



Department  
for Environment  
Food & Rural Affairs

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## **Transmissible Spongiform Encephalopathies and Animal By-Products Evidence Plan**

**Policy portfolio: Animal Health: Surveillance,  
Global Trade and Zoonoses**

**Policy areas within portfolio: Transmissible  
Spongiform Encephalopathies and Animal by-  
products**

**Timeframe covered by Evidence Plan: 2013/14–2017/18**

**Date of Evidence Plan: March 2013**

This evidence plan was correct at the time of publication (March 2013). However, Defra is currently undertaking a review of its policy priorities and in some areas the policy, and therefore evidence needs, will continue to develop and may change quite rapidly. If you have any queries about the evidence priorities covered in this plan, please contact [StrategicEvidence@defra.gsi.gov.uk](mailto:StrategicEvidence@defra.gsi.gov.uk).

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# 1. Policy context

## What are the key policy outcomes for the policy programme/area?

Transmissible Spongiform Encephalopathy (TSE) controls and surveillance (testing) protect public health and fulfil EU obligations (Regulation (EC) Nos. 999/2001 and 882/2004), facilitating trade and avoiding infraction. However, there is a widespread view that the current measures are disproportionate to the risk.

The BSE epidemic is declining:

- In 2012 there were 2 cases of BSE in GB down from a peak of over 36,000 in 1992. So far in 2013, there have not been any BSE cases confirmed in GB. No cases of BSE have been found in healthy slaughtered cattle in the GB since 2008.
- In 2012 there were 6 cases of classical scrapie in sheep and 21 cases in goats while there were 28 cases of atypical scrapie, all in sheep.

In 2010, the European Commission published the TSE Roadmap 2, its strategy for a stepwise reduction in the measures over the period 2010-2015 based on scientific advice. Defra supports a risk-based, proportionate approach that eliminates any unnecessary burdens. It strongly supports the objective set out in the TSE Roadmap 2 and looks forward to early proposals for change where the TSE measures are now disproportionate to the risk. Data from TSE surveillance and Research and Development (R&D) will support this process.

The TSE R&D programme also seeks to maintain the expertise in the techniques specific to TSEs that are necessary to ensure that the statutory Reference Laboratories (EU & National) remain viable and retain the capacity to respond to any re-emergence of Bovine Spongiform Encephalopathy (BSE) or the emergence or recognition of new TSEs which might pose a risk to public or animal health. The Foods Standards Agency (FSA) is responsible for protecting the public's health and consumer interests in relation to food. The responsibility for ensuring that TSEs do not circulate in the human population rests with the Dept. of Health (DH).

The Animal By Products (ABP) Regulation (EC) No. 1774/2002 (superseded in 2011 by the Regulation (EU) No. 1069/2009 and Regulation (EC) No. 142/2011) was introduced to respond to concerns regarding public and animal health from a number of EU crises including BSE, Foot and Mouth Disease and dioxin contamination and lays down rules for the use and disposal of ABPs. ABPs are defined as products of animal origin not intended for human consumption, including carcasses, manure, wool, feathers food waste containing products of animal origin and all catering waste. The primary objectives of ABP policy are to influence decisions at the European level to ensure that public and animal health is protected in a cost proportionate manner, to guide and ensure efficient monitoring of compliance with current ABP regulations while minimising costs to the government, and to reduce the burden associated with ABP as waste. ABP policy objectives in this area are as far as possible aligned with those of Waste Strategy which seeks to reduce the amount

of ABP-related waste going to landfill. This is being approached by encouraging the use of composting and anaerobic digestion and by supporting the development of alternative methods for use and disposal of ABP.

The TSE/ABP programme supports Priority One of the Defra Business Plan 2012-2015 to 'Support and develop British farming and encourage sustainable food production', and specifically under the heading 'to help ensure a secure, environmentally sustainable and healthy supply of food with improved standards of animal welfare.' The Welsh Government is also committed to "improved animal health and well-being through environment, countryside and planning initiatives and decision-making in Wales". In Scotland, ensuring well-treated and healthy farm (and domestic) animals, contributes towards the Scottish Government's strategic objective of a 'Healthier, Wealthier and Fairer' Scotland. Within these, protecting public health from animal related threats is a critically important role for Defra and wider Government.

TSE and ABP policy and evidence activities also contribute to the Animal Health and Welfare Board for England (AHWBE) key outcomes of "Sustained consumer confidence in food we produce from livestock" and that "[...] Endemic diseases must be tackled, brought under control and eradicated where appropriate."

The Animal Health and Welfare (AHW) research budget is held by Defra on behalf of GB administrations.

