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SCIENTIFIC STEERING COMMITTEE

OPINION ON THE QUESTIONS SUBMITTED BY EC SERVICES FOLLOWING A REQUEST OF 4 DECEMBER 2000 BY THE EU COUNCIL OF AGRICULTURAL MINISTERS REGARDING THE SAFETY WITH REGARD TO BSE OF CERTAIN BOVINE TISSUES AND CERTAIN ANIMAL-DERIVED PRODUCTS

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I. MANDATE

Following the explicit request of 4 December 2000 of the Council of Ministers, the Commission services submitted the following questions to the Scientific Steering Committee (SSC), for opinion before 15 January 2001:

I.1. On vertebral column and T-bone-steaks. "If it is considered that the Community measures concerning the testing of bovine animals over 30 months of age and the feed ban are effectively implemented and carefully controlled, under which conditions can the measures to ban bovine vertebrae for direct human consumption and as a raw material for the production of derived products such as tallow and gelatine, be considered scientifically justified?

Can the SSC consider this question under the following two scenarios:

- An effective feed ban and testing of all emergency and sick slaughtered animals over 30 months of age and random testing of dead animals.
- An effective feed ban and testing of all animals over 30 months of age?"

I.2. On thymus and spleen. "In the light of the most recent scientific developments in this field, should bovine thymus and spleen be considered as specified risk material (SRM)?

If yes, under which conditions of sourcing and/or age of animal?"

I.3. On rendered fats. "Is there any new scientific evidence with regard to BSE that justify banning the use of rendered fats produced in accordance with the SSC opinion of 26-27 March 1998, in the feed (including milk replacers) of some or all farmed animals, i.e. cattle, sheep, goats, pigs, poultry and rabbits?"

I.4. On hydrolysed proteins. "Can hydrolysed proteins derived from animal material other than hides and skins be considered as safe and be fed to farmed animals?

If not, under which conditions of sourcing of the material and/or of type of the material used and/or production process can they be considered as safe?

Is there any new scientific evidence with regard to BSE justifying banning the use of hydrolysed proteins produced in accordance with the SSC opinion of 22-23 October 1998, in feed for farmed animals?"

In addition, Commission services request the SSC to address the following questions:

I.5. On Mechanically Recovered Meat (MRM). "Under which conditions of sourcing of the material and/or of type of the material used and/or production process, can MRM derived from ruminant bones be considered as safe?"

Rather than addressing the questions one by one and independently from each other, the SSC considered that it would be more appropriate to first analyse all new data and scientific evidence that became available since it adopted its various opinions on specified risk materials and product safety and to address, as a second step, the various questions. In preparation to the in-depth analysis of this new data by the TSE/BSE *ad hoc* Group, the SSC requested its secretariat to collect as much of the new data as possible within the imposed time constraint and to compile a comprehensive overview of its opinions in respect to the 5 questions. This overview was made available to the TSE/BSE *ad hoc* group and the SSC as a working document. The TSE/BSE *ad hoc* Group prepared the basis of the SSC discussions for the present opinion at its meeting of 4 January 2001.

II. REPLY TO THE QUESTIONS

Preamble: Scientific knowledge in field of TSEs is still limited. The opinion hereafter provides an answer to the questions submitted by the Commission, aiming to minimise as far as possible the risk of induction of new cases of BSE and vCJD.

The following alternatives have been considered:

1. The total feed-ban (meat-and-bone meal derived from and applicable to all farmed animals except fish) is properly implemented.
2. The total feed-ban is not properly implemented or for animals born before the ban.

II.1. THE TOTAL FEED-BAN (MEAT-AND-BONE MEAL DERIVED FROM AND APPLICABLE TO ALL FARMED ANIMALS EXCEPT FISH) IS PROPERLY IMPLEMENTED.

With reference to all the 5 above questions, the SSC considers that cattle born after the total feed-ban, *if properly implemented* should bear a low risk of being infected, provided that (1) only animals fit for human consumption are used, (2) the total ban is properly controlled, (3) effective clinical surveillance and testing for BSE is in place, (4) SRMs are excluded from human and animal consumption, and (5) offspring of BSE-cases are culled. Under such conditions there are no reasons for considering maternal risk enhancement[1] and horizontal transmission/3rd route as requiring additional specific actions, although further investigations on these routes are necessary as a precaution.

