FINAL REPORT

ON THE ASSESSMENT

OF THE

GEOGRAPHICAL BSE RISK OF

ROMANIA

MAY 2001

NOTE TO THE READER

Independent experts have produced this report, applying an innovative methodology by a complex process to data that were voluntarily 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. This opinion is available at the following Internet address:

<http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html>

In order to understand the rationale of the report leading to its conclusions and the terminology used in the report, it is highly advisable to have read the opinion before reading the report. The opinion also provides an overview of the assessments for other countries.

FULL REPORT

1. DATA

- The available information was suitable for a qualitative GBR risk assessment.

Sources of data

Country Dossier consisting of:
- Answer to the questionnaire on geographical BSE risk assessment, received on 1st March 2001, no annexes.
- Comments on the draft report from the Romanian authorities, received on 20 April 2001, include 4 annexes.
- Comments on the draft final report from the Romanian authorities, received on 7 May 2001.

Other sources:
- EUROSTAT Year Book on Candidate and South-East European countries 2000
- EUROSTAT data on exports of "live bovine animals" and of "flour, meal and pellets of meat or offal, unfit for human consumption; greaves" from EU Member States, covering the period 1980 to 2000.
- UK-export data on "live bovine animals" (1980-1996) and on "Mammalian Flours, Meals and Pellets" (1980-2000). As it was illegal to export mammalian meat meal, bone meal and MBM from UK since 27/03/1996, exports indicated after that date may have included non-mammalian MBM.

2. EXTERNAL CHALLENGES

2.1 Import of cattle from BSE affected countries

Table 1 provides an overview of the import of live cattle into Romania, as provided in the country dossier (CD) and the exports from BSE-affected countries, as indicated in Eurostat and UK export statistics.

According to the CD, no cattle have ever been imported from UK.

This is not fully confirmed by Eurostat and UK exports statistics as according to these sources, 3 animals of the customs category “steers and yearling bulls, fat” were exported from UK to Romania in 1982. However this is assessed as being negligible.

In 1997, legal provisions were issued. They consist of an Order of the Minister of Agriculture and Food No. 33/02.06.1997, regarding a veterinary import ban for live bovines originating from BSE affected countries, and of an Order of the Minister of Agriculture and Food (MAF) No. 46/23.06.1997, amending MAF Order No. 33/1997.

Import of live cattle (n/year) into ROMANIA from BSE-affected countries																
Country	**UK**			**IT**		**DE**		**NL**		**DK**		**FR**		**IRL**	**Non-UK**	
Source:	**CD**	**EU**	**UK**	**CD**	**EU**	**CD**	**EU**	**CD**	**EU**	**CD**	**EU**	**CD**	**EU**	**EU**	**CD**	**EU**
1980																
1981						6,598	6,598							889	6,598	7,487
1982		3	3			651	651								651	651
1983																
1984																
1985						425	425								425	425
1986																
1987																
80-87:	**0**	**3**	**3**			**7,674**	**7,674**	**0**	**0**	**0**	**0**	**0**	**0**	**889**	**7,674**	**8,563**
1988																
1989																
1990																
1991								800	800						800	800
1992								3,187	3,187						3,187	3,187
1993						149	149	1,760	1,818	293	294	64	64		2,266	2,325
88-93:	**0**	**0**	**0**			**149**	**149**	**5,747**	**5,805**	**293**	**294**	**64**	**64**	**0**	**6,253**	**6,312**
1994				39	39	30	30	817	817	128	128				1,014	1,014
1995						223	223	1,890	1,402	484	484				2,597	2,109
1996				6	6	121	121	928	928	1,593	1,647				2,648	2,702
1997				36	36	317	317	723	723	35	35				1,111	1,111
1998				108	109	291	291								399	400
1999						44	44								44	44
94-99:	**0**	**0**	**0**	**189**	**190**	**1,026**	**1,026**	**4,358**	**3,870**	**2,240**	**2,294**	**0**	**0**	**0**	**7,813**	**7,380**
2000				2	2	135	135								137	137
80-00	**0**	**0**	**0**	**191**	**192**	**8,984**	**8,984**	**10,105**	**9,675**	**2,533**	**2,588**	**64**	**64**	**889**	**21,877**	**22,392**

Table 1: Live Cattle imports. Shading indicates period of different risk that UK-exports carried the agent, 1988-1993 being the period of highest risk. Sources: CD = Country Dossier, EU = Eurostat, UK = Export data from UK.

