OPINION OF THE SCIENTIFIC STEERING COMMITTEE

(1) ON THE SCIENTIFIC BASIS FOR IMPORT BANS PROPOSED BY 3 MEMBER STATES WITH REGARD TO BSE RISKS IN FRANCE AND THE REPUBLIC OF IRELAND;

(2) ON THE SCIENTIFIC BASIS FOR SEVERAL MEASURES PROPOSED BY FRANCE WITH REGARD TO BSE RISKS;

(3) AND ON THE SCIENTIFIC BASIS FOR BANNING ANIMAL PROTEIN FROM THE FEED FOR ALL FARMED ANIMALS, INCLUDING PIG, POULTRY, FISH AND PET ANIMALS.

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 27-28 NOVEMBER 2000

EXECUTIVE SUMMARY

The SSC was requested to express its opinion on the following:

1. The validity of the scientific bases for intra-community trade restrictions adopted by Austria, Italy and Spain.

a. Live animals

The recent increase in the reported incidence of BSE in France and Ireland is ascribed by the SSC to three factors:

* Real increase in incidence as predicted in its opinion on geographical BSE risk.
* Recently introduced tests are identifying cases that would not have been detected previously.
* The improved passive surveillance as a result of heightened awareness.

The SSC underlines that the current incidence figures do not require modification of the GBR-level of France and Ireland (III), as assessed in its GBR-opinion of July 2000. However, this position will be reviewed regularly in the light of the results of the intensified surveillance.

The effective implementation of the recommendations repeatedly made by the SSC on completely banning ruminant MBM from cattle feed, sound rendering and SRM removal1 would eventually lead to conditions of optimal stability and minimal propagation risk. All these measures need to be simultaneously in place. Careful control is essential.

Under these ideal conditions of optimal level of stability in the different countries, no additional measures would probably be needed with regard to international trade. However, as long as different stability levels exist amongst different countries, some trade restrictions might be justified temporarily. The decision on such temporary measures should be based not only on their immediate and longer-term risk for consumers and bovines but should also include an assessment of the level of implementation of the different BSE risk measures recommended by the SSC that determine the stability and BSE risk of the involved individual countries.

The SSC at this stage does not consider the justifications provided so far by the 3 Member States as substantial enough to support the trade restrictions. The significance of the possible additional external challenge in each case is not proven (see above). A decision on such restrictions should be placed in the context of the overall national BSE risk management systems in place in both the importing and exporting countries (which was not done). In addition, possible alternative options as indicated in this opinion of the SSC have not been considered.

1 As indicated in the SSC opinion of December 1997, the list of SRMs has to be modulated according to the geographical BSE risk evaluation of a country.

b. Embryos, ova and semen

The SSC reiterates its position that there is no scientific justification to assume a risk from imports of bovine semen, embryos and ova, provided the recommendations made in the SSC opinion of March 1999 are respected.

2. The scientific validity of measures envisaged by France:

a. The removal of the bovine vertebral column.

The SSC considers that some risk reduction can be achieved in France by means of the removal of bovine vertebrae both from the meat-on-the-bone and as a raw material for the production of derived products such as tallow and gelatine. The SSC would encourage other countries with a non-negligible BSE risk to consider adoption of such a measure.

b. The removal of the entire bovine intestine and casings.

The SSC recommends that the entire intestine should be considered as a specific risk material, regardless of the age of the animal in all cases where the exposure of the animal to the BSE agent is not negligible.

3. The possible scientific reasons for a general feed ban.

The SSC recognises that in principle the measures recommended in its various opinions will result in cattle feed with a negligible risk. However, it is aware that in practice cross-contamination of MBM-free cattle feed with other feeds which contain MBM is a serious problem which may prolong a BSE epidemic and therefore the risk to the consumer. The SSC recommends that member States conduct a risk assessment of the likelihood of such cross-contamination under their own national / local conditions. If a non-negligible risk is identified, the Committee recommends that a temporary total feed ban applicable to all farmed animals including cattle, pigs, poultry, farmed fish and to pets, as proposed by several Member States, would be the most effective approach to prevent the propagation of the disease.

THE QUESTIONS

The SSC was requested to express its opinion on the following:

1. The validity of the scientific bases for intra-community trade restrictions, adopted by Italy, Spain and Austria with regard to France and by Spain also with regard to Ireland.
2. The scientific validity of the following measures adopted or envisaged to be adopted by France:
   a. The removal of the bovine vertebral column from direct human consumption ("T-bone steak") and from the production of tallow and gelatine;
   b. The inclusion of the entire ruminant intestine in the list of specified risk materials, and this for animals of all ages, and the exclusion of casings made from it from human consumption as long as there is a risk that cattle could be infected with BSE.

