

## BOVINE TUBERCULOSIS EVIDENCE PLAN 2011/12

Evidence Plans are part of Defra's business planning processes. They have been developed for each policy programme, ongoing function or hub with a substantial evidence base

The main purposes of Evidence Plans are to help Defra policy and evidence teams to:

- Maintain a clear 'line of sight' between policy objectives and evidence needs;
- Ensure best use of others' evidence and maximise opportunities for partnerships;
- Show a clear rationale and value for money for Defra investment in evidence;
- Prepare for policy evaluation.

### 1. POLICY RATIONALE

#### 1.1 Policy context

Bovine TB is a pressing animal health problem. It is predominantly a disease of cattle but can affect a range of species including man. Bovine TB is a statutory disease and has been subject to a compulsory control scheme based on skin test and slaughter of reactors, meat inspection and milk pasteurisation since 1950. There is a significant reservoir of the disease in badgers which has hampered TB control in cattle and current diagnostic tests are not sufficiently sensitive to detect all infected cattle in a herd.

The incidence rate of bovine TB in cattle in England and Wales has been rising for 25 years and has worsened since the 2001 Foot and Mouth Disease outbreak. The area affected by bovine TB has spread from isolated pockets in the late 1980s to cover large areas of the West and South West of England and Wales. In 2009, over 25,000 cattle were slaughtered for TB in England.

The cost to Government of controlling bovine TB in England was over £63 million in 2009/10 (excluding R&D). These costs are rising year by year so there is a strong case for early effective action to turn this around. The farming industry and Government need to work in partnership to achieve eradication of bTB which would provide the following benefits.

- Protect the health of the public and maintain public confidence in the safety of products entering the food chain.
- Protect and promote the health and welfare of animals.
- Meet our international (in particular EU) and domestic legal commitments and maintain the UK's reputation for safe and high quality food.
- Maintain productive and sustainable beef and dairy sectors in England securing opportunities for international trade and minimising environmental impacts.
- Reduce the cost of TB to farmers and taxpayers.

While eradicating bovine TB is our long term goal, additional measures are needed now to stop the disease spreading and to start to reverse the rising trend.

The Coalition has committed, as part of a package of measures, to develop affordable

options for a carefully-managed and science-led policy of badger control in areas with high and persistent level of bovine TB. TB is therefore a high priority for ministers.

There is no single solution to tackling bovine TB – we need to use every tool in the toolbox. Measures aimed at tackling transmission of the disease between cattle will continue to be central to the bovine TB control strategy and need a comprehensive and balanced package of measures to tackle bovine TB. This strategy will include measures to find and control the disease in cattle, measures to control the disease in badgers and focused research and development.

Policy Objectives – Prevent spread of bTB to new areas; Rapidly eliminate TB when it occurs in a low risk and incidence area; Bear down on bTB in high risk areas.

Intended Outcomes – Avoidance of human health impacts and associated costs; Avoidance of agricultural production losses; Delivery of reduced costs to the tax payer for TB surveillance and control; Delivery of social and economic benefits to farmers, farming families and rural communities and economies by reducing the impact on farm businesses and ensuring freedom to trade; Increased appreciation and investment in farm husbandry and bio-security measures by the industry; Improvements to the credibility of the bTB surveillance and control programme leading to improved partnership with industry and the EU.

Notes:

Please note that Animal Health and the Veterinary Laboratories Agency (VLA) will merge on 1-4-2011. This evidence plan still refers to each of them separately to outline the different roles the two agencies have played in bTB evidence and control.

This evidence plan reflects the current priorities of Defra and does not necessarily reflect the priorities of the Welsh Assembly Government although we endeavour to work closely together where possible.

## **2. CURRENT STATE OF KNOWLEDGE, INVESTMENT AND FUTURE REQUIREMENTS**

### **2.1 Current state of knowledge**

*Please also [annex key references](#).*

The Bovine TB Programme is based on a strong evidence base and a good understanding of the key issues to be resolved in policy development, but there are also many remaining uncertainties. We know that TB is spread by the movement of infected cattle between herds, by within herd cattle to cattle infection and by infection of cattle from badgers. Further, we also recognise that the current TB surveillance and control regime in cattle (based on test and slaughter of reactors) is not preventing the spread of TB to clean areas, and that the incidence of disease in endemic areas appears to be increasing. Vaccination of cattle against TB is currently prohibited under EU law because it interferes with the primary diagnostic test for TB, the tuberculin skin test, and

therefore requires the development, validation and acceptance of a reliable diagnostic test to Differentiate between Infected and Vaccinated Animals (a so-called 'DIVA' test).

There are several other countries in which bovine TB is present in the wildlife population. A smaller number have a true wildlife 'reservoir', in which the wildlife population can sustain TB infection on its own, regardless of TB levels in cattle. Of those countries which have successfully eradicated TB from cattle, only Australia is known to have had a longstanding wildlife reservoir. Australia achieved TB eradication through stringent cattle controls, combined with a control programme targeting the feral buffalo reservoir. In other countries, such as the USA and Canada, a significant wildlife reservoir only became evident when TB was nearing eradication, making it necessary to introduce further control measures in certain regions. Countries outside Great Britain with a known wildlife reservoir include Northern Ireland, the Republic of Ireland, Spain and New Zealand. These countries have not been able to eradicate TB, although New Zealand has made substantial progress towards this.

