

Opinion of the
Scientific Steering Committee
on the
GEOGRAPHICAL RISK OF
BOVINE SPONGIFORM
ENCEPHALOPATHY (GBR) in the
Former Yugoslav Republic of Macedonia
adopted by the SSC on 10 April 2003

Opinion of the Scientific Steering Committee on the GEOGRAPHICAL RISK OF BOVINE SPONGIFORM ENCEPHALOPATHY (GBR) in the Former Yugoslav Republic of Macedonia – 2003

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 the Former Yugoslav Republic of Macedonia as assessed in April 2003.

THE ANSWER

The BSE-agent may have reached the territory of the Former Yugoslav Republic of Macedonia before its independence in 1992. Since 1995 significant amounts of MBM were imported from BSE risk countries. A significant risk that BSE infectivity entered processing therefore exists since some years, at the latest since 2000, when domestic cattle potentially exposed to contaminated imported MBM around 1995, could have been slaughtered while approaching the end of the incubation period. Given the instability of the system, this could have led to BSE cases.

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

The SSC is concerned that the available information was not confirmed by inspection missions as they are performed by the FVO in the Member States. It recommends that BSE-related aspects are 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.

The Former Yugoslav Republic of Macedonia 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 the Former Yugoslav Republic of Macedonia.

THE RISK ASSESSMENT

The SSC concluded that it was “likely but not confirmed” (**GBR III**) that domestic cattle in the Former Yugoslav Republic of Macedonia are (clinically or pre-clinically) infected with the BSE-agent.

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). This assessment takes account of the available information on the origin and use made of the imported cattle and MBM.
- It has been noted that the external challenge faced by the former Yugoslavia prior to 1992 was always significant. Between 1980 and 1991 it was high, mainly due to imports of MBM or due to the combined imports of live cattle and MBM from BSE risk countries. The proportion of these imports that remained in territory of the Former Yugoslav Republic of Macedonia is not known and therefore as a realistic worst case assumption, it is assumed that the external challenge experienced by the territory of the Former Yugoslav Republic of Macedonia before 1992 was high enough to make it possible that the BSE agent could have been introduced in the country.
- Live cattle imports: Over the period 1992 to 2001, 6,443 live cattle were exported to the Former Yugoslav Republic of Macedonia from BSE risk countries, of which none came from the UK. This assessment takes into account that cattle imported since 1995 could not have been rendered. This implies that the BSE-agent, should it have been present in any of the imported cattle imported since 1995, could not have reached domestic cattle.
- MBM imports: Over the period 1992 to 2001, 2,562 tons of MBM were exported to the Former Yugoslav Republic of Macedonia from BSE risk countries, of which none came from the UK.

Stability

No information was available on the BSE/cattle system on the territory of the Former Yugoslav Republic of Macedonia before 1992 but it is assumed that it was not more stable than in the Former Yugoslav Republic of Macedonia after its independence. On the basis of the available information it was concluded that the country’s BSE/cattle system was extremely unstable from 1992 to 1994; i.e. it would have recycled and amplified BSE infectivity, should it have entered the system. The same is probably true for the situation before 1992. With the disappearance of the inappropriate rendering since 1995 the system improved to stable and in 2001, with the amendment of the SRM-removal measures, it improved further to very stable.

Feeding

As no legally binding feed ban was in force, MBM could have been fed to dairy cattle until 2000. Limited evidence is provided on the enforcement of the 2000 total feed ban. Feeding is assessed as being “**not OK**” from 1992 until 2000. Feeding is “**reasonably OK**” since 2001, when the total feed ban was introduced.

Rendering

As there was one rendering facility in the territory of the Former Yugoslav Republic of Macedonia operating from 1987 until 1994 using non- appropriate rendering conditions, rendering is considered to be “**not OK**” until the end of 1994. Since 1995, there is no rendering plant in the country. Therefore rendering is regarded as “**OK**” since then.

SRM-removal

SRM could have been processed before 1995, when a rendering plant existed. Therefore SRM-removal is considered “**not OK**” from 1992 to 1994. Since 1995 SRM is not rendered anymore but buried or consumed by the human population and is therefore considered as “**OK**” since then.

BSE surveillance

BSE surveillance is not adequate to detect low level of clinical BSE incidence.

CONCLUSION ON THE CURRENT GBR

The BSE-agent may have reached the territory of the Former Yugoslav Republic of Macedonia already before its independence in 1992. After 1995 significant amounts of MBM were imported from BSE risk countries. A significant risk that BSE infectivity entered processing therefore exists since some years, at the latest since 2000, when domestic cattle potentially exposed to contaminated imported MBM around 1995, could have entered processing while approaching the end of the incubation period. Due to the absence of any rendering the processed infectivity would not have been recycled and amplified.

However, it cannot be excluded that cattle potentially infected already before the independence of the country might have been processed and rendered in the country until 1994. Until 1994 infectivity might have been recycled and amplified in the country.

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

EXPECTED DEVELOPMENT OF THE GBR

As long as the stability remains as it is, the probability of cattle being (pre-clinically or clinically) infected with the BSE-agent will continue to exist due to MBM imports from BSE-risk countries.

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 the Former Yugoslav Republic of Macedonia 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.

FORMER YUGOSLAV REPUBLIC OF MACEDONIA – SUMMARY OF THE GBR-ASSESSMENT, APRIL 2003							
	EXTERNAL CHALLENGE		STABILITY				INTERACTION of EXTERNAL CHALLENGE and STABILITY
	1980-1991: Significant 1992-1995: Low 1996-2000: High		1992-1994: Extremely unstable 1995-2000: Stable since 2001: Very stable				It is likely, that the BSE-agent could have entered the territory of the Former Yugoslav Republic of Macedonia via imports even before its independence. After the independence, significant MBM imports started in 1996, when the system was already stable.
GBR-Level	Live Cattle imports	MBM imports	Feeding	Rendering	SRM-removal	BSE surveillance	
III	UK: No imports according to country import data and according to Eurostat and other export data.	UK: no MBM imports according to all sources.	Not OK 1992-2000, reasonably OK since 2001. No legally binding feed ban until 2000 (total feed ban). Limited evidence for enforcement of the total feed ban	Not OK 1992-1994, OK since 1995. The only rendering facility operating not fulfilling the 133°C, 3 ^{bar} , 20 ^{min} standard in the country closed in 1994. No rendering of animal waste since 1995.	Not OK 1992-1994, OK since 1995 SRM could have been rendered until 1994. No rendering of SRM since 1995.	BSE has been notifiable since 1998. No BSE surveillance until 1998. Some surveillance in place since 1999, but insufficient to ensure detection of BSE cases.	INTERNAL CHALLENGE It is very likely that an internal challenge emerged in the territory of Former Yugoslav Republic of Macedonia already before its independence in 1992 due imports to former Yugoslavia and that it continued to exist and to grow until the end of 1994. Due to the absence of any rendering activities since 1995, the internal challenge fully depends on MBM imports.
GBR-trend	<u>Other BSE risk countries:</u> 5,647 according to the country import data from BE, DK, DE, NL, PO, SK. According to Eurostat and other export data 6,443 from AU, BE, DK, FR, DE, HU, IT, NL, SL.	<u>Other BSE risk countries:</u> According to country import data: 92-95: 0 t 96-2000: 1,178 t Total: 1,178 t According to Eurostat and other export data: 92-95: 65 t 96-2001: 2,497 t Total: 2,562 t					
depending on MBM imports	<u>Comment:</u> Country import data: 431 cattle imported from 1992-1994. Eurostat and other data 658 cattle imported from 1992-1994.						