3 The possible scientific reasons for a general feed ban of meat-and-bone meal, applicable to all farmed animals including cattle, pigs, poultry, farmed fish and pets envisaged by a number of countries.

BACKGROUND

In the light of the recent evolution of the number of BSE cases on its territory, France recently introduced or envisages introducing a number of additional risk management measures in order to increase the protection level of consumers and animals. A debate was also launched by several countries on the desirability of a general ban of meat-and-bone meal from animal feed, applicable to all farmed animals including cattle, pigs, poultry, farmed fish and pet food. Austria, Italy and Spain also took or envisage taking a number of measures to reduce the risk of being challenged by BSE infectivity possibly imported from France and, in the case of Spain, also from Ireland.

Following the submission by these 4 Member States of the scientific bases for these (envisaged) measures, the European Commission requested the Scientific Steering Committee (SSC) to prepare an opinion on the above listed questions.

Where appropriate, the scientific bases provide by the 4 countries have been summarised in the opinion hereafter.

PREAMBLE

In relation to the above-mentioned questions, the SSC wants to stress that the current evolution of notified BSE-cases in some countries is the result of challenge and stability conditions existing in these countries about 5 years ago. The currently observed increase in ~~clinical~~ BSE cases in France and the recent detection of some domestic BSE cases in Germany and Spain came at no surprise for the SSC as they were both expected on the basis of the GBR-assessment reports of July 2000.

The present opinion addresses the concrete and immediate questions resulting from the current situation of BSE in France and the reaction of other member states on this.

However, eventually the various issues should be addressed in a broader perspective and a more general context. For example, the risks from imports undoubtedly depends of the internal capacity of a national system to cope with this risk as well as from the degree of risk the exports carry.

The SSC's recommendations on measures that would improve stability as defined in the GBR-method, and that therefore would prevent any possible building-up of a pool of infectivity, include complete banning of ruminant MBM from cattle feed, sound rendering, and SRM removal. All these measures need to be implemented as a whole and be simultaneously in place. Moreover, a careful control is needed on the constant and efficient implementation of these measures in each country.

Regarding the risk of the propagation of BSE disease, under ideal conditions of optimal level of stability in the different countries, no additional measures would be needed with regard to international trade. However, as long as different stability levels exist, additional measures might be needed.

In deciding about these temporary measures, both, the immediate and longer term impact on consumer safety and on the risk of bovines to be exposed to the BSE-agent should be taken into account.

Given the limited time available to prepare this opinion, and the focus on France by several Member States, the present document will largely focus on the French situation. However, the same types of analysis would also apply to Ireland.

OPINION

1) Regarding import limitations for live animals, ova, semen and embryos from France.

a) Import of live cattle.

One argument put forward by some Member States is the apparent recent steep increase of the number of BSE-cases in France.

The SSC discussed this question and concluded that an increase of incidence figures as currently observed in France and, to a lesser extent, in Ireland, may be attributed to three components:

- A real increase in the true incidence, reflecting an increase in new infections of cattle in the past.
- An increase of the number of BSE-suspects that are notified because of improved passive surveillance.
- A number of cases that are discovered thanks to new diagnostic tools and active surveillance measures.

- Concerning the possible increase in true incidence the SSC confirms that this is well in line with its analysis presented in the reports on the GBR-assessment of France and Ireland:

France (source: report on assessment of the geographical BSE-risk of France, July 2000):

The domestic prevalence:

- "*During the 1980s a domestic prevalence of BSE developed, starting in 1983 at the latest (first birth cohort of a case). When the first infected domestic animals entered rendering, about one incubation-period later, infection of domestic cattle by domestic feed occurred. In the late 1980s, the number of animals getting infected will therefore have increased very fast as the system was extremely unstable and hence recycled the already present BSE-infectivity and experienced in the same time a significant external challenge via MBM.*
- *Between 1990 and 1996, due to the persisting instability of the system, the domestic prevalence will have increased continuously even if the external challenges decreased. Due to the increasing stability of the system in that period, the rate of this increase will have slowed down probably since 1992.*
- *Since 1996 a decrease in the number of new infections is expected, which will have been reflected in a decreasing prevalence of the disease in subsequent birth cohorts. However, incidence is lagging behind on this process, and an increasing incidence may well continue to be seen in the next future.*
- *Since 1998, a further strong decline in the risk of recycling the infective agent can be assumed. This made the system stable and should have induced a significant decline of the annual number of new BSE cases and a fast decline of the internal challenge."*

- The average French incidence over the last 12 months (Nov-99-15/11/2000) was 9.9 confirmed cases per million of adult (>2y) cattle.

