

**Opinion of the**  
**Scientific Steering Committee**  
**on the**  
**GEOGRAPHICAL RISK OF**  
**BOVINE SPONGIFORM**  
**ENCEPHALOPATHY (GBR) in**  
**Bulgaria**

Adopted by the SSC on 27 June 2002

## **Opinion of the Scientific Steering Committee on the GEOGRAPHICAL RISK OF BOVINE SPONGIFORM ENCEPHALOPATHY (GBR) in BULGARIA – 2002**

### **THE QUESTION**

The Scientific Steering Committee (SSC) was asked by the Commission to provide an up-to-date scientific opinion on the Geographical BSE-Risk (GBR), i.e. the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, in countries that have formally requested the determination of their BSE status in accordance with Article 5 of the Regulation (EC) No 999/2001 of the European Parliament and of the Council.

This opinion addresses the up-to-date GBR of Bulgaria as assessed in June 2002.

### **THE ANSWER**

A risk that BSE infectivity entered processing in Bulgaria first existed about 3 years after the import of breeding cattle from Switzerland, Germany and France in the early and mid 80s. Any infectivity that entered processing was probably recycled and amplified by the extremely unstable (later very unstable) system.

It is therefore concluded that it is likely but not confirmed that at least one domestic cattle in Bulgaria is (clinically or pre-clinically) infected with the BSE-agent (**GBR III**).

The SSC is aware that not all available information was confirmed by inspection missions as they were performed by the FVO in the Member States. It recommends that BSE-related aspects are continued to be included in the program of future inspection missions, as far as feasible.

### **THE BACKGROUND**

In July 2000 the SSC adopted its final opinion on "the Geographical Risk of Bovine Spongiform Encephalopathy (GBR)". It described a method and a process for the assessment of the GBR and summarised the outcome of its application to 23 countries. Detailed reports on the GBR-assessments were published on the Internet for each of these countries.

On 1 July 2001 Regulation (EC) No 999/2001 of the European Parliament and of the Council entered into force. This regulation lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies in animals (TSE Regulation). Appropriate risk management measures are defined in relation to the BSE Status category. In Annex II of this Regulation the method for the determination of the BSE status is described. It requires two steps, namely a risk assessment and the evaluation of specific criteria listed in annex II, chapter A, point (b) to (e). The Commission regards the GBR as provided by the SSC as an adequate Risk Assessment as required by the regulation. However, countries may also provide their own risk assessment in which case the SSC will be requested to provide a scientific opinion on the validity of that risk assessment as well as of its result.

In January 2002 the SSC updated its opinion on the GBR and determined that exports from all countries classified as GBR III or IV pose a certain risk of carrying the BSE agent, independent if they have or have not confirmed at least one domestic BSE case. The SSC also provided an estimate of the level of risk emitted from these "BSE-risk countries" in relation to the time of export.

Bulgaria has formally requested the determination of its BSE status in accordance with Article 5 of the TSE Regulation and subsequently the Commission asked the Scientific Steering Committee (SSC) to provide an up-to-date scientific opinion on the Geographical BSE-Risk of Bulgaria.

## THE RISK ASSESSMENT

It is concluded that it is likely but not confirmed that domestic cattle in Bulgaria are (clinically or pre-clinically) infected with the BSE-agent (**GBR III**).

## THE ANALYSIS

### 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 live cattle (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 years periods the resulting external challenge was low between 1980 and 1985, moderate from 1986-1995, and very low thereafter. This assessment takes into account the arguments brought forward by the country that allow assuming 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 years periods the resulting external challenge was negligible from 1980 to 1995, and moderate thereafter. This assessment takes into account the arguments brought forward by the country that allow assuming that certain imported MBM did not enter the domestic BSE/cattle system or did not represent an external challenge for other reasons.

As these two sources of external challenge have to be added-up, Bulgaria was exposed to a **low external challenge** from 1980-1985 and a **moderate external challenge** from 1986-2000. This makes it likely that the BSE agent was imported into the country.

### STABILITY

On the basis of the available information it was concluded that the country's BSE/cattle system was **extremely unstable** from 1980 to 1987 and **very unstable** from 1988 to current. Once the measures taken in 2000 (feed ban), 2001 (improved rendering equipment) and 2002 (SRM-ban) are properly implemented the system will become "optimally stable".

### *Feeding*

Feeding MBM to cattle was legally possible until 2000 but was most probably not standard practice. The available information on the control of the feed-ban of 2000 is not sufficient to assess its efficiency. Cross-contamination is very likely to occur also after the feed bans of the year 1995 and 2000. Thus feeding was and is **"not OK"**. 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 should be sufficient to reduce BSE infectivity but no evidence of controls is provided for the period before 1988. Since then controls of the treatment conditions apparently took place. Rendering is therefore 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 control of process conditions is confirmed, rendering can be assessed as “OK”.

