

Scientific Report of the European Food Safety Authority on the Assessment of the Geographical BSE-Risk (GBR) of MEXICO

Question N° EFSA-Q-2003-083

Adopted July 2004

Summary

The European Food Safety Authority and its Scientific Expert Working Group on the Assessment of the Geographical Bovine Spongiform Encephalopathy (BSE) Risk (GBR) were asked by the European Commission (EC) to provide an up-to-date scientific report on the GBR in Mexico, i.e. the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, in Mexico. This scientific report addresses the GBR of Mexico as assessed in 2004 based on data covering the period 1980-2003.

The BSE agent was probably imported into Mexico and could have reached domestic cattle. These cattle imported could have been rendered and therefore led to an internal challenge in the mid to late 1990's. It is possible that imported meat and bone meal (MBM) into Mexico reached domestic cattle and leads to an internal challenge around 1993.

It is likely that BSE infectivity entered processing at the time of imported 'at - risk' MBM (1993) and at the time of slaughter of imported live 'at - risk' cattle (mid to late 1990s). The high level of external challenge is maintained throughout the reference period, and the system has not been made stable. Thus it is likely that BSE infectivity was recycled and propagated from approximately 1993. The risk has since grown consistently due to a maintained internal and external challenge and lack of a stable system.

EFSA concludes that 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. The GBR is likely to increase due to continued internal and external challenge, coupled with a very unstable system.

Key words: BSE, geographical risk assessment, GBR, Mexico, third countries

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Background

History

In 1998, the EC asked the Scientific Steering Committee (SSC) to perform a risk assessment in order to establish the GBR of a country. In July 2000 the SSC adopted its final opinion on "The Geographical Risk of Bovine Spongiform Encephalopathy (GBR)" (as updated in January 2002). It describes a method and a process for the assessment of the GBR and summarises the outcome of its application. Detailed reports on the GBR-assessments were published on the Internet for each of these countries.

Determination of BSE status

In 2001, Regulation (EC) No 999/2001¹ established the rules for the determination of BSE status of a country. It determines certain measures concerning the control of BSE and concerning trade and importation of certain live animals and animal products.

Annex II of this Regulation lays down the method for the determination of BSE status. This includes two steps: an initial risk assessment, and the evaluation of additional criteria. The method is similar to that laid down in the International Animal Health Code of the International Animal Health Organisation (OIE).

The categorisation of countries has been deferred until July 2005 awaiting a review of the OIE categorisation system. In the meantime a number of transitional measures are in place, in particular concerning specified risk material and import conditions.

State of play

The Scientific Steering Committee issued an opinion on GBR (using the methodology established by the SSC in June 2000 and updated January 2002) for one third of the countries requesting the determination of their BSE status.

Prioritisation

The first priority is the re-assessment of GBR I countries, as currently no TSE related import restrictions (certification of absence of specific risk material (SRM)) apply to GBR I countries

If the preliminary re-assessment indicates that the current GBR I will not be confirmed, any delay might have negative consequences on consumer health protection. Furthermore, the GBR assessment of neighbouring countries with intensive trade contacts should be dealt with at the same time, because the outcomes are interdependent.

The major trading partners with a GBR II classification should be dealt with as second priority, in view of the SSC opinion on tallow derivatives and the draft guidance note of EMEA.

Terms of reference

In view of the above, the European Commission asks the EFSA to advice on the risk assessment for the appearance of BSE in Mexico.

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¹ Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies OJ L 147, 31.5.2001 and updates.

Assessment

EFSA refers to the Working Group Report (annex) prepared by the EFSA Scientific Expert Working Group on GBR for full details on the assessment.

External Challenge

Mexico was exposed to a **negligible external challenge** for the period 1980-1990, a **very high external challenge** for the period 1991-1995 and an **extremely high external challenge** for period 1996-2003.