The overall challenges***:***

- *"Until 1990 continuing imports from the UK of live animals and/or MBM or MBM-containing feed preparations lead, in combination with the amplification of an apparently already present internal challenge by an extremely unstable system, to an extremely high challenge at the end of the 1980s.*
- *After 1990 MBM imports were reduced, but by then, the amplification of the BSE-infectivity already present in the system led to a very fast increase in the internal challenge that most likely overcompensated the decrease in the external challenge. Therefore overall challenge continued to increase until 1996 and beyond.*
- *Since 1997/1998 and in particular after the rendering is according to standard the overall challenge decreases, but is still at a high level. However, if the measures function as expected, the decrease will accelerate in the future."*

Ireland (source: report on the assessment of the geographical BSE risk of Ireland, July 2000):

Domestic prevalence:

- *"From the stability/challenge interaction it has to be expected that incoming BSE-infectivity was amplified, leading to an increasing internal challenge.*
- *From this a steady increase of the domestic prevalence would be expected but the rather constant level of BSE-incidence between 1989 & 95 seems not to support this.*
- *Also the almost fourfold increase in the observed clinical incidence in 1996 is not in line with the expectation of a steadily increasing epidemic. If it reflects a true increase, it would indicate a stepwise-increased exposure to the BSE agent (source of infection: most probably contaminated feed) between 1991 and 1993 but this is not supported by the available information. However, it cannot be excluded that the 1996 increase was at least partly the result of an increased reporting of clinical BSE suspects. This could be explained by intensified surveillance and increased awareness of BSE, following the confirmation of the infectivity of the agent for man and the subsequent awareness raising measures of the Irish veterinary service.*
- *The prevention of new infections to any sizeable extent was unlikely to have occurred before the measures in 1996, 1997 and 1998 were implemented. Since then the domestic prevalence of BSE-infected cattle should have started to drop, but this development will only become visible in the incidence figures once those birth cohorts have been observed for at least 5 years. Until then, a further increase of the incidence figures cannot be excluded.*
- *The current prevalence of domestic infected animals, the internal challenge, is still assessed to be very2 high, in particular in the birth cohorts prior to 1996/97/98, but decreasing.*
- *Between 1989 and 1998, a total of 344 clinical BSE cases from the birth cohorts 1981 to 1994 were reported to the veterinary authorities. All but 14 of those cases occurred in domestic cattle.*
- *In 1999, 95 clinical BSE cases were reported. The birth cohorts of the 32 cases diagnosed between January and June of 1999 ranged from 1990 to 1995.*
- *Between 1 January and 17 February 2000, 24 new BSE cases were detected in the Irish cattle population. Information on the birth cohorts of these cases were not available."*

- The average Irish incidence over the last 12 months (Nov-99-15/11/2000) was 39.7 confirmed cases per million of adult (>2y) cattle.

Challenges

- *"Cattle imported from GB between 1985 – 1990 created an initially low and between 1988 and 1990 high external challenge to the Irish system.*
- *Additional sources for an external challenge at a moderate level were the importation of cattle from other European countries between 1992 and 1997 and the trade with animal feed with Northern Ireland.*

2 See definition in part I

- *The driving force, however, was the internal challenge (domestic prevalence of BSE infected cattle) building up since 1985 or before and reaching a peak between 1996 and 1998, at an extremely high level.*
- *The internal challenge, and with it the overall challenge to the system, should be decreasing rapidly since."*

These assessments should to be understood in the light of the SSC's model of the BSE/cattle system, as first described in its opinion on the GBR of July 2000 and illustrated in figure 1, below. Both countries have been exposed to external challenges from imports of potentially BSE-contaminated MBM and/or potentially BSE-infected cattle from the UK. France, for example, received about 16,000 tons of MBM from the UK in 1989 alone, and Ireland imported in 1988/90 about 6,407 cattle from the UK.

- An increase in the number of notified BSE-suspects as compared to those previously identified may partly result from an increase in awareness. This was experienced in Switzerland when active surveillance was introduced and a similar development can be apparently observed in France (pers. Communication by D.Dormont, 23/11/00).
- The introduction of rapid diagnostic tests and their application in screening programs will lead to the discovery of cases that otherwise would have remained undetected. In France a screening program is currently about 50% completed, aiming to eventually test approximately 40,000 at-risk animals in the most affected region of France. It has already (27/11/00) discovered 40 cases that would otherwise have remained undiscovered. This corresponds with the expectations of the SSC. In its GBR-opinion of July 2000[3], it stated that "*active[4] surveillance exercises in Switzerland (of adult cattle not notified as BSE or CNS suspect in fallen stock, emergency slaughter, and normal slaughter) and the UK (OTMS-survey[5]) both detected several confirmed BSE-cases that would have remained undetected by normal, passive[6] surveillance, even if targeted at animals with neurological symptoms. The SSC therefore assumed that passive surveillance does not give a true estimate of the existing BSE-cases. The Swiss and UK results indicate that it is likely that passive surveillance, based solely on notification of symptomatic BSE-suspects, will not detect more than half or one third of all clinical cases, or even fewer."*

The SSC also underlines that the current incidence figures do not require modification of the GBR-level III of France or Ireland as assessed in the GBR-opinion of July 2000. However, this position has to be regularly reviewed in the light of the results of the intensified surveillance.

