



SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE

Minutes of the 76th meeting held on 14th November 2002

At

The Hilton London Metropole
Edgware Road
London

Members: Professor P. Smith (Chairman)
Professor J. Ironside (Deputy Chairman)
Professor C. Bostock
Professor G. Bulfield
Professor R. Carrell
Dr D. Cunningham
Mr P. Jinman
Professor H. Kimbell
Professor C. Masters
Professor I. McConnell
Dr J. Safar

Technical Advisors: Mr P. Soul (Defra)
Dr P. Barrowman (Defra)
Dr J. Stephenson (DH)
Ms A. Conroy (FSA)
Dr S. Dixon (FSA)

Observers: Dr A. Allman (BBSRC)
Dr S. Baxter (SERAD)
Dr P. Crook (EA)
Dr A. Douglas (DARDNI)
Dr J. Nielson (HSE)
Dr M. Simmons (NAWAD)
Professor J. Wilesmith (VLA)
Dr D. Matthews (VLA)
Mr D Carruthers (FSA)
Dr I Hill (FSA)

Assessors: Dr M. Bailey (Defra)
Mr A. Harvey (FSA)
Dr R. Jecock (DH)

Secretary: Dr C. Boyle

Secretariat: Dr R. Pugh
Mr M. Pemberton
Dr A. Leigh
Dr C. Ravirajan

Also in attendance: Professor N. Ferguson (Paper 76/2)
Professor J. Wilesmith (Paper 76/2)
Dr M. Arnold (Paper 76/2)
Mr Philip Comer
Professor D. Jeffries (Paper 76/3)

Item 1 - Chairman's introduction

- 1.1 The Chairman welcomed Members and informed the Committee that journalists were expected to attend the open session of the meeting. The Chairman informed Members that a dedicated press officer had been appointed to SEAC to facilitate the handling of SEAC media issues, and advised Members to refer press enquiries to the SEAC press officer.
- 1.2 The Chairman welcomed Professor Neil Ferguson and Dr Christl Donnelly from Imperial College, Dr Peter Crook and Dr Raquel Duarte-Davidson from the Environment Agency, and Professor Don Jeffries, Chairman of the ACDP/SEAC TSE Joint Working Group.

Item 2 - Approval of confidential draft minutes from 11th September meeting (SEAC 76/1)

- 2.1 Members considered the confidential minutes from the previous meeting in September 2002. The draft minutes had been circulated to Members in draft form, and were subject to final approval.
- 2.2 The Chairman referred Members to paragraph 3.4, of the item 'Cattle Pathogenesis studies'. He drew Members attention to the last sentence of the paragraph which read 'In addition a previous cattle bioassay of spleen and of pooled lymph nodes did not give positive results at 86 months p.i.'. The Committee agreed that the statement should be qualified to read 'In addition a previous cattle bioassay of spleen and pooled lymph nodes from 5 cattle with clinical BSE did not give positive results at 86 months p.i.'
- 2.3 Subject to this amendment, the confidential draft minutes of the 11th September SEAC meeting were approved as the final minutes.

Item – 3 Update on the effect of oral dose on attack rate and incubation period in cattle (SEAC/INF/76/03)

- 3.1 Members were provided with an update on a Defra funded project, which is investigating the oral dose-response for bovine infected brain material on the attack rate and incubation period of BSE in cattle.
- 3.2 The Committee was informed that in previous experiments, three groups of 10 calves were orally challenged with 1g, 10g, and 100g of BSE-infected bovine brain homogenate. A fourth group received 3 x 100g of homogenate on successive days. Unequivocal signs of BSE were observed in 34 animals. Cases occurred in all 4-dose groups (with incubation period ranging from 32 to 71 months post inoculation).

- 3.3 A subsequent study was set up to determine if single oral doses of between 1g and 0.001g brain homogenate from BSE-affected cattle could produce a transmissible spongiform encephalopathy in cattle. Three groups of 15 castrated male calves were orally challenged with 0.001g, 0.01g and 0.1g of infected pooled brainstem homogenate. The source of the inoculum was the same as for the previous attack rate study.
- 3.4 The Committee was informed that a steer, challenged with 0.1g of brainstem homogenate, presented with early clinical signs suggestive of BSE at 50 months post oral dosing. The disease progressed over a period of seven months, with typical clinical signs of BSE reported at 57 months post-challenge. BSE was confirmed by histopathology and immunohistochemistry on brain tissue. A number of other animals in this dose group were showing very early signs of possible disease; however no further cases have yet been confirmed.