Stability

For the overall assessment of the stability, the impact of the three main stability factors, (i.e. feeding, rendering and SRM-removal) and of the additional stability factor surveillance has to be estimated. On the basis of the available information it was concluded that Mexico's BSE/cattle system was **very unstable** for the entire period 1980-2003. This indicates that BSE infectivity, if imported, could have reached domestic cattle and probably would have been recycled and amplified.

Feeding

Feeding meat and bone meal (MBM) to cattle was legally possible until October 2000 and the information provided indicates that it was common practice for both dairy and beef cattle. Therefore feeding was assumed to be "not OK" until the end of 2000. The feed ban is of ruminant MBM only and good evidence of its effectiveness is not provided. Therefore feeding remains "not OK" since then.

Rendering

Rendering is and was common practice in Mexico. Ruminant material is included, excluding most SRM and most fallen stock. The process used was and is not adequate for reducing BSE - infectivity. Therefore rendering is assessed as having been "not OK" throughout the reference period.

SRM-removal

There is no SRM ban. However, SRM is consumed by humans and it does not tend to enter the feed chain and fallen stock and diseased animals are incinerated. Hence SRM - removal it is assessed as **"reasonably OK"** throughout the reference period.

BSE surveillance

There is some passive and active BSE surveillance. However, given the large cattle population size, the BSE surveillance system in Mexico is insufficient. Recent plans have been introduced to increase surveillance efforts since 2004.

Conclusions

The European Food Safety Authority concludes:

1. The BSE agent was probably imported into Mexico and could have reached domestic cattle. These cattle imported could have been rendered and therefore led to an internal

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challenge in the mid to late 1990's. It is possible that imported MBM into Mexico reached domestic cattle and leads to an internal challenge around 1993.

- 2. It is likely that BSE infectivity entered processing at the time of imported 'at risk' MBM (1993) and at the time of slaughter of imported live 'at risk' cattle (mid to late 1990s). The high level of external challenge is maintained throughout the reference period, and the system has not been made stable. Thus it is likely that BSE infectivity was recycled and propagated from approximately 1993. The risk has since grown consistently due to a maintained internal and external challenge and lack of a stable system.
- 3. 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.
- 4. EFSA and its Scientific Expert Working group on GBR are concerned that the available information was not confirmed by inspection missions as performed by the Food and Veterinary office (FVO DG SANCO) in Member States and other third countries. They recommend including, as far as feasible, BSE-related aspects in future inspection missions.

Expected development of the GBR

The GBR is likely to increase due to continued internal and external challenge, coupled with a very unstable system.

Since recent improvements in the safety of MBM production in many countries or significant recent reductions in the incidence of BSE are not taken into account for the assessment of the external challenge, the external challenge assessed after 2001 could be overestimated and is the worst case assumption. However all current GBR conclusions are not dependent on these assumptions in any of the countries assessed. For future assessments and when the impact of the production, surveillance and true incidence changes has been fully quantified, these developments should be taken into account.

A table summarising the reasons for the current assessment is given in the table below.

Documentation provided to EFSA

- Letter with the ref D(2003)KVD/ip/420722 from the European Commission requesting a geographical risk assessment for the appearance of BSE in a country.
- Country Dossier as prepared by the country in response to the EC and EFSA data collection request.
- Other sources of data information i.e. exports from third countries and Eurostat
- SSC, July 2000. Final opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).

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• SSC, January 2002. Updated opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).

Acknowledgment

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Annex

Details of the assessment are presented in the report as prepared by the EFSA GBR Expert Working Group:

http://www.efsa.eu.int/science/efsa scientific reports/gbr assessments/scr annexes/566 en.html

