

EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate B - Scientific Health Opinions Unit B1 - Monitoring and dissemination of scientific opinions

Scientific Steering Committee

REPORT AND SCIENTIFIC OPINION ON:

EXPORT FROM THE UK OF BONE-IN VEAL

Adopted by The Scientific Steering Committee at its meeting of:

14-15 SEPTEMBER 2000

OPINION ON THE EXPORT FROM THE UK OF BONE-IN VEAL

THE QUESTIONS

The Scientific Steering Committee (SSC) was asked by the European Commission to assess the safety of whole carcasses from young animals (6-9 months) exported from the UK to other countries, that otherwise comply with the DBES criteria. To prepare its answer, the SSC requested the TSE/BSE *ad hoc* Group to address this question in a detailed report.

On 27 June 2000, BSE was confirmed in a Holstein/Friesian dairy cow born on 25 August 1996. The SSC therefore considered that is was necessary to assess whether the occurrence in the UK of a first cases of BSE in animal born after 1 August 1996 (a so called "BARB - Bornafter-the-real-feed ban") would affect the outcome of the risk assessment made to address question (1). The SSC requested advice from the TSE/BSE *ad hoc* Group, who discussed the issue at its meeting of 31 August 2000.

THE ANSWERS

On the first question the SSC considers that at present, that there is no evidence that bone-in veal carcasses from calves between 6 and 9 months exported in accordance with DBES criteria would imply a risk. The SSC further considers that at present, there is no evidence indicating that the risk from carcasses from 9 months old animals produced under the DBES is different from carcasses from 6 months old animals.

On the first BARB case and its relevance for the answer given to first question, the SSC considers that this case did not affect its risk assessments with regard to the DBES, because the animal would not have been eligible under the DBES¹ and because it had been accepted that (small) numbers of BSE cases would occur in animals born after 1 August 2000 as a result of vertical transmission. This single case therefore was not likely to affect the safety of veal carcasses of 6-9 month old animals eligible under the DBES as defined in the pending opinion on the export of bone-in veal.

However, the SSC considers that the available epidemiological and other information does not permit to conclude on origin of this case which needs to be carefully traced and all possible BARB cases need to be studied in detail. If their origin is maternally and the number of cases remains below the (very low and decreasing) scientifically expected numbers², then there is no reason for concern. However, should the origin be attributable to a contaminated feed source, then this would imply the need to improve the feed-ban and the control system. These issues are beyond the scope of the mandate of the EC's Scientific Committees.

The SSC also recommends that experimental protocols be urgently developed to reliably trace and study all the possible origins of BARB cases and to possibly gather non-statistical evidence on maternal transmission. Keeping alive at protected sites the parents and herd- or cohort-mates of (part of) these cases to monitor how they evolve should be included in such protocol.

¹ The animal was 44 months old, its dam had not survived for at least six months after birth.

² See also the following SSC opinions:

^{- 28-29} October 1999 on 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.

^{- 13-14} April 2000 on the UK decision to lift the ban on the consumption of meat on the bone.

EXPORT FROM THE UK OF BONE-IN VEAL

REPORT FROM THE TSE/BSE AD HOC GROUP

I. THE QUESTION

The Scientific Steering Committee (SSC) was asked by the European Commission to assess the safety of whole carcasses from young animals (6-9 months) exported from the UK to other countries, that otherwise comply with the DBES criteria.

The proposal of the UK is that consideration should be given to amending Community legislation in order to allow the export from the UK of bone-in carcasses of bovine animals of 6-9 months of age that otherwise comply with the DBES criteria.

The SSC asked its TSE/BSE *ad hoc* Group to prepare a scientific document as a basis for an opinion on the question. The present document is the ad hoc Groups report to the SSC.

