

Final Report on the assessment of the Geographical BSE-Risk (GBR) of BULGARIA – 2002

27 June 2002

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, are now serving as the risk assessment required by the TSE-Regulation (EC) 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 sufficient to carry out a qualitative assessment of the GBR.

Sources of data

Country Dossier consisting of:

- Country Dossier: Basic questionnaire for the assessment of the geographical BSE risk for Bulgaria, received 3/11/2000. No annexes.
- Answer of the Bulgarian authorities to the initial draft assessment, received on 18 January 2001.
- Comments and additional information on draft final report received 23 February and supporting documents from 12 March 2001.
- Meeting with country experts on 5 April 2001.
- Further information received on 24 April 2001 including 20 annexes.
- Note on the report for the assessment of the GBR of Bulgaria sent on 5 June 2001 to the European Commission from the Ministry of Agriculture and Forests of Bulgaria.
- Further documentation from 7 August and 24 September 2001.
- Comments on the draft report sent to Bulgaria in May 2002.
- Comments on the final draft report received in June 2002.

Other Sources:

- EUROSTAT data on export of "live bovine animals" and of "flour, meal and pellets of meat or offal, unfit for human consumption; greaves", (customs code 230110), covering the period 1980 to 2001.
- UK-export data (UK) on "live bovine animals" (1980-1996), and on "Mammalian Flours, Meals and Pellets", 1988-1996. As it was illegal to export mammalian meat meal, bone meal and MBM from UK since 27/03/1996, exports indicated after that date under customs code 230110 should only have included non-mammalian MBM.
- Export data from Cyprus, the Czech Republic, Estonia, Hungary, Lithuania, Slovenia and Switzerland.
- Report of the Food and Veterinary Office on a mission to Bulgaria, 25 February – 1 March 2002.

2. EXTERNAL CHALLENGES

Due to weak trade relations between Bulgaria and UK during the socialist regime in Bulgaria and because of price differences, the Bulgarian authorities consider imports of cattle and MBM from the UK as not probable.

2.1 Import of cattle from BSE-Risk¹ countries

- Table 1 provides an overview of the import of live cattle into Bulgaria, as provided in the country dossier (CD) and export figures from BSE-risk countries, as indicated in Eurostat and UK export statistics.
- Since 1988, in BU, all imported animals are under mandatory quarantine on arrival, due to an official special scheme signed by the Director General of the National Veterinary Medical Services (NVMS). Out of two quarantine stations, only one is used for cattle. This mandatory period is of at least 30 days for the females and of 45 days for bulls.
- According to all sources, no live cattle were imported from UK to BU; this is supported by UK export figures.
- According to the CD the imported animals were younger than 2 years of age and intended for breeding. Cattle imported between 1980-87 were slaughtered at 60-70 months of age, those imported between 1988-93 at 80-90 months of age and those imported between 1994-2000 at 60-70 months.
- BU has provided different sets of data concerning cattle imports from Germany, mainly because of the differentiation between cattle originating from the Federal Republic of Germany or the German Democratic Republic. Table 1 presents the total figures that were provided by the country for the imports from Germany.
- According to the CD 10,460 cattle have been imported between 1980-2000 from BSE risk countries.
- According to other data sources (Eurostat, export data provided by non-EU BSE risk countries) 19,334 cattle have been exported to BU, of which 17,651 came from non-UK EU Member States.
- The main discrepancies can be partly explained by the fact that the CD does not mention imports from Austria and the Czech Republic and that BU disputes the import from Germany in 1992 (next but one bullet point). The data on the imports from DE show the biggest discrepancies between CD and Eurostat data.
- It was explained by BU that 1,701 cattle imported from Germany in 1990 (after the German reunification) originated from the territory of the former German Democratic Republic and in particular from farms around the city of Dresden. These cattle are therefore not taken into account.