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| Mexico | , Summary of t | BR Level : III** | | | | |
|--|---|---|--|--|--|---|
| EXTERNAL (| CHALLENGE | | STAB | INTERACTION of EXTERNAL CHALLENGE and STABILITY | | |
| 1980-1990: Negligible 1991-1995: Very high 1996-2003: Extremely h | iigh | 1980-2003: Very unst | table | Any external challenge would have met the very unstable system and infectivity would have been recycled. | | |
| Live cattle imports | MBM imports | Feeding | Rendering SRM-removal BSE surve | | BSE surveillance | |
| From UK: None (CD* and other sources of data) From other BSE risk countries: 3,194,014 (CD) or 1,629,790 (other sources of data). | From UK: None (CD and other sources of data) From other BSE risk countries: 826,136 ton (CD) or 919,144 ton (other sources of data). | 1980-2003: Not OK MBM was legally included in cattle feed until October 2000. | 1980-2003: Not OK Process used is not adequate for reducing BSE. | 1980-2003: Reasonably OK No SRM ban. SRM is consumed by humans and it does not tend to enter the feed chain. | 1980-2003: Insufficient 1996 – 2003: Passive and some active surveillance. | INTERNAL CHALLENGE An internal challenge was highly unlikely up to 1990 but likely to be present and growing since 1993. |
| *CD: country dossier | | | | | | EXPECTED DEVELOPMENT OF THE GBR The GBR is likely to increase due to continued internal and external challenge, coupled with a very unstable system. |

^{**}GBR level is III: 'it is likely but not confirmed' that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

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European Food Safety Authority

Scientific Expert Working Group on GBR

Working Group Report on the Assessment of the Geographical BSE-Risk (GBR) of MEXICO

2004

NOTE TO THE READER

Independent experts of the EFSA Scientific Expert Working Group on GBR 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 Scientific Steering Committee (SSC) on "the Geographical Risk of Bovine Spongiform Encephalopathy (GBR)" of 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>

**** EFSA ****

Annex to the EFSA Scientific Report (2004) 4, 1-13 on the Assessment of the Geographical BSE Risk of Mexico

1. DATA

- The available information was sufficient to carry out the qualitative assessment of the GBR.
- Reasonable worst case assumptions have been used in cases were the available information was not complete.

Sources of data

• Country dossier (CD) consisting of information provided from the country's authorities in 2001 – 2004.

Other sources:

- EUROSTAT data on export of "live bovine animals" and on "flour, meal and pellets of meat or offal, unfit for human consumption; greaves" (customs code 230110), covering the period 1980 2003.
- United Kingdom export data (UK) on "live bovine animals" and on "Mammalian Flours, Meals and Pellets" (MBM¹), 1980 1996.
- Available export data from BSE risk countries.
- FAO Expert Consultation Mission, May 2003 (FAO TCP/RLA/0177): Evaluation and reinforcement of the Prevention System for the Bovine Spongiform Encephalopathy (BSE) and the Animal Feed Control System.

2. EXTERNAL CHALLENGES

2.1 Import of cattle from BSE - Risk² countries

An overview of the data on live cattle imports is presented in **table 1** and is based on data as provided in the country dossier (CD) and corresponding data on relevant exports as available from BSE risk countries that exported to Mexico. Only data from risk periods are indicated, i.e. those periods when exports from a BSE risk country already represented an external challenge, according to the SSC opinion on the GBR (SSC July 2000 and updated January 2002).

The CD notes that imports of 70 dairy cattle from UK were planned in 1984, but these animals were not imported because of Foot and Mouth Disease (FMD) regulations. Neither Eurostat nor UK export data indicate that these exports actually took place, and therefore they are not included in the final assessment.

1

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".

² BSE-risk countries are all countries already assessed as GBR III or IV or with at least one confirmed domestic BSE case.

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Eurostat records show that Mexico imported 995 cattle from other European BSE risk countries, mostly from Spain (823). There was reasonable agreement between Eurostat and the CD, which records 1182 imports. The CD provides information on the fate of some imports from Spain, which would not have posed a challenge. These were bullfighting breeds and all but 152 animals could be traced (the majority still being alive). The CD also considers the few imports from Germany and the Netherlands unlikely to have taken place due to FMD in Europe, but documentation to support this is not provided, hence they are not excluded from the possible challenge. Additionally, cattle imported from Denmark, France and Switzerland were assessed as possible risk.