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3 Final opinion of the Scientific Steering Committee on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) - Adopted on 6 July 2000.

4 Active surveillance = testing of cattle that are not notified as BSE-suspects but belong to risk sub-populations.

5 OTMS = Over Thirty Months Scheme. This scheme excludes all UK-cattle older than 30 months from the animal feed and human food chain. The survey involved sampling about 3000 cattle older than 60 months that did not show any symptoms compatible with BSE. It found 18 BSE-cases.

6 Passive surveillance = surveillance of notified BSE-suspects, i.e. cattle that are notified because of clinical signs compatible with BSE.

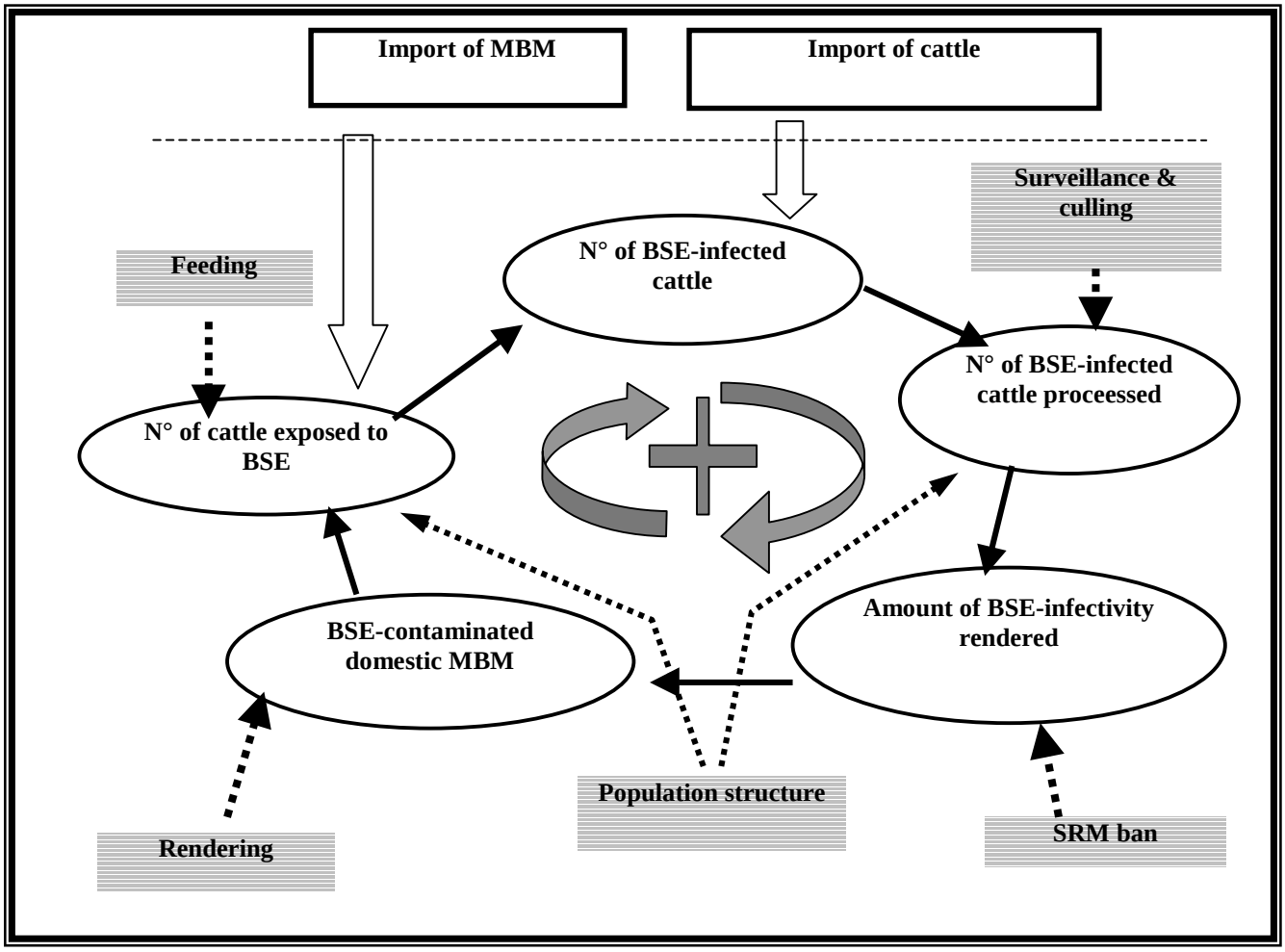

Figure 1: The model of the BSE/cattle system used by the SSC. From: Final Opinion of the SSC on the Geographical Risk of BSE, July, 2000