II. SCOPE OF THE REPORT

- 1. A "veal carcass" is, within the context of the present report, defined as the whole body of a slaughtered animal after bleeding, evisceration, removal of udders in the case of cows and skinning and separation of the head and limbs, the latter being cut off at the carpus and tarsus; "viscera" means offal from the thoracic, abdominal and pelvic cavities, including the trachea and oesophagus;
- 2. The present report is without prejudice to the recommendations made in other SSC opinions, for example with respect to safe slaughter methods.

III. INTRODUCTION (BACKGROUND)

On 9.12.97, the SSC adopted the *Report on the UK Date Based Export Scheme (DBES)* and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases, accepting in general the scientific soundness of the DBES. These were further addressed in the SSC Opinion of 20.02.98. The key elements of the scheme were an effective feed ban (from 1.08.96) designed to exclude feed-borne transmission and an offspring cull combined with confirmation of survival of the dam for 6 months, designed to significantly reduce maternal transmission.

In addition, in relation to the UK DBES, the SSC adopted the following 2 opinions:

- Opinion on *The safety of bones produced as by-product by the Date Based export Scheme*, adopted 23.10.98
- Opinion on Monitoring some important aspects of the evolution of the epidemic of BSE in Great-Britain (Status, April 1999), adopted , 28.05.99

Finally, the SSC adopted a number of opinions of indirect relevance, for example on specified risk materials (SRMs), vertical transmission of BSE, safety of products and geographical BSE risk.

As a result of these opinions, the decision to authorise the export of de-boned meat and products derived there from under the DBES was adopted on 25 November 1998 and the date when the export could commence was set at 1 August 1999 following the favourable outcome of a Community mission, in April 1999.

Council Decision 98/256 lays down rules for the export from the UK of meat derived from bovine animals under the Date-Based Export Scheme (DBES). Such exports are at present, however, limited to de-boned meat. Some UK companies have been exploring the possibility of producing and exporting "ethical" veal derived from calves, not reared in crates, just over 6 months of age (MAFF, 2000). The marked prospects for such veal would be greatly enhanced if it could be exported in bone-in form. The carcass could then be cut in accordance with local cutting preferences and practices. It could also be exported direct from the slaughterhouse rather than via a cutting plant.

The public health aspects of such a proposal should be considered by the SSC as part of its current review of its advice on Specified Risk Material (SRM) including the position on bones.

IV. RISK ASSESSMENT

The following elements are of possible interest when assessing the safety with regard to BSE of bone-in veal obtained from UK animals of 6-9 months of age and intended for the export to other countries:

1. The cattle pathogenesis experiment reported on in, amongst others, Wells *et al* (1998) and Wells *et al* (1999) detected infectivity in the central nervous system only at 32 months after inoculation. There would therefore be a 23 month margin of safety between the maximum age of veal exported in bone-in form and the detection of infectivity in that experiment. In naturally infected cattle, with longer incubation periods, the margin of safety is likely to be greater.

Infectivity has never been detected in the bone material itself. However, raw bone material may be contaminated with spinal cord, ganglia or (if it is infectious) bone marrow that remain even after their careful removal. The question needs therefore to be addressed whether these contamination levels are such that the possible residual infectivity of the final product, after its processing, constitutes a risk for humans and animals.

Regarding bone marrow no infectivity has been detected so far by mouse bioassay in field cases with clinical BSE. Data for BSE are based, however, on transmissions attempted from a very small number of animals³. Nevertheless, these findings are, in general, consistent with those in studies of the pathogenesis of BSE in cattle after oral challenge (Wells *et al*, 1996, 1998), with the exception of the detection of infectivity in distal ileum and, in a level close to the limit of detectability by mouse bioassay, in the sternal bone marrow from animals killed in the clinical phase of the disease at 38 months p.i. (but not before and not after) in this experimental study of BSE in orally exposed cattle (Wells *et al*, 1999). The inconsistent result of the absence of detectable infectivity in bone marrow in this study at the later time point of 40 months p.i. has raised, amongst other alternative explanations, the possibility that the finding of infectivity at 38 months p.i. may have been the result of an accidental procedural contamination. Nevertheless, there is limited evidence from previous studies of other TSEs that infection of bone marrow, although not part of the general pathogenesis pattern, could be a rare event occurring late in the incubation period.