The CD indicates large numbers of cattle imported from USA (~ 2.3 million since the beginning of the risk period in 1993) and Canada ($\sim 125,000$ since the beginning of the risk period in 1993).



| Country: | | Liv | е са | ttle i | impo | rts, ra | w data | a | | | | | | | | | | | | | | | | | | |
|---------------|-------------|-----|------------|--------|------|---------|--------|-------|-------|-------|-------|--------|---------------|--------|-------|--------|-------|--------|--------|--------|--------|--------|--------|-------|-------|-------------------|
| <i>MEXICO</i> | Data | 80 | Q 1 | 82 | 83 | 84 | 85 | 86 | 87 | 88 | 89 | 90 | 91 | 92 | 93 | 94 | 95 | 96 | 97 | 98 | 99 | 0 | 1 | 2 | 3 | TOTALS (R1&R2) |
| Canada | CD | 00 | | 1532 | 104 | 5547 | 8241 | 404 | 534 | | | | 31 | 32 | 30 | 16665 | 3139 | 8687 | 26538 | | | 14576 | 11718 | 5678 | | 136656 |
| Canada | other | | | 1332 | 104 | 3347 | 0241 | 404 | 334 | 420 | 1313 | 7702 | | | | 10003 | 3139 | 0007 | 20336 | 18300 | 110 | 14376 | | 114 | | 972 |
| Denmark | CD | | | | | | | | | | | | | | | | | | 209 | 55 | | 147 | 432 | 114 | 107 | 264 |
| Deminark | other | | | | | | | | | | | | | | | | | | 209 | 33 | | | | | | 0 |
| France | CD | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| Trance | other | | | | | | 9 | | | | | | | | | | | | | | | | | | | 9 |
| Germany | CD | | | | | | 9 | | | | | | | | | | | | | | | | | | | 0 |
| Germany | other | | | | | | | | | | | | | | | 136 | | | | | | | | | | 136 |
| Netherland | | | | | | | | | | | | | | | | 130 | | | | | | | | | | 0 |
| remenana | | | | | | | | | | | | | | | | 27 | | | | | | | | | | 27 |
| Spain | other CD | | | | | | | | | | | | | | | 21 | | 91 | 804 | | | | | | | 895 |
| Spain | | | | | | | | | | | | | | | | | | 91 | | | | | | | | 823 |
| Switzerland | other | | | | | | | 22 | | | | | | | | | | 91 | 732 | | | | | | | 23 |
| SWILZEITAIR | | | | | | | | 23 | | | | | | | | | | | | | | | | | | 23 |
| USA | other CD | | | 16401 | 7522 | 126155 | 102273 | 54045 | 20054 | 10224 | 22204 | 220761 | 162 | 214 | | 40041 | 12206 | 427269 | 510242 | 242001 | 201005 | 207080 | 249254 | 60022 | 25500 | 2748391 |
| USA | | | 4 | 10401 | 1332 | 136155 | 1022/3 | 34943 | 38034 | 18234 | 32204 | | 163 | | 76054 | | | | | | | | | 09932 | 23308 | 1627823 |
| UK | other | | | | | | _ | | | | | 64226 | 210344 | 251237 | /6854 | 128636 | 14641 | 115289 | 236392 | 159081 | 100481 | 1268/3 | 143/69 | | | 1027023 |
| UK | CD | | _ | | | | | | | | | | | | | | | | | | | | | | | |
| TOTALS | other | | | | | | | | | | | | | | | | | | | | | | | | | |
| non UK | CD | 0 | 0.4 | 17933 | 7626 | 141702 | 110514 | 55272 | 20500 | 10660 | 22710 | 220522 | 162 | 214 | 0 | 56706 | 15115 | 126016 | 537793 | 260606 | 210221 | 211665 | 250072 | 75610 | 20726 | 3194014 |
| non ok | other | 0 | | 0 | /030 | 141/02 | 110514 | 33312 | 38388 | 18000 | 33/19 | | 163 210344 | | 76854 | 20,00 | | 115380 | | | | | | 114 | 167 | 1629790 |
| UK | CD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | 04220 | 210344 0 | 231237 | 0834 | 128799 | 14041 | 113380 | 23/124 | 139081 | 100391 | 12/022 | 144201 | 0 | 0 | 0 |
| OK | other | 0 | 0 | 0 | 0 | 0 | 0 | | | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | v | 0 | Ů | 0 | 0 | 0 | 0 | 0 |
| | otilei | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U | U |