According to Eurostat, 22,392 bovine animals were exported from BSE affected countries (as presented in Table 1) in the period 1980-1999, while the country dossier (CD) showed that 21,877 cattle were imported. The figures of both sources are of the same order of magnitude and are therefore regarded as consistent. The exception, however, are 889 cattle, according to Eurostat exported from IRL in 1981, that are not recorded by Romania.

In addition to these exports to Romania Eurostat also indicated 956 cattle being exported from Austria to Romania between 1996 and 1999. This is not taken into account in the assessment, as Austria is currently considered GBR level II.

The country also provided detailed information on the fate of cattle imported from NL, DE, DK, IT and FR (see table 2). As all cattle imported from DK and NL were for breeding purposes, cattle imported from NL were on the average slaughtered after 62 months and those imported from DK were on the average slaughtered at 64 months (more than 5 years old on average).

Country	IT			DE				NL				DK				FR	
Year	I	S	A	I	D	S	A	I	D	S	A	I	D	S	A	I	S
1981				6,598	208	6,390											
1982				651	72	579											
83-84	*No cattle imports from these countries*																
1985				425	21	404											
86-90	*No cattle imports from these countries*																
1991								800	16	783	1						
1992								3,187	127	2,068	992						
1993				149	2	1	146	1,760	132	1,242	386	293	31	262		64	64
1994	39		39	30	10	15	5	817	95	190	532	128	14	14	100		
1995				223	47	100	76	1,890	241	768	881	484	2		482		
1996	6	6		121	4	81	36	928	56	796	76	1,593	264	510	819		
1997	36		36	317	15	38	264	723	29	342	352	35		35			
1998	108	56	52	291	35	61	195										
1999				44		1	43										
2000	2		2	135	2	12	121										
Total	**191**	**62**	**129**	**8,984**	**416**	**7,682**	**886**	**10,105**	**696**	**6,189**	**3,220**	**2,533**	**311**	**821**	**1,401**	**64**	**64**

Table 2: Information on the fate of cattle imported from BSE affected countries into Romania. I = yearly total of imported animals, D = animals dead, S = animals slaughtered, A = animals still alive.

This information shows that of around 21,900 animals imported from NL, DE, DK, IT and FR, 5,636 were still alive in April 2001 (i.e. 26%), 1,423 died on farm (6%) and 14,818 were slaughtered (68%). If it is assumed that all slaughtered or dead animals were (partly) rendered for feed, it is concluded that 74% of all imported cattle (a total of 16,200 animals) were finally rendered. About half of these cattle were imported in 1981/82 from DE and the other half after 1990 from a range of countries. It is therefore theoretically possible that the BSE agent entered rendering already during the 80s, when the imports from Germany were slaughtered or died. It is, however, more likely that this happened in the 90s, when the second wave of imports died or was slaughtered.

2.2 Import of MBM or MBM-containing feedstuffs from BSE affected countries

Table 3 gives an overview of the MBM-imports into Romania, as provided in the country dossier and compares it with the Eurostat and UK-export statistics.

According to the CD, MBM, MM, BM, Greaves, or Feedstuffs containing any of these items have not been imported from the UK until 1997, because there were no requests for import of this products. However, the import of 466 tonnes from UK in 1995 was acknowledged by Romania.

In 1997, legal provisions were issued. They consist of an Order of the Minister of Agriculture and Food No. 33/02.06.1997, regarding a veterinary import ban of animal products originating from BSE affected countries, and of an Order of the Minister of Agriculture and Food (MAF) No. 46/23.06.1997, amending MAF Order no. 33/1997.