³ The experiments were limited and not all the different bone marrow bones, at different stages of incubation have been tested.

- 2. The United Kingdom's Chief Medical Officers (CMO) (1999) have concluded that the risk from bone-in beef is now so low as to justify the lifting of he UK's ban on the sale of this product. Even bones of prime beef aged 18-30 months of age were not considered to represent a significant risk by the CMOs. The risk has to be even lower in the case of veal presently aged 6-9 months. For example, veal exported after 1 August 2000, would be from animals born on or after 1 November 1999. This is over 3 years after the UK feed ban which is today considered to have become fully effective as from 1 August 1996.
- 3. According to MAFF (2000), all conditions of the Date Based Export Scheme (DBES) would apply including:
 - > a calf would be ineligible if its dam were a suspect or confirmed BSE case; and
 - > acknowledging BSE's incubation period, a DBES eligible animal must be at least 6 months old and its dam must have lived for at least 6 months after it was born.
 - > As currently the case, the offspring of any suspect or confirmed BSE cases are immediately restricted (and DBES ineligible – as above). All offspring born after 1 August 1996 to confirmed cases continue to be slaughtered.
 - > The animal has been clearly identifiable throughout its life; its date of birth is known and all movements are recorded on an animal passport and/or on a computerised identification and tracing system;
 - > Conditions of eligibility will be strictly enforced, so that an animal will be rejected from the scheme if any information is lacking or if there is doubt about eligibility; both live animals and meat would be handled separately from animals and meat not eligible for export.

This implies that the scientific opinions in which the safety with regard of BSE of DBES-related products is assessed, can be applied.

4. In its opinion of 13-14 April 2000 on "*The UK decision to lift the ban on the consumption of meat on the bone*", the SSC therefore concluded that, as compared with the end of 1997, when the ban on the consumption of bone-in meat was introduced in the UK, and on the assumption that all risk management measures, including feed ban and the OTMS, are properly implemented, the risk associated with meat on the bone obtained, prepared and consumed as described in the above mentioned Det Norske Veritas risk assessment of 1997, has further decreased to levels 3-5 times lower than estimated in December 1997.

The SSC further concluded that the risk from meat on the bone is negligible if the bones are not from the vertebral column because the hazard from dorsal root ganglia within the vertebral column remains appreciable in infective animals. In the UK, however, the risk of human exposure to BSE from this infective material is extremely small because of the small number of infective animals estimated to enter the food chain. It can be assumed that in the context of this proposal, for the animals up till nine months of age, the risk of human exposure from infective DRG must be near to zero.

The above SSC conclusions are partly based on the report of Det Norske Veritas "Assessment of Risk from Possible BSE Infectivity in Dorsal Root Ganglia" (Comer, 1997). This report stresses that, on the basis of the pathogenesis experiment, significant levels of infectivity are present in Central Nervous System (CNS) tissues, including Dorsal Root Ganglia (DRG), in the three months prior to clinical onset of the disease. It

is assumed that infectivity in the dorsal root ganglia is the same as that in the brain and spinal cord and that the weight of the 60 DRG in a carcase is 30g, representing 3.8% of the total infective load per animal and 300 ID₅₀ per animal at an estimated infectivity density of 10 ID₅₀ per gram. (SSC opinion on BSE risk, adopted 19-20 February 1998) At nine months prior to clinical onset no infectivity has been detected. To add a margin of safety it will be assumed that infectivity may be present up to 9 months prior to clinical onset. The youngest animal ever seen was 20 months of age and would have been infective in DRG at the earliest at the age of 11 months. So the risk for an animal being infective at an age below 9 months is extremely low, taking also into account that over the period 1994 to 1996 the number of cases under 38 months declined from 27 to 14, in 1997: 7 cases, in 1998 4 cases and in 1999: 0 case. However, since 1997, no cases under 31 months were detected. The median value of the total ingestion of infectivity in dorsal root ganglia of cattle with infectivity in the CNS at less than 30 months of age, has been estimated to be 0.05 ID_{50} over the whole UK population (50.000.000) in 1997. The participation in this risk of cattle below 9 months of age must be considered as extremely low due to the age depending infectivity. In 2000 this risk should have been decreased furthermore, due to the full active MBM ban since August 1996, near to zero.