A second argument put forward by some Member States is the assumption that imports of live cattle from France would be an external challenge and could increase the GBR of the importing country.

The SSC recognizes that an import of infected animals would increase the infectious load in the importing country, as would the import of contaminated meat products. Such imports could therefore have repercussions on consumer safety and the potential development of a BSE-epidemic in the importing country. However, any single measure adopted by a country should be evaluated in the context of the appropriate implementation of all the measures recommended so far by the SSC.

The SSC notes that Austria and Italy, that propose restricting imports from France have not provided any analysis along the lines the SSC would regard appropriate and that are described below. According to the information provided by these countries, they have

neither assessed their own internal ability to cope with an external challenge that might result from such imports, nor did they analyze the level of stability in the exporting countries at the relevant period that would determine the external challenge that those exports could represent. Furthermore, these countries have provided no weighting of the adopted measures against existing alternatives and it is not fully possible for the SSC to appreciate the reasoning for the difference of the measures taken by these countries as compared to those adopted by Spain. In particular it is not evident why these countries do not address Ireland as Spain does it.

Spain has provided a more elaborated analysis:

- It has provided an analysis of the potential external challenge that import of breeding animals from France or Ireland could represent. Assuming that the "sharp increase" of the incidence figures in France and Ireland indicates that they are approaching the peak of their respective epidemics, it is concluded that the greatest external challenge from imports from these countries can be expected in the near future. This implies, according to the Spanish analysis, that imports from France or Ireland would carry a significant risk of including cattle that are incubating the BSE. No quantitative assessment of the expected risk is provided, also not in comparison to imports from Portugal or UK, the only countries for which import restrictions are currently in force.

- Concerning the stability of the Spanish system, Spain regards it essential to avoid additional external challenges. In addition Spain argues that importing potentially infected cattle would mean that the BSE-agent is present in Spain7, posing an internal challenge as long as the animals are alive. Alternative measures to cope with this challenge are not discussed.

- Referring to the SSC's GBR-opinion, Spain argues that the GBR of countries with a stability similar to Spain would decrease over time, if new challenges could be avoided and the stability maintained. Again, no alternatives to import restrictions to cope with the external challenges are discussed.

- Finally Spain points to remaining uncertainties with regard to maternal and horizontal transmission (reference: Philipps report) as an argument to restrict import of breeding animals from France and Ireland.

In deciding upon appropriate measures, several aspects have to be taken into account, including:

– The ability of the importing country to prevent potentially infected cattle from entering their domestic feed cycle and, if it does, to prevent any propagation of infectivity. This ability is defined as stability of a BSE-cattle system (see GBR-opinion of July 2000, pp.11ff). It depends on the control of imported cattle and their fate and on the various stability factors shown in figure 1, in particular appropriate

7 However, the recent discovery of a domestic BSE case in Spain has shown that this is already the case.

rendering, exclusion of SRM, avoidance of feeding MBM to cattle. It has to be stressed that all measures must be appropriately controlled and implemented.

– The effective implementation of SRM-bans in any Member State with a non-negligible BSE-risk, as proposed by the SSC in its opinion of December 1997, should provide to the consumer the best possible safeguard against exposure to the BSE-agent of the consumer in any EU Member State.

– The degree of external challenge that imported cattle may represent depends on their specific history prior to export. If exported animals were born after the exporting country reached a high degree of stability, the risk that these cattle are infected can be expected to be low, even if the GBR is still high. A high degree of stability can be assumed once rendering is fully carried out according to EU-standards, SRM and fallen stock are excluded from the feed chain, and the feeding of MBM to cattle is abolished. The latter also implies that cross-contamination of cattle feed with the BSE agent is excluded.

As alternative to restricting imports, other measures could be envisaged to cope with a possible external challenge resulting from live cattle imports. These include

- slaughtering imported cattle before reaching an age at which the animals could harbor relevant levels of infectivity would ensure an appropriate degree of consumer protection by ensuring that no significant amounts of infectivity could get into the feed cycle, in particular if SRM are excluded from both chains. This, in fact, is part of the restrictions on imports of live animals imposed by Italy and Spain. Spain has imposed an age limit of 20 months and Italy an age limit of 18 months.