Therefore, no restrictions need to be recommended for the use of the materials considered in the above 5 questions as derived from the animals born after the total feed ban.

The SSC also regards the different levels of testing for BSE outlined in the scenarios presented later in this section to be relevant for all the 5 questions.

[1] Regarding the maternal risk enhancement, the SSC considered on 7-8 December 2000 that the assumption of maternal transmission " *reflects an area of uncertainty, as the average value of about 10% is based on statistical grounds, not on experimental evidence of maternal transmission. In this context the SSC wishes to refer to the opinion of September 1997 of the former Muldisciplinary Scientific Committee (MDSC) on Maternal Transmission, in which the wording "maternal risk enhancement" is used. The latter wording is considered to better reflect the uncertainty and may cover mechanisms other than direct maternal transmission."*

In the minutes of its meeting of 24 and 25 June 1999, the SSC concluded that three of the four tests examined have succeeded in a controlled trial in correctly identifying all the BSE positive and negative samples. These three tests can therefore identify animals clinically affected by BSE. However, the results obtained from animals showing clinical signs of BSE cannot be extrapolated to animals in a pre-clinical phase of BSE. Therefore, the three diagnostic tests are helpful for monitoring purposes only if the tested animals are in the final stage of the BSE incubation period. Considering that so far more than 98% of the BSE cases in the UK were older than 40 months, it is obvious that the ability of the three tests to identify BSE infected cattle increases with the age of the tested animals. It should also be pointed out that the probability of false negatives occurring under field applications of the three tests is not yet known.

A reflection on the statistical credentials and, if the required information is available, on the cost effectiveness of test programmes will be done when the SSC addresses a pending question on the minimal requirements for intensive BSE surveillance programmes.

Scenario 1: Testing of all emergency and sick slaughtered animals over 30 months of age and random testing of dead animals.

Such a testing scheme would provide relevant and additional information on the prevalence (proportion of infected animals) in the overall cattle population and possibly in birth cohorts. However, this safeguard is only achievable once a statistically significant sample has been tested.

Scenario 2: Testing of all animals over 30 months of age.

Such a testing scheme would provide a significant additional degree of safety as far as to the possible removal of animals in the final stages of incubation, only if almost all slaughtered animals are tested. However, in no case there will be, with the presently available rapid tests, certainty of identifying all the infected animals.

II.2. THE TOTAL FEED-BAN IS NOT PROPERLY IMPLEMENTED OR FOR ANIMALS BORN BEFORE THE BAN.

If the total ban is not properly implemented or for animals born before the ban, the risk is likely to be much higher and the following specific considerations will then apply for each question. In the light of the previous disappointing experience with the reduced practical efficiency of different feed bans, the SSC recommends that the following considerations are taken into account as long as the effective application of the total feed ban and the other general conditions mentioned under II.1 are not guaranteed. In all cases it is assumed that the conditions (1), (3), (4) and (5) listed under II.1.1 are complied with.

II.2.1. With reference to question 1 (Vertebral Column and T-Bones):

Background

a. In cattle after experimental oral exposure to the agent of BSE[2] detection of infectivity in brain and spinal cord occurs very approximately after 88-90% of the incubation period and coincides with the first detection of PrPres by immuno-histochemistry. Animal numbers per experimental group were small and so this percentage could well be revised downwards by studies still in progress.

   BSE has been found in animals below 24 months however, and this could be a sufficient reason to lower this threshold age, for example to 10 months, which is half the age of the youngest BSE case so far recorded. However, the proportion of BSE cases in UK cattle aged 24 months or less at onset is less than 0.006% (or 10 animals out of approx. 177.500 cases). (0.05% or 81 cases for animals of or under 30 months of age; 0.17% or 307 cases for animals of or under 35 months of age). Since the minimum incubation period in the oral BSE exposure pathogenesis study cited above was 35 months and infectivity was first detected in the CNS at 32 months after exposure it might be argued that infectivity would reach the CNS in the greater proportion of BSE cases at a much later age.

