



House of Commons
Environment, Food and Rural
Affairs Committee

**Badgers and cattle TB:
Government response
to the Committee's
Tenth Report of
Session 2007–08**

**Sixth Special Report of Session 2007–
08**

*Report, together with oral and written
evidence*

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Environment, Food and Rural Affairs Committee

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Mr David Drew (Labour, Stroud)
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Taken before the Environment, Food and Rural Affairs Committee

on Wednesday 5 November 2008

Members present

Mr Michael Jack, in the Chair

Mr Geoffrey Cox
Mr David Drew
Mr James Gray
Lynne Jones
David Lepper
Miss Anne McIntosh

Mr Dan Rogerson
Sir Peter Soulsby
David Taylor
Paddy Tipping
Mr Roger Williams

Badgers and cattle TB: Government Response to the EFRA Select Committee's Tenth Report of 2007–08¹

INTRODUCTION

1. The Government welcomes the opportunity to provide further information to the EFRA Select Committee in response to their inquiry into *Badgers and cattle TB: the final report of the Independent Scientific Group on Cattle TB*.

2. The Government has made clear in the Secretary of State's statement to the House on 7 July 2008 that it fully recognises the seriousness of bovine TB in England. From discussions with a number of farmers who have been affected by bovine TB the Secretary of State and Defra's Ministerial Team are in no doubt about how difficult life is for those living with the disease. The Committee suggested that the Government's contention that bovine TB is a regional disease was being used to play down its seriousness. The Government was stating a fact: high incidence areas are in the South West and the Midlands and for those most seriously affected, the economic and human consequences are devastating.

3. Outside high incidence areas the control framework based on surveillance, testing and slaughter is working effectively. There are, as the Committee's queries suggest, a range of options for expanding this programme by introducing new control measures or different ways of testing, but the degree of impact they would have on disease levels, and whether or not they would offer good value for money, are far from certain. The Government has to consider how best to use the available resources, and strike a balance between disease control and the costs such measures would impose on both the industry and the taxpayer. At present the best available measures are cattle measures. In the longer term vaccination of badgers and, ideally, cattle, will add to the range of tools available within the control programme.

4. The Government rejects the Committee's view that it "is opting out of leadership" and "sub-contracting important decisions" on bovine TB. This is not the case. Leadership in tackling bovine TB is not for government alone, nor is it achieved by government taking unilateral decisions about new cattle control measures. Imposing controls without consultation may be quicker in the short term but it is not the way to make progress on reducing the impact of this disease. The Bovine TB Partnership Group is intended to be exactly that: government and industry working together to take difficult decisions. It is up to industry to decide how quickly the job gets done, and the Government shares the Committee's concern that there might be a delay if the industry declines to participate.

5. This Government remains committed to working to find the best ways to tackle bovine TB, and the best way to do that is in partnership with the industry.

CATTLE MEASURES

6. The Government did not attempt to introduce new cattle measures in July because these decisions need to be made with the industry. Such measures have not been ruled out but the farming industry should have the opportunity to be involved in decision making and that is why, in the Government's response to the Committee, it was stated that they would be discussed by the Bovine TB Partnership Group.

¹ Badgers and cattle TB: the final report of the Independent Scientific Group on Cattle TB: Government Response to the Committee's Fourth Report of Session 2007–08.

Cost Benefit Analysis

7. The Committee asked for details on the initial cost benefit analysis Defra undertook of costs of increased testing and increased use of the gamma interferon test (paragraph 12).² These are provided at Annex A.

8. In summary, the initial analysis suggests increased testing or use of the gamma interferon test would come at a high cost with limited benefits—and would be difficult to justify in terms of government expenditure. For illustrative purposes: the cash costs to Government of skin testing a herd of 60 cattle would currently be in the region of £250, whereas applying the gamma interferon test to the same herd would cost around £1,280.

9. From the results of the analysis, 6-monthly tuberculin skin testing over 20 years would incur costs estimated at £294 million exceeding the projected benefits in the region of £125 million. Even with optimistic assumptions about both its costs and benefits routine use of gamma interferon testing would incur costs (estimated at £1,177 million) far exceeding its benefits (in the region of £125 million). This approach would not be permitted under present European legislation because gamma interferon testing may only be used in addition to the skin test. Therefore, the estimates understate the costs of routine use of gamma interferon.

Understanding of the gamma interferon test and its accuracy

10. The Committee asked for details of the work to be undertaken on increasing understanding of the gamma interferon blood test and its accuracy (paragraph 12). The selection of research projects at Annex B demonstrates that the Government has focused on having a good understanding of the gamma interferon test and this has been disseminated amongst the scientific community. However, the recent judicial review on gamma interferon showed there was much work to do on increasing understanding and confidence in the farming and veterinary communities.

11. Increasing understanding and building confidence in the farming and veterinary communities are about communicating what the gamma interferon test can and cannot do effectively. The Government has already taken some steps through the advice in “Dealing with TB in your herd”, an article in Farming Link and discussions held with veterinary bodies (RCVS, BCVA) and the TB Advisory Group. There is more work to do, the review of gamma interferon, which is scheduled to finish in the autumn, will include recommendations aimed at improving confidence in, and communication of, the gamma interferon policy.

Efficiency of the tuberculin skin test

12. The efficiency of the tuberculin skin test and the factors that affect it are reasonably well understood, and have been evaluated in a large body of evidence published in the international scientific veterinary literature over the years. In its current form the skin test is accepted by the World Organisation for Animal Health (OIE) and the European Commission as the international standard for ante-mortem diagnosis of TB in cattle herds and individual animals.³ From existing evidence the animal-level sensitivity (the proportion of truly infected cattle identified as infected) of the test under UK conditions is estimated to be between 75.0% and 95.5%. Its animal-level specificity of the test (the proportion of non-infected cattle identified as negative) is considered to very high with a median value of 99.5% (78.8% to 100%).⁴ Systematic test and slaughter schemes relying on the skin test in its various guises have achieved eradication of bovine TB in those countries where cattle are the only maintenance host of *M. bovis* infection.⁵ This has been demonstrated in Scotland, the North of England and many EU member states.

13. The actual performance of the skin test under field conditions is dependent not only on the attributes of the test itself, but also on the diligence of the tester in adhering to the correct procedure. This performance is continuously monitored in Great Britain by analysing a number of TB epidemiological parameters in the British cattle population. Additionally, Animal Health is responsible for managing the skin testing regime on the ground, which includes auditing the quality of tuberculin skin testing by veterinarians and approved lay testers.

14. The Committee was interested in details of any further work which Defra is undertaking to assess the efficiency of the skin test (paragraph 12). Defra is not sponsoring at present specific field or laboratory research into the efficiency of the skin test. However, it is clear that reliable estimates of test sensitivity and specificity would facilitate estimation of the number of infected cattle likely to escape detection and the modelling of new, more efficient combinations of testing strategies for bovine TB (within the constraints of EU legislation). In recognition of this, Defra is funding a systematic review and meta-analysis of the diagnostic characteristics of tests for bovine TB. The results of this meta-analysis should inform the development of an epidemiological model of TB surveillance strategies in cattle herds, including optimal

² Paragraph numbers in brackets refer to the EFRA Select Committee Report *Badgers and cattle TB: the final report of the Independent Scientific Group on Cattle TB: Government Response to the Committee's Fourth Report of Session 2007–08, Tenth Report of Session 2007–08* (published on 23 July 2008) which can be found at: <http://www.publications.parliament.uk/pa/cm200708/cmselect/cmenvfru/1010/1010.pdf>.

³ Anon, 2008; de la Rúa 2006a. A list of references is on page 15.

⁴ de la Rúa *et al*, 2006b, 2006c.

⁵ de Lisle *et al*, 2007.

combinations of diagnostic tests to achieve and maintain freedom from infection under different scenarios. A similar methodology has already been applied to the review of diagnostic tests for TB in farmed deer.⁶ The project (SE3238: “Meta-analysis of diagnostic tests and modelling to identify appropriate testing strategies to reduce *M. bovis* infection in GB herds”), led by VLA epidemiologists with support from a working group of international experts, is due to start in September 2008 and should complete early in 2010. Further details of this project are given in Annex E.

THE BOVINE TB PARTNERSHIP GROUP

15. The Government shares the Committee’s concerns (paragraph 13) that discussions and decisions on cattle-based measures could be delayed if industry is not prepared to participate in the work of the Bovine TB Partnership Group. The Government could move ahead anyway, imposing new cattle controls on the industry and even new costs but this is not the way to establish measures that will be effective for the long battle against bovine TB which lies ahead. The Secretary of State has made it clear that control of the disease is not a matter just for the Government and that is why he decided to set up the Bovine TB Partnership Group. Government together with industry need to develop a joint plan for tackling bovine TB. The Government is ready to do this—what happens next and how quickly we move forward depends on the industry itself.

16. The Government agrees with the Committee that those organisations (paragraph 23) which represent farmers affected by bovine TB should be considered as potential members of the Bovine TB Partnership Group. However, the form the Group will take, and the extent to which it needs to be resourced, will depend on Defra’s discussions with the industry and the veterinary profession. Government has not developed a model for how this group should be constituted and operated in advance; it wants to develop the approach with industry as part of developing a genuine partnership.

17. The Government is already working closely with the non-bovine sector to develop an agreed approach, for the control of TB in such species. It has set up a review of the current controls for TB in non-bovine species, including camelids (llamas and, alpacas), goats and cats; and to develop suitable policy options that are effective, affordable and proportionate to the animal and public health risks. A Working Group consisting of representatives from Defra, the Devolved Administrations, Animal Health and the Veterinary Laboratories Agency has been set-up to take the review forward. Members of the Working Group have met with key industry stakeholders, including the British Llama Society, the British Alpaca Society, the British Camelid Society, the Goat Veterinary Society, the British Goat Society and the Feline Advisory Bureau to gain an understanding of their issues and concerns; assess the risks and impact of bovine TB on their industry; and seek their views on how the risks might be addressed. The Government intends to continue to work with the non-bovine sector, as far as possible, on matters relating to the control of TB in these species.

EPIDEMIOLOGY

18. The Government understands and shares the Committee’s concern and frustration about the fact that a conclusive answer on the transmission of bovine TB cannot currently be produced. The epidemiology of bovine TB is complex and it is known that in cattle and badgers it is primarily a respiratory disease.⁷ However if it is uncontrolled in either species, the disease may become disseminated and *M. bovis* can be excreted, intermittently, in sputum, saliva, pus, urine, faeces and milk.⁸ The work the ISG did on setting up the Randomised Badger Culling Trial (RBCT) showed it was not possible to implement the design of scientific experiment suggested by John (now Lord) Krebs to investigate the relative contribution of routes of transmission because it was not practical. TB transmission is not amenable to being investigated by experiments with controls because of the large number of variable factors, the impracticality of conducting controlled experiments on commercial livestock farms, and the need for data from a large number of representative breakdown herds.⁹

19. The inception and progress of the RBCT provided evidence to show that further research is unlikely to yield conclusive results on the question of the quantitative contribution of badgers to cattle TB and exactly how, where and when transmission occurs (Bourne *et al*, 2007a). The level of proof required to determine absolute transmission rates in this instance far exceeds that of the association with risk factors required for many other diseases; and in the case of other diseases, it is accepted that such depth of information is not a prerequisite for implementing control measures. There are several reasons for this: the epidemiology; relatively low level transmission; the chronic nature and difficulty in detecting the organism; diagnosis of the disease, and the practicality of being able to reach a conclusive answer that is scientifically sound. The main difficulty is being able to know when and how animals were exposed to TB, because it is a chronic disease and only discloses through testing some time after the animal has been infected.

⁶ EFSA, 2008. Scientific report on “Tuberculosis testing in deer”. Panel on Animal Health and 671 Animal Welfare, Question No. EFSA-Q-2006-179, Adopted on 30 January 2008. Annex to the 672 EFSA Journal 645, 1–34.

⁷ Shitaye *et al*, 2006; Clifton-Hadley *et al*, 2006; Crawshaw *et al*, in press.

⁸ Cassidy, 2005; Gallagher and Clifton-Hadley; 2000; Shitaye *et al*, 2006.

⁹ Ryan *et al*, 2006.

20. The evidence suggests that the contribution of the various means/routes of transmission and the associated transmission rates vary both geographically and over time, therefore there are no fixed values for any of the transmission parameters. It is important to note that reliable estimates of these transmission rate parameters are established for only relatively few other diseases and only under specific experimental circumstances. The extensive investigation over many years is itself indicative of the inherent complexity of the problem.

21. This level of uncertainty means the Government needs to focus on what is known. As the Government said in response to the Committee’s Fourth Report of Session 2007–08, the relative importance of the routes of infection will remain an unknown and both direct and indirect transmission of TB between badgers and cattle may occur in farm buildings and at pasture.¹⁰ The diagram below shows that the Government’s TB control strategy is aimed at ensuring that, in relation to as many routes of transmission as possible, disease spread is minimised.

22. The Committee also asked for clarification of what the Government meant by “we will continue to consider new ideas” about the transmission of bovine TB (paragraph 14). This means that the Government is open to continue to fund new ideas for further research if they are forthcoming and have the potential to shed further light on the exact means of transmission between cattle and between cattle and badgers. The Government has a long and proven track record of funding a wide range of peer-reviewed research proposals in the area of bovine TB as illustrated by Annexes D and E.

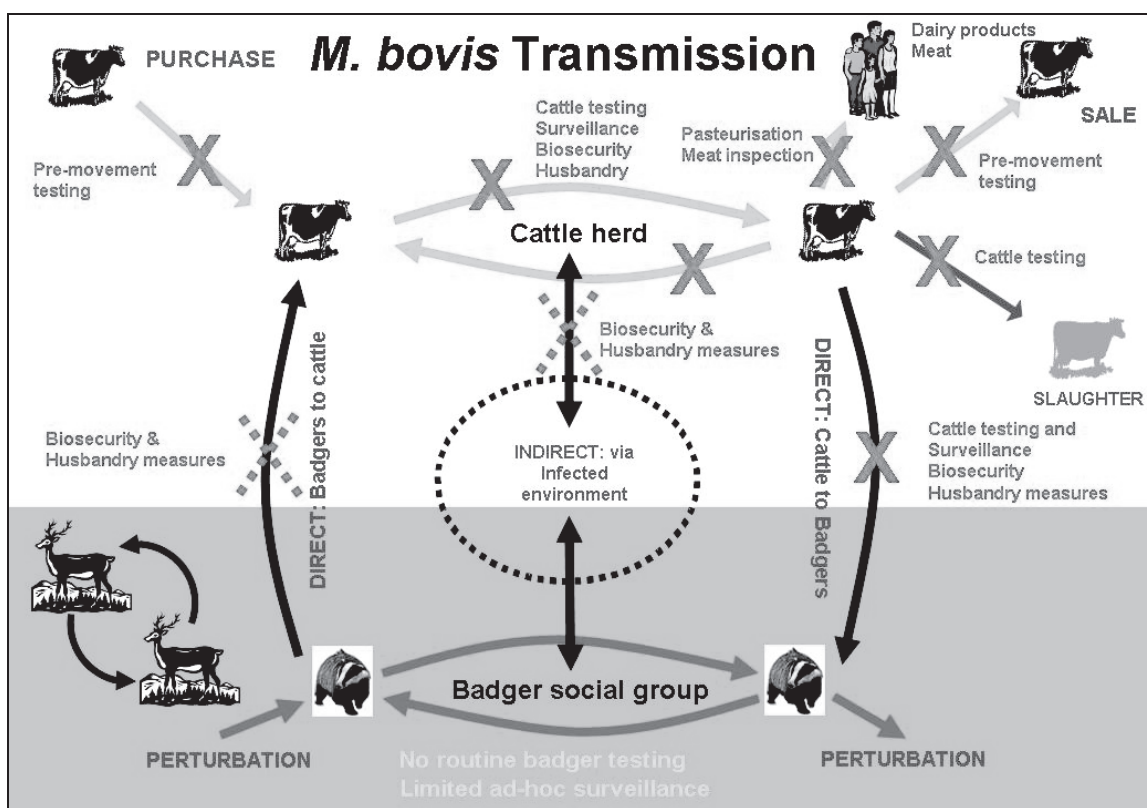


Diagram 1: Bovine TB transmission routes and available control measures. Note: the solid green crosses indicate those areas where current controls are likely to be highly effective in mitigating against that route of transmission of *M. bovis*. The dotted crosses indicate those routes of transmission where current measures are likely to be less effective.

BIOSECURITY

23. The Government agrees with the Committee’s recommendation (paragraph 15) that it should make the results of the biosecurity research available as soon as possible and is keen to do so. CSL have presented their on-going research work to interested farming and wildlife groups, which has been well received. As the Government made clear in the response (July 2008) to the Committee’s report, the Welsh Assembly Government was represented on the TB Husbandry Working Group and keeps us closely in touch with the Biosecurity Intensive Treatment Area project. The Government is awaiting their report on the project and will consider its potential for trialling a similar approach in England.

¹⁰ Johnson *et al*, 2005.

24. The Committee also questioned how the Bovine TB Husbandry Working Group will decide what biosecurity measures are effective (paragraph 15). The Husbandry Group has already done this, the first stage of its work was a comprehensive review of current research and other evidence. A list of the measures from existing advice and research, including The Philips Report: *TB and Cattle Husbandry, Report of the Independent Husbandry Panel* (May 2000) and the Central Science Laboratory (CSL) research on badger visits to farmyards (SE3029), was compiled. The Husbandry Group then worked to identify which of the evidence based measures farmers could have some assurance worked, were practical and gave some value for any investment required. The overview of their work and assessment of the evidence base and explanation of why certain measures have or have not been included in the husbandry advice is available online at: http://www.defra.gov.uk/animalh/tb/pdf/husbandry_background.pdf).

25. The Group concluded that every farm is different in terms of what husbandry measures may be effective and a pragmatic approach is needed for many measures related to minimising TB risks. What was clear was that introducing a number of measures and implementing best practice advice which focused on the risks of transmission from both cattle and wildlife might result in a reduction of bovine TB incidence. This conclusion was supported by the findings of case-control studies TB99 and CCS2005 carried out as part of the RBCT which found sufficient evidence that by applying the broad principles of biosecurity it would be possible to reduce the risk of cattle becoming infected by other animals, including badgers, and thus reduce the risk of infection.