## 2.+3. Current and near-term evidence objectives and Future evidence needs

**What are the current and near-term objectives for evidence and how do they align to policy outcomes? What are the longer-term evidence needs for the policy area/ programme?**

### **TSE non R&D**

The primary objective of TSE surveillance activity is to protect public health. The UK is obliged to comply with EU statutory requirements for having Reference Laboratories, for monitoring TSEs in cattle, sheep and goats, for scrapie genotyping and for monitoring compliance with the ban on feeding animal proteins to farmed livestock.

In addition, the non-statutory TSE scientific advice and TSE risk assessment activities funded at the Animal Health and Veterinary Laboratories Agency (AHVLA) contribute to policy development and the AHVLA archive of TSE tissues contributes to R&D.

### **TSE R&D**

The primary objectives of the research programme are to ensure that the UK has robust evidence to:

- Advise on sound and cost-proportionate changes to regulations related to existing TSEs, and
- Cope with the potential threats (economic and to human and animal health) from new or re-emerging TSEs.

This requires us to continue to develop our knowledge of the biological nature of prion diseases, to continue to develop better detection methods, or methods suitable for detecting new prion diseases, and to investigate ways to improve the control of these diseases. These objectives are being fulfilled against a background of continuing commitments to long term TSE R&D projects which will be completed within the next few years. The three main policy objectives and the associated evidence questions given in this statement are given below.

TSE Policy objective

TSE Current and near-term evidence

TSE Future evidence needs

objective

<p><b>Eradicating BSE in cattle</b></p>	<p>High Priority-Identify cost-effective strategies to detect the re-emergence of BSE or emergence of another TSE in cattle.</p> <p>High Priority-Quantify the amount of processed animal protein in animal feed.</p> <p>Medium Priority-Determine the full spectrum of prion protein disorders and the nature and significance of unusual types of BSE in cattle.</p> <p>Medium Priority-Determine if there are any differences in the BSE cases born after the reinforced feed ban.</p> <p>Medium Priority-Improve post-mortem testing of both cattle and sheep with respect to speed, cost and sensitivity.</p>	<p><b>TSE non-R&amp;D</b> consists mainly of continuing EU statutory obligations. In order to continue to deliver on our obligations with a declining budget we will need to consider transferring further costs to industry and seeking cheaper suppliers of testing. We anticipate that continued funding of statutory surveillance from the TSE policy budget plus R&amp;D TSE funding will contribute to maintenance of core TSE facilities at AHVLA and provide the capacity to increase evidence activities should it be needed in the future.</p> <p><b>TSE R&amp;D</b> is a declining evidence need with a large body of evidence already gathered on classical BSE and scrapie, but there are knowledge gaps in these areas and in the areas of new and emerging TSEs. The research programme will continue to focus on the key questions outlined in section 2, but ensure that these studies are conducted in a way that retains core UK capacity in TSEs. This core capacity will be held largely at the VLA but to a lesser, and complementary extent, at the Roslin Institute so that the UK TSE expertise is not held in a single laboratory. Future research needs will be identified in conjunction with TSE policy colleagues (including the Devolved Administrations), and our specialist advisory groups (TSE Research Advisory Group and Advisory Committee on Dangerous Pathogens. Thereafter they will be discussed with other</p>
<p><b>Minimising the risk from TSEs in sheep and goats</b></p>	<p>High Priority-Find a cost-effective method for measuring trends in the prevalence of scrapie infection.</p> <p>Medium Priority- Understanding the nature and biological significance of BSE-like scrapie in sheep and goats.</p> <p>Medium Priority-Understand how TSE strains in sheep evolve.</p>	

	<p>Medium Priority-Determine if atypical scrapie is naturally transmissible between sheep.</p> <p>Medium Priority-Understand the distribution of the atypical scrapie agent in tissues at different ages.</p> <p>Medium Priority-Determine the most cost-effective method for detecting BSE in the presence of scrapie.</p> <p>Medium Priority-Estimate the long-term impact of the National Scrapie Plan.</p> <p>Medium Priority-Determine if it is possible to reduce TSEs in goats by breeding for resistance.</p>	<p>UK research funders to avoid duplication and to investigate possible co-funding opportunities with the Biological and Biotechnology Science Research Council, Department of Health, the Medical Research Council, the Food Standards Agency, and Devolved Administrations (DAs). All discussions will include consideration of whether multi- or interdisciplinary studies are appropriate. As with statutory surveillance which needs to be maintained at some level, the TSE R&amp;D budget is not expected to decrease to zero. Surveillance activities and the identification of new threats will mean that a low level of R&amp;D will be essential long term.</p>
<p><b>Protecting public and animal health from the risk of animal TSEs</b></p>	<p>High Priority- Evaluate and improve current decontamination methods particularly with respect to unusual TSEs.</p> <p>Medium Priority -Determine the relative risk of transmission to humans of atypical/unusual animal TSEs.</p> <p>Medium Priority- Improve our understanding of the nature of the infectious agent.</p> <p>Medium Priority -Determine the best transgenic mouse models to characterise new animal TSEs cost-effectively.</p>	

**Animal By-Products**

Measures of success of the Animal By-Products evidence programme include;

- European Food Safety Authority (EFSA) agreement that novel methods for use or disposal of ABPs are safe and therefore that the supporting evidence provided to EFSA by businesses is rigorous and has been evaluated by Defra as meeting the criteria for EFSA assessment prior to submission.
- Deregulation and reduction of the burden on the ABP industry & costs to government whilst ensuring that no unacceptable risks to public and animal health arise.