   As a reasonable worst case scenario, based on available experimental results, it can be assumed that infectivity in the CNS can become detectable as from approximately half the incubation period. However, the time at which, during incubation, infectivity can first be detected in the CNS of animals with TSEs varies with the specific natural disease and, in experimental models, with host and agent variables, particularly those of PrP genotype, agent strain and route of exposure. In certain mouse models of scrapie using non-neural peripheral inoculation routes (including intragastric) detection of infectivity in brain occurs at 40-50% of the incubation period. In 263K hamster scrapie in hamsters the equivalent value is 25%. In certain models this has been shown to be preceded by infectivity demonstrable in the spinal cord.

b. In the SSC's risk assessment of 13-14 April 2000, applied to Great Britain conditions, the predicted number of BSE infected cattle entering the human food chain under 30 months of age in the last year of incubation period, with an offspring cull and with 10% maternal risk enhancement[3] hypothesis, the number of animals that could possibly infected was accepted to be very small (1.2 in 2000 and 0.8 in 2001 for whole UK cattle population, and decreasing.

   In its opinion of 27-28 October 1999, on the basis of a similar risk assessment, the SSC concluded that "*This analysis therefore means that with UK animals born after August 1st 1996 the risk of having an exported animal incubating BSE after oral feeding of residual MBM should be zero. At most one animal may be incubating BSE having been infected by maternal transmission. (…) On these grounds the SSC concludes that it is reasonable*

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2 Wells, G.A.H., Hawkins, S.A.C., Green, R.B., Austin, A.R., Dexter, I., Spencer, Y.I., Chaplin, M.J., Stack, M.J. & Dawson, M., 1998. Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update. Veterinary Record 142, 103-106..

3 See footnote 1, p.3

to consider the risk from UK DBES (Date Based Export Scheme)-meat and its products as safe as similar food derived from other Member States."

The above conclusions were valid under the following conditions that are linked to the DBES:

- BSE cases excluded and their offspring culled;
- only animals fit for human consumption;
- Feed ban fully implemented; only maternal transmission[3] as possible source of disease transmission;
- Animals below 30 months of age;
- The animals are above 6 months old and the dam has survived BSE-free for 6 months since the birth of the calf, to minimise the risk that animals are consumed that are incubation BSE as a result of maternal transmission;
- Specified risk materials have been removed (except, for calves between 6-9 months, the vertebral column); visible nerve tissues removed;
- certified slaughterhouses.

Conclusion

The SSC continues to be of the opinion that the vertebral column of bovines 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 further considers that[4], to assess the risk posed by bovine vertebrae, the probability that 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 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 and during the life span of the birth cohort under consideration. The result of monitoring with rapid post mortem tests will add information with this respect.

The SSC agrees that man should not consume meat-on-the-vertebrae of animals above 12 months of age whenever it cannot be demonstrated that the animal is highly unlikely to be incubating BSE, for example under the conditions listed in section II.1 or under other specific conditions such as the ones linked to the UK-Date Based Export Scheme (see above).

Regarding the monitoring scenarios referred to in section II.1.1 the general introductory considerations given there are valid.

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[4] 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 on 27-28 November 2000

II.2.2. With reference to question 2 (thymus and spleen)

With respect to the spleen, while there is evidence of BSE infectivity being harboured in the spleen of experimentally infected sheep, there is some limited evidence[5] indicating that the cattle spleen does not harbour detectable levels of BSE infectivity.

From the incomplete results of the various sheep and cattle BSE pathogenesis studies[6] appears further that, to date (January 2001) thymus from orally BSE dosed cattle and assayed by intercerebral inoculation in recipient cattle, has not shown infectivity after : 34 months (thymus taken from cattle 6 months after oral exposure); 28 months (thymus taken from cattle 10 months after oral exposure).

The SSC therefore concludes that there are no recent developments to change the list proposed in December 1997 of tissues that should be removed from the food and feed chains.

II.2.3. With reference to question 3 (rendered fats)

The SSC's opinion of 27 March 1998 addresses the safety of tallow derived from ruminant tissues. Since that date, some quantitative data became available on the consumption by animals of bovine-derived tallow.