While bTB does occur in wildlife species other than badgers in the UK they are not considered a significant source of infection to cattle or other livestock although this aspect of the epidemic is kept under review.

Scientific evidence indicates that in areas with high incidence of bovine TB in cattle, it will not be possible to eliminate the disease in cattle without addressing the disease in badgers. There are two main ways to control the disease in badgers: culling and vaccination.

The Randomised Badger Culling Trial (which ran from 1998 to 2007) has shown annual proactive culling over an average of 5 years will reduce the number of new confirmed cattle herd breakdowns within the culled area but cause increases outside of the culling area during the culling period due to the 'perturbation effect'. The number of badgers that can be removed before social territories are disrupted and this perturbation effect is observed is unknown.

An injectable badger vaccine - BadgerBCG - was licensed by the Veterinary Medicines Directorate in March 2010. Use of this vaccine in the field during the Badger Vaccine Study caused a 74% reduction in the number of badgers that tested positive to a serological test associated with progressive disease in vaccinated versus unvaccinated control groups. An oral badger vaccine formulation and bait delivery system are still under development.

Current badger diagnostic tests are not sensitive enough to routinely reliably identify infected badgers or setts containing infected badgers. Furthermore the most sensitive tests require a blood sample, and therefore anaesthetising the animal first, limiting their practical value. This currently prevents us from considering a selective cull/cull-vaccinate policy. There is considerable interest in whether PCR-based tests could be developed to identify infected setts.

Any culling technique must be supported by evidence that it is effective and humane for use on badgers, which currently is likely to be to cage trap and shoot or shooting free-ranging badgers. For whole sett killing, uneven distribution of a gas (carbon monoxide,

carbon dioxide or inert gasses such as nitrogen and argon) in a badger sett carries a high risk of exposing badgers to sub-lethal doses which could lead to long term and serious side-effects for the affected badgers potentially causing 'cruel ill-treatment' and thus contravening the Protection of Badgers Act 1992. It is still not currently known whether it is possible to ensure distribution of a gas at a lethal concentration to all parts of a badger sett for the required length of time and substantial further work needs to be carried out in this area should this option need to be pursued.

## 2.2 Primary objectives of evidence activities

### **bTB Research Programme**

The Animal Health and Welfare research budget covers England and Wales and we work closely with our colleagues in the Welsh Assembly Government. Most of the research we fund is applicable to both Wales and England with only a few projects specifically dealing with issues related to England.

The bTB research programme is centred on four areas of research:

#### *Vaccines*

Vaccination of cattle and/or badgers is an important long-term option for reducing the risk of bovine TB in England. A substantial part of the Defra research programme focuses on the development and licensing of badger and cattle vaccines and the total investment in vaccine development from 1998 has reached more than £30m. An injectable BCG badger vaccine was the first licensed vaccine product available from the vaccines research programme.

The aim of the current programme of research is to achieve efficacious, licensed vaccines for use in cattle and a licensed oral badger vaccine within the shortest timeframe possible. Cattle vaccines that do not sensitise animals to the skin test are a longer-term research goal.

#### *Diagnostics*

In order to control bTB more sensitive and specific cattle tests are required, particularly a DIVA test that can distinguish between an infected and vaccinated animal to accompany the BCG-based cattle vaccine, as described above.

Sensitive badger diagnostics also need to be developed in order to allow us to assess the geographical scale of the wildlife reservoir and also to possibly make informed judgements in applying control methods, for example to support a selective culling policy or inform the effectiveness of a wildlife vaccination programme. This includes both non-invasive tests to identify infected badgers, e.g. work to develop more sensitive diagnostics and development of non-invasive blood sampling devices, and tests to identify setts/areas where infected badgers are resident, e.g. development of PCR-tests to detect *M. bovis* in environmental samples including faeces and air.

#### *Epidemiology and wildlife risks*

There is a continuing need for work to help better understand the epidemiology of the disease and the interaction within and between cattle and badgers, including the development and use of mathematical models, to inform the development, application, assessment and review/evaluation of TB policy control tools. Much of the data for epidemiological analysis comes from the statutory surveillance of cattle herds (see note

at the end of section 2.2. and items 8 and 10 of the VLA bTB Surveillance Contract in section 2.3). Work is also required to identify other methods of monitoring and controlling the epidemic, e.g. improved genetic analysis/spoligotyping of isolates and understanding the genetics of resistance in cattle.

#### *Economic and social science aspects*

Social science research on factors influencing likely uptake or support of control tools (e.g. badger culling, badger and cattle vaccination, enhanced biosecurity measures and changes to cattle testing) is required if such control tools are to be successfully employed. Economic and social research will also inform our understanding of farmers' attitude and behaviour in relation to TB and help us understand the disease as an economic and social problem. Social science will also aid the development and delivery of policy: helping to build relationships with the farming community; informing our communication strategy; and contributing to the evaluation of policies.

#### **VLA bTB Surveillance Contract and Fera Service Level Agreement (bTB in wildlife: Policy support and implementation)**

The broad primary objectives of the VLA bTB Surveillance Contract and Fera Memorandum Of Understanding (MOU) policy support/surveillance programmes are to support the delivery of GB wide TB controls by AH and provide advice/consultancy on e.g. epidemiology and analysis of surveillance data, delivery of control tools etc to FFG for TB policy development.

