3.5.2. Indirect consumption.

SRM is transformed and integrated into food products in such a way that it is not detectable by the consumer. The inclusion of SRM into food products may happen voluntarily or by contamination.

3.5.2.1. Voluntary inclusion of SRM.

The use of brain or spinal cord in "paté" or sausages is an example of the voluntary use of SRM. Other SRM may also be included into food products as direct ingredients. Data are available from a recent study in Germany, where there is no ban on the use of SRM in human food, and (bovine) brain tissue was included in sausages. Lücker *et al* (1999_a-1999_d), detected CNS in 14.5% of the 69 samples of a specific sausage (Kochmettwürste) which were analysed using immuno-assays specific to bovine CNS.

3.5.2.2. Contamination of edible products with SRM.

Contamination is always possible if the inclusion of SRM is technically possible and does not create quality problems. Also MRM could be contaminated, particularly if it is produced, inter alia, from vertebral column that could include both DRG and spinal cord. It should be noted that, from a technical point of view, MRM could be included in many "meat" products. Tallow and gelatin would normally not contain any SRM but certain contamination of the raw material with brain or spinal cord could occur.

3.5.3. Estimation of the Exposure Level and of the number of persons exposed.

In order to estimate the expected number of people that would be exposed to an infected dose, several critical factors have to be considered. Some of them are related to the Sources, others to the Routes.

3.5.4 Critical factors determining the HER

3.5.4.1 Critical factors as regards to Sources

⇒ Processing risk. The probability that an infective bovine is slaughtered for food is the most relevant parameter for the Human exposure risk. Its assessment is not the subject of this report.

⇒ Age of the infected animal that is slaughtered and "normally" processed. It influences the infective load and its distribution between the tissues of the animal as indicated by the categories given in Section 3.4.1.

⇒ Infected animals per batch. As long as the BSE-cases remain geographically scattered, the number of exposed consumers would be proportional to the number of processed BSE-infected animals and the average exposure dose would remain rather constant.

If the BSE-density is so high that more than one infective animal could enter a single batch of production, the number of consumers exposed would remain stable while the dose per exposed individual would increase proportional to the number of infected animals entering the batch.

3.5.4.2. *Critical factors as regards to Routes*

⇒ Processing conditions. In principle, processing conditions could influence the level of infectivity in the product. It is known, for example, that certain production processes for gelatine and tallow reduces the infective load at least a 1,000-fold. (See SSC opinions on these products). However, normal cooking and industrial food processing of the products addressed in this opinion are unlikely to affect the level of infectivity.

⇒ Batch size. The batch size of food products into which SRM is integrated directly (meat products, paté, sausages) or indirectly (via MRM) will significantly influence the number of persons exposed. Larger batches may expose a higher number of people to a smaller dose, and vice-versa.

⇒ Serving size. Together with the batch size, the serving size influences the dose of exposure and the number of persons exposed.

⇒ Contamination. The potential for contamination with SRM (e.g. of MRM) will increase the likelihood of exposure to infectivity. The dose of exposure due to contamination is likely to be low, although the number of persons exposed could be high depending on batch and serving size as above.

⇒ Use of SRM. Deliberate use of SRM will increase the infectious load and hence the exposure dose.

Note: The route into which a given SRM will be channelled, largely depends on two factors:

⇒ Price. The relative price for brain, spinal cord and other SRM for direct consumption (direct eating), integration into higher value added products (paté or sausages), MRM (for low value added food products or pet-feed) or rendering will determine the use made of these tissues. Generally there will be a tendency to choose the most profitable option. For example, the price of the brain or spinal cord for human consumption is between 3,000 and 5,000 FF/ton (460 to 760 €/tonne). The value for the same tissues included in MRM for pet food can be 5 times lower (1,000 to 1,700 FF/ton or 150 to 250 €/tonne).

⇒ Outlet. The size of the different market outlet for the different tissues will also influence the use of the SRM. This size depends, inter alia, on traditions and eating habits but it will also be influenced by legislation.

3.6 Quantitative exposure assessment

The SSC attempted to estimate human exposure risk from all food-borne exposures, including via gelatine and tallow. However, the issue is far more complex than for geographic BSE risk and there is very limited quantitative data available for most of the critically important variables.