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

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
Austria	CD																							0
	other																71	58	181	230	3			543
Czech Rep.	CD																							0
	other															1636								1636
Denmark	CD																90			68				158
	other																90			68				158
France	CD				14		1462	2973	220		8			5										4682
	other			14			1362	3233	60		8													4677
Germany	CD	80	55	1084	196	583	770	333	5		14	1701	16	70	6					234	5			5152
	other	28	404	679	466	1025	1184	435	222		349	1705	5073	77	6					234	5	33		11925
Netherlands	CD										16	10					180	34		162	66			468
	other									16	10						34		162	66	35			323
Greece	CD																							0
	other														25									25
Switzerland	CD																							
	other	29		18																				47
UK	CD																							
	other																							
TOTALS																								
non UK	CD	80	55	1084	210	583	2232	3306	225	0	38	1711	16	75	6	0	270	34	0	464	71	0	0	10460
	other	57	404	711	466	1025	2546	3668	282	0	373	1715	5073	77	31	1636	161	92	181	694	74	68	0	19334
UK	CD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 1: Cattle imports into Bulgaria (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 opinion of January 2002.

- BU contests Eurostat figures for the import figures from Germany in 1991 (5,073 animals). BU explains that if these cattle would have been imported they would have passed through the quarantine station, but no indication can be found there. Therefore, it is assumed by BU authorities that these cattle were in transit most probably to a neighboring country (copy of registers of a border inspection post of Bulgaria were provided for 6,033 cattle exported from Germany to Turkey, via BU in 1991). No evidence for this transit action was provided but nevertheless this assessment is based on the assumption that these animals were indeed only in transit. Taking into account that Turkey imported more than 23,000 cattle from Germany in 1991 makes the transit theory at least probable.
- BU explained that the differences between Eurostat and CD data for imported cattle from Germany in 1992 are due to the fact that out of a consignment of 25 heifers and one bull, 7 cattle died in Romania before arrival in Bulgaria.
- BU indicated that out of 839 cattle imported between 1994 and 2000 from BSE risk countries other than UK as many as 315 are still alive and identified. Detailed data (individual identification, place) were provided to support that statement. The balance was either slaughtered or died on farm. It is assumed that most imported cattle are dead (fallen stock or slaughtered) and were rendered.
- As a result more than 12,600 cattle have to be taken into account for the assessment of the external challenge.

2.2 Import of MBM² or MBM-containing feedstuffs from BSE-Risk countries

Table 2 gives an overview of the MBM-imports into BU, as provided in the country dossier and compares it with the Eurostat and UK-export statistics.

- Import of MBM from the UK was banned in 1994. Since 1995 the General Directorate of the National Veterinary Service (NVS) has not issued any permit for import of meat or any other products from bovine animals originating from the UK. The UK export data do not show any exports of MBM to BU.
- According to the initial CD, not a single permit was issued by the NVS for import of MBM from BSE risk countries since 1980 and the BU authorities consider that no MBM was imported from EU Member States.
- However, in the basic questionnaire the BU authorities informed that since 1980 737 tons of feedstuffs including MBM, MM, BM or greaves were imported from Belgium/Luxembourg, Denmark, France and the Netherlands. The main proportion was pig feed (351t) and poultry feed (206t). For consistency reasons these imports are not taken into account for the assessment of the external challenge.

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”.

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
Austria	CD																							0
	other																5							5
Belgium	CD																					100		100
	other															11						111	21	143
Denmark	CD																							0
	other																						22	22
Finland	CD																							0
	other																							0
Germany	CD																							0
	other																						12	12
Hungary	CD																							0
	other																							0
Italy	CD																				80	381	82	543
	other																			79	381	82	542	
Netherlands	CD																						240	240
	other																						240	240
Greece	CD																							0
	other																			3				3
UK	CD																							0
	other																22							22
TOTAL																								
non UK	CD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	80	481	322	0	883
	other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11	50	0	0	82	514	355	0	967
UK	CD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	22	0	0	0	0	0	0	22
	other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2: MBM imports into Bulgaria (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 opinion of January 2002.