26. In paragraph 16 of their report the Committee suggest that the Government should provide more information on what “managing the impact of living in high risk areas means”. This phrase refers to assisting those farmers with herds in high incidence areas which may experience re-infection from badgers to reduce the risk of infection, but also to continue to operate their businesses, recognising that they are likely to face recurring periods of movement restrictions. The statement on 7 July 2008 set out some options which might be considered, and for which incentives could possibly be offered, but remitted this issue for consideration by the Bovine TB Partnership Group.

VACCINES

Cattle vaccine

27. The Government shares the Committee’s enthusiasm for making progress on the significant hurdles that need to be overcome before a cattle vaccine could be introduced (paragraph 18). In January 2008, as part of a discussion about bovine TB with the European Commission, the Government tried to establish clearly the circumstances in which a cattle vaccine might be acceptable. The indications were not promising because of the likely concerns from other Member States that TB infected cattle would then be undetectable using the tuberculin skin test. The Commission suggested that there might be room for discussion once a vaccine was closer to being available and it had been established that a DIVA test (Differentiating Infected from Vaccinated Animals) was feasible. While these initial discussions were not encouraging, the Government will continue discussions with the Commission and other Member States to keep them updated on progress. The Government will also continue to explore with them what can be done to ensure the required legislative changes can be made as rapidly as possible once the necessary scientific information is available. However, it also recognises that most Member States have little interest in TB vaccination because they are disease free, and may be reluctant to see changes to a control system that has served them well.

Vaccines research

28. The Committee asked about the new vaccines research being commissioned and funding of each project (paragraph 20). This work will follow on from the existing research projects to take the badger and cattle vaccines and DIVA test through the next stage of the development and licensing process. Following extensive discussions with stakeholders, which identified a number of technical and practical issues, the new research will aim to address these issues and align the programme more clearly with stakeholder priorities. The terms of reference of the additional research are therefore:

- to continue to pursue all avenues of research on vaccines for both cattle and badgers;
- to address the scientific uncertainties around oral badger vaccines in terms of both formulation and deployment to maximise the chances of success; and
- to maximise the chances of cattle vaccines being used without trade restrictions by further developing the DIVA test, improving understanding of cattle sensitisation to the skin test by vaccines and increasing research on non-sensitising vaccines.

29. By developing a practical understanding of the logistics of vaccination, improving our scientific understanding and working in partnership with the farmers and the wider community at the local level, we hope to improve farmer confidence in vaccination and ensure an oral vaccine can be deployed rapidly once it becomes available. Therefore, the aims of the injectable badger vaccine deployment project are:

- to support the long term goal of oral badger vaccination; and
- to provide an assessment of the viability of injectable vaccination.

30. These aims can only be achieved working closely with industry in both the design and execution of the project. The total cost can only be determined once the design is finalised.

31. The timetable for licensed badger and cattle vaccines is at Annex C and details of on-going Defra-funded TB vaccine research projects (including costs) are at Annex D.

32. The Government will consider how progress with research into vaccines for bovine TB can best be included in Defra's Departmental Annual Report to Parliament.

COMPENSATION

33. The Government has now lodged an appeal against the High Court judgement which is referred to in paragraph 22 of the Committee's report. The judgement accepted that, for most animals, the table valuation system is a significant improvement on the previous one which was based on individual valuations, and resulted in a significant and widespread over-compensation problem. However it did conclude that table valuations discriminated unfairly against owners of particularly valuable cattle. This does not mean, as the Committee's report states, that the court supported the view that table valuations were unfair to owners of pedigree cattle—Table valuations already treat pedigree animals separately to other animals and for most pedigree cattle, the determined table value (which is a true and contemporaneous open-market average price for same category cattle) will represent a reasonable approximation of true market value of a healthy animal. For example, in the latest table valuation for September 2008, male pedigree animals in the beef sector (aged over 12 months and up to 24 months) have a table valuation of £3,526 compared to less than £1,000 for non-pedigree animals in the same age groups; and for a number of other pedigree categories, it has been determined that individual valuations should be utilised for September 2008—as allowed for in the legislation—in the absence of sufficient sales data existing to calculate an average market price. To quote the judgment at paragraph 77:

“For the average animal, table valuations may provide an efficient, relatively inexpensive, easily administered and realistic means of determining fair compensation, and I accept the contention of the Secretary of State that in most cases the table valuations stipulated in the Order produce a valuation that is a reasonable approximation of true healthy market value. For most animals, I take it that the present scheme is a great improvement on the former provisions involving general individual valuations from the point of view of the public”.

34. Once the Court of Appeal has had the opportunity to re-consider this case, and deliver its decision, the Government will make clear what the next steps will be.

BOVINE TB AND BADGER CULLING

The decision not to cull

35. In taking its decision on bovine TB and the potential role of badger culling in controlling the disease the Government considered whether action which met the criteria identified by the ISG and Sir David King (large area where there is a high and persistent incidence of TB cattle, sustained for a number of years and carried out effectively and humanely) could work in practice and what the risks were. In considering the practicality of large area culling the Government took into account the information that had been provided by the National Beef Association and the National Farmers' Union about their plans for a large area cull (VLA9) and the Secretary of State met with both organisations in February 2008 where they described their VLA9 plans. The plans, as the Committee have seen, did not provide detailed information on how this proposal would be implemented and what was provided did not indicate that further exploration would add to the broad range of evidence already available. VLA9 did inform policy considerations by providing a sense of the level of commitment to a cull in the area and of what the industry considered possible, as well as what concerns were, for example, over security. The Government took the view that the undoubted commitment was not enough to counterbalance the long-term risks of making the disease worse if culling became patchy, was not sustained, or was disorganised for any reason, therefore, even if more information on how VLA9 would have been implemented had been available, the Government does not consider it would have affected its judgment on the risks involved.

36. Other factors considered included the public acceptability of culling badgers; the likelihood that landowners would not consent to allow culling on their land; and the likelihood that public order problems could jeopardise the cull and contribute to making disease worse. The cost, and the need to sustain funding of a culling operation for a number of years, were important considerations. It would take time for herd owners to see an overall benefit in reducing cattle herd TB breakdowns. In the Randomised Badger Culling Trial this beneficial effect did not become significant over the culled and surrounding areas until the fourth annual proactive cull. Initially in the RBCT, at the same time a reduction in herd breakdowns was seen in culled areas an increase in herd breakdowns was seen in surrounding culling areas. In considering culling as one of the Government's TB control tools the likelihood that farmers would face increased cattle breakdowns in the short term was likely to endanger support for maintaining the cull. Having considered all these factors, the Government concluded that the risk of ineffective culling making disease worse was too high.

Revisiting the policy

37. The Committee requested a clearer indication of what evidence the Government would need or in what circumstances it may revise the policy on culling (paragraph 25). The Government has made clear that exceptional circumstances may mean we need to revisit the policy. In this case exceptional circumstances are unforeseeable and we cannot say what they may be. They would not be an application to carry out a large scale co-ordinated cull, even with a commitment to sustained delivery and funding from farmers. This is because the judgement underlying the policy is that culling, in the way the science suggests could be effective, would be difficult to sustain and could make matters worse by leading to an increase in bovine TB.

38. The scientific research underway that may produce new evidence comprises the projects recently commissioned to undertake further analysis of the huge amount of data available from the Randomised Badger Culling Trial and the ongoing post-culling analysis being led by Christl Donnelly. However new or additional scientific evidence may not sufficiently demonstrate that the level of disease risk from culling can be acceptable enough for the policy to be reviewed. Science cannot be expected to deal with all the aspects of carrying out an effective cull, including practicality.

SCIENTIFIC RESEARCH

39. The Government is happy to provide the Committee with details of ongoing scientific research into bovine TB (paragraph 21). In addition to the summary of Defra-funded on-going research that we have provided at Annexes D and E, we propose that we notify the Committee as new research is commissioned and final results published in order that they are made aware of the work as soon as possible.

40. Details of all on-going and completed research projects are available on the Defra website at <http://www.defra.gov.uk/science/default.htm> and <http://www.defra.gov.uk/animalh/tb/research/projects.htm> respectively.

SCIENTIFIC ADVICE

41. The Committee commented that they were disappointed with the Government's response to their recommendation that the dialogue continue between the Independent Scientific Group on Cattle TB (ISG) and the new Government Chief Scientific Adviser (Professor Beddington) (paragraph 26). The response was directed at the Committee's specific recommendation: the Government did not rule out further dialogue with the former members of the ISG. The Committee may find it reassuring to know that at least four former members (Christl Donnelly, George Gettinby, John McInerney and Ivan Morrison) of the ISG work closely with Defra on further research as contractors and as advisers and sit on the sub-groups of the Bovine TB Scientific Advisory Body.

ADDITIONAL INFORMATION

42. The additional information mentioned in this report is provided in the Annexes attached:

Annex A	Costs and benefits of increased testing and increased use of the gamma interferon blood test
Annex B	Research: gamma interferon blood test and its accuracy
Annex C	Timetable for cattle and badger vaccines (paragraph 20)
Annex D	Government funded vaccine research projects underway including breakdowns of the funding on each (paragraph 20)
Annex E	Update on Government funded scientific research into bovine TB underway (paragraph 20)

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Department for Environment, Food and Rural Affairs

22 September 2008

Annex A

COSTS AND BENEFITS OF INCREASED TESTING AND INCREASED USE OF THE GAMMA INTERFERON TEST

BACKGROUND

The Government carried out a preliminary cost benefit analysis of increased routine cattle testing and increased use of the gamma interferon test. The analysis considered the cost of implementing each of these measures separately against the resulting savings from reduced testing and disease incidence during the 20 year period of the assessment. It attached no monetary value to the lower overall level of disease at the end of the control period that is assumed to result from the altered testing regimes. This was a simplified assessment to give an indication of the possible scale of costs and benefits of enhanced cattle testing. The Government's economic analysis is frequently refined and updated as needed to inform policy decisions.

ESTIMATED BENEFITS

The assessment of benefits was carried out without any specific epidemiological modelling of changes in testing regimes. An indication of the possible scale of the benefits was obtained from results of a simple model by the Veterinary Laboratory Agency (VLA) derived from that used by the Independent Scientific Group on Cattle TB (ISG). The VLA model was developed specifically to model the impact of several hypothetical vaccination scenarios against a baseline of the modelled future progress of bovine TB under present control strategies over a 20 year period. In the model, cattle vaccination directly affects both cattle to cattle and badger to cattle transmission. Testing and removal of more infected/infectious cattle could not achieve the same impact because it does not directly address badger to cattle transmission. Therefore it was assumed that the maximum benefit achievable from enhanced cattle testing (whether through more frequent testing or use of gamma interferon) would be the modelled percentage rate of reduction in cattle herd incidents achieved by cattle vaccination but only in those incidents arising from cattle to cattle transmission and not addressed by pre-movement testing. On this basis, the potential benefits of an enhanced cattle testing regime over 20 years would be in the region of £125 million.

The estimate of benefits is subject to great uncertainty because it depends on both the efficacy of the new intervention and on the disease situation. The version of the VLA model used for this assessment assumed that pre-movement testing is relatively highly effective in reducing cattle-to-cattle disease spread and that

this would result in a declining disease picture. This assumption leads to a lower estimate of potential benefits than might be possible if the disease situation worsened over the 20 year period. This is because greater disease implies greater costs of disease control and therefore there are greater savings to be made reducing these costs with new measures.

TESTING HERDS EVERY SIX MONTHS

The analysis of costs assumed that 25% of herds in GB have one additional whole herd test per year—equivalent to all the clear herds now on annual testing moving to six monthly testing. It did not take account of any changes to three and four yearly testing areas eg to two yearly, which would be another possible scenario. On average, each extra herd tests would cost £900 including government and farmer costs. No account was taken of changes to the scale and duration of cattle bovine TB incidents that would arise through false positives (which would add to the cost of biannual testing) and through reduced spread within infected herds (which would add to the benefits). Herd testing intervals are currently based on historic incidence of test positive animals, as set out in EU Directive 64/432/EEC.

The conclusion the Government reached from the results of the analysis was that, over a 20 year period, 6-monthly testing would incur costs estimated at close to £300 million, exceeding the projected benefits estimated in the region of £125 million.

ROUTINE GAMMA INTERFERON TESTING

During 2007–08 29,655 gamma interferon tests were carried out—the associated direct costs (ie excluding the provision of compensation for reactor cattle) for the taxpayer were £952,000. The gamma interferon test is significantly more expensive than the tuberculin skin test although the cost might be lower if, for example, testing kits were purchased on a larger scale. The average cost of a herd test using gamma interferon was estimated in this analysis to be £1,600 more than using the skin test.

The analysis assumed that all testing in annual testing areas was carried out using the gamma interferon test in place of the present skin test. This approach would not be permitted under present European legislation because gamma interferon testing may only be used in addition to the skin test. Therefore, the estimates understate the costs of routine use of gamma interferon.

The gamma interferon test is more sensitive than the tuberculin skin test, capable of detecting more cattle infected with bovine TB at an earlier stage of infection and infected cattle that are missed by the skin test. However it risks producing an unacceptable number of false positive results, because of its lower specificity, in uninfected herds. It is therefore considered technically unsuitable as a routine screening test.

The conclusion the Government reached from the results of the analysis was that, even with optimistic assumptions about both its costs and benefits, routine use of gamma interferon testing over a period of 20 years would incur costs (estimated to be approaching £1,200 million) far exceeding its benefits (estimated in the region of £125 million).

Annex B

RESEARCH: GAMMA INTERFERON BLOOD TEST AND ITS ACCURACY

PROJECT SE3013: PATHOGENESIS AND DIAGNOSIS OF TUBERCULOSIS IN CATTLE—COMPLEMENTARY FIELD STUDIES

This study (which ran between 2000–05) was designed to advance the understanding of cattle-to-cattle transmission of bTB in GB through detailed pathological and immunological investigation of cattle either naturally infected (“reactors”) or exposed to *Mycobacterium bovis* (“in-contacts”) and to assess certain diagnostic aspects of disease detection. Of the 200 reactor cattle selected, 55.5% had macroscopic visible lesions and, of the 200 in-contacts selected, 14% had macroscopic visible lesions. These in-contact animals were negative in the initial skin test. Some of these were at a very early disease stage and a portion of them would have been identified as reactors at a repeat skin test. However, the vast majority of these could have been identified more quickly and accurately in the field by using blood based tests and these results provide solid support to the use of the BOVIGAM gamma interferon assay. These animals would have been erroneously regarded as false positives by farmers and some vets in the past due to their skin test negative status, but holding the animals longer allowed them to develop visible lesions of tuberculosis.

The Final Report of this project is available on the Defra website at: http://randd.defra.gov.uk/Document.aspx?Document=SE3013_5852_FRP.doc

FIELD TRIAL IN GB CONDITIONS

Between October 2002 and October 2005, Defra funded an Animal Health and Veterinary Laboratories Agency (VLA) conducted field trial of the gamma interferon test.

The slow farmer recruitment rate meant that the trial was unlikely to be completed before 2012. Given the significance of the bovine TB problem this was considered too long to wait and so the trial was terminated early and the decision was made to make increased use of the gamma interferon test. Useful data was collected and lessons were learnt from the trial and two reports were produced: an interim one on the first 150 herds was made available to the ISG and a final one which was a full analysis of the results from all 195 herds. The final report “Laboratory testing and epidemiology support for the national gamma interferon field trial” is available on the Defra website at: http://www.defra.gov.uk/animalh/tb/pdf/gifn_trialfinalreport.pdf.

SPECIFICITY TRIAL (GREAT BRITAIN)

A trial, established to evaluate the specificity of the gamma interferon test in British conditions, confirmed the findings of previous studies by concluding that the commercially available test had a specificity of between 95% and 97%.

Findings from the trial supported the view that it would be inappropriate to use the gamma interferon test for routine screening purposes because it risks producing too many false positive results in uninfected herds. However, there would be value in making greater use of it as an ancillary test in a variety of herd breakdown situations. Defra has also used these findings to develop the current policy for the increased use of the test.

A copy of the report, “Specificity Trial of the BOVIGAM IFN Gamma Test in GB Cattle” is available on the Defra website at: http://www.defra.gov.uk/animalh/tb/pdf/gifn_specificityreport.pdf

FURTHER INFORMATION

Below is a list of other selected relevant scientific references concerning the diagnostic accuracy of the gamma interferon test. The ISG’s final report also contains references to the skin and gamma-interferon tests.

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Annex C

TIMELINE FOR VACCINES

Defra has in place an extensive research programme which can broadly be divided into five work streams:

- BCG cattle vaccines (cannot be used with the current skin test due to sensitisation)—including work investigating prime boost strategies.
- Differential diagnostic tests (to determine vaccinated from infected animals in place of the skin test, known as DIVA).
- Non-sensitising cattle vaccines—10 year + long term prospect.
- Injectable badger vaccines.
- Oral badger vaccines.

HISTORIC SPENDING

Over the last 10 years up to March 2008 we have spent £17.8 million on vaccines for bTB. The diagram and summary below sets out how this money was used and what it has delivered.

Work began in 1997 to generate live attenuated vaccines and DNA-vaccine constructs to develop vaccine candidates for both cattle and badgers. These were tested in small animal models.

The Krebs review reported in 1997. The report recommended development of cattle vaccines, which was considered more feasible and attractive than badger vaccination but with retention of the option of a badger vaccine. A research programme was set up, overseen by independent advisors (Vaccine Programme Advisory Group) and regularly peer reviewed. There was also a steering group chaired by the CVO from 2000–06 to advise on licensing issues.

Spending on vaccines has increased as their potential importance, particularly of badger vaccines, has become apparent.

<i>Time period</i>	<i>Cattle vaccine spend</i>	<i>Badger vaccine spend</i>
1997–99	£0.55 million	
1999–2005 (2 CSR periods)	£6.5 million	£0.85 million
2005–08 (1 CSR)	£6.7 million	£5.8 million

CATTLE VACCINES AND DIAGNOSTICS

Just under £11 million has been spent on cattle vaccines and associated diagnostics.

1999

Number of approaches to vaccine development were investigated, including BCG (variable efficacy and sensitises cattle to tuberculin test), live attenuated vaccines, dead vaccines, subunit (proteins, peptides or DNA) vaccines and heterologous prime boost strategies. Initially it was expected that a non-BCG vaccine would be a candidate in parallel with human vaccine work. Work to develop a challenge model in cattle in which could be used to identify suitable DIVA antigens.