The SSC requested detailed information on the use made of different bovine tissues from the Member States. Only three responded but in rather global and qualitative terms only. That information has been taken into account in establishing the scenarios described below.

In the longer term, it should be possible to construct stochastic models to estimate human exposure to not only the BSE agent but other food borne hazards such as dioxin or ochratoxin. Therefore for the purpose of the present opinion, the SSC has focussed on what is possible, i.e. scenarios, with no data on the probability of their occurrence.

4. EXPOSURE SCENARIOS

The following scenarios are intended to illustrate realistic values for the human exposure risk resulting from one infected bovine entering the human food chain and processed as an animal declared fit for human consumption.

4.1. Scenario 1 - Maximal distribution, only indirect consumption

Note: This scenario is based on data generated from a household survey in 1993, food composition databases and interviews with food industry and govern,ent departments. While the assumptions are felt to be realistic for this historic situation, it is not assuming that they describe a currently existing situation. However, it is the opinion of the SSC that the scenario illustrates a realistic upper end of the number of people that could be exposed to the BSE-infectivity. For details of calculation see Annex 1.

4.1.1. Assumptions

The entire infective material of a BSE-case is included in mechanically recovered meat (MRM). It is important to understand that a smaller amount of infectivity entering the MRM would contaminate the same amount of product – only the average infective load would be lower.

MRM is produced in batches of 5 to 7 tonnes. This information was obtained from industry and refers to current production of MRM for pet-food. It is confirmed by quality control prescriptions of the industry, which require destruction of at least 5 tonnes of MRM (=one batch) if a quality problem is recognised (bacterial contamination etc.).

About 7kg of MRM is obtained from one animal. Thus one batch contains material from up to 1,000 animals. If one of these animals is infective, the entire batch is contaminated, and it is assumed that any infectivity would be distributed evenly throughout the batch.

The average MRM content of food products varies between 100% ("meat" filling of cheap stuffed pasta could technically have been made from MRM only) and 5 to 10% (minced meat preparations, for example, could contain that fraction of MRM without technological problems).

Minced meat is normally sold in packages of 600g to households with 2.7 persons on average.

Cheap meat stuffed pasta contains about 13% of filling and is sold in 1,000g packs per household averaging 2.7 persons.

4.1.2. Conclusions

Given the large batch size and the small proportion of MRM in meat-products, one animal could contaminate 5 tonnes (pasta filling) to 116 tonnes (minced meat) of food products.

A large number of servings could thus be contaminated, albeit with a low average dose per serving.

Calculations based on the assumptions made, indicate that one 5-tonne-batch of MRM could expose about 200,000 (via "pasta") to 400,000 persons (via minced meat preparations) to the BSE infectivity (see annex 1).

The same calculation showed that the average infective load would be between 0.023 and 0.043 CoID50 per consumer if the entire infective load of the animal ends up in MRM. Excluding CNS-SRM (Brain, spinal-cord, trigeminal and dorsal route ganglia[10]) from the production of MRM would reduce the dose of exposure by about 95%.

4.2. Scenario 2 - Mean distribution, only indirect consumption

The following scenario is based on assumptions only. It serves as an illustration of a medium level of dispersion of the BSE infectivity.

4.2.1. Assumptions

The entire brain and spinal cord (700g) are mixed into paté or sausages up to a fraction of 5%.

The average serving of "paté" or sausage is 50g to 100g and could hence contain 2.5g – 5g brain or spinal cord.

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[10] Because of the risk of contamination with CNS, the vertebral column and head-bones should not be used for MRM production.

Each serving is eaten by a different person.

The remaining 12 % of the infectivity are rendered or directly fed to animals.

4.2.2. Conclusions

If "paté" or sausages are prepared in batches of 14kg, i.e. where the 700g of brain and spinal cord are just 5%, 280 servings of "paté" or 140 servings of sausages could be contaminated by one single infectious animal.

The average infective load would be between 25 and 50 $CoID_{50}$ per consumer.

If the batches are larger and the fraction of brain and spinal cord included is lower, the number of contaminated servings would increase and the infective load per consumer would decrease accordingly.