Item 4- Over Thirty Months Rule Review – modelling work undertaken by Imperial College, the VLA and DNV (SEAC 76/2)

- 4.1 The Chairman introduced the item by explaining the role of the joint SEAC/FSA Risk Assessment Group (RAG), which had already considered the modelling work undertaken by Imperial College and the Veterinary Laboratories Agency (VLA) prior to the presentation of the findings to the full Committee. Dr Jiri Safar declared a possible conflict of interest during the Committee discussion about the development of diagnostic tests.
- 4.2 Alan Harvey provided the Committee with the background to the Food Standards Agency's review of the OTM rule. The commitment to review the OTM rule was made in the FSA's review of BSE controls, which was published in December 2000. Market support measures in the form of the Over Thirty Months Scheme (OTMS) were costing £350 million per annum. It was important to consider whether the costs were still proportionate to the risk, given that i) SRM controls were likely to remove in excess of 95% of any BSE-infectivity in an infected carcase, and ii) the number of BSE cases had declined by about 40% year on year since 1992 and was now at a low level. A number of options for changing the OTM rule existed, under which all animals over 30 months slaughtered for human consumption would be subject to the EU wide testing regime; retaining the rule could not be ruled out, however. The review process was expected to be completed in the first part of 2003; recommendations to the FSA Board and to Ministers were expected to be made in May 2003.
- 4.3 Members asked how robust was the evidence that 95% of SRM was removed in practice. Members were informed that the SRM controls were rigorously policed at abattoirs by the Meat Hygiene Service. A figure of 95% was normally used as a worst case estimate because it was thought that not all infectivity was removed with SRM.

- 4.4 Three presentations relating to the modelling work undertaken as part of the OTM review were presented to the Committee.

Presentation by Professor Neil Ferguson of Imperial College

- 4.5 Professor Neil Ferguson presented the preliminary results of work to estimate the number of infected cattle that would enter the foodchain under a range of possible options to the OTM rule. Four sources of data were analysed as part of the risk analysis, i) BSE case data, ii) screening data, iii) data from the Cattle Tracing System (CTS), and iv) cattle census data.
- 4.6 Members noted the continuing decline of BSE cases. The number of cases reported in 2001 was, however, higher than expected given the overall downward trend in cases. This may have resulted from movement restrictions in place due to the Foot and Mouth epidemic.
- 4.7 An analysis of the screening data showed that the highest prevalence of BSE test positivity, about 1% of animals aged over 5 years, related to casualty animals, with lower prevalence levels for fallen stock and the lowest levels for healthy slaughtered animals. There is a marked distinction between animals above and below the age of five years, with more positives reported over the age of five. This may be due to two reasons, i) the enhancement of control measures in 1996, and ii) younger animals are less likely to test positive due to the long incubation period of the disease.
- 4.8 Using data from the CTS, it was estimated that 25% of animals over the age of three years died on farm. This was regarded as significant given that these animals are more likely to become BSE cases. The analysis noted that cattle movements were recorded retrospectively by the British Cattle Movement Service (BCMS) following the death of the animal - this appeared to be anomalous with the operation of CTS and would be followed up with the BCMS.
- 4.9 It was suggested that differential survivorship rather than under-reporting could explain the higher than expected infection prevalence in fallen stock and casualty animals, compared with animals slaughtered at abattoirs. Animals in the late stages of incubation were more likely to be sent for slaughter or die on farm, than non-infected animals.
- 4.10 The Committee was informed that it was more likely that casualty animals were reported from farms with previous experience of BSE compared with farms with fallen stock animals.
- 4.11 The current work extended the risk model published by Donnelly *et al.*, in the Proceedings of the Royal Society¹ and allowed for, i) greater