2001

Work on antigen mining for specific antigens progressed after *M. bovis* genome sequenced in 2001 revealing specific antigens for *M. bovis* not in BCG. Basic immunology work on how BCG works and its effect on skin test (2001–04).

2002

It was realised that non-BCG candidates were not forthcoming and work concentrated on identification of suitable antigens/adjuvants to improve the efficacy of BCG. Work on the differential diagnostics (Differentiating Infected from Vaccinated Animals, the so-called “DIVA” test) required to allow BCG use commenced using specific antigens in interferon gamma test.

2005

Neonatal BCG looked more promising than BCG in adult cattle and prime boost candidates BCG plus protein or subunit were also on the horizon (albeit with potential difficulties around GMO release). A decision was made to concentrate on optimising heterologous prime-boost approaches to improve BCG by:

- identifying vaccine subunit candidates that boost BCG-induced immunity in cattle;
- testing new adjuvant systems in combination with promising subunit vaccines in cattle; and
- testing TB vaccines in cattle that are in phase I clinical trials in humans.

Work also continued on development of reagents for differential diagnosis that are suitable for use in vaccinated animals.

Work was started looking at new vaccine candidates and delivery protocols in a natural transmission study in cattle. It takes over one year to do each experiment and any experiment can only do relatively small numbers at a time due to health and safety issues around housing infected animals/risk to staff.

Started to engage in private/public partnership with a pharmaceutical company, Pfizer Animal Health, and commercial work to build links with BCG supplier SSI Copenhagen.

2007

Policy work started to be addressed in earnest once the likely vaccine properties were known. Difficulties around EU negotiation (need to know candidate, data on DIVA-trade embargo risk etc).

Despite billions of dollars invested in human work worldwide, no alternative candidate vaccine to BCG yet available.

BADGER VACCINES AND DIAGNOSTICS

Just under £7 million has been spent on badger vaccine development.

1999

Work commenced but less resourced than cattle in line with the Krebs recommendations.

Identification of vaccine formulations and delivery strategies suitable for non-oral and oral vaccination of badgers. We could not keep captive badgers at VLA at this time (VLA managers' decision on safety grounds) so used mouse and guinea pig challenge models. Collaboration with the Republic of Ireland to conduct a prototypical badger immunisation trial using BCG Pasteur to get preliminary efficacy data on injectable and oral formulations. This collaboration is still ongoing.

Initially there was no reliable way of telling if a live badger was infected, which makes any vaccination studies impossible. The first step was development of species-specific diagnostic tests and reagents eg made badger monoclonal antibodies for badger INF-g this work was ongoing until 2004.

2002 Onwards

Experimental BCG vaccination/challenge studies in badgers in UK and RoI to provide information on optimal vaccine dose, formulation, route of administration, immunogenicity and efficacy. Continuation of development of delivery systems and suitable formulation for oral vaccination of badgers—developed and assessed several different potential candidates including NZ lipid, formulation which is the current front runner. Difficulties with stability of formulation and BCG and its viability in environment and stomach acid needed initial basic research on physiology, biochemistry and microbiology.

Continued search for better vaccine candidates than BCG or adjuncts to improve BCG using small animal models.

2004

VLA captive badgers used for initial BCG injectable safety study (no challenge involved). Validation of badger diagnostic tests in badgers culled in RBCT.

2005

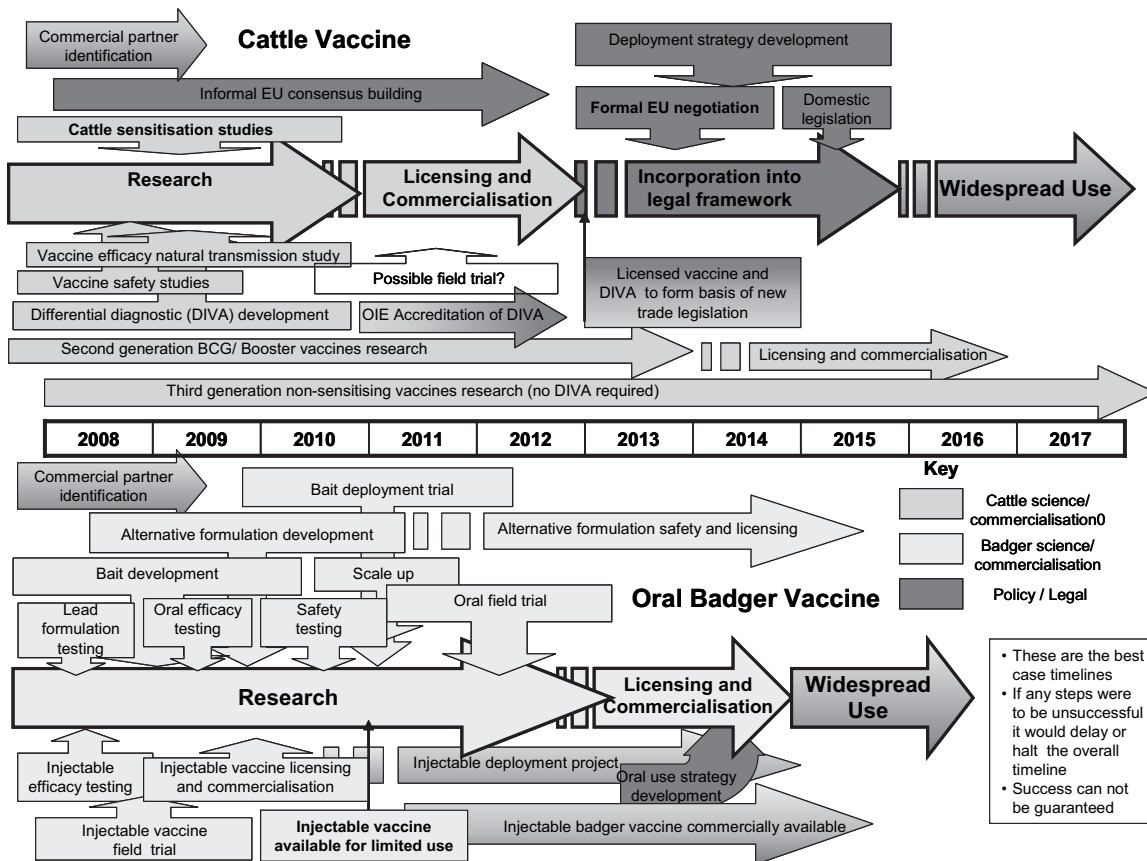
Preparatory work for Badger Vaccine Study (BVS) to test safety in the field. Experimental work ongoing on oral formulation of BCG Danish that is palatable and immunogenic to badgers, and suitable for delivery in the field—includes badger field work on bait uptake.

2006

BVS started to get field safety and potentially some efficacy data for licensing injectable BCG. Efficacy studies in an experimental setting commenced.

FUTURE WORK

The diagram below sets out the estimated timeline for future work required to deliver both cattle and badger vaccines.



The estimated distribution of funding between cattle and badger vaccines (of all types including diagnostics) is shown in the table below. All long term costs are estimates and will depend on the precise nature of the research commissioned.

Time period	Cattle vaccine spend	Badger vaccine spend
2008–11	£12 million	£8 million
2011–14	£10 million	£7 million

The larger budget for cattle research reflects the high costs of keeping infected cattle under stringent biosecurity (category 3) containment in the laboratory.

A summary of key dates is provided in the table below:

Vaccine	Estimated earliest possible date	Likelihood of successful delivery on this timescale	Other
Cattle Vaccine	BCG + DIVA (2012—licensed not available for use) 2015—available Incorporated in legislation	Medium	Non-sensitising vaccines 2018 +
Injectable badger vaccine	2010	High	—
Oral badger vaccine	2014	Low	Alternative formulation—2015 +

CATTLE VACCINES

Both efficacy and safety data are required for the licensing process. Studies into vaccine efficacy for BCG in a natural transmission setting is ongoing. Safety assessment in both neonatal (preferred vaccination age) and older cattle is underway. Licensing for use in all ages of cattle will enable a widespread initial use in all cattle followed by ongoing vaccination of younger animals. The experimental work for licensing is expected to be completed in 2011 with the licensing process completed in 2012.

Stakeholder discussions highlighted the need to ensure trade is not restricted if cattle vaccines are used. This has resulted in two additional projects. One looking at development and validation of the DIVA test to ensure it works in young animals and one looking at sensitisation of cattle to the skin test. These will be ongoing in parallel with the licensing process and feed data both into that and the policy development.

Non-sensitising vaccines were also identified as a possibility to address trade restrictions. Work is ongoing and will expand in 2010–11 once the majority of experimental work on licensing BCG is in place and more scientific expertise becomes available. These are a long term possibility and are very much at the research stage. It is not possible to say when or if they will be available.

Although the vaccine will be licensed as safe for use in cattle from 2012, EU legislation will prevent use of BCG. There are two key pieces of legislation which need to be considered:

- EU Directive 78/52/EEC and associated directives set out the criteria for national plans for the eradication of bTB. One of the criteria is a requirement to prohibit “anti-tuberculosis vaccination” under these plans. The adoption of a practice that was contrary to the requirements for such a plan, or a failure to prohibit vaccination would be very likely to be considered contrary to EC law.
- EU Directive 64/432/EEC aims to facilitate intra-community trade by ensuring that only animals with proven disease-free status can be exported to other Member States. Cattle must come from a herd with Officially Tuberculosis Free (OTF) status. As OTF status is determined through use of the tuberculin skin test and BCG interferes with this by providing false positives this legislation would need to be changed to allow the use of a DIVA test to replace the skin test in vaccinated animals.

Formal negotiations for changes to the relevant directives can only commence once a licensed product is available. However, prior to this we will be aiming to ensure once a licence is in place, negotiations can commence as quickly as possible. It is not possible to tell how long negotiations will take, but based on previous experience we have allowed three years in the timeline for the changes to EU and subsequent domestic legislation.

BADGER VACCINES

The area where greatest certainty is possible as to the delivery timescale is injectable badger vaccines. The field safety trial is due to be reviewed in early 2009 to determine if it needs to run for a final year or if sufficient data has been collected. Laboratory safety studies are complete and efficacy studies for licensing will be completed by early 2009. The project is on track for a licensed injectable badger vaccine to be available in 2010.

The full badger injectable vaccine deployment trial is expected to be started once the licensed vaccine is available in 2010 but some preliminary logistics work may commence earlier in 2009. The aim of this work is to deploy the vaccine in such a way which supports the long-term goal of vaccination and provides an assessment of the viability of injectable vaccination.

The oral badger vaccine is still at the research stage and has not yet started the development and licensing processes. The timelines are therefore much less certain. The lead formulation, if successful, would be available for use in 2014. Experiments on efficacy and safety will commence in late 2008.

There is a significant risk that the current lead formulation will not meet all the necessary requirements for an oral vaccine. To mitigate this risk, part of the additional funding will be supporting the development of alternative formulations. These are less advanced and, therefore, if they are required, it will take longer to take them through to a licensed product. This will result in a delay of at least 12 months, possibly longer in an oral vaccine becoming available.

Another key concern is the uptake of vaccine by badgers. Deployment trials using the lead vaccine candidates will commence in late 2009.

Annex D

GOVERNMENT FUNDED VACCINE RESEARCH PROJECTS UNDERWAY (INCLUDING BREAKDOWNS OF THE FUNDING)

This annex describes the aim, objectives, cost and duration of each of the Defra-funded on-going research projects concerning vaccine development. It also provides a brief description of each project. Titles of future research projects currently undergoing contract negotiation are provided at the end. Further details of these projects will not be available until we have received final project proposals for the research work and contracts for the work have been agreed and issued to the contractors. Details of all on-going and completed research projects are available on the Defra website at <http://www.defra.gov.uk/science/default.htm> and <http://www.defra.gov.uk/animalh/tb/research/projects.htm>, respectively.

SE3222:	Development of improved diagnostic tests for the detection of bovine TB
Location:	Veterinary Laboratories Agency
Start date:	01/07/2005
End date:	31/12/2008
Total cost:	£1 770 821

AIM

To identify and characterize novel diagnostic antigens to improve test specificity and to serve as reagents to differentiate infected from vaccinated cattle (differential diagnosis).

OBJECTIVES

- Complete antigen mining using comparative genome analysis.
- Perform antigen mining based on comparative transcriptomes to measure early gene expression in *M. bovis* and BCG following infection of macrophages.
- Determine the kinetics of antigen recognition following experimental infection with *M. bovis*.
- Evaluate the use of antigens prioritised in objectives 1–3 to improve sensitivity and specificity of the gamma interferon assay and to allow differential diagnosis in vaccinated animals.
- Continue the collaboration with VSD, Stormont, Northern Ireland and AgResearch, Upper Hutt, New Zealand in order to optimise, standardise and evaluate antigen cocktails for use in diagnosis in GB, NI and NZ.

DESCRIPTION

The incidence of bovine tuberculosis in GB has been increasing since 1988 despite the use of a control strategy based on tuberculin skin testing and slaughter of animals that react positively to the test. To improve the specificity and sensitivity of diagnostic tests is therefore a high research priority for Defra. The benefits of this approach are three-fold. First, improved sensitivity, particularly when novel diagnostic assays are used in parallel with the tuberculin skin test, would have a major benefit in reducing the economic burden of disease control. It has been estimated that an increase from 70% to 90% in test sensitivity would be equivalent to reducing the testing interval by a third with appreciable reduction in prevalence. Secondly, increased test specificity would have a further economic benefit by reducing the numbers of false-positive animals that may be slaughtered needlessly. Thirdly, in order to allow cattle vaccination to become a viable control policy option, diagnostic tests are required that can differentiate between infected and vaccinated cattle (differential diagnosis).

The gamma interferon test is permitted under EU law as an adjunct to the tuberculin skin test in cattle. It is a rapid and practical test and has potential to detect animals at an earlier stage of infection, but has slightly lower specificity than the tuberculin skin test used in the UK. The aim of this project is to develop specific diagnostic tests using comparative genomics to identify potential antigens that are then produced as peptide cocktails and evaluated using the gamma interferon assay. This approach is based on recent significant scientific advances achieved by VLA as part of Defra-funded projects to develop techniques for antigen mining. In this proposal we aim to complete our antigen screen to ensure that all possible candidates are identified. Specifically, we will apply a combination of comparative genomics (objective 1), and comparative transcriptomics (based on the differential gene expression of *M. bovis* and BCG inside bovine macrophages; objective 2) to identify species-specific proteins. Proteins identified in this way will be tested in cattle using peptide-based rapid screening techniques in combination with the gamma interferon assay. Antigens short-listed by these approaches will be tested for their suitability as reagents for differential diagnosis in the face of vaccination (objective 03) and for their ability to improve the specificity of the gamma interferon assay above that observed for tuberculin, particularly in animals at early stages of infection (objective 4).

The outcome of this project will be diagnostic reagents that allow the differentiation of vaccinated and infected cattle, that reach test sensitivities approaching that of tuberculin and which improve the specificity of the gamma interferon assay. In addition, antigens identified during this antigen mining operation will also be assessed for their suitability as potential subunit vaccine candidates.

SE3223:	Development of an oral BCG vaccine bait formulation for badgers
Location:	Veterinary Laboratories Agency
Sub-contractors:	Aston University/CSL/HPA/Immune Solutions Ltd
Start date:	01/01/2006
End date:	30/12/2008
Total cost:	£1 460 714

AIM

To: (i) develop a robust BCG formulation suitable for delivery to badgers in bait; (ii) assess its effectiveness using an animal model and its immunogenicity to badgers; and (iii) evaluate its safety to badgers and cattle in studies performed to GLP standards.

OBJECTIVES

- Lead vaccine formulations optimised and tested in vitro.
- Optimum bait formulation identified with which to deliver vaccine.
- Best vaccine formulation identified through protection studies in the guinea pig.
- Immunogenicity and safety of best vaccine formulation in bait evaluated badgers.
- Safety of best vaccine formulation determined in cattle.

DESCRIPTION

Bovine tuberculosis remains an economically important problem in Great Britain with potential zoonotic consequences. As such, Defra continues to have a statutory obligation to control tuberculosis in farm animals in Great Britain under the Animal Health Act of 1981, the Tuberculosis Orders, and various EC directives. The Krebs Report recommended that the option of a badger vaccine for tuberculosis should be retained alongside the development of a vaccine for cattle. The report by the Independent Scientific Group Vaccine Scoping Sub-Committee highlighted that oral delivery of BCG in bait would be the most appropriate means to vaccinate wild badgers on a wider scale, and that research efforts should be focussed on this approach. This project will build on recent advances in oral BCG formulation through the coordinated efforts of an international research consortium with expertise in vaccine production and formulation, as well as badger field work, vaccination and immunology. The outcome of this project will be an oral formulation of BCG Danish that is palatable and immunogenic to badgers, and suitable for delivery in the field. Formulations will be chosen that are suitable for large scale to GMP, thereby easing the progress to licensing and eventual evaluation and implementation in the field.

SE3224:	Continuation of the development for vaccines against bovine TB in cattle
Location:	Veterinary Laboratories Agency
Subcontractor:	Institute of Animal Health
Start date:	01/04/2005
End date:	31/03/2009
Total cost:	£5 622 823

AIM

To optimise the antigens and adjuvants used to formulate subunit vaccines for use in prime-boost strategies to boost BCG, to establish the duration of immunity to neonatal vaccination with BCG to provide the model for a prime boost analysis, and to improve the efficacy of BCG itself.

OBJECTIVES
VLA

- Evaluation of antigens identified in antigen mining project (SE3222) as subunit vaccine candidates.
- Selection of the most potent adjuvant for protein delivery.
- Determination of protective efficacy of subunit vaccine candidates in mice.
- Establish and validate immune correlates of protection and pathology.
- Compare vaccine efficacy of protein/adjuvant subunit vaccines developed in objectives 02 and 03 with proteins delivered by viral vectors in cattle.
- Assess the immunogenicity and protective efficacy in cattle of vaccines developed for the human TB vaccine effort now entering human clinical trials.
- Improving BCG through understanding of genome differences between BCG and *M. bovis*.
- Develop private/public partnership (PPP) with Pfizer Animal Health.

IAH

- Compare the immunity induced in neonatal calves to BCG Danish and BCG Pasteur.
- Establish the duration of immunity to neonatal vaccination with BCG to provide the model for prime boost analysis.
- Determine whether animals vaccinated with BCG as neonates can be effectively boosted at a later time point with either BCG or an alternative antigen in a prime boost strategy.
- Compare alternative antigens and immunological assays to distinguish between vaccinated animals that are totally immune from vaccinated animals that are infected or diseased.