Import of MBM, MM, BM or greaves (t/year) into ROMANIA from BSE-affected countries												
Period	**UK**			**DE**	**IT**	**BE/ LUX**	**IRL**	**NL**	**SP**	**DK**	**Non-UK**	
Source:	**CD**	**EU**	**UK**	**EU**	**EU**	**EU**	**EU**	**EU**	**EU**	**EU**	**CD**	**EU**
1980												
1981				3,437	20		486					3,943
1982	1	1		337								337
1983												
1984												
1985				239								239
80-85	**1**	**1**	**0**	**4,013**	**20**		**486**					**4,519**
1986												
1987												
1988												
1989												
1990				3,825								3,825
86-90	**0**	**0**	**0**	**3,825**								**3,825**
1991				19								19
1992						160						160
1993						85				21		106
91-93	**0**	**0**	**0**	**19**		**245**				**21**		**285**
1994				1				757				758
1995	466	466	466	193				63				256
1996				24	119			123		40		306
1997				28		84						112
1998				327		100						427
1999				2								2
94-99:	**466**	**466**	**466**	**575**	**119**	**184**		**943**		**40**		**1,861**
2000		0.4	0.5	65	22				0.4			87
1980-2000	**467**	**467**	**467**	**8,497**	**161**	**429**	**486**	**943**	**0.4**	**61**		**10,577**

Table 3: MBM-imports. Shading indicates period of different risk that exports carried the agent, 1986-1990 being the period of highest risk for UK imports while 1994-1999 UK-exports are assumed to have been safer than exports from other BSE-affected countries. Sources: CD = Country Dossier, EU = Eurostat, UK = UK-Export statistics.

According to the country dossier: “all imported MBM were directed to plants for mixed feedingstuffs, and used for pig and poultry feed“.

Moreover, according to Eurostat, 10,577 tonnes of MBM, were exported to Romania from BSE affected countries in the period 1981-1999 (see Table 3). All exports of MBM from “UK, Germany, Spain and Italy” were accepted by the Romanian authorities and declared as being ”correct” while no comments were made by Romania on Eurostat MBM export figures from BE, IRL, DK and NL to Romania. Romania also explained that:

- 22 tonnes of MBM imported from IT in 2000 were “concentrates protein-vitamin-minerals for pigs, which contains only protein of vegetal origin”.

- The less than 1 tonne of MBM, which was exported from Spain to Romania in 2000, was “meal made from hides of pigs”.

From the data on MBM imports it is concluded that the BSE-agent could theoretically have entered the country also by this route already in the early eighties. However, it seems to be more likely in the 90s, either in 1990 with the 3,825 tonnes imported from DE or after 1992 with the imports from BE, NL UK and again DE.

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.

Throughout the reference period Romania was exposed to an external challenge due to imports of live cattle:

- A total of 8,563 animals, were imported in 1981/82 and 85, from DE and IRL, representing a moderate external challenge.
- A total of 6,312 animals were imported between 1988 and 1993, from NL, DK, DE and FR, again representing a moderate external challenge.
- A total of 7,380 animals were imported between 1994 and 1999, from NL, DK, DE and IT, again representing a moderate external challenge.

The MBM-imports also represented external challenges:

- Around 4,500 tonnes of MBM were imported from DE, IRL, and IT between 1980 and 85, representing a high external challenge.
- In 1990 Romania imported about 3,800 tonnes from DE, representing a high external challenge.
- From 1991 to 1993 about 290 tonnes of MBM were imported, representing a moderate external challenge.
- From 1994 to 2000 more than 1,900 tonnes of MBM were imported from NL, DE, BE, IT, DK in addition to 466 tonnes that were imported from the UK in 1995. These imports again represented a high external challenge.

External Challenge experienced by ROMANIA				
External challenge		*Reason for this external challenge*		
Period	**Level**	**Cattle imports**	**MBM imports**	**Comment**
1980-1990	**High**	**Moderate**	**High**	
1991-1993	**Moderate**		**Moderate**	
1994-2000	**High**		**High**	

Table 4: External Challenge resulting from live cattle and/or MBM imports from the UK and other BSE-affected countries. The Challenge level is determined according to the SSC-opinion on the GBR of July 2000.

