



HORIZON SCANNING

ISSUE

1. To consider emerging scientific issues in relation to transmissible spongiform encephalopathies (TSEs) and to raise awareness of issues SEAC may consider in the future.

BACKGROUND

2. At SEAC 100, experts from the Roslin Institute, Veterinary Laboratories Agency, National CJD Surveillance Unit and Medical Research Council Prion Unit will outline emerging issues of TSE science from their perspective.
3. This paper outlines emerging issues and key areas from the perspective of the Department for Environment Food and Rural Affairs (Defra), Food Standards Agency (FSA) and Department of Health (DH) (see Annexes 1, 2 and 3, respectively).

ADVICE SOUGHT FROM THE COMMITTEE

4. Members are invited to comment on the issues presented at SEAC 100 and in this paper and to raise other issues in relation to the TSE science horizon.

DEFRA

To advise SEAC of possible animal-health related TSE developments in 2008.

BACKGROUND

1. World Organisation for Animal Health (OIE)

The World Organisation for Animal Health is considering current trade guidelines on scrapie and BSE in relation to the emergence of atypical forms of the diseases. While it is unlikely that changes are required to guidelines for BSE, significant revision will be required to take into account the implications of atypical scrapie.

The OIE is expected to endorse the provisional recognition of the UK as “controlled risk” for BSE, at its General Session in May 2008.

2. European Union

Many of the short term goals of the EU's 2005 TSE Roadmap have been achieved. Those outstanding include:

i) Revision of the BSE Monitoring Programme in Cattle

The European Commission is currently discussing a revision of the BSE monitoring programme in cattle, with Member States, to achieve better targeting of the surveillance activity and a reduction in the number of tests. We anticipate that there will be an increase in the testing age limit for fallen stock and for cattle slaughtered for human consumption. SEAC will be consulted on proposals to increase the testing age limit for cattle slaughtered for human consumption.

ii) EU Feed Controls

In April 2008, the European Commission is expected to seek an opinion on the feeding of fish meal to young ruminants in milk replacers.

Preliminary results from a Community Reference Laboratory inter-laboratory study on quantitative feed tests are unlikely to support the establishment of agreed tolerance levels for animal proteins in feed in the short term.

Other research on feed tests could support the feeding of non-ruminant PAP to non-ruminants in the longer term.

iii) EU Scrapie Controls

In April 2007, the EU's Standing Committee on the Food Chain and Animal Health adopted more proportionate control measures for scrapie. Following a subsequent legal challenge from France, the European Court of First Instance suspended the new measures relating to classical scrapie pending the hearing of the main case. For sheep flocks in which classical scrapie has been detected the remaining options are whole-flock cull and genotyping and culling. For goats the only remaining option is whole-flock cull. The legal case centred on scientific opinions from the French Food Safety Agency (AFSSA) and the European Food Safety Authority (EFSA) and the application of the precautionary principle. It highlights the importance of close liaison between national risk assessment bodies and EFSA. The UK is supporting the European Commission at the European Court of Justice hearing.

Other EU

In October 2007, the Commission published a call for expressions of interest to participate in a programme for the evaluation of tests for the diagnosis of TSE in ruminants (ante- and post- mortem). This call will remain open for 5 years.

3. TSEs in Cattle

We predict a continued decline in cases of BSE in the EU. The majority of UK cases are still being detected in cattle born before the 1996 feed ban. The Older Cattle Disposal Scheme closes at the end of 2008 and we are working with industry to maximise the uptake. The prevalence in successive BARB birth cohorts is extremely low and is decreasing. However, as the pre-1996 cattle population declines, BARBs will form an increasing percentage of the total number of cases.

The overall prevalence of atypical BSE appears low. Two cases of atypical BSE have been detected in UK to date in older cattle. Oral challenge studies are being planned in Europe and Japan which will provide further information on the pathogenesis. While the aetiology of atypical BSE remains unknown the long term consequences for the maintenance of key BSE controls remains uncertain.

4. TSEs in Small ruminants

The incidence of classical scrapie in UK is expected to continue to decline in the short to medium term. The incidence of atypical scrapie is expected to remain static, however absolute numbers detected are largely dependent on the extent of the active monitoring programme.

A significant in-herd incidence of classical scrapie can occur in housed goat herds and to date this has occurred in two UK herds. This is thought to be due to the fact that it is common practice for females to give birth in areas where other goats are kept and also because, assuming that the population is largely susceptible, replacements are often homebred. The EU TSE Regulation requires the culling of scrapie-affected goat herds. However, in October 2005,

GB agriculture departments agreed that this was disproportionate and that affected herds should be restricted and monitored, but culling remained an option if further cases of scrapie occurred.

Current indications suggest that there will be no evidence of naturally occurring BSE in sheep, that there will be no further possible evidence of naturally occurring BSE in goats and that there will be no evidence that either classical or atypical scrapie are zoonotic.

The European Commission is likely to propose extending the deer survey to allow Member States to meet their targets. The survey has not detected any cases of TSE in deer to date.

We are alert to the possibility of the detection of new strains of TSE in small ruminants, particularly with continued developments in TSE testing, and the possible need to seek SEAC's advice on their significance.

5. Animal By-Products

EU negotiations to amend to the EU Animal By-Products Regulation by co-decision, will continue in 2008. We do not envisage the need for SEAC's involvement in this process.