¹ Donnelly, C.A., Ferguson, N.M., Ghani, A.C. and Anderson, R.M. 2002 Implications of bovine spongiform encephalopathy (BSE) infection screening data for the scale of the British

sensitivity analysis, ii) utilisation of screening data from risk animals, and iii) estimation of the risk associated with the consumption of casualty animals. Following discussion with the RAG, the assumption that tests, using central nervous system tissue, were unlikely to detect infection 12 months or more prior to the onset of disease symptoms was used as the basis for the analysis. As estimates of infection prevalence were dependent on test sensitivity; a test that detected infectivity at the end of the incubation period would result in a greater difference between reported cases and estimated infection prevalence. Therefore, a range of test sensitivity profiles were examined within that 12-month period.

4.12 The Committee was informed that the alternatives being considered for changes to the OTM rule were, i) older age thresholds, and ii) a birth-date based cut off threshold. Therefore, the analysis assumed, i) human risk would be approximately proportional to the number of animals entering the food-chain in the last year of the incubation period, ii) all animals over 30 months destined for human consumption would be screened, and iii) a constant BSE infection risk, based on the 1996/97 birth-cohort level, for future cattle birth-cohorts.

4.13 The analysis showed different outcomes in terms of the number of infected animals entering the food chain, excluding test positives, depending on the sensitivity profile and the differential mortality rates used. The results of an analysis based on a test sensitivity profile of three months before onset and a differential mortality rate of three months before onset were presented. The differential mortality component in the model assumed that animals in the late stages of incubation are more likely to be sent for slaughter as casualty animals than uninfected animals. As the OTM threshold was increased up to a seven year of age cut off threshold, the analysis showed a proportionate increase in the numbers of infected cattle entering the food chain at each increment of age cut off point. A similar overall trend was reported when considering a birth-date cut off rule, however the rate at which the risk increased was dependent on the birth cohort. The analysis showed that the highest number of infected animals estimated to enter the food chain amounted to 10 per annum. This number would increase to 12 if casualty animals were allowed in to the food chain.

4.14 The Committee was informed that increasing the period of differential mortality would increase the risk estimates; and this was demonstrated by the presentation of equivalent results using a nine-month differential mortality rate compared to a three-month differential mortality rate. Conversely, increasing the test sensitivity period would decrease the risk estimates.

4.15 It was important to compare any increase in the estimated current risk with the historical risk, particularly prior to the implementation of the

- 4.16 In conclusion, the Committee was informed that all the scenarios examined as possible options for changing the OTM rule would result in an increased risk in terms of infected animals entering the foodchain. This was inevitable given the assumption that BSE infection incidence would remain constant for future years. Weighting infectivity (which peaks at onset) in relation to the incubation period would have the effect of reducing the level of risk whereas allowing casualty animals into the food chain would increase the level of risk.
- 4.17 Members asked about how the trends of the 2001 OTMS survey compared with the 1999 and 2000 OTMS survey trends. Members were informed that although the 2001 survey targeted younger animals, the trends for all three surveys were broadly the same; with a higher infection prevalence in risk animals, of the order of half to one percent detectable infection prevalence for animals over five years of age, with lower prevalence in healthy animals surveyed at abattoirs.
- 4.18 The Committee was informed that the baseline results assumed that test sensitivity would be close to 100% in the last three months of the incubation period. In terms of the risk to human exposure, this was represented by the number of animals 3 to 12 months from clinical onset, which were not showing clinical signs.
- 4.19 Members noted that the geographical incidence of BSE was not included in the analysis.

Presentation by Dr Mark Arnold of the Veterinary Laboratories Agency (VLA)

- 4.20 Dr Mark Arnold presented a parallel analysis on the impact of changing the OTM rule. Data from the CTS, BSE database and a Meat and Livestock Commission (MLC) survey was used to estimate survivorship. Overall numbers of cattle born into each annual birth cohort were based on CTS and census data.
- 4.21 The assumptions used in this were, i) the number of clinical cases were calculated as the sum of reported cases, i.e. BSE-positive casualty slaughter and BSE-positive fallen stock animals, ii) a constant risk of infection post August 1996, iii) all animals slaughtered over the age of 30 months would be tested, and iv) animals would be infected at three months of age. In terms of test sensitivity, outputs based on 50% sensitivity at 3 or 6 months prior to onset and 0% sensitivity at 6 or 12 months prior to onset respectively, were used.