DESCRIPTION

In 1996, Government tasked an independent scientific committee chaired by Professor John Krebs, to review the problem of bovine tuberculosis (TB) in GB. The recommendations of this committee were published in the Krebs' Report to the Minister of Agriculture Food and Fisheries in 1997. Government subsequently adopted many of the recommendations put forward by this report, including the recommendation that vaccination of cattle offered the best long-term solution for controlling the disease in the National Herd and that priority should be given to the development of a cattle vaccine against bovine TB together with an associated diagnostic test suitable for use in vaccinated animals. This view was reaffirmed in the House of Commons Environment, Food and Rural Affairs Committee's report on Bovine TB (2004) and by the findings of the Independent Scientific Group Vaccine Scoping Sub-committee. During previous Defra-funded projects, the VLA and their collaborators have made significant progress in developing TB vaccines for cattle such that we are on track with the time-scale for vaccine development outlined in the Krebs Report. Specifically they: (i) have shown that DNA or protein subunit vaccines used in combination with BCG gives superior protection against experimental challenge in cattle than BCG (heterologous prime-boost), and highlighted the need for better adjuvants for these sub-unit vaccines, (ii) have developed prototype reagents that allow discrimination between vaccinated and infected animals; (iii) have identified correlates of disease severity that can predict the success or failure of vaccination, and (iv) have developed an extensive network of collaborators involved in the Global effort to develop vaccines against human tuberculosis. This current proposal will build on these recent advances. It addresses Defra's TB research requirements identified in the AHWR research requirements document (September 2004) under heading R1. Specifically, it will concentrate on optimising heterologous prime-boost approaches to improve BCG by (i) identifying vaccine subunit candidates that boost BCG-induced immunity in cattle using antigen mining techniques developed in previous research contracts, and comparing the efficacy of these vaccines in mice and cattle (objectives 1, 3 and 4); (ii) testing new adjuvant systems in combination with promising subunit vaccines in cattle (objective 2); (iii) testing TB vaccines in cattle that are in phase I clinical trials in humans (objective 6), and (iv) continuing to utilise the close and effective network of collaborations that we have developed with the human TB vaccine community (objectives 5 and 6). VLA have also engaged in a private/public partnership with a pharmaceutical company (Pfizer Animal Health), and this relationship will be developed over the life of this proposal (objective 7). In addition, this proposal will support the continued development of reagents for differential diagnosis that are suitable for use in vaccinated animals.

SE3227:	Evaluation of the protection efficacy of vaccines against bovine TB in a natural setting
Location:	Veterinary Laboratories Agency
Start date:	01/10/2005
End date:	31/03/2011
Total cost:	£6 781 127

AIM

To determine the protective efficacy of novel TB vaccines for cattle in a natural transmission setting.

OBJECTIVES

- Develop a logistical framework for the project.
- Perform a proof of concept experiment to establish transmission rates.
- Determine the protective efficacies of cattle TB vaccines under conditions of natural transmission.
- Evaluate reagents for differential diagnosis.

DESCRIPTION

Bovine tuberculosis remains an economically important problem in Great Britain with potential zoonotic consequences. As such, Defra continues to have a statutory obligation to control tuberculosis in farm animals in Great Britain under the Animal Health Act of 1981, the Tuberculosis Orders, and various EC directives. Despite implementation of a test and slaughter strategy using the tuberculin skin test to detect infected animals, the incidence of bovine tuberculosis in cattle has been increasing exponentially since 1988. In 1996, an independent scientific commission chaired by Professor John Krebs to review the situation of bovine TB in GB concluded that the development of a cattle vaccine and associated diagnostic test had the best prospect of controlling the disease in the National Herd. This conclusion was re-affirmed in the House of Commons Environment, Food and Rural Affairs Committee's report on Bovine TB (2004) and by the findings of the Independent Scientific Group Vaccine Scoping Sub-committee, which highlighted that work on development and testing of vaccines should be maintained in order to produce a vaccine that is more effective than BCG in cattle. Significant scientific advances have been made towards this goal by VLA and our collaborators (especially AgResearch, NZ) as a result of Defra-funded projects. These advances have meant that Defra's TB vaccine programme is broadly on track with the timeline outlined by the Krebs' Report for the development of cattle TB vaccines.

However, as highlighted by Defra's Vaccine Programme Advisory Group (VPAG) at their inaugural meeting, a major barrier to progress in cattle vaccine research is the absence of experimental systems to measure vaccine efficacy in a natural transmission setting. Without this information, it is difficult to assess whether "laboratory" advances will have any significant impact in the field. The need to assess the ability of promising TB vaccine candidates to protect cattle against natural transmission of *M. bovis* was announced by the Animal Health Minister Ben Bradshaw to the House of Commons on 9 June 2005 and by Defra in an accompanying press release. In the press release it was stated that Defra would commission "further work looking at new vaccine candidates and delivery protocols in a natural transmission study in cattle at the VLA. A naturally infected herd will be used to compare the effectiveness of several vaccines".

The aim of this project is to establish a facility for generating natural transmission of *M. bovis* between cattle by assembling reactor cattle in a contained setting. This facility will then be used to determine the efficacy of promising vaccine candidates under conditions of natural transmission. This will be done by introducing sentinel vaccinated and control animals into the reactor herd and leaving them in-contact with reactor animals for 10–12 months. The protective efficacy of vaccine candidates will be determined by comparing disease rates between vaccinated and unvaccinated cattle. The first vaccine to be tested will be BCG given to neonates. Subsequent vaccines to be tested in this way will be prioritised on the basis that they have been shown to induce better protection against experimental challenge in cattle than BCG. This design was presented to and approved by VPAG, which includes a representative from the ISG, at its meeting on 12 May 2005.

SE3233:	Cattle TB vaccines: development of a DIVA test
Location:	Veterinary Laboratories Agency
Start date:	01/07/2008
End date:	31/12/2011
Total cost:	£1 692 978

AIM

To identify diagnostic reagents that allow the differentiation of vaccinated and infected cattle, that reach test sensitivities approaching that of tuberculin and which improve the specificity of the gamma interferon assay.

OBJECTIVES

- To define the antigenicity of the complete *M. bovis* complement of secreted antigens including all EAST-6 family members.
- To perform unbiased and comprehensive antigen mining based on a Gateway library approach.
- To define latency-specific antigens in cattle.
- Translational research.
- Continue collaboration with VSD, Stormont, Northern Ireland and AgResearch, NZ.
- DIVA test based on skin testing.

DESCRIPTION

The incidence of bovine tuberculosis in GB has been increasing since 1988 despite the use of a control strategy based on tuberculin skin testing and slaughter of animals that react positively to the test. To develop vaccination strategies for cattle is an important part of Defra's research into future control strategies. In order to allow cattle vaccination to become a viable control policy option, diagnostic tests are required that can differentiate between infected and vaccinated cattle (differential diagnosis) alongside current test and slaughter control strategies by developing so-called DIVA (Differentiation of Infected and Vaccinated Animals) reagents. This project is therefore aimed at the continued development and optimisation of such reagents, and the approach is based on and extends recent significant scientific advances achieved by VLA as part of previous Defra-funded projects. For example, a prototype DIVA reagent based on two defined antigens, ESAT-6 and CFP-10, has recently been validated and is now in routine use to enhance test specificity; another is being evaluated in a field trial. However, the sensitivities of these reagents are still lower compared to tuberculin and this sensitivity gap needs to be closed.

Principally, the VLA intend to complete their antigen screen to ensure that all possible candidates are identified. The assay system this project mainly targets is the gamma interferon test, which is already permitted under EU law as an adjunct to the tuberculin skin test in cattle. It is a rapid and practical test and has potential to detect animals at an earlier stage of infection; however, in its basic form, which employs tuberculin, it cannot be used as a DIVA reagent in combination with BCG. In addition, the VLA also intend to evaluate if the tuberculin skin test could be modified to allow DIVA by the application of defined and specific antigens in the skin test (objective 6).

This proposal describes a triple-track approach to improved diagnostics of product-development pursuing incremental improvement to current tests using targeted and library approaches (objectives 1–3), together with a basic research arm with a view to defining a new category of infected animals by looking at infectious-stage specific antigens (latency antigens) that may complement animals that are at disease stages when secreted antigens such as ESAT-6 or CFP-10 (objective 3). Lastly, this proposal also has a translational research objective to facilitate field application of reagents defined in this and earlier projects (objective 4). Further objectives ensure continued collaboration and synchronisation with similar research projects in New Zealand, Northern Ireland and the company producing the BOVIGAM IFN-gamma test, Prionics (objective 5), as well as evaluation of skin testing as DIVA reagent based on defined protein reagents (objective 6).

The benefits of this approach are three-fold. Firstly, DIVA reagents complementing novel vaccines will allow the implementation of vaccination as targeted control strategy alongside conventional strategies like test and slaughter and meat inspection. Secondly, improved sensitivity, particularly when novel diagnostic assays are used in parallel with the tuberculin skin test, would have a major benefit in reducing the economic burden of disease control even in the absence of vaccination. It has been estimated that an increase from 70% to 90% in test sensitivity would be equivalent to reducing the testing interval by a third with appreciable reduction in prevalence (see: Cox *et al*, Proc Natl Acad Sci USA. 2005 102(49): 17588–17593). Lastly, increased test specificity would have a further economic benefit by reducing the numbers of false-positive animals that may be slaughtered needlessly.

The hoped for outcomes of this project will be diagnostic reagents that allow the differentiation of vaccinated and infected cattle, that reach test sensitivities approaching that of tuberculin and which improve the specificity of the gamma interferon assay. In addition, antigens identified during this antigen mining operation will also be assessed for their suitability as potential subunit vaccine candidates.

CB0115:	Field trial to assess the safety and efficacy of BCG vaccine administered parenterally
Location:	Veterinary Laboratories Agency
Start date:	01/01/2006
End date:	31/03/2010
Total cost:	£5 772 656

AIM

To collect data to determine the potential for investigating the likely benefits of widespread badger vaccination with BCG and that could be used to support a future application to the VMD for a marketing licence for the use of BCG vaccine in badgers.

OBJECTIVES

- To confirm safety in, and absence of shedding from badgers of a commercial Bacille Calmette Guerin (BCG) vaccine when given parenterally to wild badgers in the field.
- To investigate the immunogenicity and efficacy of BCG in wild badgers.

DESCRIPTION

The incidence of bovine tuberculosis (bTB) in cattle in the UK continues to increase and the disease is acknowledged to be a major threat to cattle production. Since the first isolation of *Mycobacterium bovis* from a wild badger found dead on a breakdown farm in 1971, badgers have become generally recognised as a wildlife reservoir and potential source of infection for other species. Although the contribution made by badgers to cattle infection remains unquantified, independent reviewers consistently support the view that badgers are involved in the transmission cycle. Furthermore, evidence from past badger culling strategies and from the Randomised Block Culling Trial (RBCT) of badgers indicates that culling alone is unlikely to be effective in controlling cattle TB. Similarly, it is widely considered that even diligent application of measures to control the disease in cattle will be insufficient to eradicate the disease while infected badgers remain as a reservoir of infection for cattle.

Vaccination remains a potential control option and this project aims to collect data on the safety and efficacy of Bacille Calmett Guerin (BCG), the vaccine licensed for human use in the UK, given by intramuscular injection to badgers in a field setting. BCG has been used experimentally in a wide range of species, none of which has shown any adverse effect due to vaccination and it is anticipated that this study will confirm those findings. The field study is relatively small in scale but it is hoped that it will demonstrate that BCG given in this way protects wild badgers against TB when naturally exposed in the field. If both safety and efficacy are confirmed, this study will provide essential data in support of any application to the Veterinary Medicines Directorate (the body responsible for licensing veterinary drugs in the UK) for approval to use BCG vaccine in badgers.

CB0116:	Efficacy testing of BCG vaccine in badgers
Location:	Veterinary Laboratories Agency
Start date:	01/04/2006
End date:	31/03/2010
Total cost:	£1 468 743

AIM

To obtain data on vaccine efficacy; both for the injected form of BCG vaccine, as well as for any oral vaccine formulation that arises from Defra project SE3223.

OBJECTIVES

- Obtain permissions, resources and protocols for the study.
- First experiment: Determine protective efficacy of BCG Danish vaccine injected intramuscularly (IM) at dose ($2 - 8 \times 10^6$ CFU) to be used in the field study.
- Second experiment: Gather further data on the protective efficacy of BCG vaccine.
- Third experiment: Determine protective efficacy of BCG vaccine given orally.

DESCRIPTION

Cattle tuberculosis remains an economically important problem in GB with the potential to spill over into humans. The frequency of occurrence of cattle tuberculosis continues to increase and badgers have been identified as a significant reservoir for the causative organism, *Mycobacterium bovis*. Furthermore, the recent Godfray report (2004) on the Randomised Badger Culling Trial recommended that the formation of cattle TB policy by Defra should be based on the assumption that badgers are involved in disease transmission as a wildlife reservoir. Previously, the Krebs Report (1997) recommended that the option of a badger vaccine for tuberculosis should be retained alongside the development of a vaccine for cattle. Consistently with these recommendations, Defra confirmed at a Vaccine Programme Advisory Group Meeting in Spring 2005 that they have a requirement for a licensed form of injectable human TB vaccine (BCG) for badgers. There are defined steps to achieving this licence: an experimental safety study performed to Good Laboratory Practice (GLP) accreditation. Completed successfully at VLA in 2004–05; a field safety study, which commenced in Summer 2006; and demonstration of vaccine efficacy. This typically comes from experimental challenge studies in the target species, and may be supplemented with data from field studies.

Given the small scale of the field safety study (which is unlikely to demonstrate vaccine efficacy in a statistically robust way) and the lack of any obvious parameter that can be measured and correlated with vaccine efficacy in badgers without actually infecting them with *M. bovis*, experimental vaccination-challenge studies would strengthen the claims for licensing the use of BCG in badgers significantly, and is the preferred option.

The VLA have already been involved in collaborative work led by scientists in the Republic of Ireland, where it has been demonstrated that BCG administered by injection to badgers conferred significant protection against experimental tuberculosis. These studies are encouraging and supportive in a claim for the use of BCG in badgers, however the data cannot be used directly for the licensing of a BCG vaccine in GB because an undefined vaccine (laboratory stock of BCG Pasteur) was used by the Irish scientists. However, the studies proposed in this project are modelled on the successful vaccination-challenge studies performed in Ireland.

Initial experiments will aim to determine the efficacy of injectable BCG used at the dose chosen for the field safety study and administered by a route (in the muscle) shown to be safe in the GLP study. It is likely that these studies will need to be repeated in order to provide convincing evidence of efficacy for submission to the Veterinary Medicines Directorate (the body responsible for the granting of animal medicines licences, including vaccines, in the UK).

The report by the Independent Scientific Group Vaccine Scoping Sub-Committee (2003) highlighted that in the longer term oral delivery of BCG in bait would be the most appropriate means to vaccinate wild badgers on a wider scale, and that research should continue on the development of an oral vaccine; to which end Defra are funding a three year research project (SE3223) at VLA. That project began in January 2006 and will result in candidate oral vaccine(s) for badgers by 2008–09. It is anticipated that one or more of these oral vaccine candidates will be tested for efficacy in the latter year(s) of this project.

FUTURE RESEARCH PROJECTS UNDER CONTRACT NEGOTIATION

SE3224b:	Continuation of vaccine development in cattle
SE3234:	BCG GLP safety studies in cattle
SE3237:	Matched contribution for EU vaccine proposal: Strategies for the eradication of bTB
SE3246:	Development of an oral BCG vaccine for badgers—RESEARCH
SE3247:	Development of an oral BCG vaccine for badgers—REGULATORY
SE3248:	Specificity/sensitivity of ESAT6/CFP10 in the gamma interferon test

Annex E

UPDATE ON GOVERNMENT FUNDED SCIENTIFIC RESEARCH INTO BOVINE TB UNDERWAY (EXCLUDING VACCINES)

This annex describes the aim, objectives, cost and duration of each of the Defra-funded on-going research projects into bovine TB (NB: details of all research projects concerning bovine TB vaccine development are provided in Annex C). It also provides a brief description of each project. A list of future research projects currently undergoing contract negotiation are provided at the end. Please note that these are subject to change until final contracts for the work have been agreed and issued to the contractors. Details of all on-going and completed research projects are available on the Defra website at <http://www.defra.gov.uk/science/default.htm> and <http://www.defra.gov.uk/animalh/tb/research/projects.htm>, respectively.

SE3032:	The long-term intensive ecological and epidemiological investigation of badger populations naturally infected with <i>Mycobacterium bovis</i>
Location:	Central Science Laboratory
Start date:	01/04/2003
End date:	01/04/2011
Total cost:	£3 386 857

AIM

To continue to collect ecological and epidemiological data from the Woodchester Park badger population consistent with that obtained in previous years. Data has been collected from this site since the mid-1970s).

OBJECTIVES

- Obtaining data on the spatial configuration of badger social groups in the study area (by bait-marking).
- Collecting data on the size, structure and infection status of the population (by capture-mark-recapture and clinical sampling).
- The collation of collected data onto the existing Woodchester Park epidemiological and spatial databases.

DESCRIPTION

THE EUROPEAN BADGER (*Meles meles*) is implicated in the transmission of *Mycobacterium bovis* infection to cattle. The effective management of bovine tuberculosis in cattle is a fundamental responsibility of Defra. However, the development of a sustainable policy to control the spread of *M. bovis* from badgers to cattle can only be achieved through a deeper understanding of the ecology and dynamics of disease in the wildlife host, and interactions with domestic stock. This proposal describes the continuation of data collection from an intensively studied wild badger population at Woodchester Park in Gloucestershire. Since 1975 the Wildlife Disease Ecology Team of the Central Science Laboratory (CSL) has conducted research and provided advice on the ecology of badgers and the epidemiology of *M. bovis*, under contract to MAFF/Defra. The project has involved an intensive long-term programme of trapping and sampling badgers in a high density population in an area of high herd breakdown risk. This has provided data on spatial and temporal epidemiological patterns, ecological, demographic and behavioural processes that have enhanced our understanding of badger ecology, management and the epidemiology of *M. bovis* infection. The continued monitoring of the Woodchester Park badger population provides Defra with a strategic resource with which to explore a range of potential future policy options for the management of *M. bovis* transmission between badgers and cattle.