**IMPORTANT NOTE:** The Evidence Plan does not include the substantial cost (~£30m/annum) of the current statutory routine TB surveillance regime of animal sampling (tuberculin skin test, gIFN testing and slaughterhouse surveillance) which is required to confirm that herds are free of TB (qualify for TB-free status) or to detect disease for TB control (i.e. herds have their TB-free status suspended or withdrawn). This regime is delivered by Animal Health (AH) and the Food Standards Agency. It is not possible to disentangle the amount spent on surveillance versus control, and inclusion of these costs substantially skews the amount we appear to spend on evidence for the TB Programme. Furthermore, this surveillance and control regime is compulsory and therefore the evidence benefits from surveillance (whilst valuable) are incidental and the costs are non-negotiable so fall outside the remit of the Evidence Plan.

The data collected through surveillance is continually analysed as part of the ongoing analysis of surveillance data carried out by the VLA and forms the basis for most of the epidemiological modelling of the epidemic and assessment of the effect of policies.

### **2.3 Current investment in evidence**

Following the recommendations made in the 1997 Krebs review of bovine TB in cattle and badgers, the TB evidence programme has been built up and from 1998-2007 included the £48m Randomised Badger Culling Trial, which provides the most substantial piece of evidence we have on the role of badger culling in the control of bTB in cattle.

The evidence spend can be divided into research spend and the non-research evidence contracts with the VLA and Fera.

#### **Research**

The spend on research in 10/11 can be broken down into vaccines, diagnostics, epidemiology and wildlife risks and social science, although many projects cover two or more areas. There has been shift in emphasis towards vaccine development and licensing from 05/06 onwards and 79% of the total research budget is now focussed on this.

*(1) Vaccines (79%)*

Work is under way at the VLA and Fera to develop an oral vaccine and bait delivery systems for badgers in collaboration with commercial partners and researchers in New Zealand and Republic of Ireland (RoI), as this will be the most practicable application of a vaccine to a wild population. This will require the development of innovative methods to produce an oral bait palatable to badgers while maintaining the effectiveness of the live vaccine. We are also funding research projects to investigate immunological predictors of protection against tuberculosis in badgers and to carry out further numerical analysis of data collected during the Badger Vaccine Study – a 4 year field safety study (2006-2010) using the injectable BCG vaccine in a wild population of badgers – to inform estimates of efficacy and feed into modelling work to make more accurate predictions of the effects of control strategies.

The VLA are also carrying out research looking at new cattle vaccine candidates and delivery protocols, in collaboration with research in New Zealand. Work to support the BCG vaccine licence application for use in cattle is underway. Vaccination of cattle against TB is currently prohibited by EU legislation because the lead candidate vaccine BCG interferes with the primary TB diagnostic test, the tuberculin skin test. Research is also continuing on the development and validation of innovative diagnostic tests required to Differentiate Infected from Vaccinated Animals ('DIVA' tests) as vaccines based on BCG will potentially make cattle react to the current tuberculin test as if they are infected with *M. bovis*. Research is also under way on the development of an innovative new class of vaccines which will not sensitise animals to the skin test. Work is also underway to try and elucidate the relevance of tuberculin skin reactivity post-vaccination for protection.

*(2) Diagnostics (10%)*

This includes work to develop a rapid, specific and sensitive test to detect *M. bovis* in cattle at slaughter using immunomagnetic separation in combination with a phage amplification assay (IMS-phage) and the development of a PCR test and optimal sampling strategy to detect *M. bovis* in badger faecal samples.

In addition to research to develop a 'DIVA' test described above, the VLA is also carrying out work to validate new serological tests for bTB in cattle and a meta-analysis of diagnostic tests and modelling to identify appropriate testing strategies to reduce *M. bovis* infection in GB herds.

*(3) Epidemiology and Wildlife Risks (10%)*

This includes the long term intensive epidemiological and ecological investigation of the badger population at Woodchester Park and five projects commissioned to carry out a further spatial and temporal analysis of the RBCT data sets.

Work is also under way to provide evidence of a genetic basis for resistance of cattle to infection with *M. bovis* and for reactivity to currently used immunological diagnostic tests and to investigate the molecular basis and impact on host response of phenotypic variation across *M. bovis* molecular types continues.

Work to exploit the geographical localisation of *M. bovis* genotype and develop the use of 'homerange maps' to assist Animal Health with the epidemiological investigation of herd breakdowns (previously funded through the VLA bTB Surveillance Contract) continues.

We have funded the development and use of three models to predict the impacts of various control strategies on TB incidence. Two of these are at the VLA: a generic non-spatial extension of Cox's simple model for TB in cattle and badgers, which considers the effect of control strategies at a National level; and development of a new model to predict the impacts of multiple interventions and their interactions in the control of bTB in England and Wales using a spatially explicit dynamic model. The third is a mechanistic spatial model of badger TB developed by Fera which predicts effects at the local level and is being used to model various vaccination strategies, including the use of various combinations of vaccination and culling compared to either culling or vaccinating alone.

A project is also underway which aims to characterise, predict and provide suggestions for the resolution of so-called 'problem herds' i.e. herds undergoing prolonged or repeated TB breakdowns.