- 4.22 Using the results of passive and active surveillance since July 2001, a simplified back calculation type model was used to estimate the infection prevalence in each annual birth cohort. The age of onset distribution for each birth cohort was derived from case data from 1986 – 1996. The rates of slaughter for human consumption were assumed to be the same as the current culling rates.
- 4.23 Results of the total number of infected animals for each of the calendar years 2003 – 2005, slaughtered for human consumption were presented. The totals were grouped according to the number of months before clinical onset: 0 – 6, 6 – 12, 12 – 24, 24 – 36 and > 36 months.
- 4.24 The Committee noted that the results showed an increase in risk, at differing rates, across all of the options when compared with the risk associated with the current OTM rule.
- 4.25 The Committee was reassured that the qualitative conclusions from both analysis were broadly similar. The Chairman informed Members that the FSA Stakeholder Group had yet to decide which options should be further examined for changing the OTM rule. However, he noted that it was likely to include the two options considered by Imperial College and the VLA i.e. an increased age cut off and a birth date cut off.

Presentation by Mr Phillip Comer from DNV Consulting

- 4.26 The Committee was informed that DNV Consulting would use the results of the Imperial College and VLA analyses to estimate the potential exposure to the human food chain, by considering the infectivity of the individual tissues concerned.
- 4.27 The infectivity of central nervous system (CNS) tissue would be based on a mean value of 50 bovine oral ID₅₀/g with a wide range of uncertainty (10 – 1000). This derived from the SSC opinion of April 2000. Data relating to the infectivity of other tissues would be derived from results of the original cattle pathogenesis study, which had shown high levels of infectivity in CNS tissues, with lower levels for the distal ileum and tonsil. Assumptions about the infectivity of other SRM and other tissues, would be based on those used in the 1997 DNV study to look at infectivity entering the food chain. Further assumptions would be made about the rate at which infectivity increases during the incubation period.
- 4.28 Members were provided with a breakdown of infectivity relating to a clinical case of BSE, which in terms of total infectivity, amounted to 41,768 bovine ID₅₀/animal. Of this total >99% related to tissues classified as SRM. The potential routes of exposure relating to those tissues known to be infective were outlined.

Tissue	Routes of exposure
Brain	Emboli in blood and contamination of head meat.
Spinal Cord	Contamination of carcass meat.
Dorsal Root Ganglia (DRG)	Bone-in meat.
Tonsil	Contamination of tongue.

- 4.29 The assumptions regarding the potential routes of exposure were outlined. Research at the University of Bristol suggested that brain embolism may occur in approximately 4% of slaughters using captive bolt. This suggested that up to 10g of brain tissue could enter the blood stream. Therefore, the assumption that 1% of emboli would pass through the lung and end up in muscle meat, with the remainder trapped in the heart, lung or blood stream would be used in the analysis.
- 4.30 Other research indicated that detectable levels of CNS material remained on medial carcass surfaces following splitting with a band saw. Therefore, it would be assumed that 1% of this material would be transferred to meat through handling and transfer via the cutting surfaces.
- 4.31 Two key assumptions regarding the estimated quantity of DRG infectivity entering the food chain were outlined. The first concerned meat sold off the bone, it was assumed that a small amount of DRG (0.4%) would remain in meat sold off the bone. The second was to assume that amount of DRG infectivity consumed with meat sold on the bone would be highly variable. The Committee noted the reduction in the consumption of bone-in beef from 28,000 tonnes in 1997 to 10,000 tonnes in 2000 onwards.
- 4.32 It would be assumed that contamination of the tongue could occur via brain or tonsil tissue. As a result of the stunning discharge, it was estimated that 2g of brain tissue could contaminate the cheek meat. Of the contaminated material, it was assumed that 10% would contaminate the tongue during removal. With the limited data available on the contamination of tongue with tonsil, it was assumed that 1 in 20 tongues would be contaminated and that 10% of infectivity in tonsil would remain with the tongue.
- 4.33 In conclusion, the Committee was presented with the infectivity that could be consumed from one fully infected clinical case going into the food chain. Based on the assumptions made, it was estimated that, for bone-in meat, 28.3 bovine oral ID₅₀s would be consumed, compared with 17.0 bovine oral ID₅₀s for meat off the bone. Expressed as a percentage of total infectivity consumed, this amounted to 0.07% and 0.04% for bone-in meat and meat off the bone respectively for one

infected bovine. The highest single source of potential infectivity related to DRG.