Taking into account the potentially very high ruminant-derived fat consumption by young ruminants through milk replacers or as feed this opinion needs to be updated. For all countries where the presence of BSE is not highly unlikely (above GBR level I), all rendered ruminant fats and used as ruminant feed, should not only be purified to a maximum solid content of 0.15% but also submitted to a full "133°C/20'/3 bars" treatment or validated equivalent in terms of BSE[7] agent inactivation or infectivity reduction. This can be done under conditions that would have no negative effect on fat nutritional quality In addition, when used in milk replacers for veal or replacement calves, only discrete adipose tissues[8] should be used.

The above conditions are also applicable when using the ruminant-derived fats as feed for other farmed animal species (pigs, rabbits, fish, poultry, ...) because otherwise there may be a risk of cross-contamination, of dispersion of TSE infectivity in the environment or its presence in the digestive tract of these animals (that could themselves be used as raw material for the production of rendered fats).

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5 See also: (1) the SSC Opinion of 28-29 October 1999 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._(2) the SSC Opinion of 27-28 October 2000 on the Implications of the Houston *et al* paper in *The Lancet* of 16 September 2000 on the Transmission of BSE by blood transfusion in sheep. (The Lancet, Vol. 356, pp 999-1000; 955-956; 1013)

6 **MAFF (UK), 2000**. Intermediary results of the BSE in cattle and in sheep pathogenesis research.

7 It should be noted that BSE and scrapie strains have a different sensibility to autoclaving.

8 This term is used to describe those reserves of fat which can be removed readily during slaughter in the abattoir or at meat-cutting plants. It does not refer to lipid extracted from mechanically recovered meat or from many other tissues, or at a later stage in the production process. It presupposes the removal of the key associated lymph nodes,

II.2.4. With reference to question 4 (hydrolysed proteins)

Considering that TSE inactivation experiments for the production process of hydrolysed proteins from bovine hides are being initiated, but results are not yet available, at present there is no new scientific evidence implying a need for changing the SSC opinion of 22-23 October 1998 on the safety of hydrolysed proteins *derived from bovine hides*[9].

The Scientific Steering Committee concludes that the above considerations are valid for all non-SRM bovine tissues, as long as an assurance can be provided that the risk for contamination with SRMs is not higher than for ruminant hides.

The peptides and amino-acids derived from animals where BSE/TSE have not been identified does not need to undergo this procedure, provided of course appropriate microbiological standards are respected, however, problems of control and differentiation from materials derived from bovines and other ruminants should be addressed

II.2.5. With reference to question 5 (mechanically recovered meat (MRM))

In its opinion on the "Human Exposure Risk" the SSC showed that high numbers of people could be exposed to BSE-infectivity via mechanically recovered meat.

Because of this high distribution factor MRM obtained from cattle from all countries where the presence of BSE is not highly unlikely, represent a further factor of risk.

What precedes implicitly is in agreement with the report of September 1997 of the Scientific Veterinary Committee (SVC) on health rules applicable to the production and use of mechanically recovered meat. The SVC recommended that the Commission's Decision N° 97/534/EC of 31 July 1997[10] (on specified risk materials) be kept under review based on future developments in epidemiological information relating to the BSE risk / status of various regions.

In principle, the use of bones from young (less than 12 months of age) ruminants or from bones, other than the Vertebral Column or the skull, from older cattle should not pose a significant risk, even if coming from countries with a higher BSE-risk, and provided of course all normal precautions are taken (only animals fit for human consumption, removal of SRMs, etc.). However, the SSC is concerned about the practicality of distinguishing between bones from animals of various ages and bone-fragments from different bones.

The SSC wishes to acknowledge the provision at very short notice of intermediary research results, draft reports and pre-final scientific publications by the UK Research team generating the BSE in sheep research results (Dr.S.Bellworthy, Dr.S.Hawkins, Dr.S.Ryder and Dr.M.Jeffrey) and by Dr.B.Schreuder, Dr.M.Jeffrey, Dr. P.Sarradin, Dr.J.M.Elsen, Dr.T.Baron and Dr.Biacabe, Dr.D.Matthews, Dr.G.Wells and Prof.Dr.M.Ulvund.

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9 *Updated* Report and Scientific Opinion on the safety of hydrolysed proteins produced from bovine hides. Initially adopted o, 22-23 October 1998 and updated on 25-26 May 2000.

10 Replaced by 2000/418/EC, June 2000.