Table 1: Live cattle imports into Mexico (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 (shaded) are taken into account for assessing the external challenge. Risk periods are defined according to the SSC opinion of January 2002. The numbers shown in the table are the raw import figures and are not reflecting the adjusted imports for the assessment of the external challenge.

2.2 <u>Import of MBM or MBM - containing feedstuffs from BSE - Risk countries</u>

An overview of the data on MBM imports is presented in **table 2** and is based on data provided in the country dossier (CD) and corresponding data on relevant exports as available from BSE risk countries that exported to Mexico. Only data from risk periods are indicated, i.e. those periods when exports from a BSE risk country already represented an external challenge, according to the SSC opinion on the GBR (SSC, July 2000 and updated January 2002).

The CD only provides import information on MBM since 1996. According to the CD, Eurostat and UK export statistics, no imports of MBM have taken place from UK. From other European countries, the CD records 1 ton from NL, 1707 tons from Denmark (1996 - 1999) and Eurostat records 0.4 tons from France.

Large amounts of MBM were imported from USA {according to the CD: \sim 670,000 tons since the beginning of the risk period in 1993; according to USA export data: 690,000 between 1993 and 2001 only (2002 and 2003 data unavailable)} and Canada (\sim 153,000 tons according to the CD since the beginning of the risk period in 1993).

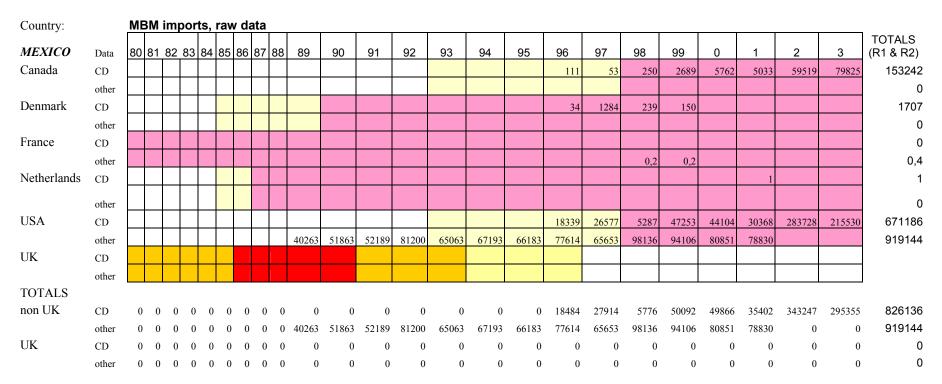


Table 2: MBM imports into Mexico (CD) and corresponding exports from BSE - risk countries. Source for export data: Eurostat and UK export statistics and, where available, export statistics from other BSE - risk countries. Note: Only imports in risk periods (shaded) are taken into account for assessing the external challenge. Risk periods are defined according to the SSC opinion of January 2002. The numbers shown in the table are the raw import figures and are not reflecting the adjusted imports 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:

According to the CD the country imported in total over the period 1980 to 2003, approximately 3.2 million live cattle from BSE - risk countries, of which conclusively none came from the UK. The numbers shown in **table 1** are the raw import figures and are not reflecting the adjusted imports for the assessment of the external challenge. Broken down to 5 - years periods the resulting external challenge is as given in **table 3**. This assessment takes into account the evidence that certain imported cattle did not enter the domestic BSE/cattle system, i.e. were not rendered into feed. In the case of Mexico, it is assumed that "cattle still alive" (imports from Spain) did not enter the rendering system.