### **SRM-removal**

There was no SRM ban before January 2002 and SRM was rendered or eaten by the human population until the end of 2001. Fallen stock is also rendered. SRM removal is assessed as "**not OK**" throughout the whole reference period. However, since 4/1/2002 an SRM-ban exists. If it can be demonstrated that this ban is properly implemented, SRM-removal would be assessed “OK”.

### **BSE surveillance**

BSE surveillance is found to be unsatisfactory. It cannot ensure detection of low level of BSE incidence.

### **CONCLUSION ON THE CURRENT GBR**

A risk that BSE infectivity entered processing in Bulgaria first existed about 3 years after the import of breeding cattle from Germany and Switzerland in the early 80s, i.e. around the mid 80s. Any infectivity that entered processing was probably recycled and amplified by the extremely unstable (later very unstable) system.

It is therefore concluded that it is likely but not confirmed that at least one domestic cattle in Bulgaria is (clinically or pre-clinically) infected with the BSE-agent (**GBR III**).

### **EXPECTED DEVELOPMENT OF THE GBR**

As long as the system remains very 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.

*A table summarising the reasons for the current assessment is given in annex 1 to this opinion. A detailed report on the assessment of the GBR of Bulgaria as produced by the GBR-Peer Group is published separately on the Internet. The country had opportunities to comment on different drafts of the report before the SSC took both, the report and the comments, into account for producing this opinion. The SSC appreciates the good co-operation of the country's authorities.*

Bulgaria – Summary of the GBR-Assessment, June 2002							
	EXTERNAL CHALLENGE		STABILITY				INTERACTION of EXTERNAL CHALLENGE and STABILITY
	1980-1985: Low 1986-2000: Moderate		1980-1987: Extremely unstable 1988- : Very unstable at current: potentially optimally stable but not confirmed				The extremely unstable (1980-1987) and very unstable (since 1988) BSE/cattle system of Bulgaria was exposed to an increasing external challenge since the early 80s (low from 1980-1985 and moderate thereafter) first due to cattle imports from BSE risk countries, later (since 1996) mainly due to MBM imports. The external challenge makes it likely that the BSE agent entered Bulgaria and the instability of the system makes it likely that it was recycled and amplified.
GBR-Level	Live Cattle imports	MBM imports	Feeding	Rendering	SRM-removal	BSE surveillance	
III	<p>UK: No imports according to country import data and to other export data.</p> <p>Other BSE risk countries: 10,460 according to country import data. According to other export data, 19,334 from AT, CZ, DK, FR, DE, NL, GR and CH.</p>	<p>UK: 22 t according to other export data and no imports according to country import data.</p> <p>Other BSE risk countries: According to country import data: 96-2000: 883 t</p> <p>According to other export data: 91-95: 61 t 96-2000: 951 t Total: 967 t</p>	<p><b>Not OK 1980-2000 Potentially OK since 2001.</b></p> <ul style="list-style-type: none"> <li>Feeding MBM to cattle legally possible until end 2000.</li> <li>Available information on control of feed bans of 1995 (imported ruminant MBM) and 2000 not sufficient to assume improvements.</li> <li>Cross-contamination likely to occur throughout the reference period.</li> <li>If the efficiency of the feed ban of 2000 is demonstrated, feeding would be "OK".</li> </ul>	<p><b>Not OK 1980-1987, Reasonably OK 1988-. Potentially OK since 2001.</b></p> <ul style="list-style-type: none"> <li>Rendering common practice in Bulgaria.</li> <li>Material includes ruminant material (SRM and fallen stock).</li> <li>Heat treatment sufficient to reduce BSE infectivity but no evidence of controls provided for period before 1988.</li> <li>Since then controls of treatment conditions apparently took place.</li> <li>Since 2001, after improved control equipment was ordered, rendering is potentially OK.</li> </ul>	<p><b>Not OK 1980-2001. Potentially OK since 4/1/2002</b></p> <ul style="list-style-type: none"> <li>Before 2002 there was no SRM ban and SRM was rendered or eaten by the human population. Fallen stock was also (partly) rendered.</li> <li>Since 4/1/2002 SRM-ban and SRM removal could be regarded "OK" if the efficiency of that SRM ban were confirmed.</li> </ul>	<p>BSE listed as notifiable disease since 1994. Compensation (market price) since 1998. Awareness training since 1995 and training of laboratory personnel since 1997. Before 1999 no BSE examinations. Active surveillance introduced in March 2001. BSE surveillance is found to be unsatisfactory.</p>	
GBR-trend							<b>INTERNAL CHALLENGE</b>
continues existing							An internal challenge could have occurred in the middle to the end of the 80s if live cattle imported from CH, DE and (after 1987) FR were rendered for feed. The resulting internal challenge would have been growing over time. This growth was supported by the continuing external challenge, making it likely that at current an internal challenge exists in Bulgaria.