- 4.34 Members suggested that the work undertaken by Bristol University in respect of brain emboli should be considered further. Questions had been raised in the past about this work, particularly in relation to the methodology used by Bristol University to obtain the results and how they related to slaughterhouse practices.
- 4.35 The Chairman identified several key issues arising from the presentations, i) that any relaxation to the current rule would result in an increase in risk, ii) it was assumed by both modelling groups that the diagnostic tests would only detect infectivity at the end of the incubation period, iii) it was assumed by both modelling groups that the future level of infectivity entering the food chain would remain constant, and iv) the implications of the findings in respect of the risk to human health.
- 4.36 Members asked whether any work relating to the incidence of vCJD would be undertaken as a result of the outcome of the modelling work. The Chairman explained that due to the levels of uncertainties concerning vCJD, it was the view of the RAG that to undertake such work would not be profitable. On the basis of the different options considered by the modellers, it was estimated that any increase in the number of vCJD cases would be less than one.
- 4.37 In respect of the large number of assumptions used in mathematical modelling, Members enquired as to how the assumptions would be tested. The Committee was informed that the modelling analysis was used as a tool to help quantify risk in areas, such as TSEs, where many uncertainties existed and that both models had been tested against key data (ref. para. 4.5). The two key assumptions that could have an impact on the outcomes of both models were test sensitivity and the level of future infection.
- 4.38 Given that test sensitivity was a key factor, Members requested an update on the work that was being undertaken in relation to the earlier detection of infected animals by EU approved diagnostic tests. It was also important to know how the detection of infectivity in the brain related to the detection of infectivity in the DRG, given that the DRG was the key source of infectivity entering the food chain. Members were informed that the second phase of the EU validation trial was ongoing; all five tests under evaluation were however primarily being developed for the purposes of detection of BSE using bovine brain stem material.
- 4.39 In respect of the other critical assumption concerning future infection levels, the Chairman commented that the scenario used in the modelling, as recommended by the RAG, was that the future infection rates should remain constant at the same level as the 1997/98 cohorts. If, however, the theory put forward by Professor John Wilesmith about the contamination of imported feed was correct, then future infection

levels could be expected to decrease following the introduction of the EU wide controls from January 2001. RAG had therefore suggested an alternative scenario to be modelled that would assume a constant level of infection up to 2001, after which it would decline.

4.40 In conclusion, whilst Members agreed with the general approach taken by the modellers to assess the risk of changing the OTM rule, there was a need to obtain further information regarding the diagnostic tests, particularly in relation to test sensitivity. Although it was accepted that this would not be possible for the risk modelling work undertaken as part of the OTM review, it would be an important factor for future discussions.

Item 5 - Revision of ACDP/SEAC Guidance on 'TSE Agents: Safe Working and the Prevention of Infection' (The TSE Guidance) : Scrutiny of new Parts 2 and 4 of the Guidance and selected Annexes (SEAC 76/3)

5.1 The Chair welcomed Professor Jeffries, Chair of the ACDP/SEAC Joint Working Group (JWG). In 1998 the JWG had published guidance on safe working with TSEs in experimental and clinical settings. The guidance is currently being updated and revised. Professor Jeffries presented Parts 2 and 4, and four annexes of the draft revised guidance. Further revisions will be presented to SEAC at a later date.