Special measures with regard to older animals would also impact on consumer safety and the BSE-epidemic, but with a certain delay. Possible measures include:

- Excluding all imported older animals from the domestic food and feed chain. In the case of Australia, the SSC has accepted that cattle imported from the UK that were confirmed to have been excluded from the domestic food and feed chain, did not pose a risk[8.]

- If animals are healthy and have been imported 5 years or more ago, testing them for BSE might be an option to decide if they pose a risk of carrying the agent. If infected prior to import they should at that time be close enough to the end of the incubation period to be detectable. Accordingly tested cattle with no evidence of BSE may be allowed entering the food and feed chains.

- It is also possible to accept animals of a very high age (e.g., older than 10 years) that were closely monitored with regard to their health status do not pose a risk. This was applied by the SSC when assessing the GBR of New Zealand. All cattle imported from UK to New Zealand were closely monitored throughout their lives and reached high ages without showing signs compatible with BSE[9] .

If the alternative measures outlined above are implemented, the SSC's view is that restricting imports of older animals as an isolated measure as an alternative to the

8 Report on the Assessment of the Geographical BSE - Risk of Australia (July 2000)
9 Report on the Assessment of the Geographical BSE - Risk of New Zealand (July 2000)

measures outlined may not significantly influence neither the consumer protection nor the risk of domestic cattle to be exposed to the agent, in particular if the presence of BSE is confirmed also in the importing Member State.

b) Regarding bovine semen, embryos and ova

The argument to ban imports of bovine semen, embryos and ova from France is that it would represent an external challenge and could increase the GBR of the importing country.

Regarding bovine semen, embryos and ova the SSC refers to its opinion on the GBR where it states that imports of bovine semen, embryos and ova are not regarded to be effective vectors for transmitting the BSE-agent and are therefore not taken into account when assessing the external challenge. The SSC also points to its previous opinion on this issue[10] where it concluded as follows:

- "On the basis of the limited data available, it appears that there is no enhanced risk of the development of BSE in the offspring of sires who developed BSE. It is therefore unlikely that semen constitutes a risk-factor for BSE transmission.
- Preliminary research results from the incomplete embryo transfer study suggest an extremely low risk of transmission (95% confidence limits: 0-1.5%). These results are consistent with maternal transmission being mediated later in the gestational period either during or following birth of the animal.
- transmission of BSE by artificial insemination is unlikely for semen derived from BSE-affected bulls early in their incubation period;
- transmission of BSE by *via* embryos and ova unlikely provided International Embryo Transfer Society (IETS) protocols are used.

The SSC reiterates its position that there is no scientific reasoning proposed that would require assuming significant external challenge to result from imports of bovine semen, embryos or ova.

2.a Regarding the safety of bovine vertebrae and intestine

The possible BSE-risks associated with bovine vertebral column is linked to contamination with spinal cord material and the infectivity of the dorsal root ganglia of cattle infected with BSE.

Bovine vertebrae as part of meat-on-the bone.

The SSC has addressed the question of the infectivity of the vertebral column already in its opinion on SRM of December 1997. There it recommended that the vertebral column of animals above 12 months should be regarded as SRM because of the close association with the dorsal root ganglia and the risk of cross contamination with spinal cord material. The SSC therefore agrees that man should not consume meat-on-the-vertebrae if a risk cannot be excluded that these carry infectivity.

To assess this risk the probability that a cattle slaughtered for human consumption is infected with BSE should be taken into account together with its age. In general, the dorsal root ganglia and the spinal cord pose a higher risk as from the second half of the incubation period. The probability of slaughtered cattle to be pre-clinically, sub-clinically

10 Opinion on the possible vertical transmission of Bovine spongiform encephalopathy (BSE) adopted by the Scientific Steering Committee at its meeting of 18-19 March 1999

and clinically infected depends on the probability of them having been exposed to the agent. This can be assessed, for example, by weighting the main stability factors, i.e., feeding (including cross-contamination), rendering and removal of SRM in the country of origin. In a highly stable situation the risk of a calf to be exposed to the BSE agent is very small or nil. In an unstable situation this risk can be considerable, depending on the presence of the agent in the system.

The SSC agrees that some risk reduction can be considered in France by means of the removal from human consumption of the meat-on-the-vertebrae. The SSC therefore would encourage other countries with a non-negligible BSE risk to conduct an assessment of the risk to human exposure of BSE from meat associated with the vertebral column (including with respect to age of the animal).

Vertebrae as part of the raw material for the production of tallow, gelatine and dicalcium phosphate.