- Moreover, the CD provides detailed information on imports of “feeds” from EU Member States. These figures represent a total of 35,757 tonnes from Belgium, Denmark, France, Germany, Greece and the Netherlands between 1984 and 1999. They were destined for pigs, poultry and weaned lambs. For consistency reasons these imports are not taken into account for this assessment. However, it could be assumed that these feeds consisted to a significant extent of MBM. This fact is proven by feed labels/recipes included in the CD. According to these, protein concentrates were imported from different Member States for pig and poultry feed containing up to 56% crude protein which is not far from the crude protein content of pure MBM (up to 70%). It has to be assumed that these “concentrates” represent MBM with added feed additives (vitamins, aminoacids, minerals).
 - In the course of the discussions with the BU authorities, they accepted that more than 880 tons of MBM were imported into BU from EU Member States.
 - According to Eurostat, 967 tons of MBM were exported from non-UK Member States to BU from Austria (5t), Belgium (143t), Denmark (22t), Germany (12t), Greece (3t), Italy (542t) and the Netherlands (240t).
 - BU considers that none of the MBM imports reached cattle and provided some evidence for this:
 - **Italy:** Two copies of veterinary certificates for MBM were provided showing that the 42 tons were imported from IT in 1999 by a company called REYA Fish Ltd., which is only dealing with fish feed. Another 240 tons imported in the same year were according to presented veterinary certificates poultry offal meal.
 - **UK:** BU contests the import of 22 tons from UK in 1995. This must have been poultry offal meal as this amount is not mentioned in the updated UK export statistics only dealing with mammalian MBM and excludes products of non-mammalian origin.
 - **Netherlands:** BU does accept the import of 240 tons MBM in 2000 and provides veterinary certificates from NL (covering 147 tons) mentioning a pig reproduction farm in BU as the destination.
 - **Germany:** BU contests the import of 12 tons of MBM in 2000 and provides a veterinary certificate for 10,5 tons, showing that these products were destined for poultry feeding.
 - **Belgium:** BU claims that 21 tons of MBM imported in 2000 were in fact fish meal. A veterinary certificate for 21 tons of fish meal was provided to substantiate this claim.
- BU contests more MBM imports but these claims can not be properly substantiated.
- Taking all the above mentioned arguments into account, BU has imported approximately 500 tons of MBM, which have to be taken into account for the assessment of the external challenge.

2.3 Overall assessment of the external challenge

The level of the external challenge that has to be met by the BSE/cattle system is estimated according to the guidance given by the SSC in its final opinion on the GBR of July 2000 (as updated in January 2002).

- Live cattle imports:

In total the country imported 19,334 (Eurostat data) live cattle from BSE risk countries, of which none came from the UK. Together these imports represent a moderate external challenge. Broken down to 5 years periods the resulting external challenge is as given in table 3. This assessment takes into account the different aspects discussed above that allow to assume that certain imported cattle did not enter the domestic BSE/cattle system, i.e. were not rendered into feed.

- MBM imports:

In total the country imported 967 tons MBM (Eurostat data) from BSE risk countries, of which none came from the UK. Together these imports represent a moderate external challenge. Broken down to 5 year periods the resulting external challenge is as given in table 3. This assessment takes into account the different aspects discussed above that allow to assume that certain imported MBM did not enter the domestic BSE/cattle system or did not represent an external challenge for other reasons.

External Challenge experienced by <u>BULGARIA</u>				
<i>External challenge</i>		<i>Reason for this external challenge</i>		
Period	Overall Level	Cattle imports	MBM imports	Comment
1980 to 1985	Low	Low	Negligible	The external challenge is mainly due to cattle imports.
1986 to 1990	Moderate	Moderate		
1991 to 1995				
1996 to 2000			Very low	Moderate

Table 3: External Challenge resulting from live cattle and/or MBM imports from the UK and other BSE risk countries. The Challenge level is determined according to the SSC-opinion on the GBR of July 2000 (as updated in January 2002).