There is considerable overlap with the TSE R and D programme as many of the issues are common to both the TSE and ABP programmes. However, the short and long term objectives of the ABP evidence programme are described in the table below.

Animal By-Products Policy objective	Current and near-term evidence objective	Future evidence needs
<p>Advising on and ensuring compliance with current regulations while minimising cost to government and industry.</p> <p>Influencing policy decisions for the development of ABP legislation at European and national level.</p> <p>Assessing how potential deregulation in the ABP sector will affect future policy options for instance by</p>	<p>High Priority- Carry out an in-house review of the evidence surrounding the ban on burial of animal by-products, and in particular fallen stock (non-R&amp;D).</p> <p>High Priority- Review current methods for the use and disposal of food waste (including catering waste) &amp; evaluate potential options of recycling food waste into animal feed (R&amp;D).</p> <p>High Priority- Encourage &amp; support (by conducting in-house reviews of applications for approval of novel ABP methods (non R&amp;D) and also by funding R&amp;D as appropriate), the development &amp; adoption of new methods for use, containment or</p>	<p>Longer term research needs will be informed by the reviews described in the current and near-term evidence objectives. It is envisaged that this will comprise of both R&amp;D &amp; non R&amp;D and will include provision of support for the development of novel methods for disposal of ABPs, e.g. anaerobic digestion. We will also consider social research to explore public perceptions to inform the development of future policy regarding increased use of food waste in animal feed. This will be taken forward in collaboration with other parts of Defra.</p>

<p>assessing industry and consumer reactions to evolving ABP utilisation.</p> <p>Support the development of alternative methods for use or disposal of animal by-products.</p>	<p>disposal of animal by-products (including fallen stock), such as bio-reduction.</p> <p>Medium Priority- Review the rationale and scientific basis of the microbiological standards for ABPs (R&amp;D).</p>	
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## 4. Meeting evidence needs

### What approach(es) will be taken to meeting evidence needs?

The approach to meeting R&D evidence needs is guided by standard Defra procedures. Prioritisation and specification of research is determined through discussion with policy colleagues (including Scottish Government & Welsh Government), veterinary advisors, disease experts, the Animal and Plant Health Evidence (APHEA) team and livestock industry sector groups as well as being informed by the Animal Health and Welfare Risk Management Cycle<sup>1</sup>. More recently, the Animal Health and Welfare Board for England (AHWBE) has also been involved in high level discussions over evidence needs.

Within the TSE programme, evidence priorities are identified through a number of channels, including:

- The TSE Research Advisory Group is an independent advisory group advising Defra on the scope of its research programme and on the progress of individual projects. The Advisory Committee on Dangerous Pathogens (ACDP) Transmissible Spongiform Encephalopathy Risk Management Subgroup also provides advice on TSE issues.
- Emerging surveillance results from the field are also used to inform future evidence activities.
- Consultation between policy teams, DAs and the evidence team and use of information on emerging national and international TSE issues – using intelligence gleaned from EU and international contacts, industry stakeholders, Non-Governmental Organisations, TSE research scientists and other experts

For Animal By-Products the UK Anaerobic Digestion & Composting Research Network (ADCORN-UK group) meets every few months to update different funders within government across UK on the progress of research activities in their areas. External links to this information is provided to the public via an information portal managed by the Waste and Resources Action Programme (WRAP). There are also close links with Defra's Food Chain Evidence Programme & the Quality and Safety of Feeds and Food for Europe (QSAFFE) consortium, also the Food Standards Agency, WRAP, the DAs and other policy teams within Defra. The exact prioritisation and specification of research needs are determined following periodic discussions with a wide range of stakeholders. Most recently an in-house review of ABP evidence needs was conducted in 2011. Priorities were determined after taking into consideration the Farming Regulation Task Force report recommendations, an assessment (based on feedback from stakeholders and also an in-house assessment) of whether controls are proportionate to the risk and review of potential areas of scientific uncertainty in the ABP regulations. Unless there is a major change in ABP policy, the next programme review of ABP evidence needs is planned for 2015.

