

Final Report on the Updated Assessment of the Geographical BSE-Risk (GBR) of ARGENTINA - 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 from the country's authorities in 1998-2002.
- 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.
- Final Report of a FVO Mission to Argentina (From 26 June to 5 July 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 that exported to Argentina. 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 July 2000 (as updated in January 2002), an external challenge.

- According to the CD, Argentina imported 19 pure-bred breeding cattle from the UK between 1980 and 1983: 14 in 1980, 3 in 1981 and 2 in 1982. Most of these cattle were dead by 1988, but some may have been slaughtered between 1988 and 1990.
- According to Eurostat, Argentina imported 103 pure bred breeding cattle from the UK between 1980 and 1983: 19 in 1980, 3 in 1981 and 81 in 1982. However, the Country provided evidence confirming that only 2 bovines were imported in 1982.

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

- According to the CD, in the period 1980-2000 Argentina imported a total of 101 animals from the following non-UK BSE risk countries: Germany (43), Spain (37), Switzerland (17) and Italy (4). These data are largely compatible with Eurostat and other data.
- In addition, according to the CD, Argentina imported 77 animals from Italy in 1980-81, 22 from Spain in 1980 and 20 from Austria in 1980. Since these animals were imported in non-risk periods they are not taken in account for the assessment of the external challenge.
- According to the CD, in 1995 all bovines imported from BSE risk countries known at that time were traced back following the provisions of the Resolution 471/95 establishing that all imported breeding animals must be recorded in a national register. Most of the animals and the farms that received these animals were identified and most of the cattle were confirmed dead or slaughtered before 1992. However, the actual fate of the imported cattle is not clear, as it is also pointed out in the FVO's Final Report, since no documentation on the tracing exercise has been provided in the CD.
- Imports of live cattle from UK were officially banned in 1990 (Resolution 429/1990). In 1995 (Resolution 382/1995) the ban was extended to imports of live cattle from BSE affected countries (countries with indigenous BSE cases).

2.2 Import of MBM² from BSE-Risk countries

- According to the CD, Argentina did not import MBM from BSE Risk countries, including the UK, in the reference period. This is confirmed by Eurostat and other sources.
- Imports of animal products from UK were officially banned in 1990 (Resolution 429/1990) and in 1995 (Resolution 382/1995) the imports of MBM from BSE risk countries (confirmed, high risk or low risk) were also officially banned.

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".

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Country:	Data	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	0	1	Total	
Germany	CD	28						15																	43
	Other							20	5																25
Italy	CD										4														4
	Other				6						4														10
Spain	CD										14	23													37
	Other										14	2													16
Switzerland	CD	2			15																				17
	Other			14																					14
UK	CD	14	3	2																					19
	Other	19	3	81																					103
ALL TOTALS																									
non UK	CD	28	0	0	15	0	0	15	0	0	18	23	0	0	0	0	0	0	0	0	0	0	0	0	101
	Other	0	0	14	6	0	0	20	5	0	18	2	0	0	0	0	0	0	0	0	0	0	0	0	65
UK	CD	14	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19
	Other	19	3	81	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	103

Table 1: Live cattle imports into Argentina (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 updated in 2002.

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:

It is assumed that in total the country imported over the period 1980 to 2000 125 (CD and Eurostat) live cattle from BSE-risk countries, of which 24 came from the UK. Together these imports represent a negligible external challenge. Broken down to 5-years periods the resulting external challenge is as given in table 2.

- MBM imports:

The country imported no MBM from BSE risk countries, including the UK, in the period 1980 to 2001. Therefore, the associated external challenge was negligible.

External Challenge experienced by <u>ARGENTINA</u>				
<i>External challenge</i>		<i>Reason for this external challenge</i>		
Period	Overall Level	Cattle imports	MBM imports	Comment
1980 to 2000	Negligible	Negligible	Negligible	

Table 2: 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.

3. STABILITY

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

Feeding

According to the CD, 237 feed mills are registered in Argentina. Most of them currently produce concentrates for different species, including cattle (170 feed manufacturers), pigs, poultry and pets.

Use of MBM in cattle feed

- According to the CD, in Argentina MBM is not used for cattle feed. Cattle are raised using an entirely extensive production system that makes the maximum use of all-year-round pasture as a low cost food resource. Only a few pedigree breeders and a small part of the dairy industry feed cattle with concentrate rations from vegetable protein sources.

