# Opinion of the

# Scientific Steering Committee

# on the

# GEOGRAPHICAL RISK OF BOVINE SPONGIFORM ENCEPHALOPATHY (GBR) in

# San Marino

Adopted by the SSC on 27 June 2002

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## 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 San Marino as assessed in June 2002.

## THE ANSWER

It is assumed that the BSE-agent, should it have entered the territory of San Marino, could not have been recycled and amplified within San Marino. However, some cattle from San Marino might have ended-up in the Italian BSE/cattle system and the BSE agent could have reached cattle in San Marino via Italian feedstuffs until end 2000.
It is therefore concluded that it is likely but not confirmed **(GBR III)** that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

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 2001Regulation (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.
San Marino 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 San Marino.

## THE RISK ASSESSMENT

For San Marino, the SSC concluded that it was "likely but not confirmed" **(GBR III)** that domestic cattle in San Marino 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).

- Live cattle imports:

In total the country imported 5.800 live cattle from BSE-risk countries, of which none came from the UK. As in San Marino there is no rendering industry, no animals could be rendered and enter the feed chain. Therefore, these animals do not represent any challenge to San Marino.

- MBM imports:

The country imported no MBM as such from BSE-risk countries but it imported between 1992 and 2001 about 10,000 tons of feeding stuffs and feed supplements, all from Italy (GBR III with about 60 cases). Assuming that a certain fraction of these feeding stuffs and feed supplements was contaminated with 1-3% processed ruminant proteins, the equivalent of 100 to 300 tons of MBM probably reached the BSE/cattle system of San Marino, representing a low to moderate external challenge throughout the period 1980 to 2000. Although, in absolute terms, the amount of MBM imported yearly in the period 1980-2000 might be perceived as a small one, it would be sufficient to expose a large proportion of the small cattle population in San Marino, thus representing a "significant" challenge.

Imports to San Marino of MBM-contaminated feeding stuff should have finished at the end of 2000, as the feed-ban was published in December 2000 and Italian feeding stuffs should have become void of MBM.

### STABILITY

There is an interlinkage of the BSE/cattle system of San Marino with the Italian system, mainly due to the fact that all industrial feed used in San Marino came from Italy, carrying the same risk as any other Italian feed. The feedstuffs imported from Italy were potentially contaminated with MBM and could have lead to a wide exposure of the cattle population in San Marino to the BSE-agent, which was apparently present in Italy since some time.

On the basis of the available information it was concluded that the country's BSE/cattle system was **extremely unstable** from **1980** to **1999**. Due to the improvement of the rendering system in Italy the risk of receiving contaminated feed from Italy should have somewhat decreased in late 1999 and the system became **neutrally stable** in **2000**. The system became then **optimally stable** in **January 2001** because of the feed-ban preventing the introduction of the BSE-agent via Italian feed, which in turn should anyway be void of any MBM since January 2001.

#### *Feeding*

Feeding (R)MBM to cattle was legally possible until December 2000 and even if it was probably not widespread, supplementary feed, imported from Italy, was given to domestic cattle or could have reached them via (accidental) cross feeding of non-ruminant feed on farms. Feeding was, therefore, **"not OK"** until December 2000. Theoretically the feedstuffs from Italy should have been void of mammalian MBM since 1994 (MMBM-ban) but apparently they were not, as demonstrated by the BSE cases found in Italy born after 1994. Control of the December 2000 feed ban is carried out in San Marino by on site controls (at farms, dealer) and feed sampling. No

positive samples were found so far and feeding is regarded to be **"OK"** since January 2001. This is also supported by the assumption that Italian feed should be void of any MBM since January 2001.

### *Rendering*

In San Marino there are no rendering plants. By-products or waste from the slaughterhouse and/or animals that died/were killed on the farm have always been either buried or sent to authorised Italian rendering plants. Accordingly rendering is judged, like for Italy, as **"not OK"** for the period 1980-1999 and **"OK"** thereafter.

### *SRM-removal*

Since March 1997, all SRM of slaughtered animals are incinerated in the incinerator next to the slaughterhouse. Before that they were already partly incinerated since 1982, when the incinerator close to the central slaughterhouse became operational. However, with regard to the stability of the BSE/cattle system also SRM removal is regarded like for Italy as **"not OK"** from 1980 to 2000 and **"OK"** thereafter.

### *BSE surveillance*

Until end 2000, the surveillance of BSE was only passive and therefore unlikely to detect low levels of incidence. Since the beginning of 2001, the surveillance system is considered to be quite good, now including active sampling of animals without clinical signs of BSE. However, the small sample size that is only possible will continue making it difficult to recognise low incidence levels.