6. TSE Research

Defra's TSE research budget continues to undergo a managed decline of approximately 10% a year. The expenditure in the 2007/08 financial year is predicted to be £11.4million, approximately 28% of Defra's total animal health and welfare research budget. Priority will be given to responding to new research needs, such as understanding the implications of atypical TSEs for animal and public health, and maintaining our world-class expertise in TSEs that has been developed over the past 2 decades. We will continue to seek the recommendations from various expert panels when any major decisions are required. For example, a review of VLA's TSE Archive and the Ripley and Arthur Rickwood sheep flocks was undertaken in November 2007.

Research projects that will be completed, or yield information, in 2008/9 include:

- long-running projects where cattle have been challenged with BSE or scrapie
- the design of optimal surveillance strategies for detecting scrapie in sheep
- optimal methods to apply an ante-mortem test for classical scrapie in sheep
- investigations on the possibility of a carrier state in ARR/ARR sheep
- investigations on atypical scrapie, including surveys of historical samples
- research aimed to develop blood tests for scrapie in sheep
- research to develop improved infectivity assays for TSEs, either transgenic mice or using cell culture-based methods

The detection of cases of atypical scrapie in VLA's Arthur Rickwood flock and bluetongue restrictions could compromise the availability of TSE-free sheep for research.

7. Responsibility and Cost Sharing

Defra's consultation on options for increasing responsibility and cost sharing with industry will close on 15 April 2008. Areas for consideration in the short term are the BSE monitoring programme, the Ram Genotyping Scheme and the Scrapie Monitoring Scheme.

FSA

1. TSEs In Food Animals

The Agency will continue to monitor the levels of TSE diseases in food animals and the associated food-borne risks to human health.

BSE has continued to decline and is now at a very low level in those cattle that are eligible for human consumption. The Agency's work with respect to BSE will therefore, over the next few years, be directed towards keeping the food safety controls under continuous review with the aim of maintaining effective public health protection at a level that is proportionate to the risk (see also below).

At the same time, in view of the significant uncertainties that remain about TSEs, the Agency will continue to be watchful for any new information that might affect our current assessment of the risk to human health from these diseases. The particular areas which we currently consider need to be monitored include:

- TSEs in sheep, including any evidence that BSE might be present in the UK flock or that other sheep TSEs might pose a risk to human health (including through milk);
- unusual BSE;
- deer, with particular reference to the Agency-funded work to investigate BSE in deer and the current limited statutory surveillance for TSE in deer being undertaken by Defra.

2. More proportionate BSE/TSE controls

The Agency will be continuing its work to secure more proportionate BSE controls over the next few years. The work planned for next year includes:

- consideration of changes to the BSE monitoring programme. As indicated by Defra, changes to the European rules on BSE testing of cattle are currently under discussion. The FSA will wish to consult SEAC on the implications for public health of specific proposals for change which are expected to emerge from those discussions in the New Year;
- an extension of the current work which is underway to develop more proportionate system of enforcement of the specified risk material (SRM) controls in abattoirs to include SRM controls on cattle aged over thirty months;

- the ongoing review on the controls on bovine head meat in relation to the risk of contamination by CNS material.

As a recent AFSSA Opinion refers to the potential for restricting the tissues that have to be removed as SRM (e.g. by raising the age at which tissues are designated SRM), we can expect the SRM controls themselves to become an issue over the medium/longer term (as envisaged in the TSE Roadmap).

3. TSE Research

The Agency's TSE research programme includes

- projects investigating the risk to humans from atypical scrapie and unusual BSE
- a number of projects working towards the development of an ante-mortem test for animal TSEs
- risk assessments to provide key information to support the Agency's policy that the TSE controls in place should be proportionate.

DH

- The Department of Health remains committed to a precautionary approach to CJD, and will continue to review evidence of CJD epidemiology to ensure that the precautionary approach is applied appropriately.
- A better understanding of prevalence remains a key issue for the Department. We continue to support the National Anonymous Tonsil Archive and the collection of 100,000 pairs of tonsils, and continue to seek other routes for prevalence estimation.
- The Department will continue to support work on instrument decontamination as recommended by the Engineering and Science Advisory Committee into the decontamination of surgical instruments including prion removal (ESAC-Pr).
- The Department will seek the advice of the Advisory Committee on the Safety of Blood Tissues and Organs (SABTO) on the use of prion reduction filters by the blood services and may wish to refer to SEAC for risk assessment advice.
- The Department will continue to monitor the potential developments of blood tests for vCJD infection, focussing on the specificity and sensitivity of such tests. If such a suitable test is developed, we will consider its use for both research and health care purposes in accordance with SEAC's position statement on antemortem diagnostic tests and the advice of our other advisory bodies.
- The Department will refer to SEAC any further evidence relevant to the Risk Assessments on dentistry as it becomes available.
- The Department will continue to provide support for the voluntary sector in their work with affected patients, their families and carers.
- The Department will continue to fund and support the National CJD Surveillance Unit in Edinburgh.
- The Department will continue to work with the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy Working Group to ensure that they provide advice on the appropriate risk management actions in health care and other

settings. We will support the Working Group in the revision, dissemination and implementation of its guidance.

- The Department will continue to support the CJD Incidents Panel in its actions to ensure that health care organisations have and take the appropriate actions to manage incidents involving possible transmission of CJD.