On the basis of the available information, the assessment of the overall external challenge is as given in Table 4 above. Between 1980 and 1990, the external challenge experienced by Romania was high mainly due to imports of MBM from DE, IRL, IT and UK but also potentially supported by the live cattle imports. Between 1991 and 1993 the overall external challenge was moderate due to live cattle and MBM imports from BSE affected countries. Since 1994, the external challenge has been high again, mainly because of exports of MBM from NL, DE, BE, IT, UK, DK and SP but further increased by the relatively high n° of imported cattle that were rendered.

3. STABILITY

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

Feeding

Already in 1982 a feed ban was introduced by Decree of State Council 50/1982, prohibiting the use of MBM, MM, BM, Greaves or Feedstuffs containing any of this for ruminants. In the centrally planned economy the composition of dairy rations was approved centrally for each species and category of animals. In accordance with provisions of the said Decree, the use of protein meals in ruminant feed was not allowed; it was accepted only for the diet of porcine animals and poultry.

In June 1997, this ban was confirmed by an Order of the Ministry of Agriculture (46/1997). The ban prohibits feeding to ruminants of greaves of animal origin and premixes or feedingstuff that contains greaves or proteins of animal origin.

In 1997 also the production of concentrates and premixes containing proteins of animal origin, including MBM, for ruminants was banned in Romania.

Detailed information on Romanian feed production was provided in the country dossier. Currently there are 62 plants producing feedingstuffs in Romania. The

national feed production decreased from around 4,700,000 tonnes in 1983 (peaking year) to around 900,000 tonnes in 2000 while the production of feed for ruminants decreased from around 632,000 tonnes in 1983 to less than 9,000 tonnes in 2000. It is noted that production of feed for all species decreased strongly since 1990 while the imports of MBM increased (see Table 3).

The available information on feed controls does not allow assuming that voluntary or in-voluntary (cross-contamination) of MBM in cattle feed was excluded before 1997. The measures taken in 1997 make thereafter a voluntary inclusion unlikely but cross-contamination (see there) is still not excluded.

Rendering

Since 1974 all corpses, animal waste and confiscates are compulsory processed at 130ºC, during 90 minutes (pressure was not mentioned in the CD, Sanitary Veterinary Law No. 60/1974, with amendments, Chapter III, Art. 143).

Since 1997 bovine raw materials was processed at 133°C / 3 bars / 20 minutes (Orders of the Minister of Agriculture and Food No. 33/1997 and 46/1997).

All MBM produced was, according to the CD, used for pig and poultry feeding.

Today there are six rendering plants processing meals containing proteins of animal origin in the country while there were nine plants in 1997; one closed in 1998, two in 1999.

According to CD, there is no sub-industrial rendering as “the farms have not anymore facilities, equipments or the legal permission to process fodders at sub-industrial level, in view of feeding the animals”.

The volume of bovine raw materials annually processed dropped from 42,000 in 1997 to 40,000 tonnes in 1998, to 32,000 tonnes in 1999 and to 16,700 tonnes in 2000. According to the CD, at current “daily quantities of raw material from bovines, entering processing units are very reduced, and these quantities are not sufficient to a batch (12 tonnes / sterilisation equipment)”.

According to CD 38 controls (nature of controls not specified) were carried out in the rendering plants in 1997, 26 in 2000 (slightly more than 4 controls per year and per plant in average).

Inspections are carried out by inspectors of the National Sanitary Veterinary Agency and by territorial inspectors, in accordance with the National Surveillance Program. The controls are focused on:

- the observance of general measures in the rendering plants (requirements concerning the origin of raw material, the processing conditions);
- physical and chemical examinations (proteins, NH_3, acidity, Kreiss reaction), bacteriologic determination (total number of germs, Salmonella, Coliform bacteria, etc.), parasitological exam;
- verification of final destination of final products.