## CONCLUSION ON THE CURRENT GBR

It is assumed that the BSE-agent, should it have entered the territory of San Marino, could not have been recycled and amplified within San Marino. However, some cattle from San Marino might have ended-up in the Italian BSE/cattle system and the BSE agent could have reached cattle in San Marino via Italian feedstuffs until end 2000.
It is therefore concluded that it is likely but not confirmed **(GBR III)** that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

## EXPECTED DEVELOPMENT OF THE GBR

As in Italy the GBR of San Marino will decrease over time as the possibility of new BSE cases born after the ban of December 2000/January 2001 is regarded to be very small.
The GBR of San Marino should be decreasing at the rate by which cattle born before the total feed ban (before 2001) leave the national system (slaughter, cull).

*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 San Marino 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.*

## SAN MARINO – Summary of the GBR-Assessment, June 2002

| | EXTERNAL CHALLENGE | | STABILITY | | | | INTERACTION of EXTERNAL CHALLENGE and STABILITY |
|---|---|---|---|---|---|---|---|
| | **1980-2000: Significant**<br>**2001: Negligible** | | **1980-1999: Extremely unstable**<br>**2000: Neutrally stable**<br>**2001: Optimally stable** | | | | San Marino has to be seen as a sub-system of Italy and hence an extremely unstable system was exposed to significant external challenges. This made it likely that contaminated feed reached domestic cattle in San Marino. |
| ***GBR-Level*** | ***Live Cattle imports*** | ***MBM imports*** | ***Feeding*** | ***Rendering*** | ***SRM-removal*** | ***BSE surveillance*** | |
| **III**<br>**GBR-trend**<br>**decreasing** | <u>UK</u>: No imports according to country import data and to other export data.<br><br><u>Other BSE risk countries</u>: 5,800 according to country import data from AT, FR, DE and IT. No imports according to other export data. | No MBM imports as such but all feed stuffs are imported from Italy.<br><br><u>UK</u>: No imports according to country import data and to other export data.<br><br><u>Other BSE risk countries</u>:<br>Feed imports according to country import data:<br>92-95: 3,848 t<br>96-2001: 6,253 t<br>Total: 10,102 t<br><br>Assuming an average MBM content of 1-3% the total MBM imports might have been around 100-300 tons, all from Italy. | **Not OK: 1980-2000, OK: since 2001.**<br>• Feeding (R)MBM to cattle legally possible until December 2000.<br>• No feed-producing industries in San Marino.<br>• All feed imported from Italy.<br>• Cattle could have consumed Italian feed as such or via (accidental) cross feeding on farms.<br>• December 2000: ban of animal proteins derived from mammals from livestock feed. Controlled by inspections on farm and feed sampling.<br>• March 2001, Regulation prohibiting feeding of animal protein to animals. | **Not OK: 1980-99, OK: since 2000.**<br>• No rendering plants in San Marino therefore judgement as for Italy.<br>• By-products or waste from slaughterhouse and/or animals that died/were killed on the farm buried or sent to authorised Italian rendering plants.<br>• Since 1982, next to only slaughterhouse existing, one incinerator for animal waste (including SRM).<br><br>• Since October 2000, incineration of all animal that died on farm (fallen stock) compulsory. | **Not OK: 80-2000, OK: since 2001.**<br>• As for rendering SRM-removal judged as for Italy because the feed in San Marino could have been partly derived from Italian SRM.<br>• Since 1982 incineration of slaughter waste in San Marino but incineration of SRM not compulsory.<br>• March 1997, all SRM of slaughtered animals incinerated. | Notification of any animal disease, including BSE, compulsory since 1984.<br><br>Compensation provided: 80% of value.<br><br>Until end 2000, surveillance of BSE only passive and therefore unlikely to detect low levels of incidence.<br><br>Since beginning of 2001, surveillance system quite good, now including active sampling of animals without clinical signs of BSE.<br>However, only small sample-size possible. This makes it difficult to recognise low incidence levels. | **INTERNAL CHALLENGE**<br>An internal challenge might have occurred in San Marino as soon as it occurred in Italy, where this is estimated for 1983.<br><br>Since 1990 it is regarded likely that an internal challenge existed in Italy and accordingly also in San Marino.<br><br>Since 2001 the internal challenge decreases with the rate at which cattle born before 2001 die or are slaughtered. |