Research on the effect of removing badgers from an ecosystem has been carried out in the past during the RBCT, and any similar operations in future would also be assessed for environmental impact. We also liaise closely with colleagues in Defra's wildlife unit who are currently examining immunocontraceptives as a method of population control of badgers in urban areas.

#### *(4) Economics and Social Science (1%)*

Only one of the projects funded by the R&D programme currently sits in this category, which is a social science project to investigate farmer confidence and attitudes towards the use of badger and cattle vaccines to control TB, both with and in the absence of badger culling.

### **Non-research Evidence contracts**

**The bTB Surveillance Contract with the VLA includes the following ongoing surveillance and advice needs:**

#### *(1) Lab capacity for the gamma interferon testing of cattle blood samples*

Using a diagnostic test for TB that will maximise the number of animals correctly identified as test positive. This work aims to:

- Use the BOVIGAM Interferon Gamma (IFN- $\gamma$ ) test by applying it to samples submitted by Animal Health, in compliance with policy guidelines;
- provide IFN- $\gamma$  testing capacity for ~30k tests per annum;
- provide data management and on-going analysis of data; and
- provide epidemiological and test consultancy support.

#### *(2) Provision of Tuberculin*

Manage the supplies of bovine and avian tuberculin to enable the national GB and NI TB herd monitoring programme of skin testing to be successfully maintained. It achieves this by providing guidance and advice to Defra on the management of the "Contract for the Manufacture and Supply of Avian and Bovine Tuberculin PPD – RMP5380" between Defra and Prionics (Formerly DLO Holding B.V), including receiving, storing and distributing tuberculin in accordance with Good Distribution Practice (GDP).

### *(3) Support for molecular epidemiology*

This project supports the National TB Control Programme by providing molecular typing data and analysis, and molecular epidemiological expertise in the area of bovine tuberculosis in cattle, badgers and other species. The project aims to:

- Develop molecular epidemiological surveillance data (spoligotyping and VNTR typing) on the status of *M. bovis* infection in cattle and other mammals within GB;
- provide descriptive analysis of the national and local incidence of molecular types of bTB, including spatial and temporal disease trends;
- provide molecular epidemiological identification and monitoring of potential sources of infection for cattle including from abroad;
- provide support for Defra in meeting the policy needs;
- provide in depth analysis of the molecular typing data sets to derive fundamental and reliable data for effective policy decisions. Exploiting the molecular data to provide advice on possible improvements to the tuberculosis control programme;
- develop an internationally approved system for identifying *M. bovis* genotypes, to monitor *M. bovis* genotypes Internationally, to facilitate international communication and the speedy recognition of imported strains; and
- to maintain world-class expertise in molecular typing and epidemiology and to investigate, recommend and implement improvements to genotyping.

### *(4) TB vaccination models*

Several models of TB epidemiology and control are already available, with various approaches and strengths. A proposal for development of a spatially explicit model at the resolution of individual holdings has been submitted. However, assuming development of the new model proceeds, the existing model will need to be available to respond to requests for model predictions during development of the new model. The new model will be used to respond to requests for modelling support as early as possible. This project aims to provide:

- TB model runs and interpretation in response to urgent requests;
- peer review of recent TB modelling at VLA; and

maintenance of a catalogue of existing bovine TB models and knowledge about current TB modelling.

- *Archiving of badger research samples and data management*

The purpose of this project is to maintain an archive of samples collected during the Randomised Badger Culling Trial (RBCT), Badger Vaccine Study (BVS), and Vaccine Efficacy Studies (VES) and respond to requests for data or samples by researchers or non-governmental bodies.

### *(5) Gamma Interferon Assay: Inclusion of ESAT-6/CFP-10 and new tuberculins into routine testing*

This project aims to:

- compare performance of the ESAT-6/CFP-10 peptide cocktail (EC) with that of Weybridge PPD-B/A to support OIE validation process;
- compare performance of EC and Rv3615c peptide cocktails with new tuberculin set; and
- gain operational experience of using EC and Rv3615c alongside tuberculin.

### *(6) Marketing Authorisation Holder for injectable BCG vaccine for badgers*

The MAH for the use of injectable BCG vaccine in badgers in the UK is the VLA. This project aims to manage the Limited MA for injectable BCG vaccine in badgers, across

multi-disciplinary groups both internal and external of the Defra organisation.

*(7) Surveillance for BTB – Infection status of cattle in Great Britain*

This project aims to provide Defra with:

- Surveillance data about the *Mycobacterium bovis* infection status of cattle herds within Great Britain resulting from i) statutory and voluntary skin testing, ii) slaughterhouse monitoring, iii) mycobacterial culture;
- compliance with the responsibilities concerning notification of suspected and confirmed cases of tuberculosis specified in the Tuberculosis Orders (as amended); and
- advice about possible improvements to the tuberculosis control programme, based on comprehensive, accurate and current surveillance data. This includes the development of a PCR-based test for rapid identification of *M. bovis* in cattle tissue.

*(8) TB in cattle post-mortemed at VLA regional laboratories*

This project aims to provide Defra with a capacity to undertake post mortem examination of cattle with suspected *M. bovis* infection, that cannot be consigned to an abattoir or knackers yard for post mortem examination and a capacity to undertake detailed post mortem examination of cattle reacting to the tuberculin test, where the testing history of the herd suggests that non-specific sensitisation or fraudulent tampering with test results was occurring.