SRM and fallen stock

Until 1995, SRM and ruminant fallen stock was rendered for feed.

In 1995 a partial SRM-ban was put in force. Since then it has not been allowed to send bovine brain and spinal cord from slaughterhouses to rendering plants (National Sanitary Veterinary Decision No. 46695/1995, corresponding to a partial transposition of EU Council Directive of 27 November 1990). The rational for this Decision bans the processing into MBM of corpses from ruminants, products and by-products which de facto prohibits the use of such ruminant products not intended for human consumption for cattle feed.

Since 29.01.2001, by Order of the Minister of Agriculture, Food and Forestry 101322, Article 3, rendering of carcasses from ruminants and of products from ruminants in view of obtaining protein meals is prohibited. These materials are destroyed by incineration. It was explained that this new order (confirming the feed ban of 1997) was adopted as a consequence to press coverage of BSE in Europe and to reassure consumers in Romania.

Cross-contamination

According to CD, the following measures prevent cross contamination:

- separated production lines for each type of feedingstuffs and for each species exists since 1974 (Law No. 60/1974 as amended),
- each transport vehicle has had to be cleaned and disinfected since 1974; these operations are mentioned in the sanitary veterinary certificates issued for each mean of transport;
- until 1990, only specialised farms have existed in Romania; today there are also individual farms, in which owners have been feeding animals from their own resources (they do not use meals containing protein of animal origin);
- in June 1997 the production of concentrates and premixes for ruminants was banned in Romania.

Between 15 and 40 samples of cattle feed have annually been tested by an ELISA test kit for the presence of mammalian protein in cattle feed and the identification of the species every year since 1995. None were found positive. It was explained that the ELISA test was carried-out since 1995 due to exports to United States (ELISA test is required by USA). The test allows the specific and sensitive detection of animal proteins. The limit of detection depends on the concerned species and of the heat treatment applied to the sample; the value of the detection limit is between 0,5 and 2%. The ELISA kit allows the simultaneous identification of up-to four species.

The ELISA- results are evaluated visually and it seems that reading results with a spectrophotometer is not standard procedure. To carry-on a more sensitive test, a “cut-off” value is calculated. The samples with a smaller value of absorbance than the “cut-off” value are considered positive. The cut-off value was, however, not specified.

Figures on numbers of controls carried out since 1997 were provided, indicating that feed samples were taken in feed plants and in cattle farms for analytical controls. However, no information was provided on the number of samples taken, or on the results of the analyses that were carried out.

On the basis of the available information, it is considered that cross contamination could and can still occur, albeit several factors seem to be in place to reduce the risk. The mentioned ELISA test is not sensitive and reliable enough to conclude that low cross-contamination (below 0.5%) would have been detected. Also the number of feed samples annually examined is too low.

Conclusion on the ability to avoid recycling

In light of the above-discussed information, it is assessed that the BSE agent, should it have entered the territory of Romania, would 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

In 1994, the cattle population counted, according to Eurostat, 3,481,000 animals, of which 1,784,000 were cows.

At current, the cattle population is slightly more than 2.4 million cattle, of which 1.5 million animals (59,6%) are dairy-cows over 24 months, slaughtered at 8 years or more on average.

		Total (all ages)	Over 24 months old						
			Male			Female			
Period			Meat	Breeding	Work	Meat	Dairy	Breeding	Work
At current	N°	2,439,854	125,743	34,606	30,831	115,957	1,454,278	201,065	9,570
	Age*	81	25	27	108	97	97	35	91

Table 5: Cattle population structure (age*: average age at slaughter in months)

In Romania, there are two main farming systems in which cattle are reared:

1. In the traditional system, farmers rear cattle in limited numbers (1-3 per farm).
   These animals are feed exclusively with fodders of vegetal origin. During the winter period, preserved fodders are used, like hay, beet, maize, barley; during the summer, the animals are feed by free pasture, without receiving other additional food. Approximately 3,700,000 traditional house holdings are counted, of which approximately 1,200,000 rear cattle.
2. The second system of cattle rearing is more intensive in nature and the animals are kept and reared in larger farms.
   The proportion of this system was reduced due to the change of the regime and of the form of propriety in Romania, after 1990. Until 1990, this system was very well developed (90% from bovine livestock were kept and reared in big farms). In 2000, the proportion is inverted. Also the cattle that are reared in this system are feed, according to the country, exclusively with fodder of vegetal origin. Dairy cows are receiving, however, protein-vitamin-minerals supplements (made with proteins of vegetal origin).