With regard to the use of bovine vertebrae as a raw product for the production of tallow, gelatine and dicalcium-phosphate, the SSC confirms its opinion of April 2000 as follows.

The most important risk reduction results from the removal of the tissues that carry the highest infectivity at the end of the incubation period. The additional safety level resulting from the removal of the vertebral column is much lower. Whether or not a tissue should be removed has to be decided upon in the light of the residual risk levels that are considered to be acceptable. However, for the time being, and in the light of the preliminary results presented in the report of the Working Group on Quantitative Risk Assessment11, the SSC considers that the additional safety gained from the removal of vertebral column for the production of tallow and gelatine is limited in countries with a GBR level below IV, but should be considered as sufficiently important to exclude it in GBR level IV countries.

Apart from the apparent factors such as the (evolution of the) incidence and prevalence of the disease and the processing conditions, it is clear that other conditions such as the actual stability of BSE in a country and the age at slaughter will affect the level of risk associated with vertebral column. Where the risk assessment by the an interested country shows that it is appropriate, the removal of the vertebral column should be considered in countries with a GBR level below IV or for animals at risk.

11 Preliminary Report on Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow. Submitted to the Scientific Steering Committee at its meeting of 13-14 April 2000.

2.b The scientific validity of the inclusion of the entire ruminant intestine in the list of specified risk materials, and for animals of all ages.

France's argumentation to consider the whole intestine, from duodenum to rectum as SRM, can be summarized as follows:

- **Proven possible infectivity of the ileum of calves;**
- **Also parts of intestine other than the distal ileum contain lymphoid and neural tissues, be it to a lesser extent, in which replication of prion would be possible; cleaning of the intestine is not 100% sufficient to remove all this tissue, as shown by microscopic analyses.**
- **Although there is some experimental evidence that these other parts of the *bovine* intestine not resulting in disease in mice, the mice bio-assay tests are less sensitive susceptible than cattle-to-cattle tests.**

In its opinion on SRM of December 1997, the SSC reviewed available experimental data showing infectivity of the distal ileum in the mouse bio-assay. Considering it to be unrealistic to expect a reliable differentiation between the ileum and other parts of the intestine under slaughterhouse conditions, the SSC recommended the entire intestine from duodenum to rectum to be regarded as an SRM independent of the age of the animal in all cases where the exposure of the animal to the BSE agent is not negligible.

In view of the new information by the French AFSSA that histological analyses of casings made from intestines have found neural and lymphoid cells also in parts of the gut other than the ileum (and also after casing preparation), the SSC re-iterates that the entire intestine (and casing made there-off) should be regarded as being an SRM, whenever it is not highly unlikely that the slaughtered animals are infected.

3. Possible scientific reasons for a general feed ban of meat-and-bone meal, applicable to all farmed animals including cattle, pigs, poultry, farmed fish and pet food.

Infected MBM is at the origin of the large BSE epidemic in UK. One of the hypotheses to explain the "Born-after-the-ban" cases in France is cross-contamination of animal feed. By banning the use of MBM for all animals, this risk is minimized. A complete ban of feeding all farmed animals with MBM containing feed significantly facilitates the controls.

The SSC is aware that cross contamination with possibly BSE-contaminated ruminant MBM is a serious problem, able to prolong a BSE-epidemic and therefore the risk for the consumer. This reasoning is clearly supported by the many cases born after the various feed-bans in Switzerland, the UK, France and in other countries in spite of the many preventive measures adopted to improve their stability against BSE (see the SSC opinion of 7 July 2000 on geographical BSE risk).

The importance of cross contamination even in a situation where rendering is according to EU-standard and SRM and fallen stock are excluded from the feed chain has been

demonstrated. Also the risk resulting from materials stored since before an effective ruminant MBM feed ban was implemented needs to be considered.

However, when discussing the scientific justification of banning mammalian proteins from all feeds, the SSC wants to draw attention to its opinion on intra-species recycling. This opinion points, on the one hand, to some theoretical risks linked to feeding possibly TSE-contaminated feeds to non-susceptible animals. These risks include the possible build-up of a pool of infectivity in animals that are not developing the disease but may be able to harbor and potentially replicate the agent. This risk is higher in the case of intra-species recycling, due to the absence of a species barrier. Also the risk of adaptation of the agent to hitherto non-susceptible hosts is mentioned. On the other hand the opinion points out that there is no epidemiological evidence that pigs, poultry or fish are susceptible to BSE or that BSE has moved into these species. So far there is no scientific evidence of the occurrence of TSE in farmed pigs, poultry and fish. Only pigs have been found to be susceptible to intra-cerebral challenge under experimental conditions. Also the hypothesis that pigs, poultry or fish do act, after oral challenge, as healthy carriers of TSE-agents is not supported by the limited[12] experimental data available. It is also pointed out that in some other species that could be fed animal/fish by-products, namely felines and several zoo animal species, including primates, TSE cases have been reported. These species are therefore more at risk than the mentioned food-animals to develop pools of infectivity and to spread the agent. (See also the recent opinion of the SSC on SRM in feed for fur-animals.)