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

3. STABILITY

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

Feeding

It was stated that there was never a tradition in Bulgaria to include of MBM in feed for ruminants. From 1980 until mid 1995, fattening and dairy calves were fed with high level of proteins, but these were later reported to be of plant origin.

It was indicated that on the basis of Bulgarian State Standard N°1643 of 1987, compound feed were centrally defined and that since 1966 these standards were absolutely mandatory throughout the country. MBM was not an approved ingredient for ruminant feed and some feed formulas were described to demonstrate this. It is, however, clear that MBM was included in the rations for pigs and poultry. It is also noted that the provided Bulgarian standards for ruminant feed included the categories: “fodder additives, stimulating and other products – imported; binding substances for granulating – imported”. However, according to the FVO report home compounders are not bound to the mentioned feed standards.

In 2001, only 45 feed mills out of 81 were approved by NVMS. 34 of the approved feedmills are multi-species feedmills. The total national feed production was given as around 1,500,000t in 1995 and 710,000 t in 1999, of which 56% for pigs, 38% for poultry, 5.6% for cattle and 0.4% for other animals. A detailed list of 29 major feed plants was provided indicating that most plants were producing feed for ruminants as well as for non-ruminants in the same production lines. Only 6 plants have 2 production lines of which, according to the CD, one was exclusively dedicated to ruminant feed. However, the annual production of ruminant feed that was indicated in that table for the year 1999/2000 amounts to about 7,745t or nearly 11% of the total annual feed production of 710.000t.

Feedbans

- A first “ban” was issued on 23 October 1995 (Order No. I-4817) prohibiting to feed poultry feed to ruminants. This is not a feed ban protecting cattle from BSE.
- With another order (No. I-4818) also issued on 23 October 1995 the use of RMBM imported from EC Member States for the production of compound feed for ruminants is prohibited.
- Only on 10 October 2000 an order (No. 09 1002) was issued prohibiting the use of MBM for the production of compound feed for ruminants.

Potential for cross-contamination and measures taken against

In order to avoid cross-contamination the following legislation was issued:

- Order (No. 09-733) of 28 June 2001 prohibiting the production of ruminant feed in feedmills, which are not equipped with a dedicated production line. This order was repealed by an order (No. 09-68) of 22 January 2002, which prohibits the production of ruminant feed in feedmills using MBM for any product not having a

dedicated production line (for the production of feed without the use of MBM). Also labelling provisions for MBM containing poultry and pig feed are set (“this feed is forbidden for the feeding of ruminants”).

- Instructions were issued in January 2002, that each produced batch of ruminant feed has to be sampled and checked for the presence of MBM. A batch can only be released for feeding once a negative result is obtained.
- The CD also states that since the 60s the following practices were adopted in Bulgaria in the feed plants, not specialized for individual animal species: “after each feed production batch for bovines, pigs and poultry, a few tons of bran are flushed in the line. The produced feed is then separated into individual columns, packed and labeled with indication of the composition and the animal species it is intended for”, however no evidence on the efficiency of these measures was provided.

Risk of cross-feeding on multi-species farms

Small farmers in Bulgaria practice mixed rearing of cattle, pigs and poultry. It is stated that these animals are fed on fodder of plant origin obtained on the farm and small farms cannot afford to buy other feeds for their animals.

Control of feed bans and cross-contamination

The BU authorities claim that since November 1995 on the spot inspections of feedmills have been carried out. The frequency of the checking is different in the various regions– two to four times a year.

The effectiveness of the controls of the ban to feed MBM to ruminants is doubtful, because:

- A comprehensive national feed control programme concerning the implementation of the ban is missing.
- Since 2001, ruminant feed is sampled and checked for the presence of MBM (2001: 41 samples, 2002: 122 samples). The method used to analyse the samples is microscopy. However, the EU method is only used since January 2002. So far all samples were negative, which is very surprising taken into account the structure of the BU feed industry and against all experience in the Member States.