MBM imports:

According to the CD the country imported in total over the period 1980 - 2003 approximately 826,000 tons MBM from BSE - risk countries (according to "other data": ~ 919,000 tons), of which none came from the UK. The numbers shown in **table 2** are the raw import figures and are not reflecting the adjusted imports for the assessment of the external challenge. Broken down to 5 - years periods the resulting external challenge is as given in **table 3**. This assessment takes into account the evidence that certain imported MBM did not enter the domestic BSE/cattle system or did not represent an external challenge for other reasons. However, in the case of Mexico, there was not sufficient evidence to remove any quantities of MBM from the external challenge.

| External Challenge experienced by MEXICO | | | | | | | | |
|--|----------------|------------------------------------|----------------------------------|--|--|--|--|--|
| External | challenge | Reason for this external challenge | | | | | | |
| Period | Overall Level | Cattle imports | MBM imports | Comment | | | | |
| 1980 to 1985 | Negligible | Negligible | Negligible | | | | | |
| 1986 to 1990 | | | | | | | | |
| 1991 to 1995 | Very high | High | Very high | Due to MBM imports from USA since 1993 and cattle imports from USA/Canada since 1994 | | | | |
| 1996 to 2000 | Extremely high | Extremely high | | Due to imports from USA / Canada | | | | |
| 2001 to 2003 | Extremely high | Very high | Due to imports from USA / Canada | | | | | |

<u>Table 3</u>: 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

Use of MBM in cattle feed

Until 11th October 2000, MBM could and was legally included in cattle feed.

Feed bans

The law prohibiting the use of ruminant MBM in ruminant feed was published on 11th October 2000. According to the FAO mission, implementation of the ban began in 2002.

Potential for cross - contamination and measures taken against

In feed mills, lines are not always separated. According to the CD flushing is used to clean in - between lines, and feed mills carry out in - house controls. According to the CD, controls during transport and on farms are not regularly carried out, but inspections may occur on the farm. No details are provided on the kind or frequency of these control measures, the dates checking of cross contamination began, or on the results of these inspections.

Control of feed bans and cross - contamination

According to the CD, checks occur to ensure that plants do not use ruminant MBM in feed stuff production for ruminants. This may have been helped by regulations defined in 1999 that allowed ruminant feed production to use MBM only from rendering plants that do not process ruminant material. However, detailed outcomes of control procedures, tests carried out or quality control are not provided.

It is concluded that cross contamination is possible.

Rendering

- A rendering industry exists in Mexico and raw bovine materials are normally rendered. This includes fat tissue, bones, horns and hooves but not usually viscera, eyes, brains or spinal cords. About 90 % of the rendered material is of bovine origin and the rest consists mainly of pork material. 58 plants produce MBM, with an annual production of between 150,000 and 250,000 tons per year. It is estimated that about 6 % was destined for bovines in 2000.
- The rendering process standard (133° C/20^{min}/3^{bar}) is not applied. According to the CD, there are guidelines in place so that the standard process will be used in the event that a BSE case is discovered.
- According to the CD, regulations were introduced in 1999 to ensure that the processing of animal offal and its employment in animal food took place in two



plant types: 1). plants processing material of ruminant origin plus other species (such as pig) and 2). plants processing only non-ruminant material. Plants corresponding to the first category are prohibited from the preparation of foodstuffs intended for ruminants. The fulfillment of this procedure is checked annually through veterinarians. Specific results of checking procedures are not supplied in the CD.

Specified Risk Material (SRM) and fallen stock

There is no SRM-ban. SRM is normally destined for human consumption. According to the CD, fallen stock from pasture and diseased animals are incinerated and not rendered.

