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Foreword

It is the role of SEAC to provide independent advice to Government on the risks to humans and animals from TSEs and to provide timely assessment of the emerging science that impacts on these risks. During 2006 SEAC and its Subgroups considered a wide range of issues pertaining to this remit.

The welcome decline in the incidence of BSE in the UK and the low numbers of BSE cases elsewhere in Europe, has prompted the European Union to consider possible changes to the surveillance and control measures introduced to protect human and animal health from the threat of BSE. SEAC provided advice in relation to the new information and risk assessments required to properly evaluate the effect of potential changes to control measures.

The continued surveillance for TSEs in sheep has led SEAC to the conclusion that the prevalence of BSE in the UK sheep population is most likely to be zero, or very low, if present at all. The emergence of atypical scrapie is a cause for concern, as there are currently insufficient data to reach any conclusions regarding the potential risks of this disease to human health. Research to inform this assessment is urgently required and is now underway. SEAC will closely monitor the findings as they emerge to assess the potential implications of atypical scrapie on human health and animal welfare. SEAC has been actively involved in assessing new scientific data which may impact on the future of the National Scrapie Plan.

The decline in the incidence of probable and possible vCJD cases, although very welcome, cannot be taken as an indicator that the epidemic is nearing its conclusion. Uncertainty remains about the effect of genetics on the susceptibility of individuals to the disease and the incubation period of the disease. Data suggest that future clinical cases of vCJD are likely in individuals of different genotypes with incubation periods as long as several decades. Furthermore, there is considerable uncertainty about the number of individuals that may be subclinical carriers of vCJD infection. SEAC has been proactive in stressing the importance of work to ascertain the prevalence of subclinical vCJD in the UK population. Risk assessments, although containing many uncertainties, suggest that human to human transmission via certain medical procedures is possible. Indeed, it is already clear that vCJD is efficiently transmitted from subclinically infected blood donors to recipients of that blood.

Key parameters to understanding the vCJD epidemic and to making better risk assessments, are the prevalence, age and genotype distribution of subclinical vCJD. SEAC recommends that large scale studies, in particular the National Anonymous Tonsil Archive (NATA) and a proposed post mortem tissue archive, be conducted with urgency to enable estimation of these parameters. It is anticipated that preliminary data from NATA should be available in 2007.

As the number of subclinical carriers of vCJD is uncertain and there is no test available currently to identify them, measures in place to minimise the risks of human to human transmission of vCJD. Further measures to minimise the risks, such as more effective decontamination of surgical instruments, filters to remove vCJD infectivity from blood and a viable blood test to identify subclinically infected individuals are under development. SEAC provided advice on how the effectiveness of such technologies should be evaluated and validated.

It is my hope that, in 2007, SEAC will see significant progress on improving our understanding of the vCJD epidemic, enhanced understanding of atypical scrapie and management of this prion disease, new data on how prion infections are transmitted and how future transmissions may be prevented. SEAC is expected to play an important role in assessing changes in risk to human and animal health, in particular in assessing the change in risk when relaxation of regulations is being considered.

I would like to thank Drs Jacky Chambers and Peter Rudge who have completed their terms of office on SEAC for their time, commitment and input into the deliberations of the committee. I am pleased to welcome Professor Alun Williams onto the committee. I welcome the reappointment of Peter Jinman, Deputy Chair, for a third term and the reappointment of Professors Graham Medley, Nigel Hooper, Margaret Stanley and Ms Diane McCrea for second terms of office.

I am particularly grateful to all the researchers who have provided and presented their unpublished research to SEAC as it is vital that the committee has access to research findings as they emerge.

Finally, I would like to thank the members of SEAC and its Subgroups for the enthusiasm, energy and insight that they bring and the Secretary and Secretariat for the support they provide SEAC.

Professor Chris Higgins

Chair of SEAC

About the Committee

SEAC is an independent expert advisory committee that provides scientific advice to the UK Government on transmissible spongiform encephalopathies (TSEs) such as bovine spongiform encephalopathy (BSE), atypical and classical scrapie and variant Creutzfeldt-Jakob disease (vCJD). The committee's deliberations may be initiated by requests for advice from Government Departments, the Devolved Administrations, SEAC members, other advisory committees or enquiries from members of the public. The Chairman of SEAC may convene Subgroups to examine specific issues in greater detail. Subgroups have clear terms of reference and are required to report to the main committee.