4.3. Scenario 3 – Concentration, only direct consumption

This scenario is based on realistic historical data. The assumption, that the entire infectivity outside the brain is not entering the food chain is, however, rather optimistic.

4.3.1. Assumptions

No MRM produced from bovine material.

Brain directly eaten at average servings of 100g.

The remaining infective tissue is rendered or directly fed to animals.

4.3.2. Conclusions

5 persons would eat the brain of the assumed infected animal. They would be exposed to 1,000 $CoID_{50}$, each.

The estimated exposures from these and similar scenarios are plotted in Figure 2, as number of exposed consumers against exposure dose, measured in $CoID_{50}$. No attempt has been made to consider the relative likelihood of these outcomes.

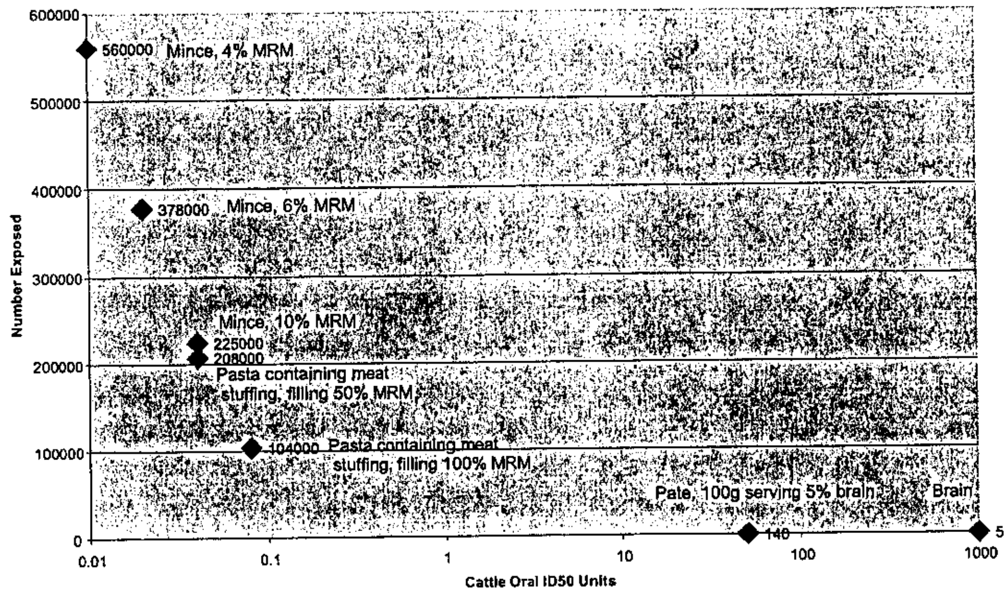

Figure 2: Summary of Exposure Estimates from Scenarios

- Mince, 4%, 6% MRM = Minced meat, containing 4%, 6% MRM, servings of 100g
- Meat stuffed pasta, filling 50%, 100% MRM = Meat stuffed pasta, filling consists of 50%, 100% MRM, serving = 370g containing 13% filling
- "Paté", 100g serving, 5% brain = "Paté" prepared with 5% brain and served at 100g portions.
- Brain = Brain, directly consumed in servings of 100g

5. IMPLICATIONS

1. Previously the SSC emphasised that brain, spinal cord, neuronal ganglia and the ileum of an infected bovine contain the highest concentration of BSE-infectivity. These tissues, therefore, are of particular concern in terms of their potential to induce human vCJD although the dose needed to induce human infection is not known.

2. Intestines used from young infected animals are of particular concern since they become infectious in an early stage of the BSE-incubation.

3. The SSC is aware of the direct human consumption of both intestines and brain material by many population groups within the EU and now has evidence of brain and spinal material being used in common meat products such as pâtés and sausages.

4. Wherever the direct consumption of intestine or central nervous tissue is still legally possible, there is a greater likelihood of inducing human infection because of the potentially high infective load of these tissues and hence the high dose involved in consuming them.

5. The pessimistic realistic analyses presented in the three scenarios are recognised to be based on uncertain assumptions. These relate to the rate of transfer of all SRM, in particular the brain and spinal cord, of an infected animal into a batch of food, its distribution within that batch, the estimate of the batch size of a meat ingredient and its incorporation into common food stuffs.