Conclusion on the ability to avoid recycling

In light of the above information, it has to be assumed that the BSE agent, should it have entered Mexico, could 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

Detailed information is provided in the CD on the cattle population and their husbandry system. Approximately 30 million cattle is the national population of which the majority is for beef production, and approximately 6 % dairy. Approximately 34 % of animals are over 24 months old. In dairy cattle, 59 % of the milk production is derived from intensive production.

The average age and weight at slaughter varies according to rearing system. Slaughter tends to occur at approximately 3 years on extensive pasture, 2 years on semi-intensive, 1.3 years on intensive fattening, 6 - 7 years for dairy cows and 10 years for breeding cows.

BSE surveillance

Notification of BSE is compulsory since 21 September 1994. Awareness/training measures were initially put in place in 1994 and increased in intensity since 1997 (leaflets, training scheme on BSE - related issues, sampling manual). Laboratory personnel have been trained since 1997 in surveillance, diagnostic techniques and risk management in Mexico but also in Canada and USA. Since November 1998 a trilateral agreement (Mexico - USA - Canada) on an exchange program in relation to BSE has been set up, that focuses on diagnostics and surveillance.

The methods used for BSE suspects are described. Since the end of 1996, histopathology has been used. Together with Canada and USA, a project on immunohistochemistry as a diagnostic technique has been jointly set up, and the same monoclonal commercial antibodies will be used in the three countries.

In the years 1996 to 2003, a total of 2047 animals have been tested for BSE (1726 > 29 months of age), with active surveillance in place since 1997. Since 2000, some fallen stock has also been targeted. No positive test results have occurred.

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The CD describes a program for increased BSE surveillance beginning in 2004 ("Program of Epidemiological Vigilance and Prevention of BSE for 2004"). This is a programme developed in conjunction with the "Commission of Mexico to the United States for the Prevention of Foot and Mouth Disease and other Exotic Illnesses of Animals".

3.3 Overall assessment of the stability

For the overall assessment of the stability, the impact of the three main stability factors (i.e. feeding, rendering and SRM - removal) and of the additional stability factor, BSE-surveillance, has to be estimated. The guidance provided by the SSC in its opinion on the GBR of July 2000 (as updated in 2002) is applied.

Feeding:

Feeding MBM to cattle was legally possible until October 2000 and the information provided indicates that it was common practice for both dairy and beef cattle. Therefore feeding was assumed to be "not OK" for the period 1980-2000. The feed ban is of ruminant MBM only and good evidence of its effectiveness is not provided. Therefore feeding remains "not OK" also for the period 2000-2003.

Rendering:

Rendering is and was common practice in Mexico. Ruminant material is included, excluding most SRM and most fallen stock. The process used was and is not adequate for reducing BSE - infectivity. Therefore rendering is assessed as having been "not OK" throughout the reference period (i.e. 1980-2003).

SRM-removal:

There is no SRM ban. However, SRM is consumed by humans and it does not tend to enter the feed chain and fallen stock and diseased animals are incinerated. Hence SRM-removal it is assessed as **"reasonably OK"** throughout the reference period (i.e. 1980-2003).

BSE surveillance

There is some passive and active BSE surveillance. However, given the large cattle population size, the BSE surveillance system in Mexico is insufficient. Recent plans have been introduced to increase surveillance efforts since 2004.

On the basis of the available information it has to be concluded that the country's BSE/cattle system was and is very unstable. Incoming BSE - infectivity would have been recycled and quickly amplified. The stability of the BSE/cattle system in Mexico overtime is as given in **table 4**.



| Stability of the BSE/cattle system in MEXICO over time | | | | | | | | | | |
|--|---------------|---------|-----------|---------------|--|--|--|--|--|--|
| Sta | bility | | Reasons | | | | | | | |
| Period | Level | Feeding | Rendering | SRM removal | BSE surveillance | | | | | |
| 1980 to 2003 | Very unstable | Not OK | Not OK | Reasonably OK | 1996 – 2003: passive and some active surveillance | | | | | |

<u>Table 4</u>: 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 (as updated in 2002).