   At current, the breakdown of the small number (550) of larger farms size with cattle that still exist is as follows:
   - 135 farms with less than 50 animals;
   - 115 farms with 51-100 animals;

- 62 farms with 101-150 animals;
- 36 farms with 151-200 animals;
- 202 farms with more than 201 bovine animals.

According to the CD co-farming does not exist in large farms but only in the traditional house-holdings, that regularly rear several species. However, the latter are normally not able to purchase any additional feeding. In view of the average national milk yield (2,925 l/cow/year) this is reliable. The average yield in high yield dairy herds is around 6,500 litres/cow/year, requiring supplementary feeding.

Surveillance and culling
BSE is notifiable since 1993.

In 1999, a new legal basis for compulsory national and international notification, fully harmonized with Decision 82/894/EEC and Decision 92/450/EEC was adopted (Ministry of Agriculture Order No. 156).

In accordance with Government Decision 614/1995, the farmers will be compensated at market value of the animals in case of BSE, suspected cases of BSE or for bovine animals slaughtered for diagnosis.

Detailed description of criteria for BSE suspects was provided by the CD. However, this description includes "Selected sub-populations of higher risk animals:
- cattle imported from BSE – affected countries;
- cattle which have consumed potentially infected feedstuffs from BSE-affected countries;
- offspring of BSE – affected cows;
- animals which have consumed feedstuff contaminated with other TSE agents".

It is not clear how this can be assessed by farmers and / or (official) veterinarians, as to how many cattle in the country this corresponds to.

Awareness training:
According to CD, awareness training has been in place since 1995. Laboratory personnel from the Central Veterinary Laboratory of Bucharest was trained in NADC, Ames, Iowa (USA) in 1995 and 1996, in France in 1997 (the same person each year) as well as in Weybridge (UK) in 1998 and in France in 2001 (the same person + a second one, one time in both countries).

Since 1995, annual training is carried out for 15 veterinarians of official laboratories and for all veterinarians in 41 districts.

In February 2001 the laboratory experts received a training in France on immuno-enzymatic technique for the determination of PrP^{res}.

Laboratories:
According to CD, since 1993 in Romania, there has been a state sanitary veterinary network that carries out an active and passive BSE surveillance for both native and imported cattle. This network consists of:
- the National Laboratory for TSE of the Institute for Diagnosis and Animal Health in Bucharest;

- 15 histopathology laboratories “specialised for TSE” of District Sanitary Veterinary laboratories.

The National Laboratory is the national reference laboratory and it co-ordinates the network of the 15 “TSE District Laboratories”, each of them working in close relation with 1 to 4 other District laboratories of the neighbourhood (there are 41 counties and laboratories in total). Since 1993, laboratories are said to work in accordance with the OIE manual (criteria described for confirmation of BSE cases are following the manual).

The 15 “TSE” District laboratories are allowed to carry out BSE examinations themselves but in case of positive or inconclusive results, they send samples to the national reference laboratory for confirmation.

In case of suspicions, cattle heads are collected by veterinary surgeons, the histology examination is decided by the local district veterinary services and brains are sampled by experts of the 15 district laboratories.

Surveillance:
According to CD, all cattle herds, native and imported, are monitored. Histology examinations are carried out on bovine animals over 24 months of age (domestic and imported animals) as follows:
- with nervous signs,
- with “recumbent bovine syndrome”,
- slaughtered by necessity with other signs then nervous signs,
- with progressively weight loss,
- dead due to unknown causes,
- imported in the last 10 years from BSE contaminated countries with international notification, officially listed,
- imported, slaughtered by necessity or dead, in quarantine period,
- slaughtered and dead which are in transit through the Romanian territory.