5.2 Professor Jeffries reported that the current guidelines have been well received both nationally and internationally. However, since they were first published there have been major advances in scientific knowledge, including, for example, evidence for the thermostability of TSE agents. The JWG has proposed that subsequent guideline documents be produced in a ring bound format so that sections can be updated as needed. In addition, sections will be individually downloadable from a website to facilitate updating. The documents that were presented to SEAC were the near final drafts of:

- Part 2 (Health and Safety Management of TSEs)
- Part 4 (Infection Control of CJD and Related Disorders in the Healthcare Setting)
- Annex A – Distribution of TSE infectivity in Tissues and Body Fluids;
- Annex B - Diagnostic Criteria;
- Annex E - Quarantining of Surgical Instruments and Annex I -After Death.

5.3 Members were invited to consider the draft TSE guidance and the Annexes presented, and comment on any aspect as necessary. Following any amendment, Members were asked to agree that the revised guidance could be recommended to DH Ministers for early publication.

Part 2 Health and Safety Management of TSEs

- 5.4 It was agreed that this part would benefit from more detailed referencing of existing legislative documents. Members suggested a rewording of paragraph 2.14, third bullet point, where the text should emphasise infectivity for humans rather than infectivity in general. In addition, Members considered that Paragraph 2.20 should include reference to laboratories handling animal TSEs as well as human TSEs.

Part 4 Guidance for the Health Care Setting

- 5.5 Members were informed that, in terms of handling surgical instruments, much of the approach for Part 4 is based on risk assessment depending on the type of CJD, the risk status of the patient, and the tissues involved in the procedure.
- 5.6 Members were informed that a major revision had been made to Part 4 of the guidance which details the abandonment of the longer holding time for autoclave procedures. This was prompted by recent research. The guidance was summarised in two tables (4b and 4c) which, depending on defined scenarios, recommend either standard processing for decontamination or removal of the instruments from circulation. It was noted that current standard autoclave decontamination procedures adopted by Central Sterile Services Departments (CSSDs), operate at a higher autoclave temperature (134-136°C) for a holding time of 3 to 5 minutes. Instruments, which are removed from circulation, are either stored for studies on decontamination research or disposed of by incineration.
- 5.7 Members raised concerns regarding current standards of surgical instrument decontamination. Guidelines were considered to be effective only if there were appropriate audit procedures in place to ensure compliance. Members commented that it would be helpful to commission research into the degree of compliance with guidelines by health services. It was noted that guidelines issued by the National Institute of Clinical Excellence (NICE) suggest appropriate audit tools within the guidelines. However, it was agreed that monitoring compliance is a risk management option and was therefore outside the remit of the Committee and the JWG.
- 5.8 Members were informed that the DH had secured additional money from the Treasury to spend on decontamination procedures; in addition, hospitals have been provided with self-audit tools. It was recognised that the involvement of Strategic Health Authorities was important in terms of monitoring their local providers.
- 5.9 Professor Jeffries informed the Committee that he also chaired the Decontamination Research Group. The group meets six-monthly to review the research work investigating the efficacy of decontamination procedures for various types of instruments used in surgery and other

invasive procedures. The aim of the group is to make more definitive recommendations in the future on the practice of Central Sterile Services Departments (CSSD), whilst also providing input into the DH risk assessment on the risk of transmission of vCJD via surgery. The DH also informed the Committee that the Decontamination Science and Engineering Group, which is in the process of being set up, could consider appropriate auditing procedures as part of its remit.

5.10 Members requested clarification on the target audience for the revised guidelines. It was explained that the guidance was intended as an information resource for local policy within healthcare settings. Members were informed that the final document would be comprehensively indexed together with a glossary of terms.

5.11 Members requested clarification on the term “local policies” which was used throughout the revised guidelines. It was noted that there are a number of policies and audit accreditation schemes, which have been adopted, in the healthcare environment. However it was agreed that the JWG would ensure that the revised guidelines would provide appropriate reference to “local policies”.

5.12 Members noted that CSF was classified as a low risk body fluid in the 1998 version of this document. However, paragraph 4.18 of the revised guidance stated that there was “no evidence of infectivity in CSF”. The literature had shown that bioassay of CSF had usually resulted in irregular and sometimes negative transmissions. More recent work had also failed to detect abnormal PrP in CSF. However, it was agreed that these comments would be forwarded to the JWG Drafting Group for consideration. The JWG agreed CSF remained a low risk fluid (see Annex A), but for purposes of practicality in terms of laboratory handling of CSF the JWG considered it may be appropriate, based on a local risk assessment, to dispense with certain containment measures

Annex A Distribution of TSE infectivity in Tissue and Body Fluids

5.13 Details of assumed levels of infectivity for vCJD and non variant CJD were listed at Annex A. Members suggested that, as there were now actual measurements of levels of infectivity for some of the tissues, these data could be included in a third column of the table.

