# OPINION OF THE SCIENTIFIC STEERING COMMITTEE ON THE GEOGRAPHICAL BSE-RISK (GBR) AND ITS EVOLUTION OVER TIME IN THE EUROPEAN UNION MEMBER STATES

Adopted by the SSC at its plenary meeting of 21/22 February 2002

This opinion was prepared by the GBR-Peer Group and endorsed by the TSE/BSE adhoc group at its meeting on 7/2/2002

# **DRAFT**

# OPINION OF THE SSC ON THE GEOGRAPHICAL BSE-RISK (GBR) AND ITS EVOLUTION OVER TIME IN THE EUROPEAN UNION MEMBER STATES

### The question:

The SSC has been requested to provide an up-to-date assessment of the geographical BSE risk of the Member States of the European Union, taking account of the latest information and data that are available, including those provided by the Member States in their application for a BSE-Status categorisation.

# **Background:**

Regulation EC/999/2001 addresses the risk management measures needed for transmissible animal spongiform encephalopathies. It links these measures to the BSE-Status of the countries concerned, including Member States. It is therefore necessary that all Member States and all other countries which desire to trade certain products with the EU are categorised with regard to their BSE-status. The regulation foresees 5 categories and specifies the conditions for each of these. One condition is that a risk assessment is carried out, forming the basis for the subsequent status categorisation.

The Commission has decided that for the purpose of the Regulation the SSC's GBR assessment provides for the necessary risk assessment. Countries may, however, provide their own risk assessment in which case the SSC will be asked to provide a scientific opinion on the validity of it.

### **Opinion**

### Introduction:

In the year 2000<sup>1</sup> the SSC assessed, with the exception of Greece which did not provide the needed data, the GBR of all the Member States of the European Union. It applied an innovative methodology based on an integrated evaluation of "external challenge" (i.e. imports<sup>2</sup> of live animals and MBM from countries with notified cases of BSE) and of "stability" (i.e. ability to avoid recycling of BSE-infectivity). This method was also described in the GBR-opinion of the SSC of July 2000.

Two countries (UK and PT) were classified as GBR IV; nine countries (BE, DK, FR, DE, IRL, IT, LUX, NL and SP) were classified as GBR III and three (AT, FINL and SW) as GBR II. Since then, BSE-cases have been notified in DE, IT and SP, confirming the GBR assessment, but also in AT, SF and GR. The finding of BSE in AT and SF lead the SSC, among other considerations, to update its GBR-assessment methodology. This update was adopted by the SSC in January 2002. It foresees that "external challenge" results not only from live animals and MBM imports from countries with notified BSE-cases, but also from such imports from GBR-III countries with no notified BSE-cases at time of the assessment. This refinement of the methodology has been adopted by the SSC to prevent in the future too optimistic GBR assessments.

<sup>&</sup>lt;sup>1</sup> Opinion of the SSC on the Geographical Risk of Bovine Spongiforme Encephalopathy, July 2000

<sup>&</sup>lt;sup>2</sup> With regard to Member State the term « import » also includes the introduction of the considered commodities into the territory of a Member State from another MS of the European Union.

### Updating the GBR-assessment for EU Member States

There is no reason for applying the above-mentioned refined methodology for GBR assessment to EU countries already assessed as GBR III or IV in the year 2000. Even if the external challenge experienced by these countries would turn out to be larger than initially evaluated, there would be no change of the GBR level attribution already carried out by the SSC.

On the other hand the GBR assessments for AT and SF needs to be revised in order to correct the underestimation of the external challenge that resulted from the fact that only imports from countries with confirmed BSE were taken into account. For Greece a full assessment has to be carried out for the first time, and for Sweden a verification of its GBR-assessment is needed because an underestimation of the external challenge cannot be excluded.

# General considerations applying to all Member States:

The country reports that were adopted by the SSC in 2000 provided for each country a conclusion on the current GBR of that country in early 2000. In addition it also gave an evaluation of the expected development of the GBR. In most cases the latter indicated a decrease of the risk over time as a consequence of the many measures adopted. Some recommendations were provided for further reducing the GBR by increasing the stability of the country's BSE/cattle system.