In the light of the available information it is concluded that cross-contamination of cattle feed with MBM was and is likely to occur, in particular in the multi-species feed mills operating only one production line.

Rendering

- An Instruction (legal act with binding force) signed by the Director General of the Science and Productive Association "Veterinary Activities" (the name of the NVS at that time) signed on 15.04.1986, which contains technological requirements to the process of yielding and manufacturing of 'bone-protein' fodder powders was brought to the attention of the European Commission with the Bulgarian note dated 5 June 2001. Section 'B' of this Instruction reads as follows:

“1. The big and small valve shall be closed, these valves been placed on the pipe taking away the tissue (juice) vapours.

2. *The action of the mixing mechanic device shall be stopped, so that it could be turned into direction 'boiling-drying'.*
3. *Steam shall be flowed in the steam vessels of the destruction tank and into the mixing mechanical device until it reaches 4-5 atmospheres pressure and temperature of 130-135°C.*
4. *This thermal (heat) mode shall be kept for no less than 20-30 minutes."*

This Instruction has been notified to all rendering plants' managers and control bodies, and it was obligatory to meet and comply with its requirements. However, no data on the compliance with this regulation were provided.

- The order of 23 October 1995 (Order No. I-4817) specifies that the rendering parameters have to fulfil the following: 133°C, 3 bar, for 30 min.

The CD stated that all rendering plants throughout the country have always been equipped for work at high temperatures aiming at the destruction of spore-forming bacteria (Anthrax).

The rendering industry

A rendering industry exists in the country (6 plants). Bovine materials, including SRM and fallen stock, have always been rendered for feed production, together with materials from other species. However, animal waste including SRM and fallen stock may also be buried.

The production of MBM declined by more than 60% between 1990 and 2000. Bulgaria explained that during this period the total number of plants decreased from 11 to 6, and that privatisation of rendering plants occurred in 1996. The latter explains partly the severe drop in production from 1996 to 1997 by 36% alone. The significant increase of the inflation rate that was recorded in that year and that slowed-down the entire economy was one of the causes.

Year	Annual Production (tonnes)	Year	Annual Production (tonnes)
1990	14,477	1996	12,171
1991	12,934	1997	7,802
1992	14,359	1998	7,848
1993	13,982	1999	5,899
1994	14,808	2000	5,590
1995	13,857	2001	4,094

Table 4: Production of MBM (by years, total for the country).

Controls

Between 1972 and 1992 a dedicated rendering plant service in the Ministry of agriculture was responsible for rendering plant inspections. However, information on inspection from that period are not any more available while since 1993, on average, 1 - 4 controls have been carried out each year in each of the nine rendering plants to which the provided information referred. Controls were targeted to identify the compliance with all sanitary and technological requirements, including taking and testing samples from each individual batch of MBM produced, the absence or presence of salmonella and of anthrax spores included. The CD indicates that

according to a Bulgarian State Standard, samples were mainly checked by microscopic and organoleptic testing.

Official veterinarians are responsible for the control on the activities of each individual rendering plant. 47 certificates so produced in four rendering plants were provided, referring to years in the period 1988 - 2001. From these certificates it appears that the parameters indicated above were "minimum" conditions that were not exactly followed. The temperatures recorded vary between 132°C and 137°C, the pressures recorded vary between "no pressure mentioned" and 5 atmospheres and the duration of heat treatment varies between 40 minutes and "at least 1 hour". These certificates indicate, however, that official control services have verified heat treatment conditions since 1988, in at least four rendering plants, and apparently more intensively since 1994, mainly in one plant. They also show that appropriate heat treatment conditions were frequently realised but not always.