SE3039:	Identification of changes in individual and global farmer behaviour relating to the movement and management of cattle in the UK with particular reference to the introduction of bTB control measures
Location:	University of Liverpool
Start date:	01/05/2007
End date:	30/04/2009
Total cost:	£289 530

AIM

To monitor changes in farmer behaviour, particularly in terms of cattle movement, following the introduction of bTB control measures designed to assess the likely efficacy of legislation introduced to lessen the spread of bTB in the UK.

OBJECTIVES

- To identify the time-line of policy events relevant to changes in farmer behaviour.
- To conduct comprehensive time series and temporal analysis of cattle movement data.
- To identify farmer-perceived behavioural change since introduction of pre-movement testing and to understand these behaviours and factors that underlie them.

DESCRIPTION

Bovine tuberculosis (bTB) control measures in Great Britain have recently been modified in an attempt to curtail the current epidemic. The mainstay of these measures is the pre-movement testing of cattle. These legislative interventions impose additional cost (both financially and in terms of time) on farmers and may, therefore, alter farm management, particularly with regard to cattle movement. There is therefore a need to monitor changes in farmer behaviour, particularly in terms of cattle movement, following the introduction of these measures to assess the likely efficacy of legislation introduced to lessen the spread of bTB in the UK.

The principal objectives of this work are to identify global and individual level behavioural changes that have occurred since the introduction of bTB control measures and to identify factors motivating these changes. The project consists of three interrelated studies. First, in order to make tangible correlations between behavioural change and modifications to bTB control, a review of all major policy changes to affect the livestock industry over the last five years will be conducted. A time-line of important dates in the announcement and implementation of Government legislation directly affecting the livestock industry will be produced. These include changes to the farm subsidies, handling of fallen stock, and lifting of the “over-thirty-months” scheme. Here the timing of reporting of the relevant legislation in the farming press will also be investigated.

Second, in order to identify changes in farmer behaviour with regard to cattle movements, a detailed network and time series analyses of RADAR cattle movement data will be conducted. Any such analysis needs to recognise the multiplicity of legislation and other pressures under which the cattle industry operates. The livestock industry has been required to adapt to changes in consumer demands, food safety, trade and movement controls over recent decades. Hence, recent bTB control measures are one part of a wide range of changes that have occurred during this time and variation observed in the movement data can only be attributed to recent modifications of bTB control measures by first identifying pre-existent underlying trends. This group have previously reported seasonal and long-term trends in cattle movement data for the period 2002–05 (prior to recent changes to bTB control) and now propose to update existing time series analyses to include data from 2005 to early 2007 in order to identify changes that may be attributable to changes in bTB control.

Initial analyses will investigate the numbers of cattle moving as well as trends in the distances over which cattle are moved. However, analysis of individual farm-level data provides only limited information. Previous work using network analysis has demonstrated that substantial changes, important in the transmission dynamics of infectious agents, may be evident in the cattle movement network despite little or no apparent variation in individual farm measures. Therefore, the group will utilise their expertise in network analysis of large datasets to identify changes in the global behaviour of the cattle industry. They will formally identify change points in trends and correlate them with important dates in the announcement, implementation of bTB, control measures.

Thirdly the effect of recent changes to bTB control on farmer behaviour will be investigated through questionnaire and interview of farmers themselves. Concurrently with time-series analysis, a range of exploratory surveys will be conducted, together with personal interviews to assess factors and conditions which underpin motivation for change since the bTB pre-movement testing. The exploratory survey will identify perceived recent changes in the management of cattle on individual farms and within the industry more generally. Follow-up interviews will seek to verify these changes on-farm, [on-farm or on farms?] and to identify and explain factors responsible for the variation in changes among farmers in different regions. Subsequently, a questionnaire will be used to assess the most important factors impacting on relevant behavioural decisions. These surveys will be conducted in areas with varying degrees of sensitivity to the effects of TB in cattle. Such approaches are essential to capture the regional variation in disease prevalence. Where possible, perceived changes will be verified using RADAR cattle movement data.

This proposal has several strengths. First, it will utilise existing expertise in time series and network analysis to identifying trends in cattle movements, both in terms of farm-level factors (numbers of animals and distances moved, and types of premises moving cattle) and population-level factors (component size and density). Second, it will utilise expertise in measuring behaviour through analysis of movement records; and the proposal is strengthened by experience in communications with farmers. Third, the interdisciplinary skills of the project team will promote novel approaches to the evaluation of agricultural policy. This team have extensive experience in the investigation of the psychological aspects of decision-making and behaviour in a wide range of businesses. Application of these methods to the cattle industries will provide novel insight of the effect of bTB control on the behaviour of these sectors.

SE3040:	A preliminary analysis of existing data to provide evidence of a genetic basis for resistance of cattle to infection with <i>M. bovis</i> and for reactivity to currently used immunological diagnostic tests.
Location:	Roslin Institute
Sub-contractors:	Scottish Agricultural College/Veterinary Laboratories Agency
Start date:	01/07/2007
End date:	30/06/2008
Total cost:	£144 211 (100% WAG funded, project managed by Defra)

AIM

To examine the extent of genetic variation for resistance of cattle to infection by *M. bovis*.

OBJECTIVES

- Identify herds and cattle present in the Defra VETnet TB database in CTS and dairy industry databases.
- Using the linkage established between VETnet, CTS and industry databases, develop an integrated database identifying both animals appearing in the VETnet TB database and their contemporaries present at the time of testing with pedigree and relevant aspects of performance.
- Define and calculate a set of epidemiological and genetic covariates to be used for modelling.
- Construct and refine models of TB-related data accounting for genetic, operational and environmental factors.
- Interpret outcomes and develop recommendations from final models.

DESCRIPTION

There is both anecdotal evidence pointing to genetic variation for resistance of cattle to infection of *M. bovis*, and published experimental evidence in deer for significant genetic variation in resistance and reactivity to diagnostic tests. However this has not been properly quantified in the cattle population and it remains a possibility that such genetic variation exists and is a factor influencing the outbreak currently observed in the UK. The genetic variation may be expressed in resistance to infection, in the response to the diagnostic tests, or both. The opportunity exists to test these hypotheses using the data collected during the current outbreak on animals that react to the diagnostic test and/or exhibit disease and combining this data with industry databases, particularly dairy databases, that contain additional information on herd mates and pedigree.

The outcome of this analysis will firstly resolve the debate on the potential extent of genetic variation in the UK herd in resistance and reactivity to diagnostic tests and will inform subsequent epidemiological analysis. Secondly, given the presence of genetic variation, the results will: (i) provide a preliminary quantification of the impact that current testing policies may have on the degree of resistance to infection present in the cattle population, and would provide recommendations on if and how the tests may be adapted to avoid such negative consequences; (ii) provide breeding companies with information that will allow them to target the marketing of bulls identified as genetically more resistant to areas in which *M. bovis* is more prevalent; and (iii) provide a firm foundation for the identification of genes with large effect on resistance, which in turn will lead to more effective breeding programmes.

SE3119:	Cost-effectiveness of farm husbandry manipulations
Location:	Central Science Laboratory
Start date:	01/11/2005
End date:	31/10/2009
Total cost:	£1 042 493

AIM

To investigate husbandry measures that might be effective at reducing badger to cattle TB transmission within the bounds of farm buildings.

OBJECTIVES

- Identify husbandry measures effective at reducing or preventing badger visits to farm buildings.
- See if different measures provide a detectable change in the risk of farms having a TB breakdown.
- Estimate the economic costs of different measures.
- Estimate the cost efficiency of different measures.

DESCRIPTION

Recent research at the Central Science Laboratory (CSL) has identified visits to farm buildings by badgers (*Meles meles*) as potentially important in the transmission of *Mycobacterium bovis* (the causative agent of bovine tuberculosis) to cattle. Defra-funded project SE3029, undertaken at the CSL, indicated that this may be a common and widespread problem on cattle farms throughout the south-west of England and that certain farm husbandry characteristics may influence the frequency of visits. Experimental investigation of husbandry practices to reduce badger visits to farm buildings has been recommended by the Independent Husbandry Panel and the Godfray Review.

This project aims to identify and measure the benefits and costs associated with two broad husbandry practices by manipulating them on a series of farms within a factorial experiment. Each measure may achieve a different result. Therefore, an investment appraisal will be conducted to identify and estimate the potential benefits and costs of each husbandry practice. The benefits derived from each measure, both in isolation and in combination with others, will be assessed as the ability to affect a change in the frequency of badger visits to farmyard resources and quantify the effect this has on the risk of badger-cattle interactions (both direct and indirect) as a result of farmyard modifications. This will allow estimation of the benefits (valued in £GB) of disease exposure risk-reduction methods. Wider social benefits (eg potential benefits to farming communities) will be identified from an extensive literature review and discussions with the NFU and Defra. The cost-effectiveness of the manipulations will be analysed using profitability indicators such as net present value (NPV), benefit:cost ratio and internal rate of return. Risk and uncertainty will be assessed via sensitivity analysis.

The results will be directly relevant to Defra's policy on controlling TB in cattle by providing a quantified estimate of the benefits produced through improved farm husbandry methods. This will also be of direct benefit to the farming community who will be provided with information on which to make informed judgements on whether and how to invest in improved husbandry methods to reduce risks to herd health.

SE3221:	Volatile organic compound analysis for the rapid diagnosis of disease: TB in badgers and cattle as proof of principle
Location:	Veterinary Laboratories Agency
Sub-contractor:	Cranfield University
Start date:	01/01/2006
End date:	31/12/2008
Total cost:	£457 390

AIM

Investigate new diagnostic methods, that might improve the means of testing live animals for TB, giving rapid, accurate results.

OBJECTIVES

- Build a device to allow collection of exhalations from cattle and determine if such samples of breath correlate to fresh samples.
- Obtain samples from cattle and badgers for analysis and determine the infection risk associated with such sales from TB infected cows.
- Determine the accuracy of e-nose and SIFT-MS for the detection of TB in cattle and badgers and identify the nature of at least two volatile organic compounds associated with TB.

DESCRIPTION

Developments in genomics have highlighted the concept of “array technologies” and the potential power of understanding “disease signatures”. Recently, significant progress has been made in developing tests for the rapid diagnosis of disease, based on the detection and analysis of volatiles present in clinical samples, using chemical sensor arrays coupled with multi-variate data analysis.

The generic nature of sensor technology is such that it has the potential to be applied across a wide range of core Defra activities. These include rapid pen-side detection and diagnosis of infectious diseases in animals, improving the speed of diagnosis of infectious disease by culture, improving the quality and flavour of food and environmental monitoring (of water, soil animal waste etc) for quality and contamination. It is thus a truly cross-cutting technology which has the potential to be applied to objectives under the six science themes laid out in Defra's Science and Innovation Strategy document.

The VLA have recently obtained proof of principle that it is possible to differentiate badgers and cattle with tuberculosis from healthy controls by analysing the volatiles present in serum using an electronic nose (eNose). The aim of this project is to evaluate more fully the analysis of volatile organic compounds (VOC) for tuberculosis detection using two different devices: the eNose and SIFT-MS (selective ion flow tube mass spectrometry).

Bovine tuberculosis remains an economically important problem in Great Britain with potential zoonotic consequences. As such, Defra continues to have a statutory obligation to control tuberculosis in farm animals in Great Britain under the Animal Health Act of 1981, the Tuberculosis Orders, and various EC directives. Despite the current test and slaughter control programme, the frequency of occurrence of bovine tuberculosis continues to increase and badgers have been identified as a significant reservoir for *Mycobacterium bovis*. The Krebs Report [1] highlighted the need to develop improved diagnostic assays for bovine and badger tuberculosis. These are expected to offer improvements in terms of diagnostic accuracy in both species and could have significant impact on the control of bovine tuberculosis.

If successful, the technology underpinning both approaches could be used to develop rapid diagnostic tests which could be performed on farms or in the field. Such a test for TB would complement current immuno-diagnostic assays such as tuberculin skin testing, blood-based IFN-gamma assays and serology. In the longer term such tests could be developed for use by farmers (or local vets) to monitor their own livestock for a range of infectious diseases. Tests/technology arising from this project have the potential for commercialisation, and as such this takes the work beyond the realm of the Evidence Base Unit (FFG, Defra).

SE3230:	The problem bTB herd—characterisation, prediction and resolution
Location:	Veterinary Laboratories Agency
Sub-contractor:	University of Cambridge, CIDC
Start date:	01/04/2007
End date:	30/04/2010
Total cost:	£411 556

AIM

To define and characterise the problem herd, predict outcomes of possible control strategies and to recommend appropriate actions.

OBJECTIVES

- Defining and describing potential “problem” herds with characterisation of principal risk factors.
- Defining and describing the avian reactor “problem” herd.
- Developing decision trees for AH so that appropriate control actions can be based on data accumulated in (potential) problem herds during a TB incident, through analysis of cases, actions and outcomes.
- Developing decision trees for AH so that appropriate control actions can be based on data on potential problem herds and their surroundings, before a TB incident has occurred, through analysis of cases, actions and outcomes.
- Disseminating the above findings to Defra, AH and the broader scientific community.

DESCRIPTION

Since the foot and mouth epidemic of 2001, both the distribution and intensity of bovine tuberculosis in the national herd of Great Britain have increased, such that until recently the national trend showed a yearly increase of 18% in confirmed incidents. The current control programme is designed to detect infection (by routine skin testing, slaughterhouse inspection and movement tracing), to remove infection as thoroughly as possible (by short interval testing) and to prevent spread to other herds (by pre-movement testing and movement restrictions).

By its nature, much of the programme is reactive. Parish testing intervals, for example, tend to be modified only after a changed risk of infection is detected, usually several months after the risk has actually increased. Pre-movement testing is a welcome recent step in preventing new cases occurring in areas of previous high or low risk, and the present proposal would yield needed methods for estimating its effectiveness. However, this programme, apart from modifying parish testing intervals and allowing discretion to treat some “high risk” categories of herd more severely (such as dealer herds), treats all herds in a similar fashion. Yet some herds are known to be “problem” herds, ie experience has shown that these herds are more likely to have new incidents (sometimes repeatedly), tend to have more affected animals when they do break down, repeated short interval testing may take a long time to clear infection, or total or partial herd slaughter is deemed necessary to eliminate infection . . . and so on, depending on the definition of “problem herd” adopted.

This project first seeks to define and characterise the “problem herd”, then to predict outcomes of possible control strategies, and finally to select appropriate actions. For example, herds can be described according to their disease history before focusing on the characteristics of those herds that may predispose to the defined “problem”. VLA is now in an excellent position to define and characterise different types of “problem” herd, using detailed and relevant datasets. They include VetNet, the British Cattle Movement System database, the TB99 and CCS05 herd questionnaires and VLA’s molecular typing datasets. Both in size of database and in integrating them, VLA has more experience at using these datasets for investigating TB epidemiology than any other institute. “Problem herds” will be focussed on in conjunction with the experience of specialists in TB in both Defra and Animal Health (AH) to help focus on the key characteristics for investigation.

Currently available datasets provide useful data on all types of “problem” herd except for the thousands of herds that have positive avian tuberculin responses. These can delay identification of any bovine TB infection that has occurred. There are several aspects to be considered. For example, herds may not be detected as infected at a routine herd test, introducing a dangerous delay; individuals may not be detected during a confirmed breakdown, resulting in undue extension of the incident; or, again, herds may clear restrictions only to find further infection at the six month check test because infection was not detected at previous tests. This issue will be treated as a separate objective within the study.

It is anticipated that, by using the BCMS data in particular, it will be possible to quantify how dangerous these “problem” herds are in terms of risk of spread to other herds. By using the full range of data it will be possible to attempt to quantify the risks they pose to themselves (in terms of further incidents and degree of within-herd spread). How costly these herds are in the context of the whole control programme could then be quantified, utilising cost data recently gathered in other Defra-funded projects. These outputs would inform the best approaches to controlling the bTB risk to, and presented by, these herds.

An important element of this study will be to develop tools for predicting which herds would fit into “problem” categories, and tools for recommending cost-effective control actions (decision trees or in some cases Expert Systems). These could then help AH decide on what action to take to control the risk presented. The decision trees could use information accrued from suspected “problem” herds, either: information accumulated before and during a TB incident, leading to recommendations for eliminating infection; or information that is available before infection has been detected, leading to recommendations for reducing the risk of the herd becoming infected or spreading infection. Information of significance might include: herd size, type, and other husbandry details (source: VetNet, CCS2005 and TB99 data); biosecurity details, eg efforts to exclude wildlife from buildings, to prevent cattle coming into contact with wildlife, or coming into contact with other herds (CCS2005 and TB99 data); movement history: numbers of animals moved into the herd, and the time they had spent in herds with various levels of bTB prevalence (source: CTS and VetNet data); distribution of the risk of infection with bovine TB in GB (geographical (GIS) analysis of VetNet data); and information gaps—and needs for additional investigations—as identified in this process. The project will develop decision trees that can enable AH to be more proactive in the elimination of infection in “problem” herds, and to prevent the emergence of new problem herds.

SE3231:	Validation and epidemiological application of molecular methods for monitoring <i>M. bovis</i> survival and dissemination in the environment.
Location:	Veterinary Laboratories Agency/University of Warwick
Start date:	01/05/2007
End date:	30/04/2010
Total cost:	£1 309 583

AIM

To validate and optimise specific real time quantitative PCR methods for the detection and quantification of *M. bovis* in the environment.

OBJECTIVES

- To validate RD4 *M. bovis*-specific DNA-based surveillance methods and compare DNA extraction methods (Ring Trial).
- To prove that molecular detection correlates with detection of *M. bovis* cells in environmental samples.
- To determine viability of *M. bovis* cells and carry out typing studies of soil IMC extracts.
- To evaluate non-invasive molecular screening tool to detect hotspots of *M. bovis* contamination on farms with persistent bTB breakdowns.
- To evaluate an environmental screening tool to detect hotspots of *M. bovis* contamination on farms with persistent bTB breakdowns.
- To determine viability of *M. bovis* cells and typing studies of soil isolates.

