Table 9: Details on positive cases < 48 months since 1 January 2001 until February 2002

Age	Country	Target group	Date of birth
28	Deutschland	Emergency slaughter	September 1998
29	Deutschland	Emergency slaughter	August 1998
42	Danmark	Healthy slaughtered	May 1998
42	France	Healthy slaughtered	August 1997
43	España	Emergency slaughter	July 1997
43	España	Emergency slaughter	December 1997
44	Deutschland	Fallen stock	September 1997
45	España	Healthy slaughtered	October 1997
47	España	Fallen stock	August 1997

Comments:

a) In 2001, the BSE rapid testing programme carried out covered, in the age class below 24 months, 726.275 animals in Germany, 3.991 animals in Ireland and 1.014 animals in Belgium. None was found positive. In approx. 1.2 million healthy slaughtered animals tested between 24 and 35 months, no test positives were found, but 2 positives were found in emergency slaughters below 36 months. The tests on approx. 1.2 million healthy slaughtered animals between 36 and 47 months show a total of 3 test positives. An additional 4 positives were detected in emergency slaughters and fallen stock in that age class. For animals 48 months or above the number of BSE positives increases rapidly to 30 positives in approx. 0.8 million healthy slaughtered animals.

Only few assessments exist to judge whether the human exposure risk resulting from the above incidences. They do not provide evidence to conclude that the current risk in the EU countries has decreaseds compared to those assessments:

- The risk assessment referred to in the Opinion of the Scientific Steering Committee of 14 April 2000 (EC, 2000a) on The UK decision to lift the ban on the consumption of meat on the bone. This assessment made reference to the predicted numbers of BSE infected cattle that may enter the human food chain under 30 months of age, and that were in the last year of BSE incubation period. The predicted numbers were 1.2 infective cattle in 2000 and 0.8 animals in 2001. The UK slaughter statistics for these years were respectively 2.2 and 2.3 million cattle.
- The 1997 assessment of the human exposure risk of consuming dorsal root ganglia in meat-on-the bone in the UK. (DNV, 1997):. Depending upon the scenario used, the median value of the total infectivity in Dorsal Root Ganglia (spinal cord residues not included) to which the whole UK population (= the societal risk) would have been exposed in 1997 (all consumed meat from animals below 30 months) was estimated in that assessment to range from 0.004 to 0.25 human oral ID_{50} units (with 0.05

human oral ID_{50} units for the most likely scenario). The corresponding 95% percentiles are $2x10^{-5}$ to 63 human oral ID_{50} units. The number of animals slaughtered for consumption was approx. 2.3 million.

The median value of the corresponding average individual risk ranges from $7x10^{-11}$ to $5x10^{-9}$ human oral ID_{50} units consumed in 1997 by each individual. The corresponding 95% percentiles are $4x10^{-13}$ to $1x10^{-6}$ human oral ID_{50} units.

- The 2000 assessment of the human exposure risk of consuming dorsal root ganglia in meat-on-the bone in the Ireland. (DNV, 2001): In Ireland, in 2000 (before the obligation to remove the vertebral column from animals above 12 months and before the generalised rapid testing of animals, but taking into account that approx. 89% of the Irish meat production is exported), the median value of the total infectivity in Dorsal Root Ganglia (spinal cord residues not included) to which the whole Irish population would have been exposed (= the societal risk) was estimated in that assessment to range, depending upon the scenario used, from 0.008 to 0.6 human oral ID_{50} units. The corresponding 95% percentiles are $5x10^{-5}$ to 110 human oral ID_{50} units. The number of animals slaughtered for national consumption (exports excluded) was approx. 0.2 million (and 0.195 million being less than 36 months).

  The median value of the corresponding average individual risk ranges from $3x10^{-9}$ to $2x10^{-7}$ human oral ID_{50} units consumed in 2000 by each individual. The corresponding 95% percentiles are $2x10^{-11}$ to $4x10^{-5}$ human oral ID_{50} units.