- MBM prices are high in comparison to vegetable protein sources, in part due to the growth of the export market for MBM. Detailed relative prices were provided. According to the CD, there is an economic disincentive in Argentina to use MBM as a protein source if plant proteins can replace it.
- According to the CD, in 2001, 244.000 tons of MBM were produced in Argentina. 35.000 tons were exported. All the MBM produced goes into concentrates for non-ruminants. Poultry and pig feed is the major use of the domestic MBM as these species are managed much more intensively than cattle.
- The voluntary inclusion of MBM in cattle rations is not known to have ever occurred in Argentina, and is regarded as unlikely, taking in account the issues discussed above.

Feed bans

- A ruminant MBM-to-ruminant feed ban was implemented in 1995 (Resolution 252/1995). The ban was extended in June 2002 (Resolution 485/2002) by prohibiting the feeding of mammalian MBM to ruminants.

Potential for cross-contamination and measures taken against

- The same production line is used to produce concentrates for various species. Therefore, the potential exists for cross-contamination of MBM-free concentrates produced for cattle with MBM-containing concentrates produced for pigs, poultry or pets.
- According to the CD, intensive production of both cattle and poultry or pigs on the same farm is not found but small numbers of pigs or poultry may be raised on the same farm for home consumption.
- According to the CD, animal feed containing MBM is stored in bulk or in polypropylene bags in separate areas until it is marketed. This should allow adequate stock management and sampling for quality control purposes. Since the ruminant MBM to ruminant ban (1995), this ban has to be clearly stated on the product label.
- Guidelines to prevention cross-contamination in the feed mills have been issued very recently (April 2003) by the SENASA.

Control of Feed bans and cross-contamination

- According to the CD, since the implementation of the ruminant MBM to ruminant feed ban in 1995, the feed mills officially approved and registered are subjected to official inspections.
- Laboratory tests for cross-contamination were introduced in 1997 based on microscopy and a species specific ELISA tests. A sample is considered positive when it is found to be contaminated by at least a 0,3 % of mammalian protein and if the result is confirmed by an ELISA test (detection limit: 1%) or a second microscopic test. Experience in the EU shows that a ruminant MBM to ruminant feed ban is extremely difficult to control using these procedures. From 1997 to 1999, 109 samples were examined and 18 were found positive for ruminant proteins. In the year 2001 one positive sample was detected among 74 samples analysed. No information is available on the actions taken.

- In March 2002 an enforced official control programme was set up increasing the random sampling in ruminant holdings and feed mills (Resolution 485/2002)
- Since June 2002 controls are aimed at enforcing the mammalian MBM to ruminant feed ban. A procedure to apply in case of MBM contamination of ruminant feed was also set up. This procedure includes inspection and preventive measures as the intervention and sampling of all produced batches of ruminant feed. A program of visits and audits to ensure the compliance of the feed ban in farms, feed mills, and during transport and storage is carried out in the period 2002-2003. In this framework, from March 2002 to April 2003 60 holdings and 16 feed mills were audited and 2081 samples were analysed. 85 samples were found positive (due to adulteration and cross-contamination)
- In June 2002, the FVO Report pointed out that the official controls were not yet adequate to demonstrate an effective compliance with the feed ban. Since then, Argentina has applied further measures in order to follow the recommendations of the FVO Report.

Rendering

- According to the CD, there are 70 rendering plants operating in Argentina. 31 plants are linked to large slaughterhouses. All but one of the slaughter plants with rendering capabilities are single species (cattle) only.
- The rendering process involves only materials from slaughterhouses and cutting plants. Most of the material is from cattle although, sometimes, small quantities of porcine and/or equine material are used. According to the CD, all material comes from animals fit for human consumption. This material is processed under 130°-145°C at atmospheric conditions for 4-5 hours after been crushed to a maximum particle size of 50mm.
- All animals/materials declared unfit for human consumption must be processed in a digester under batch pressure (125°C/1,5 bar/1-3 hours) and buried or sent to a landfill.
- According to the CD, all rendering plants are under official inspection. The controls are focused on the checking of the records provided by the plant. However, no details were provided on the frequency, criteria and results of these inspections. Moreover, the FVO Final Report pointed out that the controls are not fully effective and could not be demonstrated that both material, fit and unfit for human consumption, are always processed separately and the required parameters are achieved.