Romania explained that BSE examination was carried out when all other CNS diseases diagnosis (Rabies, listeriosis, etc.) were negative. However, the CD also mentions that a combination of the two approaches (clinical and histology surveillance) is carried out, targeted mainly on animals over 20-24 months of age.

Results:
Since 1990, no BSE suspect among domestic animals and imported animals has ever been examined by the country laboratory.

The results of BSE examination on non-suspect animals are presented in Table 6 below. According to the CD, the criteria for examination are:
- "Animals imported from specific (BSE affected) countries and from non-specific ("BSE free" according to CD) countries at the end of their productive live or in emergency slaughter (but without BSE signs)."
- "Domestic bovines which were presented for emergency slaughter with different diagnoses but without BSE signs."

Among the total imported animals since 1993, the breakdown of animals tested for BSE per country of origin has been as follows:

- 1,146 animals from NL,
- 149 from DK,
- 113 from Germany,
- 7 from Italy,
- and 1 from France.

It is noted that 33 animals from Austria, 11 from Moldavia and 5 from USA were also tested for BSE. All were found negative.

Year	N° Domestic cattle examined for BSE (> 24 months)	Differential Diagnosis	N° Imported cattle examined for BSE	N° of doubtful	N° of positive
1990	0	Aujeszky' s disease Rabies Listeriosis Non specific meningoencephalitis	0	0	0
1991	0		0	0	0
1992	0		0	0	0
1993	8		4	0	0
1994	114		10	0	0
1995	228		33	0	0
1996	193		143	0	0
1997	412		329	0	0
1998	361		314	0	0
1999	491		241	0	0
2000	717		391	0	0
Total	**2,524**		**1,465**	**0**	**0**

Table 6: Non-suspect cattle that were examined for BSE, results of their examination.

It is assumed that all animals examined corresponded to the definition of animals eligible for examination (as defined above). However, it appears that not all animals eligible were actually examined as, according to the CD, in total 12,638 animals have been imported since 1988 from DK and NL alone.

On the basis of the available information, passive and active surveillance are not assessed as being sufficient to detect low levels of BSE-incidence. The activities are mainly focused on imported animals but do not cover adequately the domestic cattle population of Romania.

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) and of the additional stability factors, mainly cross-contamination and surveillance plus culling, has to be estimated. Again the guidance provided by the SSC in its opinion on the GBR of July 2000 is applied.

Feeding: A feed ban was adopted in 1982. However, no information is provided on analytical controls of the first feed ban and results thereof, or on enforcement measures. Also after the confirmation of this feed ban in 1997 controls were

insufficient to guarantee absence of MBM from cattle feed. Therefore feeding is assessed as "not OK" before 1997 and “reasonably OK” since then.

Rendering: Until 1997 a heat treatment was applied that is not known to reduce BSE-infectivity. Rendering is therefore “not OK” until 1997, when 133°C/20min/3bar was ordered to be applied. However, no information is provided on enforcement procedures. Rendering is therefore still only assessed as "reasonably OK".

SRM-removal: There was no SRM ban before 1995. Between 1995 and 2001, brains and spinal cords (partial ban) were withdrawn from the feed chain and the order de facto excluded all ruminant offal not fit for human consumption from rendering. Since January 2001, fallen stock and SRM are incinerated. However, as no information was provided on enforcement and monitoring of these bans, SRM-removal is assessed as "not OK" throughout the reference period.

Other stability factors: BSE (passive and active) surveillance is existing but not regarded to be sufficient to detect low levels of BSE-incidence. Cross contamination cannot be excluded to occur. Therefore other factors are assessed as reducing the stability of the system to some extent.

