Decree 24 548 of 3 July 1934, and Decree 27 932 of 28 March 1950. As BSE is an exotic notifiable disease, it is included in the list of diseases, to which sanitary emergency measures are applied, with destruction of animals and stamping-out, stockowners are entitled to compensation, should an outbreak occur.

From 1990 to 2000, the number of abnormal CNS-suspect cases that were analysed annually for BSE were below the OIE requirements. Taking into account the over 24 months population of 83 million, it appears that the 200-350 samples taken annually were insufficient. All analyses were carried out in the context of the rabies control programme. The method used for the examination and confirmation of BSE-suspects was only histopathology.

Year	Rabies positive	Rabies negative	Number of Rabies negative examined for BSE
1990	566	527	216
1991	662	678	160
1992	739	758	337
1993	935	981	284
1994	892	914	295
1995	1053	1127	368
1996	1083	1190	341
1997	1124	1058	127
1998	1150	1207	362
1999	868	815	362
2000	1496	1482	300
2001	1357	1617	484
2002	1310	2930	458
Total	13235	15284	4092

<u>Table 6</u>: Laboratory diagnosis for rabies in bovine nervous tissue and surveillance of imported animals and of animals with neurological symptoms sampled between 1990-2002. Source: Country dossier.

Active surveillance was initiated in February 2001. Normative Instruction n°8 of 13/2/2001 established that animals imported from BSE-risk countries must be

submitted to BSE examination after death, irrespective of its cause, and subsequently disposed of. In 2001, 484 tests were performed, and 458 in 2002.

According to the CD, in February 2002 (Normative Instruction SDA 15 of 15/2/2002) the active surveillance for BSE was strengthened by laying down rules for collecting samples at abattoirs, including bovines aged over 30 months from intensive or semi-intensive beef farms (breeder or raising farms) and from dairy farms. All bovines destined for emergency slaughter at those abattoirs must be sampled for BSE. In 2002, according to preliminary data provided by the Brazilian competent authorities, 4075 brain samples were collected in the 11 abattoirs included in the surveillance scheme. All tested negative to histopathological examination. The field surveillance targeted at bovines displaying neurological or behavioural disorders and/or progressive disease conditions was reinforced. Moreover, all rabies laboratories must forward rabies negative brain samples to a BSE laboratory whenever the bovines sampled are over 24 months of age.

The Normative Instruction of 15 February 2002 also laid down the rules for accreditation and monitoring of laboratories for ruminant TSEs. This laboratory network comprises 3 units and is foreseen to include up to 7 labs until end 2002. Histopathology examination is to remain the basis of BSE laboratory testing, complemented by immunohistochemistry or, if necessary, Western Blot. The latter methods should be used for 1) cases without conclusive diagnosis, such when samples are negative for rabies, but display no histopathological alterations and 2) for cases where there are vacuolar alterations resulting from processing artefacts, post-mortem alterations or from other diseases that may cause neuronal vacuolisation.

According to the CD, since September 2002 the specific Brazilian legislation for BSE is being reformed in order to improve the prevention programs. Measures to reinforce the awareness and training of the officers, producers, field workers, animal transport and slaughterhouse workers are in process (In 2002, 24 courses were performed being 699 the number of personnel trained).

On the basis of the available information (n° of annually examined bovine brains below OIE requirements, potential to not detect BSE in CNS-suspects due to sample processing and handling procedures, and no active surveillance), it cannot be assumed that the surveillance was able to detect small numbers of clinical BSE cases.

The improvements from the recently introduced efforts to implement an active surveillance of at risk populations cannot be assessed until further information and first results are available.

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 amended in 2002, is applied.

Feeding

Feeding of any MBM to cattle was legal until 1996, when a ruminant MBM to ruminant feed ban was introduced. However, also after the implementation this feed ban contaminated foodstuff could have likely reached cattle due to cross-contamination. Therefore feeding is assessed as "not OK" before and after the 1996 feed-ban. The reinforced mammalian MBM to ruminant feed ban installed in February 2001 improved the stability to "reasonably OK".

Rendering

Rendering is considered "not OK" throughout the reference period because the process parameters don't appear to meet the 133°C/20min/3bar standard.

SRM-removal

SRM removal is "**not OK**" throughout the reference period because SRM are rendered for feed, even if fallen stock is not rendered.

BSE surveillance

BSE-surveillance has been carried out under the rabies surveillance program until January 2001. This surveillance was not adequate to detect low level of clinical BSE incidence. The situation was somewhat improved when the active surveillance system was installed in February 2001.

Stability of the BSE/cattle system in <u>BRAZIL</u> over time							
1	Stability	Reasons					
Period	Level	Feeding	Rendering	SRM removal	BSE surveillance		
1980 to 2000	Extremely Unstable	Not OK	Not OK	Not OK	\downarrow		
2001 -	Very Unstable	Reasonably OK	Not OK	Not OK			

<u>Table 7</u>: 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).

4. CONCLUSION ON THE RESULTING RISKS

4.1 Interaction of stability and challenges

In conclusion, the stability of the Brazil 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 had to be met by the system, in addition to external challenges that occurred

INTERACTION OF STABILITY AND EXTERNAL CHALLENGE IN BRAZIL							
Period	Period Stability External Challenge						
1980 to 1990	Extremely	Negligible					
1991 to 1995	Unstable	Very Low	Highly Unlikely				
1996 to 2000		Negligible					

<u>Table 8</u>: 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 January 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 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.

In the case of Brazil, since 1980 until 1990 an extremely unstable system was exposed to only negligible external challenges. From 1991 to 1995 the extremely unstable system was exposed to a very low external challenge, and from 1996 to 2000 it was exposed to negligible external challenges. No UK-imported cattle, and a limited number of cattle imported from some BSE risk countries entered rendering. In view of the above-described reflection it is highly unlikely that the registered external challenges could have led to an internal challenge in Brazil throughout the reference period.

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 Brazil there is no significant challenge resulting from MBM, as only negligible MBM imports took place.

4.2 Risk that BSE infectivity entered processing

• A very low risk that BSE infected cattle entered processing in Brazil, occurred in the mid 90s when cattle imported from BSE risk countries could have been slaughtered.

4.3 Risk that BSE infectivity was recycled and propagated

An extremely unstable system was exposed from 1991 to 1995 to a very low
external challenge, which was largely mastered by the specific measures, targeted
on the imported animals and specific circumstances i.e. only a very limited
number of cattle are fed with concentrates in Brazil. If BSE infectivity entered the
system, it would have been propagated and amplified but this possibility is
regarded to be highly unlikely.

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.
- This assessment depends fully on the information about the fate of animals imported from the UK and other BSE-risk countries which was provided by the Brazilian authorities.

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

- If the stability of the system in Brazil remains as low as it was, any external challenge could lead to an increase in the GBR of the country.
- Enforcement of the Normative Instruction n° 8 by which all remaining live cattle that were imported from BSE risk countries will be destroyed at the end of their productive lives is essential.
- The measures initiated in 2001 and reinforced in 2002, however, are potentially increasing and improving the stability of the system and could make it less vulnerable to external and/or internal challenges.

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.
- The improvement of the passive surveillance as well as the adoption of an active surveillance system did already start in February 2001. It will provide additional confirmation of the current assessment of the GBR and its development in the future.