SEAC meets around five times a year with the majority of its business conducted at public meetings. Agendas, summaries, discussion papers and minutes of meetings are published on the SEAC website. Since September 2004, recordings of meetings may be viewed via the website. There are occasions when the committee considers certain information, such as pre-publication material or confidential medical data in reserved business sessions. Summaries of these discussions have been made available on the website from November 2004. Once the information considered in these sessions has been published, full details of the discussion and the relevant papers are placed on the website.

SEAC website (www.seac.gov.uk)

The website carries:

- information about the committee's history, terms of reference and current membership
- agendas, discussion papers and minutes of meetings
- committee statements
- register of committee members' interests and the SEAC code of practice
- SEAC's annual reports from 1997 onwards and reports of independent reviews of SEAC in 1997 and 2002
- information about the membership and work of the SEAC Subgroups.

Main issues considered by SEAC and SEAC Subgroups

SEAC met five times in 2006. An overview of the main issues considered and recommendations made is given below. Readers are advised to consult the minutes and statements on the website for the full record of SEAC's discussion of these issues with the conclusions and recommendations:

SEAC 91

- An update on the epidemiology of bovine spongiform encephalopathy (BSE).

- The potential risks of BSE transmission from medical implants containing bovine material. SEAC considered that the source of the material was crucial to manage the risks. Risks were reduced when material is used from young animals from countries with good surveillance procedures and a low prevalence of disease.

- Methods to evaluate the efficacy of prion reduction filters. SEAC considered it critical that evaluation includes testing filters under circumstances that model the human situation as closely as possible.

- The use of livestock and crops from a farm where TSE research had been conducted. SEAC considered that there is no evidence for a TSE risk from the uses proposed.

- A preliminary risk assessment of potential vCJD transmission via endodontic procedures. SEAC considered that vCJD transmission via endodontic dentistry may, under certain hypothetical but plausible scenarios, be sufficient to sustain a secondary vCJD epidemic. However, there are uncertainties around the data and assumptions underpinning the assessment. Research underway will address some of these uncertainties. Once complete and / or other data become available, the risks should be reassessed. Although it is unclear whether or not vCJD infectivity can be transmitted via endodontic files and reamers, it would be prudent to consider restricting these instruments to single use, as a precautionary measure.

SEAC 92

- TSE infectivity in blood. SEAC concluded that the precise time in the incubation period of vCJD at which the human blood becomes infectious is unclear. It may be infectious from at least, if not before, the middle of the incubation period as the source of infectivity in blood is not understood. Infectivity in blood can be disseminated, but not diluted out, by distribution

to a large number of recipients. Consequently, pooling of potentially infectious material, or in other ways disseminating infectious material between a number of recipients, will not reduce the number of people infected, and may increase the number of people infected.

SEAC 93

- Chronic wasting disease (CWD) in UK deer. SEAC agreed that, based on current data, CWD poses relatively little risk to human health, or to the health of cattle, sheep or goats in the UK. Nevertheless, as a risk cannot be excluded, a watching brief should be maintained.

- Report of an assessment of the animal feed supply routes. SEAC welcomed the comprehensive report noting feed assurance schemes, surveillance and controls in place substantially reduce the risk of contamination of feed with mammalian meat and bone meal (MMBM). There is a need to maintain awareness, continue effective enforcement of the controls and refine the specificity of tests for MMBM in feed.

- European Union TSE Roadmap. SEAC considered it important that departments review proposals for possible changes to TSE controls or surveillance and seek advice from SEAC as appropriate and in light of emerging data that may alter risk assessments of changes to controls.

- Methods to evaluate new surgical instrument decontamination technologies. SEAC recommended independent and quantitative evaluation of the effectiveness and reliability of new decontamination technologies prior to implementation. Evaluation strategies should be standardised and include quantitation of the effect of treatments on the infectivity of vCJD, or closely related prions, adhering to stainless steel. Research should be conducted to examine the relative resistance to decontamination of stainless steel contaminated with wet compared with dried-on material.

- BSE pathogenesis studies. SEAC concluded there is no evidence of a threshold dose of BSE at which the probability of infection becomes negligible. Reliable detection of abnormal prion protein (PrP^{Sc}) in the central nervous system (CNS) is only possible in the few months prior to, and during, the clinical stage of infection. Low levels of PrP^{Sc} in peripheral nervous system tissues could be detected at the same time, or after, PrP^{Sc} was detected in the CNS.

SEAC 94

- An update on TSE testing in Northern Ireland.

- An update on the epidemiology of human prion diseases.

- An overview of the surveillance, epidemiology and management of BSE and vCJD in the Republic of Ireland.