<table>
<tr><th colspan="6">Stability of the BSE/cattle system in ROMANIA over time</th></tr>
<tr><th colspan="2">Stability</th><th colspan="4">Reasons</th></tr>
<tr><th>Period</th><th>Level</th><th>Feeding</th><th>Rendering</th><th>SRM-removal</th><th>Other</th></tr>
<tr><td>1980-1990</td><td rowspan="2">Extremely Unstable</td><td rowspan="2">Not OK</td><td rowspan="2">Not OK</td><td rowspan="3">Not OK</td><td rowspan="3"></td></tr>
<tr><td>1991-1996</td></tr>
<tr><td>1997–2000</td><td rowspan="2">Unstable</td><td rowspan="2">Reasonably OK</td><td rowspan="2">Reasonably OK</td></tr>
<tr><td>at current</td></tr>
</table>

Table 7: Stability resulting from the interaction of the three main stability factors and the other stability factors. The Stability level is determined according to the SSC-opinion on the GBR of July 2000.

On the basis of the available information it has to be concluded that the country's BSE/cattle system was extremely unstable until 1996 and is still unstable since 1997.

4. Conclusion on the resulting risks

4.1 Interaction of stability and challenges

The conclusions on the stability of the Romanian BSE/cattle system over time and on the external challenges 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 external challenges that occurred.

Before 1996 the extremely unstable system was exposed to high and moderate external challenges resulting from live cattle and MBM imports. It is therefore likely that the BSE agent entered Romania in that period, reached domestic cattle and was recycled

and amplified. This makes the occurrence of an internal challenge likely, at the latest in the 90s but theoretically also earlier. Whenever it occurred, it would have increased even without any further additional external challenges. The external challenges that continued to be experienced, however, fuelled the growth of the internal challenge further.

INTERACTION OF STABILITY AND EXTERNAL CHALLENGE IN ROMANIA			
Stability		External Challenge	Internal challenge
Period	Level	Level	
1980-1990	Extremely Unstable	High	Likely present and growing over time
1991-1993		Moderate	
1994-1996		High	
1997-2000	Very Unstable		
At current			

Table 8: 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.

4.2 Risk that BSE infectivity entered processing

If the BSE-agent was imported into the country by the earliest imports of breeding cattle from DE in 1981, these cattle could have been processed while being closed to the end of the incubation period in the mid 80s. If it was only imported with the cattle imports of 1991 or thereafter potentially infected cattle could have been slaughtered/processed in the mid 90s. If BSE-contaminated MBM was imported and reached domestic cattle, incubating domestic cattle could also have been processed in the mid 80s or the mid 90s. A processing risk therefore could have existed since from the mid eighties onwards but at the latest since the mid nineties. In view of the instability of the system, this risk increased over time.

4.3 Risk that BSE infectivity was recycled and propagated

Given the extreme instability of the system the BSE infectivity that entered processing since the mid eighties or the mid 90s at the latest was most probably recycled and quickly amplified.

5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK

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

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

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

- As long as the stability remains as low as it is, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent will increase even without further external challenges, in particular within the specialised dairy population,.
- Any further external challenge will increase the risk that, over time, a BSE epidemic will develop in the country. This could not be registered by the existing inadequate surveillance for a long time.

5.3 Recommendations for influencing the future GBR

- Improving the stability of the system would render it less vulnerable to external challenges and would reduce, over time, the GBR. Ensuring through better controls that indeed no MBM is fed to cattle and reliably excluding fallen stock and SRM from entering the feed cycle will significantly increase stability. Better control of appropriate rendering processes will also contribute. Excluding intensive dairy cattle that are most at risk of having received MBM from rendering would also increase stability, as would excluding cattle that were imported from BSE-affected countries.

- Passive (i.e. reliable notification and examination of animals showing clinical signs compatible with BSE) and active surveillance (i.e. sampling by means of rapid screening of asymptomatic at-risk cattle populations) would allow monitoring the efficiency of the stability enhancing measures. Suitable at-risk populations are for example adult cattle in fallen stock and emergency slaughter. In the case of Romania older dairy cattle, being most at risk of having consumed MBM, could also be seen as such a target population, as could cattle that were imported from BSE-affected countries.