Optimal stability would be needed to ensure the elimination of any recycling of BSE-infectivity, and hence to maximise the rate of decrease of the GBR. Optimal stability can only be assumed if evidence is provided that:

- (i) it is highly unlikely that any cattle is exposed to ruminant MBM or other potentially contaminated feedstuffs, either voluntarily or via cross-contamination;
- (ii) rendering is carried out only in plants that reliably operate at 133°C/20<sup>min</sup>/3<sup>bar</sup>;
- (iii) SRM-removal and safe disposal<sup>3</sup> is ensured both from imported and domestic cattle;
- (iv) fallen stock is excluded from the feed chain; and
- (v) adequate active surveillance is carried out<sup>4</sup>.

It is reasonable to assume that, in a country in which all the above-mentioned optimal stability conditions are met, no further domestic cattle can be infected by BSE through the oral route. After several years (e.g. 5)<sup>5</sup> with no new BSE-cases detected in the cattle population born after the achievement of the optimal stability conditions, it would therefore be reasonable reconsidering the GBR-assessment. It is suggested to establish a set of indicators and criteria that should be regularly monitored for providing an adequate base for such a future revision of the GBR. Even if there is excellent surveillance these indicators should include all those of critical importance for optimal stability. The guidance for third countries on the conditions for an "effective feed ban" that can be found on the internet site of the European Commission<sup>6</sup> gives a good orientation for the practical requirements that should be met.

<sup>&</sup>lt;sup>3</sup> This may include a rendering step that should, whenever immediate incineration is not guaranteed, also comply with the 133/20/3 standard.

<sup>&</sup>lt;sup>4</sup> The increase in BSE numbers, revealed by the better surveillance, should be taken into account when considering reclassifying countries from GBR III to IV. Already the surveillance system has confirmed the GBR\_III classification of many countries and revealed that Austria and Finland should be transferred from GBR II to III; Greece is also now in GBR III.

<sup>&</sup>lt;sup>5</sup> The SC suggests addressing the scientific basis of the length of this period in a specific scientific opinion.

<sup>6</sup> http://europa.eu.int/comm/food/fs/bse/bse30\_en.pdf

# Stability situation in the European Union Member States

During the recent years the European Community has adopted a series of legislative acts that put the obligation on all Member States to comply with all the above-mentioned conditions needed for optimal stability. The key issue is therefore to comply with the Community legislation and the optimal stability conditions.

Obviously, partial compliance and even occasional breaches and leaks in the system would favour a recycling of BSE-infectivity and generate new domestically-infected animals. This would slow down the decline of the GBR considerable.

The significance of breaches and leaks in terms of BSE-amplification is obviously dependent, among other factors, on the number of infectious units<sup>7</sup> of BSE-infectivity present in the country. A reliable, national, well-structured management and control framework is crucial to ensure that optimal stability is achieved and maintained throughout.

### The current GBR of EU-Member States:

The information provided by EU Member States when applying for BSE-status categorisation clearly shows that since the last GBR assessment was finalised (July 2000) a number of initiatives have been taken to ensure optimal stability and to reduce the BSE-risk. However, it will require time until these measures will reduce the GBR-level. BE, DE, DK, FR, IRE, IT, LUX, NL, SP remain in GBR III<sup>8</sup>, PT, and UK will remain in GBR IV.

For AT, SF, SW and GR a detailed up-to-date GBR assessment will be provided in separate scientific opinions of the SSC.

<sup>&</sup>lt;sup>7</sup> One Cattle Oral Infectious Dose is defined as the amount of infectivity in 0.1g of infective brain material.

<sup>&</sup>lt;sup>8</sup> If surveillance identifies more than 100 domestic BSE cases per million adult cattle in the domestic herd in a period of 12 months, a country would fulfill the criteria for GBR IV. However, the SSC is of the opinion that most of the increase in BSE cases that is currently recognised in most EU-Member States is a result of the significantly improved surveillance rather than indicating an increase in risk.