In 2001, all rendering plant managers have been informed that they must buy recording devices in order to monitor, check and control heat treatment parameters. All rendering plants not equipped with such devices or not following 133°C / 3 bar / 20 min parameters will be closed (no indication on dead line for complying with this order and no indication of legal basis of this order were provided).

SRM and fallen stock

- On 4 January 2002 an order (No. RD 09 6) was issued requiring the removal, separate collection and destruction of SRM. The definition of SRM does not cover vertebral columns.

Previously, there was no SRM-ban and during the last 20 years SRM and fallen stock have been included in the raw material entering rendering.

However, a substantial part of the SRM is traditionally consumed by humans in Bulgaria.

Conclusion on the ability to avoid recycling

In light of the above-discussed information it is concluded that the BSE-agent, should it have entered the territory of BU, it would have been recycled and potentially 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

The cattle population was approximately 1,8 million animals in 1980 (of which 712,000 dairy cows). According to the latest information provided the cattle population is around 680,000 animals, of which around 380,000 are older than 24 months.

The cattle population decreased from 1980 to 2000 with a significant drop in 1993 (less 26%). It was indicated that at that moment a large proportion of the animals allocated to private owners were immediately slaughtered when co-operatives were privatised as many people concerned were already living in towns and did not want to keep these animals.

At present, almost two thirds of the cattle are females for breeding, one third corresponds to males for meat production (slaughtered between 17-21 months).

According to the CD the average milk yield (varying between 2,600 liters and 3,450 liters / cow/ year since 1980) was such that on average plant proteins are sufficient to cover the needs and animal protein are not necessary. At current the average milk yield is 3,150 liters / cow / year.

BSE surveillance

Notification of BSE has been compulsory since 1994. Compensation (for cases, for BSE-suspects and for culled “at risk” animals) has been in place since 1998, at the amount of the market price.

Awareness training has been in place since 1995. About 1,000 state veterinarians and 2,000 private veterinarians are practicing in Bulgaria. All veterinarians have passed a training course on BSE, illustrated with video material on clinical signs of the disease. The slaughterhouses staff members, the farmers, and the persons involved in the transportation of animals are supplied with abundant instructions for the measures related to the protection against BSE. All protection measures are widely advertised through the mass media (TV, radio, newspapers, specialized publications etc.).

An Order of the Ministry of Agriculture and Food Industry was issued on 23 October 1995 for BSE laboratory investigation of all cattle that have shown clinical symptoms similar to those of BSE. Two senior officials have been sent to Weybridge in 1998 to be trained on this issue.

Laboratory personnel have been trained since 1997. Experts from the Central Veterinary Research Institute (CVRI) in Sofia were commissioned to a specialized training course on BSE diagnostics in the laboratory of Weybridge, UK. At present the laboratory diagnostics of BSE in the CVRI is carried out by experts that have attended the BSE training course in Weybridge.

The following diagnostic methods are foreseen and they will be carried out by the Central Research Veterinary Institute and by the Bulgarian Academy of Sciences:

- patho-histological examination of brains of BSE suspects or ill cattle for detecting BSE specific changes;
- immuno-histochemical examination for confirmation of the specific abnormal protein (prion) in the brain;
- direct electronic microscopy by the method negative contrast for confirmation of the so called “scrapie-associated fibrils” in the brains;
- immunoblotting test based on the Western blotting procedure for prion check;
- ELISA including extracting procedure and ENFER tests.

Histopathology is used to verify BSE-suspects (the specific histological lesions in brains are used as criterion for the confirmation).

At current, brains of cattle are examined by histology, immuno-histology and Western-blot (no “rapid test” used). A suspicion is confirmed if two of these examinations are positive. In case of suspicion, confirmation from internationally recognised reference laboratories of EU Member states will also be requested.

Passive surveillance

Before 1999, no BSE examinations had ever been performed and no domestic or imported BSE suspects had ever been notified. The only examinations performed were carried out on 2 rabies suspected cases in 1999 and another 2 in 2000.