SRM and fallen stock

- No SRM-ban existed until 2002. On April 2002, with the circular N° 3477 it was established that brains and spinal cords of slaughtered animals – both healthy and emergency slaughtered– must be thermally treated and not be included in the feed chain. This measure does not cover all the tissues considered as Specified Risk Material by the Scientific Steering Committee³.

³ Opinion on TSE infectivity distribution in ruminant tissues (state of knowledge, December 2001) (adopted on 10-11 January 2002) as updated in November 2002.

- According to the CD, offal, including brain and spinal cord, reach a high price as human food and/or utilisation in the cosmetic industry and excluding SRM from rendering by using it for human consumption might be considered as kind of a “de-facto” SRM-ban.
- Animals that died in a holding are buried-on-farm. They do not enter in the rendering system. Animals that die in or during the transport to the slaughterhouse are usually rendered as discussed in the Rendering section.

Conclusion on the ability to avoid recycling

In light of the above-discussed information it has to be assumed that until the middle of 2002 the BSE agent, should it have entered the Argentinean territory could have been recycled and amplified. From the second half of 2002 onwards, the BSE agent, should it have entered could have been recycled but the chance that it reached the cattle via feed decreased remarkably.

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 2002 the estimated total cattle population in Argentina was about 52 million heads. Out of this total, adult cows (> 30 months of age) account for 42% of the total cattle population, hence the total adult population is more than 23 million.
- The majority of cattle farms are for extensive beef production (91%) and only a small part is intended for dairy production (9%). Both beef and dairy production systems take advantage of abundant grass pastures. 60% of the cattle population is concentrated in the 4 provinces in the humid Pampa region where grass production is excellent.
- An average of 11 million cattle is slaughtered each year. 45% of the slaughter cattle are less than 24 months of age, including approximately one third of the steers. The remaining steers are slaughtered between 24 and 30 months of age. Cows and bulls older than 30 months of age account for 23% of the annual slaughter, approximately 2.5 million animals.

BSE surveillance

- In 1990 BSE was declared as notifiable foreign (exotic) disease. In 1997 BSE was listed as an officially notifiable disease and the mandatory reporting was established (Resolution 172/97).
- An official definition of a BSE suspect was published in 1998.
- According to the CD, a formal surveillance system was established in 1992. In 1993 the surveillance system was completed in response to OIE guidelines revised at that time. Since then, the surveillance has been focused on the sampling and testing for BSE of cattle in “bad condition” (downer or diminished), cattle with

CNS disease symptoms or imported from BSE risk countries. In addition, in order to reach the OIE requirements, adult healthy animals from risk sub-populations i.e. dairy farms, has been also tested .

- In 1995 it was implemented a system to trace, identify and monitor imports from BSE countries including the establishment of a national registry of imported breeding animals (Resolution 471/1995). Destruction and histopathologic examination of brain samples at the end of the productive life of the imported animals was and is required.
- In 1996 an improvement of the surveillance system (Resolution 234/96), was established, including the investigation of suspicious clinical cases on farm, detected by the owner or by the SENASA-trained veterinarians and animal-health technicians. An active BSE surveillance is targeted at apparently healthy cattle from 3-7 years of age arriving at slaughter plants, where clinical signs would be most likely if the cattle had been exposed at a young age, and at animals that died or were dying at arrival to the slaughterhouses.
- Fallen stock was not regularly included in the surveillance as they are destroyed on farm.
- All diagnostic testing for TSEs are carried out at the officially-approved INTA (National Institute for Agricultural Technology) laboratory. Two diagnostic tests are used in the TSE surveillance system: Histopathology and Western Blot. The latter one accounts for approximately 1/3 of the tests and is used in brains from animals with clinical neurological signs and for cases in which the histopathologic examination is unclear.
- Between 1992 and November 2002, 15,075 brain samples were examined from different species by means of histopathology and Western Blot. Both histological lesions and biochemical results were suggestive of BSE in no case.