- Evaluation criteria for ante mortem diagnostic tests for subclinical vCJD. SEAC recommended that tests should be independently and rigorously validated using a clearly defined protocol that includes testing of blood from vCJD cases.

SEAC 95

- An update on a case of atypical scrapie in a sheep flock used for research purposes considered free of TSEs. The founder animals of this flock were from New Zealand, a country considered free of TSEs.

- A mathematical model to estimate potential exposure of the UK population to BSE after cattle carcases had been processed in abattoirs and cutting plants. SEAC was content with the methodology and suggested a number of refinements to the model, noting many assumptions used were based on expert opinion. In models of this nature, it would be useful to not only consider usual events, but also rare or unexpected events, that could potentially give rise to large health risks to provide information on how such events may be prevented.

- An update on a working group on a post mortem tissue archive convened in response to a previous recommendation from SEAC[1]. SEAC noted that a post mortem tissue archive was critically dependent on the support of coroners' offices and development of the archive should be strongly encouraged and supported.

- A preliminary mathematical model to estimate human exposure to BSE arising from potential changes to BSE control measures in Great Britain. SEAC generally accepted the methodology and data used and made suggestions for refinements. Once further refined, the model would provide a very useful tool to analyse the effect of potential changes to BSE controls.

SEAC statements

SEAC published the following statements in 2006:

- vCJD and endodontic dentistry;

- TSE infectivity in blood;

- Chronic wasting disease in UK deer (update of the 2004 statement);

1 http://www.seac.gov.uk/statements/state260106.htm

- Methods to evaluate decontamination technologies for surgical instruments;

- Evaluation criteria for ante mortem diagnostic tests for subclinical vCJD.

SEAC Sheep Subgroup

The SEAC Sheep Subgroup met on 24th January 2006 to consider emerging scientific developments on atypical scrapie and possible implications for the National Scrapie Plan (NSP) and human and animal health. The Subgroup issued a statement which was endorsed by the main committee at SEAC 91. The Subgroup concluded that there is currently insufficient data to make any conclusions about the risk to human health or animal health and welfare from the finding of atypical scrapie in UK and European small ruminant flocks. However, as transmission to humans is theoretically possible, it is important that research on transmission of atypical scrapie in transgenic mice expressing the human prion protein gene be conducted to inform assessment of the risks. The new scientific data and identification of atypical scrapie, while of concern, do not justify immediate changes to the NSP. Nevertheless, it is strongly recommended that the NSP be kept under continuous review as new findings emerge.

The SEAC Sheep Subgroup met again on 13th October 2006 to consider the latest science on TSEs underpinning the NSP Ram Genotyping and Welsh Ewe Genotyping Schemes. The Subgroup issued a statement which was endorsed by the main committee at SEAC 95. The Subgroup concluded that the prevalence of BSE in the UK sheep population is most likely to be zero, or very low if present at all. Consequently, any impact of the schemes on human health from removing BSE from sheep is likely to be negligible. The effect of the schemes on the prevalence of atypical scrapie is unclear, however they would remove a large proportion of classical scrapie infections.

SEAC Epidemiology Subgroup

The SEAC Epidemiology Subgroup met on 9th November 2006 to consider the nature and future profile of the vCJD epidemic, taking into account new research, the possibility of human to human transmission and the likelihood of a self-sustaining epidemic. It also assessed approaches for surveys to estimate the prevalence, age and genotype distribution of subclinical vCJD. The Subgroup updated its previous statement on the vCJD epidemic, which was endorsed by the main committee at SEAC 95. The Subgroup made a number of recommendations:

- The planned testing of samples under collection for the National Anonymous Tonsil Archive (NATA) should be progressed with all possible urgency

- Testing samples collected by NATA and a proposed post mortem tissue archive, are the best methods for data collection in order to improve the estimates of the prevalence, genotype and age distribution of subclinical vCJD.

- Given the potentially valuable information that might be obtained by attributable testing and the lack of data on the effect of attributable testing on consent for tissue collection, a study be conducted, in parallel with the post mortem archive, to assess whether attributable testing would negatively influence consent for tissue testing. Should such a study indicate that attributable testing does not appreciably reduce the yield of samples, attributable collection of post mortem samples should be seriously considered.

- Enhanced clinical surveillance for vCJD in the elderly should be considered.

- Clinical monitoring and, with patient consent, post mortem vCJD tests should be considered on individuals from groups at risk of vCJD.

- Development of a combined model for the surgical and blood routes of vCJD transmission to explore the effect of interactions between these routes should be supported.

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