6. The SSC sought to avoid some of these uncertainties in its enquiry of Member States, but it was not possible to refine them because of a lack of reliable data and alternative analyses of risk.

7. The SSC would welcome different views based on new evidence or different analytical approaches, which would allow more reassurance to be given to policy makers and the public.

8. However, with the assumed widest distribution of SRM in food products, up to 0.4 million people could be exposed to infected material when only one infected animal with pre-clinical disease, close to the end of the incubation period but passed as fit for human consumption, enters the food chain.

9. Recent evidence suggests that in countries with a reported low incidence, the actual rate of BSE infected animals entering the food chain is not nil. It should be acknowledged that under such circumstances presently available methods to prevent that an infected animal entering the food chain are far from being satisfactory. The capability of the recently evaluated post-mortem BSE-tests to

identify pre-clinical BSE-cases has still to be determined before they should be considered for mass screening of pre-clinical animals.

10. The SSC therefore reaffirms its original analysis that the removal from the food chain of specified risk materials would significantly decrease the risk of vCJD.

11. Since there is inter-Member State transfer of animals, cross-border trading in animal organs and marketing of offals, ingredients and processed foods into and out of most EU Member States, it is reasonable to conclude that the risk of human exposure to BSE infectivity within any one country is not necessarily linked to the geographical burden of infectivity in the cattle within that Member State.

12. The ideal level of protection of consumers from exposure to BSE-infectivity is the absence of infected animals from the human food chain. In the event that this cannot be reasonably guaranteed, the second level of protection of consumers from exposure to BSE infectivity is the removal of SRMs, particularly CNS-based SRMs which account for 95% of the infective load in a BSE-case approaching the end of the incubation. Failure to do so is likely to expose a large number of consumers to an unnecessary risk.

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Annex I : Details of Scenario Calculations

General Assumptions

- Total infectivity in one fully infected animal: 8.000 $CoID_{50}$ (Cattle oral ID_{50} units)
- Number of persons per household: 2.7

Scenario 1

Burger Meat

- MRM is produced in batches of 5 to 7 tonnes. Assume batch size is 5 tonnes, packaged in 20kg packs (250 x 20kg).
- Assume all infectivity (8000 $CoID_{50}$) from one infected animal gets into a batch of MRM. (this would be very unlikely)
- Burger meat is produced in batches of 1 tonne, and may contain 5 - 10% of MRM.
- Burger meat/mince is normally sold in packages of 600g for one household (2.7 persons on average).

Calculations

➢ If 3 x 20kg packs of MRM are included in one 1000kg batch of MRM (6%), then 5 tonnes (250 packs) of contaminated MRM could contaminate 84 batches of burger meat.

➢ 84 tonnes of burger meat represent 114,000 (84,000 / 0.6), 600g packs that could expose 378,000 (114,000 x 2.7) persons.

➢ Average exposure would be 8,000 / 378,000 = 0.02 $CoID_{50}$ per person.

➢ Note: If MRM content is reduced, more people are exposed to a smaller dose, e.g.:

No. 20kg packs MRM per ton batch of mince	Percent MRM	Tons of mince contaminated	People exposed	Average exposure per person [$CoID_{50}$]
5	10%	50	225,000	0.04
4	8%	63	280,000	0.03
3	6%	84	378,000	0.02
2	4%	125	560,000	0.01
1	2%	250	1,125,000	0.007

Meat Stuffed Pasta

- Cheap meat stuffed pasta contains about 13% of filling, which could be up to 100% MRM.
- Meat stuffed pasta is sold in 1 kg packs to an average household of 2.7 people.

Calculations:

➢ If 100% MRM is used in filling, one batch of MRM could contaminate 38,500 1kg packs of meat-stuffed pasta, exposing 104,000 people to an average dose of 0.08 $CoID_{50}$.

➢ If 50% MRM used in filling, one batch of MRM could contaminate 77,000 1kg packs of Meat stuffed pasta, exposing 208,000 people to an average dose of 0.04 $CoID_{50}$.