*(9) Surveillance for BTB – Epidemiological consultancy*

This project aims to provide Defra with management and analysis of surveillance data related to the RBCT, TB control in cattle and any badger control initiatives, and the provision of written and verbal advice, and attendance at meetings in support of Defra's development of TB control options, including reviews of different aspects of TB control, contributing scientific input into control initiatives, and other research initiatives where steering groups require VLA staff attendance either as members of the groups or as special advisors or as distributors of scientific information.

*(10) Infection status of companion animals, farmed species (excluding cattle, water buffalo and bison) and wildlife (including hotspot submissions)*

The main purpose of this project is to provide surveillance for TB in mammalian species other than cattle (such as farmed and wild deer, cats, dogs, camelids, goats, sheep and pigs). The project also covers wildlife samples from any Hotspot Survey. Surveillance data will be derived from post mortem examination of carcasses, histopathological examination of tissue samples and mycobacterial culture and DNA fingerprinting of isolates submitted to VLA from a number of sources. Additional objectives include provision of support for Defra in meeting the policy needs; advice about possible improvements to the tuberculosis control programme, based on comprehensive, accurate and current surveillance data; and maintenance of *M. bovis* culture and PCR products collections for isolates from species other than cattle.

**The Fera Service Level Agreement includes:**

*(1) Badger and bovine TB advice and support*

To supply expert advice on badger ecology for policy development. To assist in evidence based policy development for TB Programme.

*(2) Administration of consequential loss schemes for SE3032*

In order to keep goodwill of farmers over whose land Defra requires access for the Woodchester Park project agreement has been given to pay reasonable consequential losses incurred in TB herd breakdowns in cattle, after valuation by an independent third party.

### *(3) Badger Vaccine Deployment Project (BVDP)*

Defra's broad aims for the project are to deploy injectable badger vaccines in a way which: Supports the long-term goal of badger vaccination, including the training of lay-vaccinators; assesses and maximises the viability of badger vaccination and supports its use; and gains farmer confidence in the principles of vaccination. Fera will contribute to these aims by fulfilling the following objectives:

- Recruit livestock farmers to the project on a voluntary basis;
- manage local communications with participating landowners, and contribute to Defra's wider communications efforts;
- maintain data management systems and information website;
- carry out badger sett surveys in project areas;
- develop and update standard operating procedures and additional protocols for trapping and vaccine deployment;
- amend the previously agreed training course as necessary to accommodate the recent changes to the scope of the project. This is in order to deal with issues around ensuring compliance with legal and welfare requirements of trained individuals who are not contracted to Fera;
- contribute to the development of a registration scheme for lay vaccinators to trap and vaccinate badgers, to provide a framework to allow monitoring and auditing of lay vaccinators; and
- trap and vaccinate badgers in the Stroud project area.

The BVDP is set to run from 2009 to 2015, divided into two phases: 'set up' and 'delivery'.

- The 'set up' phase ran from May 2009 to July 2010, when the licensed vaccine became available. This phase covered the transfer of responsibilities from Defra to Fera; development of project protocols, data management and audit processes; sign-up of participants; badger sett surveys; procurement exercise for contractors.
- The 'delivery' phase covers the period between July 2010 and March 2015, when the Stroud area will receive annual vaccination. During 'delivery', Fera staff and lay vaccinators will be trained, accredited and licensed; badgers vaccinated; completion of landowner sign-up and completion of badger sett surveys.

### *(4) Approaches for the use of badger vaccination in combination with culling*

The aim of this work is to utilise current models of TB in badgers and cattle and investigate a variety of combined management strategies and prioritise in terms of expected reduction in herd TB incidence and to assist in evidence based policy development for TB Programme.

## **2.4 Identifying and prioritising new evidence needs**

R&D Programme:

Following consideration of the priorities of the Coalition Government, expectations and requirements of the European Commission (including the TB sub-group of their task force on the eradication animal diseases), advice from our existing external advisory group, internal veterinary advice, the views of the Bovine TB Eradication Group for

England (which advises Ministers on TB policy) and the recommendations of the Society of General Microbiology's 2008 review, we have identified the following as priorities for our evidence programme:

#### High Priority

- Badger oral vaccines;
- cattle injectable vaccines/non-sensitising vaccines;
- cattle diagnostics;
- epidemiology of the disease and modelling of the effect of different interventions;
- understanding the social and economic aspects of our bTB policies on farmers and other stakeholders.

#### Medium priority

- the ecology and behaviour of badgers as pertaining to bTB;
- understanding changes in badger numbers in recent years and badger ecology particularly the effect of low level perturbation on disease transmission to measure the effect of low level culling e.g. selective culling;
- improved methods for detecting infected badgers or infected setts e.g. PCR-based tests;
- development of whole-sett culling methods e.g. gassing;
- development of non-lethal forms of badger control e.g. immunocontraceptives.

The amount of work carried out in these areas will vary depending on the available budget, policy priorities and the success of previous research.