Sub-populations	Year											Total
	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	
CNS symptoms	36	40	23	22	249	254	92	92	152	195	116	1271
Bad condition		90		42	37	162	47	62	146	70	71	727
Fallen Stock											340	340
Emergency											129	129
Imported		1				3	2	5	1	6	16	34
Healthy		888		57	76	964	1161	1197	1778	3273	3249	12643
Total	36	1019	23	121	136	1378	1464	1356	2077	3544	3921	15075

Table 3: Total number of samples tested for TSEs in Argentina from 1992 to May 2002.

- It is concluded that the quality of surveillance was insufficient prior to 1992. Since then it has been constantly increasing, especially since 1996. However, the surveillance would not be able to discover all clinical BSE cases, should these occur. This assessment is also supported by the absence of a compensation scheme for suspect cases, the negative incentive is not regarded to be as effective to stimulate notification. The active random sampling is not reaching sufficient numbers to significantly improve the quality of the surveillance system.
- The surveillance including in addition to animals showing clinical signs also randomly sampled older but apparently healthy animals presented for slaughter

and animals in bad shape is seen as a positive point but would require larger numbers to effectively increase the ability of the system to identify clinical BSE cases.

- From April 2003 (Resolution 95/03) the sampling plan will be extended to animals of risk sub-populations (i.e. fallen stock). According to this Resolution the total number of samples must comply with the OIE requirements.

3.3 Overall assessment of the stability

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

Feeding

Feeding of MBM to cattle was legally possible until 1995, even if apparently uncommon. Feeding ruminant MBM to cattle was officially banned in 1995. Controls of this feed ban only started in 1997 using techniques with a relative high detection limit. Experience in EU has shown that ruminant MBM to ruminant feed bans are extremely difficult to control. It is hence assumed that feeding was "**not OK**" for the period 1980 to middle of 2002. From the second half of 2002 it is considered "**OK**" because evidence was provided that the mammalian MBM to ruminant feed ban was properly implemented and controlled.

Rendering

The rendering systems do not appear to meet the 133°C/3 bar/20 min. standard. It can be assumed that the process has only a reduced BSE-inactivation capacity. Should BSE enter the rendering, the produced MBM would probably still contain significant fractions of the incoming infectivity, therefore rendering is assessed as "**not OK**" for the reference period.

SRM-removal

Brains and spinal cord from cattle fit for human consumption are usually intended for human consumption. From 2002 a partial SRM ban is implemented covering only brain and spinal cord. SRM from condemned or fallen stock is digested and buried or sent to a landfill and it is unlikely that it could reach cattle. This factor can be considered to be "**reasonably OK**" throughout the reference period.

BSE surveillance

Regarding the surveillance system up to now, Argentina would probably not have been able to detect small numbers of clinical BSE-cases. The new measures will, if suitable numbers of high-risk animals are tested, improve this surveillance.

Stability of the BSE/cattle system in ARGENTINA over time					
Stability		Reasons			
Period	Level	Feeding	Rendering	SRM removal	BSE surveillance
1980 to June 2002	Very Unstable	Not OK	Not OK	Reasonably OK	↓
July 2002-	Neutrally stable	OK			

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).

4. CONCLUSION ON THE RESULTING RISKS

4.1 Interaction of stability and challenges

In conclusion, the stability of the Argentina 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 ARGENTINA			
Period	Stability	External Challenge	Internal challenge
1980 to June 2002	Very Unstable	Negligible	Highly Unlikely
July 2002 -	Neutrally stable		

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 January 2002).

- A very unstable system and since July 2002 a neutrally stable system was exposed to a negligible challenge.
- The risk that BSE-infected material, derived from imported animals, entered the feed production was considered to be negligible, given the small number of imported cattle.
- Given the negligible level of the external challenge, no internal challenges occurred.

4.2 Risk that BSE infectivity entered processing

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

4.3 Risk that BSE infectivity was recycled and propagated

- Due to 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 neutrally stable system, any substantial external challenge could lead to an increasing GBR.

5.3 Recommendations for influencing the future GBR

- As the system in Argentina is neutrally stable, it is important to avoid any challenge.
- Upgrading the rendering system to comply with the "133°C/20min/3bars" standard, would significantly increase the stability of the system and would make it less vulnerable to future external challenges, should they occur.
- Results from an appropriate intensive surveillance programme, targeting at risk populations (fallen stock, emergency slaughtered cattle) could verify the current assessment and confirm the assumed absence of BSE from the Argentinean territory.