The SSC also signals (see opinion on intra-species recycling) that there is a danger that if the treatment or disposal conditions are too restrictive, increasing amounts of material would simply be stored, buried or burned and the total risk increased. Environmental risks, for example by spreading of the agent by rodents feeding on not completely and properly treated materials for disposal or by incompletely burned materials spread on arable land. may lead to hitherto unknown new risks for man and animals. (See also the SSC-opinion on SRM in feed for fur-animals.) The appropriate risk reduction conditions need to be defined and already in June 1999 the SSC called for a separate analyses of these issues.

What precedes implies that avoiding a possible risk at a given level may create a risk at another one (see also the SSC opinion of 26-27 October 2000 on Safe handling, transport and temporary storage of MBM which may be contaminated with a BSE agent or other pathogens). The SSC, therefore, recommends that a integrated risk assessment is carried out, taking due account of all aspects relevant to the issue of feeding mammalian proteins to non-ruminants.

In view of the arguments that might support continuing feeding of mammalian proteins to non-ruminants and the above mentioned cross-contamination issue, the SSC recommends

12 This mention refers also to the fact that, for example for pigs, the testing of infectivity should be done for a large list of tissues (not only CNS) and at various stages of a possible incubation period (not only after several years).

that if recycling of animal material as feed to animals is applied[13], measures that reduce the risk to recycle TSE-infectivity are implemented. These include[14]:

– In any country where the geographical BSE risk is higher than I, no ruminant-derived feed should be fed to ruminants;

– In countries with a geographical BSE risk level of IV, no ruminant- or other BSE-susceptible animal-derived meat and bone meal should be used as feed for mammalian animals and a total feed ban to all farmed animals and pets should be considered. For the other species (fish and poultry), the recommendations listed in the next paragraph, should apply.

For countries with geographical BSE risk levels of II and III, the following recommendations are valid:

- Only raw materials as listed in the SSC opinion of 24-25 June 1999 on “Fallen stock” [see pages 11-18 of the opinion] are acceptable for recycling;
- All recycled animal protein material should be treated with "133°/20’/3bars" or equivalent conditions because this would reduce any infectivity by a factor of at least 1000;
- Appropriate slaughtering methods should be applied, to avoid possible distribution of infectious material to other parts of the body that are subsequently rendered while SRM are excluded;
- Not only cross-contamination of ruminant feed with ruminant_protein should be avoided but also cross-contamination of non-ruminant feed with high-risk material (SRM). Possibly contaminated materials stored since before a MBM feed ban should be carefully removed.
- A number of additional recommendations are made in the SSC opinion of 17 September 1999 on The risk born by recycling animal by-products as feed with regard to propagating TSE in non-ruminant farmed animals.

Tallow, gelatin, dicalcium phosphate and hydrolyzed proteins should be produced under appropriate conditions, as defined in the SSC opinions, as this will effectively reduce infectivity entering their production;

What precedes implies that the SSC - provided that all the above preventive measures recommended are implemented properly - does not necessarily the advocate banning feeding of animal materials to non-ruminant farm animals or pet animals, even in

13 The SSC has addressed at several occasion (see for example its opinions on Fallen stock, on Recycling of waste material and on the Safety of Ruminant blood) the possible risks associated with recycling and intra-species recycling in general. It recommended [in its Opinion on the Safety of ruminant blood] that intra-species recycling should as a matter of principle be avoided. The SSC recommends that this issue should form the object of a complementary opinion.

14 See also the various opinions of the SSC on the safety of products. It has to be understood that the above measures would not be able to reach a zero risk should infectivity enter the recycling loop, and that due to the long incubation time of this type of disease a significant risk would have build up before an incidence becomes visible (as has been seen in the case of BSE in the UK).

countries were the presence of BSE cannot be excluded, is likely or is confirmed at a lower level.

With respect to BSE/TSE matters, the SSC repeatedly stated that its opinions are only valid provided the recommended measures, including regarding cross-contamination, are properly implemented. Should the risk assessment carried out by an interested country show that this is not the case for a certain period of time, a temporary total MBM feed ban would be the most effective approach to stop the propagation of the disease.

All opinions and reports of the SSC can be found on the Internet at the following address:
http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html#opinions