VLA bTB Surveillance Contract: In addition to the ongoing activities described above we are likely to need additional epidemiological analysis of the impact of various badger control strategies i.e. culling and vaccination and possibly work to provide estimates of badger TB prevalence. The surveillance contract also needs to maintain adequate provision for VLA to carry out the validation of any new promising diagnostic assays for bTB in cattle as they become available.

Fera Service Level Agreement: There is a need for badger survey work to be carried out in RBCT proactive and survey-only areas to investigate changes in badger population that could inform policy development and modelling work. We also anticipate a need for Fera's assistance with knowledge transfer (e.g. on wildlife ecology and husbandry measures) in the delivery of the biosecurity element of the Farmer Advice Project.

Meat Hygiene Service (MHS) Service Level Agreement: Improvement of post-mortem surveillance for bTB in all red meat animals slaughtered commercially for human consumption.

Animal Health costs: Need to maintain adequate funds for the anticipated year on year increase in the number of cattle tested.

## **2.5 Secondary benefits of evidence activities**

Funding of oral vaccines will assist the Biodiversity Programme who face similar issues in delivering vaccines to wildlife species to prevent disease or reduce the population humanely through immunocontraception. The knowledge gained on badger ecology will also assist the Biodiversity Programme who are tackling the issue of controlling urban badgers.

The team of scientists at VLA are internationally recognised experts on bovine TB and have amassed significant expertise in the area of vaccination, as have those at Fera on badger ecology. Loss of key personnel from reduced funding would result in a significant delay or jeopardise the delivery of vaccines and diagnostics and be a loss of expertise to the TB Programme as a whole. The current research portfolio mitigates this risk to some degree as there is a sufficient balance of research and development to retain the strategic capacity required to deliver the programme, although as more vaccines licensing work and less fundamental research is commissioned this risk may increase.

## **2.6 Alignment to long-term evidence challenges and Reform Plan objectives**

There is strong alignment with the Defra Business plan ( item 1.3 iii ) which states Defra's intention to, "Develop [...] affordable options for a carefully-managed and science-led policy of badger control in areas of high and persistent levels of bovine TB."

This may initially involve badger culling and/or badger vaccination. The Coalition government are also committed to a package of measures to control and ultimately eradicate bTB. This will require continued investment to achieve a licensed oral badger vaccine, a licensed cattle BCG vaccine and DIVA test.

Bovine TB was originally identified as an area of "continuing research need" in the Evidence and Investment strategy published in January 2010. This has recently (July 2010) been revised into the growing need/high priority area by the CSA.

bTB and other animal diseases fall under the big evidence challenge of a "sustainable food supply" and to a lesser extent under "protecting ecosystem services" and "adapting to climate change". Dealing effectively with animal disease such as bTB also forms part of the department's "licence to operate" to show that we can deal effectively with animal health issues as the "4<sup>th</sup> emergency service."

## **3. INTERNAL CAPABILITIES - USING DEFRA'S EVIDENCE SPECIALISTS**

### **3.1 Range of knowledge disciplines needed**

Veterinary - specialist veterinary expertise, e.g. in epidemiology, state veterinary medicine, public health and infectious disease control.

Scientific - the range of disciplines needed to address bTB include microbiology, immunology, genetics, molecular biology, pathology, ecology, epidemiology and mathematical modelling. Understanding and commissioning the programme's evidence needs, ongoing monitoring and assessment and interpretation of evidence to make relevant to policy development and to practical applications for disease control therefore requires broad scientific expertise.

Social Science - where the success of policies depend on farmers to act in particular ways it is important to understand the motivations and attitudes of farmers therefore we need social science input into policy formulation and communication. We also need to improve trust in Defra among both the public and farmers which also requires input from social scientists

Economics - TB surveillance, control and compensation are very expensive and long-term in accrual of benefit. We therefore need economic expertise in evaluating different policy options.

Operational research- To assist in mathematical modelling and options appraisal.

### **3.2 Access to internal specialists**

TB evidence expertise is provided by vets and scientists from a range of disciplines integrated in the Bovine TB Programme plus scientists in the Veterinary Research Unit and Biodiversity Programme plus economic advice from AHW economists. We have recently (August 2010) been assigned some social scientist resource.

### **3.3 Future resource needs and filling gaps in expertise**

The biggest need is for some dedicated time from a social scientist to bTB. Given the social and economic complexity of bTB and the move from “Big government” to a “big society” we need to focus more effort in winning hearts and minds rather than imposing regulations, as this will require a culture change on our part we need support on social science issues. The recent allocation of 30% of the time of a social scientist should help greatly.

## **4. EXTERNAL KNOWLEDGE SUPPLY AND PARTNERS**

### **4.1 Strategic external capabilities and suppliers**

Research and Development: is largely carried out at the VLA and Fera. We currently also fund researchers come from Universities (e.g. Warwick, Cambridge, Bristol, Glasgow and Queens University, Imperial College London and the University of West England), research institutes (e.g. the Roslin Institute) and occasionally the private sector (e.g. manufacturers of the IDEXX test).

Surveillance: is carried out by the VLA, with Animal Health and the Meat Hygiene Service.

### **4.2 Leverage and partnerships**

Research: The BBSRC fund many projects on more basic research into bTB. Defra utilises the Government Partnership Award mechanism to offer partial funding to projects of interest to Defra which have applied to the BBSRC as well as monitoring relevant results from current BBSRC projects.