4. CONCLUSION ON THE RESULTING RISKS

4.1 <u>Interaction of stability and challenges</u>

In conclusion, the stability of the Mexico BSE/cattle system in the past and the external challenges the system has coped with are summarized in the **table 5** 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 had to be met by the system, in addition to external challenges that occurred.

| INTERACTION OF STABILITY AND EXTERNAL CHALLENGE IN MEXICO | | | | | | | | | |
|---|---------------|--------------------|----------------------------------|--|--|--|--|--|--|
| Period | Stability | External Challenge | Internal challenge | | | | | | |
| 1980 to 1985 | | Negligible | Highly unlikely | | | | | | |
| 1986 to 1990 | Very unstable | regugible | riigiiiy uniikeiy | | | | | | |
| 1991 to 1995 | very unstable | Very high | Likely to be present and growing | | | | | | |
| 1996 to 2000 | | Extremely high | since 1993 | | | | | | |
| 2001 to 2003 | | | | | | | | | |

<u>Table 5</u>: 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 (as updated in 2002).

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 feed reached domestic cattle. Cattle imported for slaughter would normally be slaughtered at an age too young to harbour large amounts of BSE infectivity or to show signs, even if infected prior to import. Breeding cattle, however, would normally live much longer and only 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. In case of Mexico this implies that an internal challenge caused by live cattle imports (predominantly from USA or Canada) first occurred in the mid to late 1990's and continued to the present.

On the other hand imports of contaminated MBM 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 case of Mexico this implies that an internal challenge caused by MBM imports (predominantly from USA or Canada) first occurred around 1993 and continued to the present.

In view of the above - described consideration the combination of the very / extremely high external challenges with a very unstable system makes the occurrence of an internal challenge likely in Mexico from approximately 1993 onwards.

4.2 Risk that BSE infectivity entered processing

It is likely that BSE infectivity entered processing at the time of imported 'at - risk' MBM (1993) and at the time of slaughter of imported live 'at - risk' cattle (mid to late 1990's). The high level of external challenge is maintained throughout the reference period, and the system has not been made stable, leading to increased internal challenge.

4.3 Risk that BSE infectivity was recycled and propagated

It is likely that BSE infectivity was recycled and propagated from approximately 1993. The risk has since grown consistently due to a maintained internal and external challenge and lack of a stable system.

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 <u>The expected development of the GBR as a function of the past and present stability and challenge</u>

- The GBR is likely to increase due to continued internal and external challenge, coupled with a very unstable system.
- Since recent improvements in the safety of MBM production in many countries or significant recent reductions in the incidence of BSE are not taken into account for the assessment of the external challenge, the external



challenge assessed after 2001 could be overestimated and is the worst case assumption. However all current GBR conclusions are not dependent on these assumptions in any of the countries assessed. For future assessments and when the impact of the production, surveillance and true incidence changes has been fully quantified, these developments should be taken into account.

5.3 Recommendations for influencing the future GBR

- Measures that improve the stability of the system, will, over time, reduce the probability that cattle get infected with the BSE-agent. Possible actions include
 - strict removal of SRM and/or fallen stock from rendering,
 - pressurized rendering processes,
 - significant improvement of ban on use of ruminant MBM in cattle feed, supported by regular sampling of such feed for the non-occurrence of MBM.
- Improved passive and active surveillance, i.e. sampling of animals not showing signs compatible with BSE from "at risk" cattle populations, such as adult cattle in fallen stock and emergency slaughter, by means of rapid screening, would allow monitoring the efficiency of the stability enhancing measures.

Documentation provided to EFSA

- Letter with the ref D(2003)KVD/ip/420722 from the European Commission requesting a geographical risk assessment for the appearance of BSE in a country.
- Country Dossier as prepared by the country in response to the EC and EFSA data collection request.
- Other sources of data information i.e. exports from third countries and Eurostat data.
- SSC, July 2000. Final opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).
- SSC, January 2002. Updated opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).

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