  In the above risk assessments, animals slaughtered more than 9 (UK) or 12 (Ireland) months before are assumed not to have significant infectivity. This differs from the current SSC position that half of the incubation period should be considered as possible start for the presence of infectivity in the spinal cord and dorsal root ganglia.

One could consider that the current human exposure risk in the EU Member states is below the above risks assessed for the UK in 1997 and 2000 and for Ireland in 2000. These risk assessments are however not easily exploitable for an interpretation of the 2001 EU survey results because of the numbers of animals involved, the boundary conditions (spinal cord detectable infectivity-free at 12 months before onset or at half the incubation), the age profiles of slaughtered animals and the consumption patterns in the various Member States. The assessment of the human exposure risk in the various EU Member States resulting from an increase above 12 months would therefore require an additional analysis [an adaptation of the above risk assessments to other Member States] that would require the following additional information:

- the number of BSE-infected bovines being slaughtered for human consumption in the last year of their BSE incubation period [worst case: in last 50% of their BSE-incubation period]

- the consumed DRG-infectivity per bovine of type I expressed as : (a) bovine oral ID_{50}s and (b) human oral ID50s for various assumed species barriers.

b) The BSE statistics for the EU Member States show that the evolution of the BSE epidemic is not in phase for all Member States. In several countries where the epidemic started later, the observed number of cases may still be increasing.

c) The overall relatively low number of BSE positives in 2001 for the EU as a whole in the age classes up to 48 months, may be biased by the low figures in countries where risk management measures are in place since several years. In other countries (e.g., Spain and Germany) the numbers of positives in that age class represent a non-negligible percentage of the overall incidence. Some bias might also result from the fact that testing of healthy animals is only compulsory for animals above 30 months if they are intended for human consumption.

V. CONCLUSIONS

1. The TSE/BSE *ad hoc* Group considers that risk assessments are scientifically sound but apply only to the UK and to Ireland. The produced risk estimates cannot be generalised for other countries, because consumption patterns[6] and BSE incidence are different.

2. Preparing similar assessments for other countries, or for the EU's continental part as a whole, would require the preliminary collection of the corresponding information, part of which is not likely to be readily available but would need to be collected by surveys.

   An essential element in such risk assessment is the moment into the incubation period as from which the spinal cord and dorsal root ganglia can contain infectivity. Data from a single experiment, mostly referred to as the *cattle pathogenesis study*, has in the past been interpreted as showing that detectable infectivity in the spinal cord is only present in the last months of the incubation period, which would justify the consumption of meat-on-the bone or of vertebral column bones [for gelatine and fat production] up to an age of 12 months before the expected possible appearance of clinical signs. The TSE/BSE *ad hoc* Group considers however that the BSE in cattle pathogenesis study, which is a single experiment, cannot be exploited to express the time of detectable infectivity in the Central Nervous System tissues as a fraction of the total incubation period and that the limited number of animals used in this study do not allow to conclude that infectivity is absent in the spinal cord until a few months before clinical signs are manifested.

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[6] Quantities consumed by individuals, parts of the carcass used for the production of meat-on-the-bone, frequency of consumption of meat-on-the-bone and other carcass parts to which dorsal root ganglia may be attached, age distribution of the animals slaughtered, ...

From other experiments with other animal species and for which more data are available (e.g., mice, hamster, primates, sheep, ...) it may be concluded that the assumption made by the SSC on 12 January 2001, i.e., that in general, as a reasonable worst case assumption, the dorsal root ganglia and the spinal cord are considered to pose a higher risk as from the second half of the incubation period, remains valid.

3. The condition for increasing the age limit beyond 12 months would be the above recommended risk assessment showing that the total infectious load to which a Member State is exposed is below an acceptability level [set by the risk manager].

4. The TSE/BSE *ad hoc* Group considers that, given the different epidemiological history of BSE in the various EU Member States, and the corresponding different history of risk management measures (especially feed bans), it may be useful in this exercise to comparatively assess the BSE risk according to cattle age group for the different EU Member States.

VI. LITERATURE:

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