The Economic and Social Research Council are also a source of funding of projects related to bTB evidence and most recently have funded several bTB related projects through the interdisciplinary Rural Environment and Land Use programme.

As bTB is currently not a significant public health or food safety issue there is relatively little contact with the Department of Health or the Food Standards Agency (FSA) on research issues. The Health Protection Agency (HPA) has been asked for advice on a number of occasions.

The Veterinary Research Unit lead on the Animal Health European Research Area NETWORK (ERANET) which allows coordination of animal health research across European countries. While currently there is no bTB research funded through this ERANET there may be scope for cross-governmental approaches in future.

Research knowledge is shared with other countries particularly Ireland, New Zealand

and Spain who have a significant and/or growing wildlife reservoir of disease, to ensure that research programmes are complementary rather than duplicative. We actively collaborate with Ireland and New Zealand on oral vaccines research and are jointly negotiating on commercial issues. Matched funding is also provided for some EU funded TB vaccines research at VLA.

Surveillance: EU through participation in Commission's Task Force and other EC means. A TB Eradication Plan has been approved, along with EU funding, by the Commission for 2010. VLA provide OIE representation and act as an EN reference laboratory for bTB. A link with the HPA and FSA is maintained through the TBP veterinary team on surveillance issues to do with human health.

#### **4.3 Use and value of advisory bodies and external specialist advisers**

TB research and research-based components of both the VLA bTB Surveillance contract and Fera MOU are informed by the advice of the bTB Science Advisory Body. This was established in 2008 when the Independent Scientific Group on Cattle TB (ISG) had been disbanded with the remit :

- To provide independent expert oversight of Defra-funded bTB research, identify gaps in our evidence base and to provide independent advice on the strategic direction of, and priorities for, all Defra-funded bTB-related research.

When requested:

- To provide independent expert scientific advice on bTB to Defra, drawing on Defra's bTB science activities, their relationship with Defra's bTB policy goals, and the wider UK and international science base; and
- To provide independent interpretation of bTB-related science.

The bTB SAB consists of four independent scientists and is Chaired by Prof. Quintin McKellar. The other three members in turn chair three sub-groups which focus on Vaccines, Diagnostics and Epidemiology and Wildlife Risks. Each sub-group meets at least twice a year.

At bTB SAB and TB SAB sub-group meetings, research needs are discussed and refined. Ongoing research projects are also scrutinised at meetings and so the bTB SAB and its sub-groups act as a "continuous peer review" function. The implications of recent results from Defra funded and other research are also discussed. We also use independent experts ad hoc for peer review and advice outside bTB SAB, where appropriate.

To date the bTB SAB has focussed mainly on project level and tactical issues as the main policy aims were clearly identified but with the recent change in bTB policy they can now play a more strategic role as the new policy is developed.

One member of the sub-group is also an independent consultant on the vaccines projects and advises Defra on vaccine licensing issues. This is essential as there is little commercial interest in licensing a badger or cattle vaccine and therefore Defra has to lead on the licensing of these products.

We also rely on opinion from veterinarians, scientists and policy makers in Animal Health, Natural England, Food Standards Agency (including the Meat Hygiene

Inspectorate), Welsh Assembly Government, Scottish Government, Department of Agriculture and Rural Development (NI) and Department of Agriculture Fisheries and Farming (RoI) to help ensure our surveillance and research programmes are relevant, robust and offer value for money.

## 5. MEETING NEW EVIDENCE NEEDS

### 5.1 Overall approach to meeting your evidence needs

Our overall approach to meeting our research needs is guided by standard Defra procedures.

The exact prioritisation and specification of research needs will be determined following discussions between TB programme staff, VRU staff and the bTB SAB plus input from ministers on specific topics they want addressed. We also canvass researchers themselves for research ideas and consider both solicited and unsolicited concept notes on an ad hoc basis.

Research needs thus identified will be procured either through open competition or direct commissioning with open competition as the default position. All applications will be peer reviewed externally regardless of procurement route.

Final reports will be 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 and also maintains expertise in TB science in the UK.

Project level - Projects are monitored by annual reports, regular site visits and also by inviting project leaders to present to the appropriate bTB SAB sub-group. Some large projects will also have dedicated steering groups depending on the perceived need for more scrutiny/communication with policy colleagues if resources allow.

Programme level –The entire bTB research program is due for review in 2011.

#### Addressing the questions posed by the guidance

*How will you ensure, where appropriate, a multi- and inter-disciplinary approach to your evidence activities?*

The bTB Science Advisory Body is composed of experts from natural sciences, economics and social sciences who will also advise on where a multi- or inter-disciplinary approach is needed. They have said that bTB needs a more coherent strategy on the role of social science in informing Defra's TB policies. The multi-disciplinary integrated team in both TB Programme and VRU ensures a broad and relevant approach to our evidence gathering and interpretation.

This will result in a clear description in the specification of research needs and of the approaches expected with a clear outline of how researchers will work together.

*How will you ensure value for money from your investments?*

Commission of research via Open Competition generates a competitive bidding process that helps reduce the cost of individual research projects. Peer review of all projects (Value for Money is a specific question we ask peer reviewers to consider) and close monitoring of projects also ensure that the project does not drift off course and that researchers can, when feasible, adjust projects mid-stream in the light of new policy priorities. Close engagement of the policy team ensures that relevant research is commissioned.