Active surveillance

A program for active BSE monitoring between March 2001 and December 2001 was provided by the country authorities. According to this program, it is intended to test (histopathology, IHC) all bovine animals:

- with CNS disorders (any cattle that have shown clinical signs similar to BSE),
- and all cattle over 24 months old:
 - intended for “emergency slaughter”;
 - fallen stock;
 - imported from BSE risk countries (the list of countries, dated 30 January 2001 refers to Denmark, Germany, the Netherlands, France and Austria);
 - fed with feeds and feedstuffs assumed to be potentially contaminated with meat-bone meals (MBM) or with processed animal proteins;
 - progeny of BSE infected animals and progeny from cattle imported from countries where BSE has been confirmed.

The following symptoms are included in the “CNS category”: movement disturbances, abnormal posture, low position of the head, ataxia, difficulty in turning, tooth grinding, falling, difficulty in climbing, weakness, abnormal positioning of hind legs during lying, reduced rumen movement, without any change in the appetite, bradycardia, weight loss, reduced milk production, progressive weight loss and recumbency.

It was later indicated that all animals imported from BSE risk countries will be tested as well as all animals over 30 months slaughtered for human consumption.

It is intended to test at least 1,890 animals, despite the fact the program indicates explicitly “all animals” of the category described and at least 10% (189) samples should be fallen stock. A breakdown of the total number of samples per region is indicated. It varies between 40 and 100 samples per region (a total of 28 regions).

In 2001, 401 examinations had been carried out (254 healthy slaughtered, 113 emergency slaughtered, 6 fallen stock, 20 cattle imported from BSE countries and 8 offspring to such cattle). All laboratory examinations showed negative results. As of end of May 2002, 43 cattle have been examined for BSE with negative results.

As from August 2002, a monitoring program according to Regulation No 999/2001 will be implemented using a rapid post mortem test.

Conclusion on the ability to identify BSE-cases and to eliminate animals at risk

If BSE is present in the country, with the monitoring/surveillance system in place, it is unlikely that it would be detected.

3.3 Overall assessment of the stability

For the overall assessment of the stability the impact of the three main stability factors and of the additional stability factor, surveillance, has to be estimated. Again, the guidance provided by the SSC in its opinion on the GBR of July 2000 is applied.

Feeding

Feeding MBM to cattle was legally possible until 2000 but was most probably not standard practice. Therefore, feeding was "**not OK**" until the ban from the year 2000. Cross-contamination is very likely to occur. However, once the efficiency of the 2000 feed ban is confirmed by sufficient feed controls, feeding can be regarded "OK".

Rendering

Rendering was and is common practice in Bulgaria. Material includes ruminant material, including SRM and fallen stock. The heat treatment, which was required since 1986 should have been sufficient to reduce BSE infectivity. No evidence of controls is provided for the period before 1988. Since then controls of the treatment conditions apparently took place. Rendering is assessed as having been "**not OK**" before 1988 and "**reasonably OK**" since then. Once the improvements that started in 2001 are fully completed, and registration and process control conditions are confirmed, rendering can be assessed as "**OK**". This would make the system neutrally stable.

SRM-removal

There is no SRM ban before January 2002 and SRM was rendered if not eaten by the human population. Fallen stock is also rendered for feed. SRM removal is therefore assessed as "**not OK**" throughout the reference period. However, if the SRM ban of January 2002 is efficiently implemented SRM-removal could be assessed as "OK".

BSE surveillance

BSE surveillance is found to be unsatisfactory. This therefore reduces the stability.

Stability of the BSE/cattle system in <u>BULGARIA</u> over time					
Stability		Reasons			
Period	Level	Feeding	Rendering	SRM removal	BSE surveillance
1980 to 1987	Extremely unstable	Not OK	Not OK	Not OK	↓
1988 to 2000	Very unstable		Reasonably OK		

Table 5: 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.