DESCRIPTION

Bovine tuberculosis (bTB) is a serious and growing disease of cattle in Britain. The study of *Mycobacterium bovis*, the bacteria that causes bTB, poses particular challenges with regard to its specific detection once deposited in soil due to its similarity to closely related species that are also found in the environment, and due to the intrinsic nature of the environmental bacillus once deposited via contaminated animal excreta. Information gained from sequencing the complete genome of *M. bovis* has revealed a number of unique DNA sequences (or regions of difference (RD)) compared to other closely related species, and these differences provide a basis for the development of highly specific DNA probes that detect and amplify only *M. bovis* DNA. A region of difference known as RD4 is deleted in *M. bovis* but not in other closely related species, and this fact was exploited to develop a DNA detection and enumeration technique (real time PCR) specifically for *M. bovis*.

This proposal will extend past research to optimise PCR assays that will allow discrimination between *M. bovis* and closely related species from environmental samples. A ring trial will be performed by participating research institutes (VLA and Warwick University) to test the sensitivity, specificity, reliability and reproducibility of the PCR on a range of positive and negative laboratory and field samples. Complementary studies will address questions about the viability, abundance and metabolic activity of *M. bovis* cells in different environmental substrates. Growth of the cells isolated from PCR positive environmental samples on culture media will be performed in an attempt to identify the strains found in the environment and compare these to strains found in the tissues of infected cattle and badgers. Towards field application of the PCR, environmental sampling protocols will be developed in the context of improving farm biosecurity, and as a non-invasive marker of badger infection.

SE3232:	The molecular basis and impact on host response of phenotypic variation across <i>M. bovis</i> molecular types
Location:	Veterinary Laboratories Agency/Institute of Animal Health
Start date:	01/09/2007
End date:	31/08/2010
Total cost:	£130 045 (BBSRC GPA)

AIM

To determine the impact of *M. bovis* molecular types on the bovine innate immune response and to identify the pathogen constituents that modulate this response.

OBJECTIVES

- Do distinct molecular types of *M. bovis* induce differential immune responses in the bovine host?
- What are the constituents of the pathogen that trigger these responses?
- Validation of immunomodulatory mechanisms.
- Data Management.

DESCRIPTION

Bovine tuberculosis (bTB) is one of the most difficult animal health problems that the farming industry in Great Britain faces today. The number of cattle infected with bTB has been increasing year on year by 18%, which leads to serious losses for affected farms due to the slaughter of infected animals and the imposition of cattle movement restrictions. Government spending on disease surveillance and compensation to farmers has also been following this upward trend, with spending over 2004–12 expected to top £1 billion. From these statistics it is clear that the current disease control strategy is not working,

yet the reasons for this are not obvious. One possibility is that new forms of the causative agent of bTB, *Mycobacterium bovis*, have evolved in GB that are able to circumvent the current control measures. Research by the VLA has found that evidence for this latter scenario is supported by the presence of a range of different types of *M. bovis* circulating in GB that seem to be successful in spreading around the country from their original place of isolation. This project sets out to determine whether these diverse types of *M. bovis* interact with the immune system of cattle in different ways, and so explain their success. To achieve this the groups will take advantage of the recent availability of the complete DNA sequences of both *M. bovis* and the bovine host. This will allow them to explore how the host and pathogen interact with each other at the level of individual molecules, and to build up a more detailed picture of how *M. bovis* causes disease in cattle. The information coming from this project will help government policy makers to develop new control strategies based on the exploitation of epidemiological information, and offers the chance to stop the upward spiral of bTB disease burden and linked expenditure in GB.

SE3235:	To improve the sensitivity of spoligotyping for direct tissue application
Location:	University College, London
Start date:	01/09/2008
End date:	30/04/2009
Total cost:	£58 285

AIM

To identify improvements which could be made to the current method of spoligotyping to increase sensitivity of the procedure.

OBJECTIVES

- To develop a modified LATE-PCR spoligotyping protocol.
- To validate this protocol and compare with the existing spoligotyping procedure in use at VLA Weybridge.

DESCRIPTION

Spoligotyping is a DNA fingerprinting technique which is widely used in identifying and tracking strains of MTB complex organisms involved in outbreaks of disease. The technique is particularly useful for typing strains of *M. bovis* and is used in the surveillance programme of outbreaks of bovine tuberculosis affecting cattle and other wildlife in the UK. This PCR-based method is perfectly adequate when applied to DNA of sufficient quantity and quality, such as that provided by culture, but yields a partial fingerprint in up to 50% of cases when applied directly to DNA isolated from clinical samples (compared to cultures of the same cases). This may be due to the sparsity of mycobacteria in some tissues.

This project will investigate improvements which could be made to the current method of spoligotyping to increase sensitivity of the procedure. It is hoped this will obviate the need for, or at least markedly reduce, the time of culture before typing is applied. The time to results could be reduced from a few weeks to a few days. This should find application in a range of situations, such as in routine typing of cattle tissues, slaughterhouse cases and environmental and fixed archival samples where culture may not be feasible.

SE3236	Multiplex PCR to distinguish between <i>M. bovis</i> and BCG and <i>M. microti</i>
Location:	University College, London
Start date:	01/05/2009
End date:	31/08/2009
Total cost:	£31 540

AIM

To develop a multiplex PCR which will simultaneously detect and quantify three members of the MTB complex *M. bovis*, the vaccine strain *M. bovis* BCG, and *M. microti*.

OBJECTIVES

- The development of specific PCR methods for *M. microti*, *M. bovis* BCG based on primers flanking specific deletions RD1^{mic} and RD1^{BCG} respectively. The combination of these methods with the *M. bovis* RD4 method (Taylor *et al*, 2007).

- “Checkerboard” optimization of PCR components & conversion of the optimal primer set combinations into Taqman methods using linear hybridisation probes labelled with appropriate fluorescent chemistries.
- Determination of minimum detection limits of the multiplex using environmental samples spiked with DNA standards and viable cells. Transfer to VLA RT platform & preparation of final report.

DESCRIPTION

Bovine tuberculosis is a chronic granulomatous disease mainly affecting lymph node and lung tissues of cattle. It is caused by *Mycobacterium bovis*, a member of the *Mycobacterium tuberculosis* (MTB) complex group of bacteria. At the genome level, *M. bovis* shares over 99% identity with *Mycobacterium tuberculosis*, the agent of human tuberculosis and other members of the MTB complex. Sequencing of key members of the MTB complex has shown differences due to deletions in the genomes which allow the development of methods for species identification. This proposal concerns the development of a multiplex PCR which will simultaneously detect and quantify three members of the MTB complex *M. bovis*, the vaccine strain *M. bovis* BCG, and *M. microti*, which mainly affects small mammals.

SE3239:	A county Parish Holding Herd (CPHH) level spatial and temporal analysis of the Randomised Badger Culling Trial (RBCT) dataset
Location:	University of Bristol
Start date:	01/10/2008
End date:	30/09/2010
Total cost:	£287 457

AIM

To perform finer scale analyses to look at the incidence of bTB in cattle by farm and in badgers in smaller space/time areas of the RBCT and to test the hypothesis that bTB cannot persist without the presence of both cattle and badgers and that removal of one or other leads to a decay in environmental persistence that may provide alternative policies for control of bTB.

OBJECTIVES

- Selection of the appropriate data from the VETNET and RBCT databases.
- Construction of definitions of closeness between farms and badger data and construction of time-dependent predictor variables to indicate numbers and percentages of close individuals (both badgers and other cattle).
- Construction of cattle movement predictors.
- Development of time to event (survival) models to examine risk factors.
- Assessment of the effect of the assumed perfect sensitivity/specificity of the TB test.
- Evaluation of plausibility of modelling competing risk models to model both risk of infection and probability of cure/re-infection based on data.
- Preparation of papers.

DESCRIPTION

In this project the researchers will look in detail at the relationship between TB cases in cattle and TB cases in badgers at a finer level than that looked at originally in the Randomised Badger control trial (RBCT). They will consider the areas of the RBCT selected for proactive culling and survey only and match data collected on culled badgers with the individual cattle herd breakdowns. They will then look at associations between individual cattle herd breakdowns (CHBs) that occur and the numbers of badgers both infected and non-infected with TB that are trapped and culled close to the herd along with other close CHBs that occur. They will also look at associations between CHBs and prior cattle movements both in terms of numbers of movements and the infection history of former herds. They will consider the hypothesis that removal of either badgers or cattle may successfully control bTB in cattle. Appropriate statistical analyses that account for the temporal nature of the data as well as the spatial structure that exists will be performed. They will evaluate whether such a finer grain analysis of the data results in different findings than the original trial area level analysis and how detailed and fine scale an analysis the data can support.

SE3240:	Spatial and temporal analysis of cattle herd breakdowns in the RBCT
Location:	Central Science Laboratory
Start date:	01/09/2008
End date:	31/08/2009
Total cost:	£61 286

AIM

To identify sources of unexplained variability in the response of cattle herd breakdowns to badger culling treatments in the Randomised Badger Control Trial (RBCT), by taking into account the finer spatial and temporal detail of treatments and responses.

OBJECTIVES

- To estimate the effects of uncertainty in cattle herd testing on the measured effect size for RBCT treatments, using Monte Carlo simulation.
- To characterise the spatial pattern of disease in the RBCT, in individual herds and badger social groups, using Mantel testing of similarity matrices.
- To characterise the spatial-temporal clustering of disease, among herds and badger social groups, using point pattern analysis based on K-function analyses.
- To analyse the influence of variation in treatments, including the timing, duration, location and extent of culling operations, on disease dynamics in badgers and cattle, using Generalised Linear Mixed Models and Generalised Geo-Additive Mixed Models.
- To undertake a survival analysis, analysing the influence herd, badger and environmental covariates on the hazard of cattle herd breakdowns, using Cox-proportional hazard models, allowing direct comparison with Irish badger culling analyses.
- To investigate the interactions among the components of the Cattle:Badger:Disease system, using Structural Equation Modelling.

DESCRIPTION

The Randomised Badger Culling Trial (RBCT) examined the number of cattle herd breakdowns (CHBs) due to bovine tuberculosis in response to proactive and reactive badger culling, at the scale of replicated blocks of 100km². This design was entirely suitable for evaluation of policy options at a large scale. Unsurprisingly, there remained after statistical analysis considerable unexplained variability in the number of cattle herd breakdowns, much of which is likely to relate to the localised nature of environmental conditions, including the status of the badger population. This project will investigate the fine-scale nature of variation in the fate of individual herds during the RBCT, by conducting a range of spatially-explicit analyses that take into account small scale variation in time and location of treatments and responses. The project will address three elements of the identified research needs:

1. investigate the location and timing of CHBs in relation to badger culling, and the infectious status of badgers;
2. identify the effect of variation in the extent of culling treatment areas within the 1-2km buffer zones; and
3. identify any differences in the outcomes seen on confirmed and unconfirmed CHBs.

SE3241:	Spatial-temporal analysis of the Randomised Badger Culling Trial
Location:	Veterinary Laboratories Agency
Start date:	01/09/2008
End date:	28/02/2010
Total cost:	£246 706

AIM

To construct a web-based interactive GIS mapping tool for the visualisation of the RBCT reactive data which can be used to assist in the epidemiological analysis of the reactive trial areas and provide a better understanding of how spatial and temporal factors affect the incidence of confirmed and unconfirmed breakdowns, and the effects of culling on a small scale.

OBJECTIVES

- To produce a web-based GIS mapping tool capable of visualising all relevant RBCT data, enhanced by information available from existing datasets (IACS, VETNET, CTS, VLA/Defra and ERGO archives), and by newly acquired or produced information about parcel-resolution land use.
- To conduct an epidemiological analysis of the data from the reactive areas, using the archive created in objective 1 and considering, in particular, the location, timing and severity of CHBs in relation to the location, timing and intensity of badger culling in the trial, and the infectious status of the badgers removed, incorporating *Mycobacterium bovis* genotyping of badger and cattle.
- To determine the likely proportion of unconfirmed breakdowns that represented true herd infections, their contribution to the epidemiology of bovine tuberculosis (bTB) within the RBCT trial areas and the extent to which these herds are spatially related to clusters of infected herds and infected badgers.
- Development of a method to estimate the contribution of badgers to bTB infection of herds using pattern analysis of numbers of reactors.
- To identify factors that can explain differences between farms within reactive areas that experienced a breakdown and farms that did not and which may protect from bTB, using the data archive compiled by objective 1 including new data relating to spatial features extracted from maps.

DESCRIPTION

The ISG has performed and published a comprehensive and top-level analysis of the data collected by the Randomised Badger Culling Trial (RBCT) and associated studies. However, further insights would accrue from a descriptive spatial-temporal representation of the data and sequence of events during the RBCT. In particular, further insights are needed into the mechanism by which culling may increase herd breakdowns and how this may be ameliorated.

The first aim of this work is to produce an archive of data pertaining to the reactive component of the trial that will include data collected as part of the trial and existing data sets maintained by the VLA, Defra and Animal Health. This will be supplemented with environmental data such as climate and landscape features, census data and Geographical Information System (GIS) databases including satellite imagery and aerial photography (objective 1). This archive will be used to construct a web-based interactive GIS mapping tool for the visualisation of the RBCT reactive data that will display and summarise the data collected in the reactive component of the RBCT in a collection of maps layering information that can be explored interactively.

This GIS tool will then be used to assist in the epidemiological analysis of the reactive trial areas. The location, timing and severity of infections in cattle herds will be evaluated in relation to the location, timing and intensity of badger culling during the trial. A descriptive epidemiological analysis will be performed to describe the sequence of events and the spatial and temporal relation between a confirmed Bovine Tuberculosis breakdown (CHB) on a farm, its associated culling operation and the distribution of subsequent breakdowns, incorporating badger activity, infection status and cattle and badger genotype information (objective 2). Part of this will be an extension of previous work carried out at the VLA to estimate the temporal relation between culling and subsequent breakdowns in the nearest herds and contiguous herds.

Within trial areas there were holdings that experienced a breakdown and holdings that did not. The visual representation of the reactive areas and data archive will be used to identify factors that may affect the risk of breakdowns, such as farm management factors and landscape and environmental factors that may affect exposure to badgers. Novel information about landscape factors such as length of boundaries, location of crops etc, will be extracted from the maps and utilised in a comparative epidemiological analysis to identify factors that may reduce the risk of a CHB (objective 5).

In addition, the wealth of data collected during the RBCT presents a unique opportunity to assess the importance of other factors that may greatly contribute to Bovine Tuberculosis control. In objective 3, factors will be identified that determine whether a unconfirmed breakdown will eventually be confirmed as truly infected with *Mycobacterium bovis* and assess the contribution of unconfirmed breakdowns to the epidemiology of bTB in all RBCT areas. In objective 4, the relationship between the monthly pattern of the number of reactors for breakdowns and the most likely source of infection will be estimated.

The research described will build on the knowledge base gained from SPIDA (a web based interactive mapping tool developed at the VLA) and could also be viewed as a pilot for how environmental, landscape and disease data might be combined to inform control strategies. It will enhance the RBCT data archive providing an extensive array of new environmental variables in the reactive area for current and future research. The epidemiological analyses proposed will provide a better understanding of how spatial and temporal factors affect the incidence of confirmed and unconfirmed breakdowns, and the effects of culling on a small scale.

 FUTURE RESEARCH PROJECTS UNDER CONTRACT NEGOTIATION

SE3238:	Meta-analysis of diagnostic tests for bTB in cattle
Location:	Veterinary Laboratories Agency
Start date:	01/09/2008
End date:	29/01/2010
Total cost:	£175 289

AIM

To establish the best estimates of the classical test characteristics of sensitivity and specificity for diagnostic tests for bovine tuberculosis in cattle in GB and how we can maximize accurate diagnosis using single tests or a combination of tests and use this information in a control strategy to reduce the incidence of bTB in GB.

OBJECTIVES

- To provide a qualitative description of diagnostic tests currently used to assess infection with *Mycobacterium bovis* in cattle including test practicality.
- Through bibliographic searches of scientific databases identify studies that have measured test sensitivity and/or specificity of diagnostic tests for *M. bovis* in cattle.
- Using standard meta-analysis techniques estimate the sensitivity and specificity of diagnostic tests that are practical to use to assess infection with *M. bovis* in cattle in GB.
- To show how combinations of tests may be used to control bTB in GB and potentially achieve freedom from infection.

DESCRIPTION

Bovine tuberculosis (bTB) caused by *Mycobacterium bovis* is a significant endemic disease in cattle in Great Britain (GB). There were confirmed new incidents of bTB in 2.5% of British herds in 2006 and the incidence has been rising steadily since the early 1990s. The single intradermal comparative tuberculin test (SICTT) is the bedrock to current control of bTB in GB, but other tests exist including the interferon gamma blood test which already supplements the SICTT in specified circumstances. Reviews have been conducted of diagnosis of bTB in cattle, but there has been no attempt to conduct a statistical analysis to summarize available data about the accuracy of the tests. There is no consensus about the best values to use for GB. The study will identify published data measuring the performance of a range of diagnostic tests for bTB including the SICTT, interferon gamma, culture of *M. bovis*, histology, post-mortem inspection and other blood based tests. A Working Group comprising over 15 experts in veterinary disease, bTB and diagnostic tests will review these studies and extract information about the accuracy of the diagnostic tests. These data will be combined using standard statistical methods to obtain best estimates of the accuracy of the tests. This information will then be used in statistical models to predict the best combination of tests that could be used in strategies to control and reduce the incidence of bTB in GB. A range of models designed to represent the different disease scenarios across GB will be developed and the effect of a range of testing strategies including frequency of testing and different combinations of diagnostic tests will be examined. The project will draw heavily on the experiences of the Working Group that recently conducted the review of diagnostic tests for bTB in deer and developed models for designing control strategies for achieving freedom from infection with *M. bovis* in deer.

SE3242:	Further analyses of spatial and temporal trends in the cattle data associated with the Randomised Badger Culling Trial
Location:	Imperial College, London
Start date:	15/10/2008
End date:	30/04/2010
Total cost:	£379 625

AIM

To investigate any seasonality in the risks of TB infection, estimate the impact of proactive and reactive culling on infection incidence, analyse the effects of proactive culling using individual herd data including measures of local TB risk and investigate ongoing trends in TB incidence among cattle herds in proactive and survey-only trials areas.

OBJECTIVES

- Analysis of seasonality in TB infection incidence.
- Investigating biological plausibility—estimation of the impact of proactive and reactive culling on infection incidence by quarter year.
- Analysis of the effects of proactive culling using individual herd data including measures of local TB risk.
- Ongoing monitoring of TB incidence in cattle herds in RBCT areas.

