



NINETY FOURTH MEETING OF THE SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE

The Spongiform Encephalopathy Advisory Committee held its 94th meeting in Belfast on 21st September 2006, and discussed the following:

CURRENT ISSUES

SEAC was informed about the following issues:

- Publication of a report by the Scientific Committee on Emerging and Newly Identified Health Risks¹ following a public consultation. The report had been revised in light of comments from SEAC and other committees.
- An interim report from the Implementation Review Group concluding that the bovine spongiform encephalopathy (BSE) testing system for cattle aged over thirty months had worked satisfactorily since its introduction. The report is available on the Food Standards Agency (FSA) website².
- The FSA referred attendees to the FSA website concerning an investigation into an alleged breach of Over Thirty Months BSE testing controls³.
- The Clinical Governance Advisory Group, convened to advise the Department of Health (DH) on appropriate arrangements and care for individuals 'at risk from variant Creutzfeldt-Jakob disease (vCJD) for public health purposes', will meet on the

¹European Commission Scientific Committee on Emerging and Newly Identified Health Risks (2006) Safety of Human-derived Products with regard to vCJD http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/scenihhr_cons_02_en.htm

²<http://www.food.gov.uk/aboutus/ourboard/boardmeetings/boardmeetings2006/boardmeeting130706/agenda13jul06>

³<http://www.food.gov.uk/news/newsarchive/2006/aug/srmupdate0708>

10th October 2006 to finalise its report. The report is anticipated to be released in November 2006.

- The membership and draft terms of reference for an expert group to be convened by the Health Protection Agency (HPA) to consider the most effective means, including post-mortem testing, of ascertaining the prevalence, age and genotype distribution of vCJD infection in the United Kingdom (UK), as recommended by SEAC⁴. The committee's comments on the scope of expertise on the group and the draft terms of reference would be referred to the HPA.

UPDATE ON TSE TESTING

SEAC was presented with statistics showing the annual number of transmissible spongiform encephalopathy (TSE) cases from surveillance of cattle, sheep and goats in Northern Ireland since 2000. The data showed a decline in the incidence of BSE. Few or, in some years, no TSE positives in sheep had been found.

CJD UPDATE

SEAC was updated on the latest figures on the number of sporadic CJD (sCJD) and vCJD cases up to September 2006. From May 1990, 845 cases of sCJD had been identified in the UK with a mean age at death of 67 years and genotype distribution of 64% MM, 18% MV and 18% VV at codon 129 of the prion protein gene. One hundred and sixty two cases of vCJD had been identified in the UK with a median age of death of 28 years. Statistical analysis showed the incidence of vCJD peaked with 28 deaths in 2000.

Elsewhere, 34 vCJD cases had been reported with a distribution of 20 in France, four in the Republic of Ireland, two in the United States of America (USA), two in the Netherlands and single cases in Italy, Canada, Saudi Arabia, Japan, Spain and Portugal. In two Irish cases, both USA cases, one French case, the Japanese and Canadian cases, infection was presumed to have occurred in the UK.

All vCJD cases that had been genotyped were MM at codon 129 of the prion protein gene. However, findings from studies of

⁴ <http://www.seac.gov.uk/statements/state260106.htm>

humanised mice and genotyping of samples testing positive in a retrospective survey of abnormal prion protein in appendix and tonsil tissue suggested that cases of vCJD infection, and possibly clinical vCJD, in genotypes other than MM could be expected.

Epidemiological studies on the relationships between recipients or donors of blood from or to vCJD cases were reviewed.

REPUBLIC OF IRELAND PERSPECTIVE OF TSEs

SEAC was provided with an overview of the surveillance, epidemiology and management of BSE and vCJD in the Republic of Ireland.

HORIZON SCANNING

The committee was informed by representatives from the Department of Environment, Food and Rural Affairs, FSA, DH and the National CJD Surveillance Unit about issues that may require future consideration by SEAC including:

- proposals arising from the European Commission's TSE Roadmap such as possible changes to specific risk material (SRM) controls and tolerance levels for fishmeal in ruminant feed.
- aspects of the contingency policy if BSE were found in the national sheep flock.
- ongoing research on the animal and possible human health implications of atypical scrapie.
- the DH programme to ascertain better the prevalence of vCJD infection in the UK.
- protocols for the evaluation of diagnostic tests and decontamination technologies for vCJD.
- possible re-evaluation of risk assessments of secondary vCJD transmission should they be modified in light of new data.

PUBLIC QUESTION AND ANSWER SESSION

Answers were given to questions from the public about the implications of historic exposure to bone meal in non-agricultural fertiliser, the appropriate transport of SRM and the timing of possible changes to restrictions on bovine vertebral column.

EVALUATION CRITERIA FOR ANTE MORTEM DIAGNOSTIC TESTS FOR SUBCLINICAL vCJD

DH requested SEAC advice on evaluation criteria for rapid ante mortem diagnostic tests to detect subclinical vCJD.

SEAC noted that current prototype tests were all based on detection of abnormal prion protein. However, the relationship between the presence of abnormal prion protein and vCJD infectivity is not well understood.

SEAC recommended the independent evaluation and validation of diagnostic tests prior to implementation. Preliminary evaluation of the specificity and sensitivity of tests could be achieved by using blood spiked with brain material from vCJD cases. Blood from animal models may also provide a useful source of test material. However it is very important that final evaluation also includes testing of blood from vCJD cases, as spiked blood may not be closely representative of endogenous infectivity in blood. SEAC suggested a number of risk assessments need to be carried out in advance of testing to ascertain what sensitivity and specificity is needed. It is critical that appropriate arrangements are made for collecting suitable material, storing and managing it. It is also of utmost importance that the ethical implications of ante mortem testing for vCJD are addressed prior to implementation of a blood test. SEAC agreed to produce a statement of its deliberations.