On the basis of the available information it is concluded that the country's BSE/cattle system has been extremely unstable until 1994 and is still very unstable since then. If the measures introduced in 2000, 2001 and 2002 (feed ban, improved rendering, and SRM-ban) are efficiently implemented the system would be seen to be optimally stable, i.e. the risk of new infection would be minimal.

4. CONCLUSION ON THE RESULTING RISKS

4.1 Interaction of stability and challenges

In conclusion, the stability of the Bulgarian BSE/cattle system in the past and the external challenges the system has coped with are summarised in the table below. From the interaction of the two parameters "stability" and "external challenge" a conclusion is drawn on the level of "internal challenge" that emerged and that had to be met by the system, in addition to external challenges that occurred.

An external challenge resulting from cattle import could only lead to an internal challenge once imported infected cattle were rendered for feed and this contaminated domestic feed reached domestic cattle. Cattle imported for slaughter would normally be slaughtered at an age too young to harbour significant of BSE infectivity or to show signs, even if infected prior to import. Breeding cattle, however, would normally be about two years when at import and live for 5 to 7.5 years or more in Bulgaria after import. 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. Special measures taken to avoid processing of imported cattle into feed could influence the risk of this happening. In Bulgaria, incubating cattle imported from

Germany, Switzerland and France could thus theoretically have been slaughtered and rendered in the mid 80s.

INTERACTION OF STABILITY AND EXTERNAL CHALLENGE IN BULGARIA			
Stability		External Challenge	Internal challenge
Period	Level	Level	
1980-1985	Extremely Unstable	Low	Unlikely but cannot be excluded
1986- 1987		Moderate	Likely present and growing
1988–2000	Very unstable		

Table 6: 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.

On the other hand imports of contaminated MBM, MM, BM or greaves 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 view of the above-described reflection the registered moderate external challenge to Bulgaria could have led to an internal challenge in the end of the 80s if live cattle imported from Germany, Switzerland and (after 1987) France were rendered for feed. It is considered that imports of live cattle from eastern Germany, although high in numbers, were less challenging than from the western parts of the country. The exceptionally high exports from Germany to Bulgaria in 1991 would have increased the risk strongly if these animals did not leave Bulgaria again.

If indeed incubating cattle were rendered in Bulgaria, the agent would have entered an extremely unstable (after 1996 a very unstable system) and would have been recycled and amplified. The resulting internal challenge would have been growing over time.

The external challenge that was experienced after this initial introduction supported this development. Of particular importance are the recent MBM imports into Bulgaria from BSE risk countries in 1998/99 and 2000.

4.2 Risk that BSE infectivity entered processing

A risk that BSE infectivity entered processing first existed about 3 years after the import of breeding cattle in the early 80s, i.e. around the mid 80s. Given the instability of the system, this risk increased over time, when domestic incubating animals were processed.

4.3 Risk that BSE infectivity was recycled and propagated

Given the instability of the system the BSE infectivity that entered processing since the mid 80s was probably recycled and 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 system remains unstable, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent continues to grow, even if no further external challenges are experienced.
- If the measures implemented in 2000, 2001 and 2002 are efficient, the system would be optimally stable and the GBR would decline with the rate at which cattle born before the system became optimally stable leave the system.

5.3 Recommendations for influencing the future GBR

- Improving the stability of the system, in particular by avoiding any MBM being fed to cattle but also by excluding SRM and fallen stock from entering the feed cycle, would be most appropriate. The total feed ban of 2000 (2002) and the SRM ban (4/1/2002) and the improvements of the rendering equipment (2001) contribute to the stability. If properly implemented the system becomes optimally stable.
- Improved surveillance, e.g. by strengthening passive and effectively implementing active surveillance, would improve the basis for assessing the BSE-situation in Bulgaria, the active surveillance including sampling of asymptomatic at-risk cattle populations (adult cattle in fallen stock and emergency slaughter), e.g. by means of rapid screening with BSE-tests.