Also, in a confidential pre-publication, Donnelly *et al* (2000) present, for the years 2000 and 2001, predicted numbers of BSE infected cattle that may enter the human food chain under 30 months of age, in the last year of BSE incubation period, i.e. having potentially infective central nervous tissue as in clinical cases ("infective cattle"). The predicted numbers are 1.2 infective cattle in 2000. The corresponding number is 0.8 animals in 2001.

- 5. The question on the risk that bones vertebral column, skull, and/or other bonesproduced as offal under the conditions of the DBES may carry the BSE-agent was addressed in the SSC opinion on "*The safety of bones produced as by-product of the DBES*", adopted 22-23 October 1998. The risk that animals processed under the DBES do carry BSE is regarded as negligible. Given the age limit of 30 months it is possible to assume that the risk that bones and bone marrow are infective is negligible. Only nervous and CNS-tissue attached to or spilt over bones could pose a non-negligible risk if an animal would be slaughtered under the scheme which has been infected very young. In the context of the present proposal with an age limit of 9 months, this risk can be considered to have further decreased near to zero.
- 6. On the evolution of the epidemic in the UK, the SSC concluded in its opinion on "*Monitoring some important aspects of the evolution of the epidemic of BSE in Great-Britain*" adopted 27-28 May 1999, that the current and expected evolution of number of BSE cases in UK (1999-2004) are in line with all models, but the tail of the epidemic will not necessarily present a constant decline. The current numbers of cases are in line with the scientific expectations. As long as the presence of BSE can only be verified on the basis of clinical symptoms, the risk of animals falling under the DBES to develop BSE can not be drawn before 2001. A that time, 5 years after the critical date, the majority of animals infected shortly after that date, should show clinical signs.
- 7. In the SSC opinion of 10 December 1999 on "*The human exposure risk (HER) via food with respect to BSE*", a definition was made, on the basis of the available knowledge, of three categories of cattle which have different potential levels of infectivity, mainly as a function of their age at slaughter. Depending on the category, the infectivity which could enter the food chain will differ, both in quantity and with regard to the specified

risk tissues: Veal calves (less than 1 year), prime beef (older than 1 year, but less than 30 months) and Mature cattle (older than 30 months). As for veal calves it was stated that " The infectivity in the CNS tissues of these animals can be considered to be negligible. However, there may be infectivity in the intestines, in particular the ileum."

V. SUMMARY AND CONCLUSION

The Scientific Steering Committee (SSC) was asked by the European Commission to assess the safety of whole carcasses from young animals (6-9 months) exported from the UK to other countries. The proposal of the UK is that consideration should be given to amending Community legislation in order to allow the export from the UK of bone-in carcasses of bovine animals of 6-9 months of age.

At the request of the SSC, the TSE/BSE *ad hoc* Group prepared a scientific document as a basis for an opinion on the question. The TSE/BSE *ad hoc* Group considers that at present, that there is no evidence that bone-in veal carcasses from calves between 6 and 9 months exported in accordance with DBES criteria would imply a risk. The ad hoc Group further considers that at present, there is no evidence indicating that the risk from carcasses from 9 months old animals produced under the DBES is different from carcasses from 6 months old animals.

VI. ACKNOWLEDGEMENT

The present report is based on a draft prepared by Dr E.Vanopdenbosch in collaboration with Dr. Ph.Verger, and discussed at the TSE/BSE *ad hoc* Group meetings of 22 June and 31 August 2000.

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