5.14 It was acknowledged that vCJD tissues with known infectivity levels were available for brain, spleen and tonsil. It was agreed that these figures could be included as a footnote to the table.

Annex E Quarantining of surgical instruments

5.15 The Committee requested clarification on the term “supplemental disinfection”(paragraph E 7). It was agreed that that further explanation would be added to the text.

Annex I After Death

- 5.16 Annex I 9 provides advice on dealing with cadavers and tissues from patients at risk of CJD. It recommends that enquiries should be made as to the clinical status of the donor before using any material for teaching or research purposes. Members considered that this recommendation was weak and suggested whether it would be possible to test donor cadavers or tissues.
- 5.17 It was suggested that the JWG Drafting Group could discuss this issue with the inspector of anatomy in the United Kingdom (Dr Jeremy Metters). However, Members were informed that any testing would be subject to the consent of the family; in this case of familial CJD, this could raise a number of sensitive issues. Similarly, a negative test result would not necessarily mean that a person had not been exposed to infectivity, and was not incubating disease at the time of death.
- 5.18 Members expressed concern that paragraph I 13 implied that there was an expectation, subject to a risk assessment, that tissues would usually be returned to relatives. The Committee was informed that the practice adopted depends entirely on the level of consent obtained at the post mortem. If consent were not given for the tissues to be retained, then they would be returned to patients relatives, buried or cremated, and disposed of respectfully. However, many of the relatives recognise the need for retention of these tissues for research and for future investigation.

Sections presently missing from the guidance

- 5.19 The Committee was informed that practices, which relate to last rites and ritual washing, had not yet been included. However, this was dependent upon the secretariat being successful in securing appropriate information.

Conclusion

- 5.20 The Committee acknowledged the effort involved in the production of these guidelines, Members agreed that the guidance would be extremely useful.
- 5.21 Members were informed that the remaining sections were under further revision and would be presented to SEAC at a future meeting. Subject to the suggested amendments, the Committee endorsed the revised guidelines, and recommended they be submitted to DH Ministers for early publication.

Item 6- Update on review of Environmental Pathways

- 6.1 Dr P. Crook from the Environment Agency provided an update on the Review of Environmental Pathways, which has been commissioned by Environment agency (EA).
- 6.2 The Committee was informed that Det Norske Veritas (DNV) had prepared an assessment report on “Risks from BSE via Environmental Pathways for the Environment Agency” in 1997. In the light of increased state of current scientific knowledge and practical experience, the Environment Agency had commissioned DNV to conduct a Review of this original risk assessment.
- 6.3 A second draft of the report has been submitted to the EA which has been peer reviewed by a panel of international experts. The panel raised a number of concerns relating to the assumptions and the methodology used by DNV in the risk assessment. The Agency is currently discussing the peer review comments, and depending on the outcome, the final report will be presented to SEAC at a future meeting.

Item7 - Susceptibility of New Zealand sheep to TSE infectivity and linkage with PrP genotype-an update.

- 7.1 Members were informed of an interim result in a Defra funded study which is investigating the effect of PrP genotype linkage on susceptibility to TSE infection. A sheep of the ARR/ARR genotype, considered to be naturally resistant to TSEs, had succumbed to BSE at 33.5 months post inoculation following intracerebral inoculation with BSE infected bovine brain homogenate.
- 7.2 In a separate ongoing experiment at the VLA, ARR/ARR sheep have been challenged with a 5g oral dose of BSE infected brain homogenate. All tissues examined up to 46 months post challenge had so far proved negative. In contrast ARQ/ARQ sheep, challenged with the same inoculum showed infectivity in some tissues from as early as 4 months post challenge.
- 7.3 The Committee was informed that the results of this experiment would be discussed in more detail at the forthcoming Sheep Sub-Group meeting on 11 December 2002.