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<sup>1</sup> Del Rio Vilas et al, An integrated process and management tools for ranking multiple emerging threats to animal health, Preventive Veterinary Medicine (2013), 108: 94– 102

Once identified and prioritised, R&D and non R&D evidence needs (such as the current review of the burial ban) are either addressed in-house or procured through open competition or direct commissioning, with open competition as the default position. The complexity of the issue under consideration and also the availability of in-house expertise are taken into consideration when deciding what the most appropriate method to gather evidence is. Multi- and inter-disciplinary approaches are used with a range of disciplines (e.g. veterinary, scientific, economics, social science, etc) utilised as appropriate for addressing evidence needs in-house and also for the procurement of evidence needs to contractors with the necessary expertise. All applications are peer reviewed externally (complemented by internal expert review) regardless of procurement route. Internal expert review engages appropriate policy colleagues, DAs, veterinary experts, scientists and, where appropriate, social researchers to ensure that all proposed research is challenged for policy relevance in line with government strategic objectives. External peer review engages academic experts as well as industry representatives to ensure there is both academic as well as operational challenge to all proposed research.

R&D projects are monitored by annual reports, site visits and by advisory groups for larger projects that require a greater Defra and/or stakeholder steer. This close relationship also allows feedback of changing policy priorities to the researchers during a project (which can allow for projects to be adjusted if necessary). In addition final reports are peer reviewed where appropriate and revised if necessary prior to publication on the Defra web-site. Researchers are also strongly encouraged to publish their results in peer reviewed journals. The goal is to fund high quality scientific research that informs policy decisions.

Defra engages in a range of international fora for the purposes of information exchange and research coordination and participation in, for example, the European Research Area network (ERA-NET) and the EU framework programme. This approach has levered significant funds from EU organisations. The ERA-Net has resulted in a total expenditure of approximately €45M of which Defra contributed approximately €5M, in support of two research calls. This kind of coordinated approach facilitates international collaboration, thereby increasing the availability of expertise from other national research groups and maximising the benefits to individual participants.

Defra also engages for the development of alternative methods for use or disposal of animal by-products with key external partners such as the ABP industry as they have a commercial interest in the development & adoption of new methods.

## 5. Evaluating value for money and impact

### **What approach(es) will be taken to maximise and evaluate value for money and impact from evidence?**

R&D is procured according to the Evidence Handbook and is subject to internal expert input and external peer review that provides an independent scientific challenge.

An effective multi- and inter-disciplinary approach to fulfilling evidence needs is ensured through use of relevant expertise, advisory bodies and collaboration with other funding bodies (e.g. the Biological and Biotechnology Science Research Council) both in GB and externally. There is also increasing engagement internally with teams such as the Animal and Plant Health Evidence and Analysis (APHEA) team, which offer expertise in economic analysis and social science advice. This alongside external peer review ensures robust and high quality evidence in R&D evidence.

Furthermore, value for money is ensured through peer review of all project proposals received (value for money is a specific question we ask peer reviewers to consider) and close monitoring of projects to ensure the project does not drift off course and also that researchers can, when feasible, adjust projects mid-stream in the light of new findings and/or changing policy priorities.

The evaluation of evidence in Defra is an important and continuing activity at project level and contributes toward ensuring that good quality, robust evidence is used to underpin departmental policy.<sup>2</sup> Evaluating the impact of evidence on policy development is complex and often only possible over the long term. Evaluation will necessarily be linked to Defra's Evidence Investment Strategy, which provides a strategic overview of how evidence fits with Defra needs. Programme level evaluation to assess the impact of evidence on policy will be explored (depending on available resource) following publication of the new Evidence Investment Strategy. It will be important that evidence currently being explored will have time to make an impact and for any new direction emerging from the new Evidence Investment Strategy to be tested and incorporated.

Project specific dissemination strategies are developed at the start of every project to ensure effective communication including how the evidence generated from the work will be used by policy, how stakeholders will be involved and how knowledge will be retained and promoted. Each project is also evaluated once completed with regard its delivery, timeliness and policy impact either through internal or external review.

Evidence also feeds into the development of guidance documents for the industry & the public, and where appropriate, is disseminated directly to the industry and stakeholders via meetings and workshops.

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<sup>2</sup> <http://archive.defra.gov.uk/corporate/docs/policy/evidence-policy-report.pdf>

Policy objectives are regularly tested through discussions with internal and external stakeholders (through expert groups). European and international institutions, other Government Departments and Devolved Administrations are also used to inform policy development and implementation.

Recent examples of the impact evidence has had on ABP policy development include the relaxation of UK national rules (and harmonization with EU requirements) on use of Category 2 mammalian meat & bone meal as fertiliser, and the identification of thermo-resistant viruses posing a relevant hazard in Category 3 ABPs used as raw materials in composting and biogas plants which may be used in the validation of composting and anaerobic digestion processes using alternative transformation parameters.