DESCRIPTION

An important challenge in understanding how, when and where tuberculosis (TB) transmits to and between cattle is that infections are not immediately apparent. In most cases, infections are detected when cattle are tested using a skin test which measures each animal's immunological response to the bacterium that causes TB in cattle (*Mycobacterium bovis*). The skin test indicates the presence or absence of infection, which can be later confirmed after a post-mortem examination of the animal, but it does not provide information on when the infection occurred. Thus, those investigating the disease learn that an infection occurred, but subject to caveats about test performance, the insights are limited to the knowledge that the infection happened between the date of the current skin test indicating infection and the date of the most recent past skin test (if any) showing no evidence of infection.

This limitation means that careful statistical analysis is required in order to investigate any seasonality in the risks of infection. This project will investigate this issue directly to determine whether cattle appear to be at higher risk of becoming infected with *M. bovis* in some months than others. If there were big differences in risks by month, then advice to farmers regarding biosecurity measures (designed to limit opportunities for disease spread) could be improved by highlighting when extra vigilance would be most beneficial.

Not being able to determine precisely when cattle became infected also complicated interpretation of the results of the Randomised Badger Culling Trial (RBCT), which tested two potential badger culling strategies to determine whether they reduced the amount of TB in cattle. This project will also investigate, using statistical models, what the information collected from skin tests performed on cattle in the RBCT means in terms of how badger culling affected the risks of cattle TB infections over time, in RBCT trial areas and on nearby land. Further analysis of RBCT data will also investigate if/how badger and cattle herd densities immediately surrounding herds affected their TB risks and the impacts of badger culling on these TB risks.

Finally, the project will investigate ongoing trends in TB incidence among cattle herds in proactive and survey-only trials areas following the completion of a Defra-funded contract which ends on 31 March 2009. The results will be reported to Defra in August 2009 and February 2010. The results of these investigations will be submitted to scientific journals where they will be subject to review by independent scientists prior to publication. Furthermore, members of the project team will give presentations of the results both to other scientists and to stakeholder groups.

SE3243:	Analysing the Randomised Badger Culling Trial from a National Cattle Perspective
Location:	University of Glasgow
Start date:	01/10/2008
End date:	30/09/2010
Total cost:	£127 926

AIM

To ask what the national British perspective can tell us about the RBCT analysis and to extrapolate from the RBCT and determine how best to control the spread of the areas where cattle are deemed at high risk of becoming infected (HRAs).

OBJECTIVES

- Determine the best fit and likely credible ranges for herd BTB prevalence, consistent with recorded breakdown rates.
- Determine the overlap in at the population (herd-to-herd) level between core regions for *M. bovis* genotypes.
- Develop simple cellular automata models of genotype mixing at the herd level.

- Determine whether inclusion of badger density and genotype distribution data in GB result in a statistically significant improvements in fit for models of BTB spread due to cattle movements.
- Identify the extent to which breakdowns in the RBCT may be influenced by events at the national geographical scale.
- Identify better ways of predicting rate of High Risk Area (HRA) spread.
- Identify appropriate control strategies for new HRA's, including new boundaries to established regions and isolated HRA's.

DESCRIPTION

The epidemic of bovine tuberculosis (bTB) in British cattle is a growing problem with substantial economic costs to farmers and the government. It is both a problem of animal health and a zoonosis with occasional serious health consequences. While there has been considerable time, effort and expense devoted to understanding the causes of its spread and its control, thus far a coherent, integrative study that uses the considerable datasets characterising the genetic population structure of *Mycobacterium bovis* (the aetiological agent of bTB) and the demographics of British cattle to describe the epidemic on a national scale and evaluate control policies in this context has not yet been undertaken.

The Randomised Badger Culling Trial (RBCT) confirmed the role of badgers in the maintenance of bTB in GB, and provided evidence that cattle-to-badger transmission is potentially an important part of the epidemiological picture. Further, it was recommended that the benefits of badger culling were largely offset by an increase in incidence outside removal areas, unless those removal areas were impracticably large. However, the Chief Scientist's report on the RBCT re-opened the case for badger culling, making the assessment of alternative control strategies of vital importance. Interpretation of the RBCT on a national scale will require more inference about how bTB transmission might vary with badger densities and cattle demographics across GB, a problem exacerbated by the substantial increase in the last decade of the geographical areas where cattle herds are tested annually for bTB, and therefore deemed to be at high risk (HRAs). In contrast to the RBCT, the Offaly study in the Republic of Ireland has shown that under the conditions in Ireland, widespread culling of badgers was an effective strategy. While interpretation of these results in the GB epidemiological, social and legal context should be undertaken with caution, they emphasise that identifying the most viable British control strategy requires a more precise understanding of whether or not currently defined HRAs are likely to become more widespread, where these areas are likely to be, and whether a single approach to control is appropriate across all GB.

This project will use RBCT data on the relationship between badger and cattle bTB both in the presence and absence of culling in combination with the populations genetics data derived from all bTB breakdowns throughout GB, and the detailed recording of individual cattle movements in the cattle tracing system. *M. bovis* genotypes derived from cattle show a remarkable level of spatial clustering; with patterns that appears to have been stable for at least the past decade. Using a combination of simple mathematical models of within-herd and spatial-spreading epidemics and tools from social network analysis, how these patterns are maintained will be analysed. This project will therefore provide insights into how HRAs themselves spread, thereby better informing control of bTB with the aim of preventing this spread, and providing additional insight into the extent to which the recommendations from the RBCT are dependent on the locations chosen for the RBCT triplets.

Witnesses: Rt Hon Hilary Benn MP, Secretary of State for Environment, Food and Rural Affairs, Ms Gabrielle Edwards, Programme Manager, Bovine TB Programme and Mr Alick Simmons, Deputy Chief Veterinary Officer, Department for Environment, Food and Rural Affairs, gave evidence.

Q1 Chairman: Ladies and gentlemen, if you are all sitting comfortably, as they say, we will begin. Can I formally welcome the Secretary of State for Defra, Hilary Benn, Gabrielle Edwards, the Programme Manager for the Bovine TB Programme, and Alick Simmons, the Deputy Chief Veterinary Officer. Thank you all very much indeed for coming and joining us this afternoon. Secretary of State, this is the first time that you have come before the Committee since Defra had its priorities changed and aspects of climate change went to the new energy and climate change department. We are delighted that you are still there guiding the ship of Defra, but I think it might be quite a nice opportunity for us if you could spend just a minute or two telling us now, in terms of the priority of your departments, how you see things. Climate change was your number one

priority in the previous department. How have you rearranged the ship of state now in terms of priorities in the department?

Hilary Benn: First of all, Chairman, it is a pleasure to be here. Can I say about the change, that I think to bring energy and climate change together was absolutely the right thing to do. Defra retains, as you will know, responsibility for climate change adaptation, and a host of other responsibilities. I suppose I would describe it like this: Defra's job is to help all of us to live sustainably within the earth's ability to accommodate us. We have got a particular priority now for food. In a sense, the change has reflected the consultation paper on food security which I published in the summer, because as I reflected on this question in my first year in post it was pretty clear that you could not continue, as some

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had argued, to say: “Whatever happens in the world out there, we will always be able to grow or to buy the food from somewhere”, on the one hand, but, on the other hand, be looking at climate change, drought, deluge, rising population, export bans and the rising price of energy and so on. In announcing the establishment of the Council of Advisers on Food Policy this shows the particular priority that growing food sustainably and the supply chain is going to have. Ultimately, it is about Defra continuing to play a part in helping people to make the changes that are needed so that we are able to live sustainably and to use resources in a way that does not end up depleting what the earth has given us.

Q2 Chairman: I am delighted that you kicked off with food because you will realise that today Parliament is being lobbied by beekeepers. You may well have been “smoked out”, if I do not use the wrong phrase on that—some of my colleagues were when they went to see them—and last night when Defra were responding to the press release of the beekeepers it was said that you were developing a bee strategy, but you dismissed the beekeepers’ claims for additional resources in terms of their research requirements. When we last had the Permanent Secretary here, she indicated that this strategy was in the pipeline. Where is it?

Hilary Benn: Can I say, Chairman, I hope people do not think that somehow we have dismissed the arguments which the beekeepers are putting, because I met Tim Lovett about a month-and-a-bit ago, following on a conversation I had with him at the Royal Show earlier this year. Can I say, first of all, this is an issue which I take very seriously and which we should all be concerned about, and I think the beekeepers deserve enormous credit for what they have done to raise public awareness of the problem. As we know, for the UK, partly it is about the weather but it is partly about longer-term changes that are affecting bees. Just to give some context, we spend about £1.7 million a year on our inspectors, who provide a lot of training and practical advice which, I know because Tim Lovett told me, is much welcomed by beekeepers. We are spending about £200,000 a year on R&D; this year we have put together, with the Welsh Assembly Government, an additional £120,000 precisely because of colony loss to assist with some more research; Rowse Honey have put another £100,000 in and the Wellcome Trust is looking at this (they held a symposium a couple of weeks ago). When I met Tim Lovett I said that the bee health strategy we published for consultation in April, the consultation ended at the end of August, and it is all about identifying priorities. There is also a National Audit Office study looking at research and bee health, and this is likely to publish its findings early on in the New Year. I think it is right and proper that we should have the benefit of that advice in taking decisions. I have followed up particular issues that Tim Lovett raised with me on availability of medicines, and the Veterinary Medicines Directorate is working on that, and I could provide a note for the Committee if that would be helpful,

because there are some very practical issues about licensing, and so on, which we are taking forward. We have set up a forum of research organisations to look at what the gaps are, because I think part of the answer to the beekeepers’ request for £8 million is: “Have we identified what the areas in which we need to have research done are?” It seems to me that is the first question you have to ask before you can then say: “Have we got the resources to make it happen?” I intend to set out what more we are going to do, because I recognise that we need to do more, when we get the results of the National Audit Office study early in the New Year.

Q3 Chairman: So once you have the NAO study and you have looked at all this additional work that you have been discussing, when can beekeepers expect this to be pulled together in the much-promised strategy?

Hilary Benn: In fairness, the strategy was out there in consultation and it has got a lot of good stuff in it, but what I intend to do is respond very speedily once the National Audit Office has completed its work, so that everyone can be clear about what further steps we can take to deal with what is a real problem.

Q4 Miss McIntosh: Secretary of State, you said that the money you spend on research and development was £200,000. How much did the department spend on taxis?

Hilary Benn: On taxis? I would have to go away and check what the precise sum was.

Q5 Miss McIntosh: Is it not the truth—

Hilary Benn: But, yes, it is about £200,000 a year for research.

Q6 Miss McIntosh: Would you, perhaps, consider spending more on research and spending less on taxis?

Hilary Benn: We will always look to minimise the use of taxis for the work that officials do. However, as I have already indicated, Miss McIntosh, I recognise that there is an issue here that we need to address, which is why we are working so hard in the way that I have just set out. It is not just a question of government putting in funding for research; that is why, for example, we have been talking to the Wellcome Trust. We need all the help we can get from all of the quarters to try and identify exactly what the problem is and what practically can be done about it.

Q7 Chairman: In that note that you are very kindly going to produce for the Committee, which we would obviously want to publish on our website, could you also address a point that was raised in *The Times* of 31 October, where it reviews work done by a scientist, Brenda Ball, who was working with colleagues at Rothamsted and there is a suggestion that they had found some antibodies which dealt with some of the disease issues which are currently besetting the bee population? There are then issues as to why that research was stopped, and what has

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happened to its outcome. I think the industry would be quite interested to know that. So perhaps that note could address that issue.

Hilary Benn: I would be very happy to ask my officials to follow that up, Chairman.

Q8 Chairman: Good. Thank you very much indeed for dealing with those issues. Let us move on to the main substance of our inquiry. As you know, and unusually for this Committee, when the Government produced its response to our report on bovine TB we produced what we described as a qualified version; we put some observations which were perhaps less than flattering about some of the conclusions that you had reached. We felt, given the importance of this subject, that we would invite you back here to discuss matters in a little more detail. Since then you have formed an alliance with a number of bodies to set up a Bovine TB Eradication Group, and we will talk about that in just a moment. The raw facts of the matter are that, given the existing situation, it does not seem to me as if the measures that you have put in place in terms of more regular testing, cattle movement requirements and bio-security measures are having a great deal of effect. I am advised that during the first seven months of this year there were 3,062 new incidents of TB in cattle herds, 23,444 cattle slaughtered, and that was 7,060 more than during the first seven months of last year, when some 16,384 cattle were killed. That does not exactly speak volumes for the control programme we have in place. Why has it gone up so much?

Hilary Benn: I wish we knew. It is a bad year, there is no question about that, and the disease does have a cyclical pattern.

Q9 Chairman: Secretary of State, when you look at the amount of money that your department has been spending, the legions of reports which have been written, the work of the independent scientific groups, etc, etc, should we not now know how to answer the straightforward question: "What are the factors that account for a very significant increase in disease against a background of increasing numbers of measures to counteract it?"

Hilary Benn: I was just going to say, Chairman, that part of the answer is the more you look the more you will find. As you will be aware, we have changed the testing programme, and that is one of the explanations. Secondly, I would say—and I think it goes to the heart of what you said as a Committee in response to the Government's response to your original report—I think there are further steps that need to be taken, but I came to the conclusion (and I know you did not, as a Committee, wholly take kindly to it) that having reached a decision about culling that we should establish a working relationship with the industry in dealing with this terrible disease and the impact that it has on farmers—and I think everybody here is only too well aware of that—we have to do it together and we have got to build on the kind of model that we have used extremely successfully in dealing, for example, with Bluetongue. My experience in dealing with a range

of animal diseases has led me to the conclusion that you have to share the problem, and the problem is felt most acutely by farmers, and you need to take decisions on the basis of a partnership, a discussion, together. So, for instance, the ISG said to me, in reaching its conclusion on culling: "We think you should have additional cattle controls." I thought about that very carefully and I could, when I made my announcement to the House in July, have said: "And I have decided that there are going to be additional cattle controls put in place." I decided not to do that because I think there are costs, there are advantages and disadvantages to doing that, and I think it is right that we should sit down with the industry, which, after all, is more affected by this than anybody else, and say: "What do you think?" Then the decisions that are taken about what further steps are required are likely to have greater weight and greater force than if I take those decisions in isolation. We have had a period of time when the industry said: "We are not going to sit down and talk with you about this", and that is why I welcome so much the fact that we have been able to reach agreement on establishing this Eradication Group, because it now gives a basis to us for taking it forward. It is quite a deliberate process on my part because I think it is a better way of taking those decisions, Chairman, in answer to the questions you rightly put to me about what more are we going to do to deal with the rising incidence. I think it is a better way of dealing with it than the way we have done in the past.

Q10 Chairman: Can I ask your two colleagues: you are the technicians—Mr Simmons, you are a vet—why can we not answer a question like: "Why are we getting more of a disease that we have a great deal of knowledge about?" Is it because you are still struggling to understand the epidemiology?

Mr Simmons: There are a number of factors we need to take into account here. The epidemiology is immensely complex: we are dealing with an organism which has a number of different hosts; we are dealing with an organism that has an extremely unusual way of interacting with its hosts, and making a diagnosis not particularly easy, unlike some other diseases, but in addition to that it is a highly dynamic situation. So, as the Secretary of State says, the way forward is to develop a partnership with industry to recognise that there are gaps in this and use what tools we have, which we accept are relatively limited.

Q11 Chairman: In your reply to the Committee's report I seem to remember language like that being deployed but you rejected doing any more work on the epidemiology.

Hilary Benn: On the transmission?

Q12 Chairman: Yes.

Hilary Benn: Yes. We have invested quite a lot in that, as you will know.

Q13 Chairman: But you have not got the answer.

Hilary Benn: No, we have not, Chairman, and I have just had a letter from the Bovine TB Science Advisory Body, which gives us advice on this. This is from Quintin McKellar, the Chairman, and he has looked at that and he has said (and I quote, for the Committee's assistance): "We would advise that further research is unlikely to yield conclusive answers" (this is on the particular question of transmission) "on the exact means of transmission between cattle and badgers." So we have invested a considerable amount of money in trying to find better answers to the question about the precise means of transmission. I think, while we remain open to ideas, and that is the point that we made in our response, those who advise us from—

Q14 Chairman: Forgive me. I am a simple soul in this. If you have a human disease, one of the first things you do is try and work out how it spreads, so that when you develop a plan to deal with it you know what you are up against. You are about to embark on the Eradication Group—fine—but if you do not know how the disease is spread how on earth are you going to work out in this group what the plan is to eradicate the disease?

Hilary Benn: The truth is we know some things but we do not know all the answers, and just because we do not know all the answers does not seem to me, with respect, Chairman, that the group cannot get on with trying to decide what further steps might be taken to try and deal with it. The problem is here now and it is getting worse, as your question drew attention to. I am not convinced that we should wait before we take further steps to see whether further research can answer the question, given that we have put a lot of effort into trying to answer it.

Mr Simmons: I would draw your attention to one or two quite simple facts. Going back to the 19th Century we managed to eradicate rinderpest, contagious bovine pleural pneumonia, and rabies from this country without even knowing what the agent was, never mind how it was spread. So the application of proper controls which are robust, widely accepted and entered into freely with the people that are going to have to be the actors in the process is generally very, very successful.

Q15 Chairman: This is the adoption of the 19th Century approach to a 21st Century problem?

Mr Simmons: Not necessarily, no. Like I say, I think there are a number of principles that could be applied to disease control which indicate that you do not need to know everything about a disease before you can start tackling it.

Q16 Mr Drew: Two questions. We have always talked in the past about TB control measures, and we all know we are not able to control the disease, and now we have got a body with the title TB Eradication. That seems to be rather a leap of faith. My second question is: when you look at the research evidence, some of us are beginning to read and re-read some of the findings. Should we not be focusing much more on really trying to deal with the

core of the problems and forget some of the other research, which may be very interesting but we seem to be always reinventing. Some of the papers we have received in evidence for today are, at least, just proving what we already knew. I am not sure if that is helpful.