Annex 2: Opinions adopted by the SSC since November 1997 on questions related to Transmissible Spongiform Encephalopathies (status : 8.12.1999)

N°	Date of adoption	Title of the opinion
1.	9 December 1997	Listing of Specified Risk Materials: a scheme for assessing relative risks to man
2.		Report on the UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases
3.	22-23 January 1998	Opinion of the Scientific Steering Committee on defining the BSE risk for specified geographical areas
4.	19-20 February 1998	Opinion on the revised version of the UK Date Based Export Scheme and the UK proposal on compulsory slaughter of the offspring of BSE-cases, submitted on 27.01.98 by the UK Government to the European Commission
5.		Final Opinion on the contents of a "Complete dossier of the epidemiological status with respect to TSEs".
6.	26-27 March 1998	Opinion on BSE risk
7.		Opinion on the Safety of Tallow
8.		Opinion on the Safety of Meat and Bone Meal
9.	25-26 June 1998	The safety of dicalcium phosphate precipitated from ruminant bones and used as an animal feed.
10.		Possible links between BSE and organophosphates used as pesticides against ecto- and endoparaistes in cattle.
11.	24-25 September 1998	Opinion on the risk of infection of sheep and goats with Bovine Spongiform Encephalopathy agent.
12.		Report and Opinion on mammalian derived meat and bone meal forming a cross-contaminant of animal feedstuffs.
13.		Scientific Opinion on the safety of organic fertilisers derived from mammalian animals.
14.		Updated Scientific Report on the safety of meat and bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals, presented to the Scientific Steering Committee on 24-25 September 1998.
15.	22-23 October 1998	Report and Scientific Opinion on the safety of hydrolysed proteins produced from bovine hides.
16.		Opinion on the safety of bones produced as by-product of the Date Based Export Scheme.
17.	10-11 December 1998	Updated Report and Scientific Opinion on the safety of tallow derived from ruminant tissues
18.		Updated Report and Scientific Opinion on the safety of gelatine
19.		Preliminary opinion on a method to assess the geographical BSE-risk of countries or regions

20.	21-22 January 1999	Report and Scientific Opinion on the evaluation of the "*133°/20'/3 bars heat/pressure conditions*" for the production of gelatine regarding its equivalency with commonly used industrial gelatine production processes in terms of its capacity of inactivating/eliminating possible TSE infectivity in the raw material.
21.	18-19 February 1999	Report and Scientific Opinion on the Safety of Gelatine (updated version of opinion adopted on 21-22 January 1999)
22.		Opinion on a method to assess the geographical BSE-risk of countries or regions, including the Manual for the assessment of the geographical BSE-risk.
23.	27-28 May 1999	Opinion on Monitoring some Important aspects of the evolution of the Epidemic of BSE in Great Britain (Status, April 1999)
24.		Opinion on: Actions to be taken on the basis of (1) the September 1998 SSC Opinion on the risk of infection of sheep and goats with the BSE agent and (2) the April 1999 SEAC Subgroup report on Research and Surveillance for TSEs in sheep.
25.	24-25 June 1999	Opinion on risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.
26.	22-23 July 1999	Opinion on the conditions related to "BSE Negligible Risk (Closed) Bovine Herds".
27.		Opinion on the policy of breeding and genotyping of sheep, i.e. the issue whether sheep should be bred to be resistant to scrapie.
28.	16-17 September 1999	The risk born by recycling animal by-products as feed with regard to propagating TSE in non-ruminant farmed animals.
29.	28-29 October 1999	Opinion on the Scientific Grounds of the Advice of 30 September 1999 of the French Food Safety Agency (the *Agence Française de Sécurité Sanitaire des Aliments,* AFSSA), to the French Government on the Draft Decree amending the Decree of 28 October 1998 establishing specific measures applicable to certain products of bovine origin exported from the United Kingdom.
30.		Summary Report based on the meetings of 14 and 25 October 1999 of the TSE/BSE *ad-hoc* group of the Scientific Steering Committee on the Scientific Grounds of the Advice of 30 September 1999 of the French Food Safety Agency (the *Agence Française de Sécurité Sanitaire des Aliments,* AFSSA), to the French Government on the Draft Decree amending the Decree of 28 October 1998 establishing specific measures applicable to certain products of bovine origin exported from the United Kingdom.