*When deciding evidence priorities, how will you ensure risks are adequately assessed and addressed?*

All research is inherently risky and a balance needs to be struck across a research portfolio between short-term projects to address immediate needs and longer term projects which lay the foundations for short urgent pieces of work to address specific policy needs and also between low risk projects that may not be very insightful and more ambitious projects which carry a higher risk of failure.

Using independent advice and internal expertise decisions are taken on how crucial a particular project is to the overall programme and the consequences of a failure to provide a result or the implications of Defra basing decisions on an erroneous result.

To mitigate these risks, regular monitoring of projects is carried out to determine if they are on track in terms of deliverables and also if the quality of the output is fit for purpose particularly as the purpose may have changed from the time when the project was commissioned.

Other risks that are considered in creating and managing a research portfolio include the possibility of an unexpected result that contradicts the status quo and possibly Defra policy. Such results should be seen as opportunities and courage is needed not to shy away from asking questions that could lead to awkward answers.

*How do you see existing links with other funders/partners developing, and what additional partnership opportunities might you explore? How will you measure the success of partnership working in the future?*

bTB is a statutory disease primarily of concern to Defra, but we will work closely with the BBSRC who fund less applied research in this area and will seek to influence their funding of bTB related work through offering partial funding of BBSRC proposals through Government Partnership Awards. VRU lead on the Animal health European Research Area NETWORK (ERANET) which allows coordination of animal health research across European countries.

Outside of formal networks opportunities lie with countries with similar bTB issues to the UK most notably Ireland, New Zealand, the USA and Spain who also have wildlife reservoirs to a similar or lesser extent than the UK. We have been collaborating for several years with the Irish government and New Zealand researchers on the development of oral badger vaccines, and with New Zealand researchers on cattle vaccines.

*How will you assure yourself of the quality/robustness of the evidence you invest in directly and evidence you use from other (internal and external) sources (Annex A provides prompts on processes/procedures to consider when assessing evidence*

quality)?

The scientific quality of our research is assessed by peer review before during and after the project by our advisory group internal experts and additional external peer reviewers as necessary.

*How will you ensure evidence is used appropriately to inform your policy area and communicated effectively to appropriate customers? How will you evaluate the impact of evidence you invest in?*

Extensive meetings between contractors, Veterinary Research Unit and TB Programme to ensure that project results are transmitted and where appropriate interpreted for use in a policy context. This close relationship also allows feedback of changing policy priorities from TB Programme to the researchers during a project which can allow for projects to be altered.

*How will you ensure the collection of information to help evaluate whether or not the programme, ongoing function or hub has delivered its objectives*

**Policy Objectives** – Prevent spread of bTB to new areas; Rapidly eliminate bTB when it occurs in a low incidence area; Bear down on bTB in high risk areas.

**Intended Effects** – Avoidance of human health impacts and associated costs; Avoidance of agricultural production losses; Delivery of reduced costs to the tax payer for bTB surveillance and control; Delivery of social and economic benefits to farmers, farming families and rural communities and economies by reducing the impact on farm businesses and ensuring freedom to trade; Increased appreciation and investment in farm husbandry and bio-security measures by the industry; Improvements to the credibility of the bTB surveillance and control programme leading to improved partnership with industry and the EU.

The major measurable output in the success of the bTB programme is the incidence and severity (e.g. number of reactors, duration) of confirmed cattle breakdowns and this data is routinely collected in the TB control schemes. It is extremely difficult to assign any changes in incidence to one particular policy out of the suite of controls applied to bTB although estimates could be made.

More concrete deliverables from the bTB research program over the next 5 years are: a licensed cattle vaccine and validated DIVA test and a licensed oral badger BCG vaccine. The development of these products is contingent on the effectiveness of the BCG vaccine in trials and, in the particular case of the oral vaccine negotiations with suppliers of particular formulations. The research programme also endeavours to deliver a validated PCR test, although this is dependent on improving the sensitivity of the sampling regime.

## **5.2 Evidence investment forecast**

The maintenance of a high level of investment in bTB is required, particularly for the development and licensing of vaccines and diagnostics that are needed to implement control policies. There is currently no incentive for the pharmaceutical industry to invest in this area.

**Annex****Key references supporting the current state of knowledge** [\[Return to Section 2.1\]](#)

Krebs, J. R., Anderson, R., Clutton-Brock, T., Morrison, I., Young, D., Donnelly, C., Frost, S. and Woodroffe, R. (1997). Bovine tuberculosis in cattle and badgers. London, MAFF Publications, PB3423.

<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/publications/krebs.htm>

The Independent Scientific Group which co-ordinated the Randomised Badger Culling Trial published its final report in 2007.

[http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/isg/report/final\\_report.pdf](http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/isg/report/final_report.pdf)

On-going analyses of data from RBCT areas have been published by Jenkins et al (2010).

<http://www.plosone.org/article/info:doi/10.1371/journal.pone.0009090>

The Society for General Microbiology review of bTB research 2008

<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/tb-report.pdf>

The bTB Science Advisory Body report to the CSA and CVO 2008

Details of on-going and final reports of completed R&D projects funded by the TB R&D programme are available on the website.

<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/current-research-projects.pdf>

<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/research/projects.htm>

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