Hilary Benn: Clearly the Committee has views, as do others, on where the research effort ought to be put. That is why we have the science group to advise us. One of the things which the Eradication Group is going to look at is indeed that, because with all of the means we have available to us, all of the things that we could do, all of the research that could be undertaken to try and give us information to help us to deal with the disease, the purpose of the group is to look at all of these things and to share responsibility for that process. We have to be clear and straight about this: eradication is a long-term goal, and the title has been chosen because that, in the end, is what it was agreed the group would be called. The immediate priority is to try and control and reduce, and obviously we all have an aim to try and eradicate. One of the things, of course, that we are putting additional resources into is vaccination, which is one of the things that the Committee recommended that we should do, and I responded to that because it seems to me that if—if—we can make that work, and you have seen, as I understand it, the scientists who have been working on this, and so have I, and they are working extremely hard, this must be a better way of trying to deal with this than the measures that we have available currently.

Q17 Mr Drew: I just wonder why, given, as you know, where I am coming from in terms of my support for the vaccination approach, we do not put more resources—and I know you plan more resources for vaccination—into vaccination, and look at some of the other research projects as much more tangential to that.

Hilary Benn: I am absolutely open to suggestions and arguments that we should look at the priorities that we have got. The purpose of the group is indeed to ask those questions, and I have a genuinely open mind because, in the end, I am interested, as is the Committee, in finding things that work to deal with the problem. I have asked the question in relation to vaccination: if we put in even more would it speed it up? And the answer I have had is: no, it will not speed it up; it just gives you (I hope I have characterised this correctly) greater likelihood that what you are investing in is going to produce results—recognising that nothing is certain and you will have seen the timelines on vaccination. For an injectable vaccine there are some field trials going on at the moment, and one of the things that we are very keen to do, as you will be aware, is the injectable deployment project to start to show that this might have an effect, recognising that, for reasons probably of practicability, an oral vaccine for badgers is likely to be more productive, but that is slightly further away.

Chairman: We are going to talk about vaccines in a little bit more detail, but I want to bring Roger Williams in on this first point.

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Q18 Mr Williams: Thank you, Chairman. Following the Government's response to this Committee's report, you suggested that a group be set up to deal with TB. Certainly industry representatives were very reluctant to be involved. What has been the trade-off here? Is it the introduction of the term "eradication" into the name of the group? If so, that is really upping the ante, is it not?

Hilary Benn: I do not see it in those terms. Let us be honest about what has gone on. In the light of the decision I took about culling, a lot of people were very cross and angry. We all know that. The immediate reaction was: "Well, if that is not going to happen then we are not going to sit down and talk." That is a natural reaction, particularly in the light of the terrible impact which the disease is having on those most affected. I had the opportunity to visit Mr Cox's constituency a month-and-a-bit ago and, not for the first time, felt the force of that. So it is natural that there should have been that response. I recognise that that was likely to happen, but I also believe absolutely sincerely that the only way we can do this is together. Therefore, we had to wait and we have reached an agreement about what we call it. What the make-up is going to be, the precise membership, is still to be determined. For me, the single most important thing is we have now got agreement that we are going to sit down together and work on this and look at all of these questions (some of which have already been raised and others which we will no doubt address in the course of this evidence session), because it is a shared problem. We are all trying to deal with it; we all want to try and do the right thing and the best thing, and we have to work together on it, and I am very pleased that we have been able to find a way forward. To be perfectly honest, I do not mind what we call the group—that does not matter—what matters is we have the opportunity to sit down and work on it together. We have now got that chance and I welcome that very much. I recognise that it has not been easy for the industry to take that step but I think it shows real leadership.

Q19 Chairman: Defra are chairing this, are they not?

Hilary Benn: Yes. That is the way it is going to work.

Q20 Chairman: So when would you determine its work programme?

Hilary Benn: As soon as we have got the membership sorted out then the group itself will discuss that and work it out. There is a whole range of things that we suggested could be discussed. The members of the group will no doubt bring a range of things that they want to discuss, and my view is it is for the group to determine what it wants to look at, what it wants to consider and what recommendations it wishes to make.

Q21 Mr Williams: So there is nothing ruled out?

Hilary Benn: Nothing is ruled out at all.

Q22 Chairman: Just before I bring Mr Cox in, are you going to have it as an open-ended commitment as to how long it goes on thinking, or are you going to set some end date by which it should report?

Hilary Benn: The model I have very much in mind is the Bluetongue group that we have had in place working for some time. It addresses the problems of today and thinks ahead about what needs to be done tomorrow. So it is not as if it is a group that is going to meet, cogitate, come up with a list of recommendations and then go away.

Q23 Chairman: Is it going to move with the speed of the solution to Bluetongue? That would be a revolution in bovine TB control, would it not?

Hilary Benn: It will make recommendations about action that needs to be taken, but my intention in wanting to establish such a group is it is going to be intensely practical, wrestling with these difficult problems, including the trade-offs: "If you do more of this then it will have an impact and a cost"—

Q24 Chairman: If we invited you back, say in late Spring, would you be hopeful that this group might have come up, at least, with a plan?

Hilary Benn: It depends on your definition of "late Spring".

Q25 Chairman: It depends how late Spring is, really! Let us say the beginning of June next year.

Ms Edwards: There will be particular issues that come up in the course of business where we would really want to talk to that group, and we would hope that they would be able to come to some quite quick recommendations on particular issues. For example, we would like to talk to them very early on about the vaccine deployment project and proposals around that. That is quite different from the output at the end being a plan.

Q26 Chairman: Let me just raise a practical issue with you, because the Badger Trust, in their usual, helpful way, wrote to us and they have raised with us the number, for example, of what they see as large numbers of overdue animals for their TB tests. That is a pretty practical, basic parameter on the way we go about controlling TB at the moment. They have given a huge number of animals which they reckon by the end of July this year will be overdue for their tests in the West Country; they quote a figure of 224,640. I hope that is right. It seems an awfully large number of animals, but there are obviously some overdue ones. How are you going to fix that problem? That seems to be rather fundamental.

Ms Edwards: There is a whole range of reasons why tests might be overdue. Sometimes it is just farmers deciding when best to schedule their tests within a relatively small window, for example, so that they get the test done in a way that will qualify for pre-movement testing. The vast majority of those tests are overdue for anything up to three months. There

is, undoubtedly, a number of tests that are overdue for longer than that, and we certainly would want to look at measures to try and deal with that.

Q27 Chairman: The reason I mention it is that the Secretary of State talked about looking at vaccine issues. Those are for the future. There is a huge amount of work being done, but on a very basic thing there is a problem: overdue cattle for testing under the existing regime.

Ms Edwards: In terms of thinking with the members of the group about what they should focus on, we would certainly be very keen to look at those very practical issues about delivery of the control programme we have at the moment, as well as looking at longer-term changes in it.

Q28 Mr Cox: There is a shortage of vets in the West Country, or a shortage of people who can carry out the tests. They are having to wait for weeks before they can get the test done.

Ms Edwards: I have not seen evidence of that.

Mr Simmons: I do not believe that is a reason for the overdue tests. As Gabrielle has set out, there are a number of reasons for it, but a chronic shortage of vets is, I think, overstating the case, if I may say so.

Q29 Mr Cox: I have been there in your Vet's office, and that is what I am told by them, let alone by the farming community. People are having to wait some weeks before they can get a test in the West Country. I will give you case studies, if you like.

Hilary Benn: It would be very helpful if you would, Mr Cox.

Q30 Chairman: The reason I raise this issue is I am just a little bit surprised that vaccine was edging into the conversation now when dealing with some of these practical problems seemed like a jolly good starting point. My job is not to set the agenda for this group; they know more about it than I do!

Hilary Benn: With respect, Chairman, I was giving that as one example. There is a long list of things; vaccine is one. The research programme—where that should be directed; advice—we have got the husbandry group which has done some work; we have commissioned some more research on bio-security; advice and information that we give to farmers; what other steps can be taken to help farmers who are actually having to live with the disease; how you communicate, and then a lot of other things—the question of cattle controls, which you have already touched upon. There is no shortage of things to discuss. It is for the group to determine what it thinks the priorities are. I come back to my point about the reason why we are so keen that we should do it in this way, because this is a shared problem. One of the difficulties we have had—how can I characterise this?—is not that there has been a bit of a stand-off but it is not a very effective way of trying to deal with it. That is why bringing everybody together and saying: “Come on, what are we going to do together?”, and: “Here's the money that we are spending, here are the priorities currently. What's your view about whether they

should change?” is a better way of doing it, but it is for the group to determine what the priorities are. After all, the industry representatives are going to be on it and have the greatest incentive of all to ensure that effective action is taken to deal with this terrible disease.

Q31 Paddy Tipping: One of the things that drives the policy is the cost. In the current year it has cost £80 million. You have produced information that suggests that by 2012–13 the costs could go up to £200–300 million. So between now and then it is going to cost £1 billion. Is there not a need to get some movement in this? The Government is hard up, is it not? It is a lot of money to be spending.

Hilary Benn: It certainly is, and we certainly need to get movement which will be effective in trying to control the disease. It is quite hard to forecast ahead because one would have to ask: “How many cases are you going to find?” and “What is the incidence going to be?” What is going to happen on compensation?” Of course, we have made a change and that is currently the subject of legal action, judicial review, and we are contesting the judgment that was made. It is costing a lot of money. One of the questions for the group to look at is: “Given what is being spent, are the places where it is being spent the most sensible ways, and if you want to do more over here do you want to do less of something else over there?” I think it is right and proper the group should be able to ask those questions and make recommendations on that very point.

Q32 Paddy Tipping: Are you happy, as someone who manages and is responsible for this, that on the face of it prices are spiralling up when you have got other commitments and other priorities? This is dead money. It really is dead money.

Hilary Benn: Nobody can be happy about the incidence of bovine TB at all, which is why all of us have an interest in trying to take effective steps to deal with it. Sure, everybody would much rather be spending money on other things, but you have to do what is required in order to deal with the problem that you are faced with now.

Q33 Mr Drew: So what has happened to the TB Advisory Panel? Does that still exist, or is this going to be replaced by the Eradication Group?

Hilary Benn: We are reviewing its role, I think, in the light of the establishment of the Eradication Group. I think the Eradication Group, in effect, is going to take on the function. It has played a very valuable role, and I want to place that on the record, but I think since we have now got progress on the Eradication Group it is likely to give way to that group in taking the work forward. We will still, of course, have the Science Advisory Body that I have already referred to, and of course that has four sub-groups: one of which looks at vaccination; one on wildlife and epidemiology, one on diagnostics and one on economic and social research—basically, looking at the economic impact on farmers who are affected by the disease. So that is the sort of structure that we have got.

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Q34 Mr Williams: Perhaps I need to put on record my entry in the Members' Interests as a cattle keeper, and one who is suffering at the moment from the TB outbreak. The holding, I must emphasise, is in Wales and, obviously, not the direct responsibility of Defra.

Hilary Benn: I am sorry to hear it.

Q35 Mr Williams: In Wales there is a slightly different approach taking place. The Assembly Government is committed to testing all cattle over 42 days old within a year. That would normally take four years, so there is a huge investment in testing in Wales at the moment. Has that approach ever been considered by Defra as part of the approach to, first of all, getting an understanding of the scale of the disease and then, perhaps, a better understanding of how it is spread and how it can be contained?

Hilary Benn: I do not know whether, in the past, it has ever been considered.

Ms Edwards: Not in my knowledge.

Hilary Benn: We are looking with interest at what the Welsh Assembly Government is doing. We did a sort of rough and ready calculation of what it might cost if we were to do it here, and I think it was about £25 million. Now, you have to make a judgment: have we got the resources to do it, and what do you think the benefit of taking that action would be? There would also be a question, going back to Mr Cox's point, about how long it would take you to do it and what resources were available.

Mr Simmons: Clearly, if you were going to pile all the veterinary resources, or, perhaps, some lay testing resources, into that it would stretch the entire veterinary resource within the country, particularly if you have to squeeze it in over a very short period of time. There are other ways of finding out where the disease is, and surveillance through slaughter house cases is generally a reasonably effective way of doing it. It is not perfect—I would not suggest that—but in general the identification of cases of TB through slaughter houses is a pretty good indicator, in areas where the prevalence is pretty low, of diseases appearing.

Q36 Mr Williams: In terms of slaughter house observations, how many herds have been identified as having TB through slaughter house observations rather than through a skin test?

Mr Simmons: I do not have the figures to hand, I am afraid, but we can provide those for you. The numbers are still going up steadily, but not hugely.

Q37 Mr Williams: Would it be a good idea to have a complete test of all animals over 42 days in hotspots rather than throughout the country? In England there are areas that are relatively free of TB, and it probably would be wasteful to test, but in the hotspots themselves would it be a good idea?

Mr Simmons: We have always taken a risk-based approach to testing, which is based on herd history, or the history of the disease in the parish and immediate vicinity, and then applying that retrospective knowledge to the rate at which we test. So, the period of testing once a year is applied within

the hotspot areas, and then where the risk is generally considered to be somewhat lower it is every two years, and hence three and hence four where the risk is considered to be very, very low. That is under continual review.

Ms Edwards: Do you want the slaughter house figures?

Q38 Mr Williams: Yes.

Ms Edwards: Within the first seven months of 2008 we found 591 animals through slaughter houses but only 55% of those, so far, have been confirmed through culture.

Q39 Chairman: Only 55%—what?

Ms Edwards: Have so far been confirmed bacteriologically through culture.

Q40 Mr Williams: Could you get the figures, perhaps, and let us have how many herds that have not been identified as being TB herds were identified through slaughter house observations? The Chairman did emphasise the fact that a number of tests are late, at the moment, and running late. The late-lamented Lord Rooker described VetNet, which is the current IT system used by Animal Health to keep records of TB testing, as out-of-date. Do you think the IT system is something to do with the fact that testing is not kept up-to-date?

Ms Edwards: I would not have thought so. My understanding of the way the animal health system works is that farmers are given notice of when they need to get their tests done by, and that is a pretty automatic process. Then as soon as their tests are overdue, because there is a zero tolerance policy, a letter is issued imposing movement restrictions. So that is a pretty automated process. Where they get into more difficulties is over issues such as tracing and the time that that takes.

Mr Simmons: In addition to that, the Animal Health agency is investing a considerable amount in a business reform programme which will address the whole issue of the routine testing of herds and other inspection processes the organisation is responsible for. That is under way at the moment.

Q41 Mr Williams: I am surprised you are having trouble in tracing, because you have DCMS now which is meant to be working very well, or rather well. Surely, that is the process rather than VetNet that is used in tracing animals.

Mr Simmons: VetNet draws upon a number of different sources of data, including BCMS in order to be able to trace animals for testing.

Q42 Chairman: Do you do any kind of forecast about the amount of undetected TB that is still out there?

Ms Edwards: No.

Hilary Benn: How would you know?

Q43 Chairman: You might estimate on a probability basis in a population of cattle what might still be there.

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Mr Simmons: I think, perhaps, I could make an attempt at doing that. In the past we have used, certainly many years ago, models to look at a number of different risk factors that would help us identify areas which might be at risk, but almost invariably those models and other investigations have identified areas which have merely had a history of problems before. So, therefore, proximity to previous breakdowns, or having had a breakdown yourself, was the most likely indicator, or predictor, of having further disease. Of course, the concerns about the movements of animals elsewhere and, perhaps, buying animals which have undisclosed disease from herds that have got undisclosed infection is always a risk, which is why we introduced a premium for testing to reduce the risk of spread elsewhere where the factors of risk, so to speak, are less easily established to be understood.

Q44 Mr Gray: Very briefly, I am just amazed by the suggestion that you have got no clue at all how many animals there will be reacting positively in the future. I will tell you. They went from 13,000 to 19,000 in the first six months of this year, so this time next year it will be 25,000; that is 6,000 more, the year after it will be 31,000 and then 37,000. That is what it is going to be. Is that not right? Why can you not just draw a straight line graph or are you scared to do that?

Mr Simmons: Having been asked many times in my current role to predict the next disease outbreak I am always very conscious that that is a tremendously professionally risky thing to do.

Q45 Mr Gray: But if you look it up in the last few years it has gone like that. Why cannot one just predict that it will go like that?

Hilary Benn: Just to give you one example, Mr Gray, in 2005 the number of new cases in England was 2,904. In 2004 it was 2,612. If you had drawn your line you would have said, "It is going to go up". The following year, 2006, it was 2,721, so I think what that demonstrates, and it is a point I made right at the beginning, is that there is a certain cyclical nature to this, the trend line is quite clear; I think that is the reason why you cannot just say that.

Q46 Miss McIntosh: I understand you are on target for monitoring the spread of cattle TB and reducing the spread of cattle TB to new parishes. Should you not have a target to commit to fighting the disease and controlling the disease and containing the disease where there are hotspots of the disease already?

Hilary Benn: I think you are referring to PSA9.

Q47 Chairman: We are, yes. How are you doing it?

Hilary Benn: How are we doing what? How are we getting on with PSA9?

Q48 Chairman: Yes.

Hilary Benn: I think the answer is okay but there is a problem with the PSA in truth. It lasts until March 2009 and the difficulty, and my colleagues will correct me if I get this wrong, is that in the period that you have been looking at to measure progress

on PSA9 was the aftermath of the foot and mouth outbreak of 2001, which has an impact on your baseline because you have got, I think it is, two moving five years totals. Maybe when we set it up in the first place we should have realised that you would have this problem, that you would get to a point where the impact of the 2001 foot and mouth outbreak was in one lot of figures and not in the other, and it means that what you are measuring as you go—and I hope I am making sense—means that the baseline is moving because of the problem of foot and mouth in 2001. You can set a certain amount of store by it but not a huge amount, I think, would be a fair summary.

Q49 Miss McIntosh: How concerned are you at the spread of the incidence of TB in cattle now moving to non-bovine species?

Hilary Benn: We are clearly concerned about that, although one has also to take account, looking at the figures, of the fact that in 2006, Miss McIntosh, we made it a requirement to notify, so I suppose part of the answer is to what extent is it an increase, and the figures overall clearly show that, but also to what extent is it, because there is a requirement to notify, more reporting of what may already have been there? The truth is we do not know the answer.

Q50 Miss McIntosh: Can I ask how convinced you are that there is no possibility of a public health issue?

Hilary Benn: The Health Protection Agency's assessment is that the risk to human health is low, and, if you look at the number of human cases, I have got a run of figures from 1997—32, 24, 28, 19, 24, 17, 15, 14, 24, 27. The last figures I have got are for 2006.

Q51 Miss McIntosh: It is flat-lining, but basically we are talking about dogs and cats, are we not, so if it is coming into household pets are you at all concerned that there may be a crossover?

Hilary Benn: The figures would not appear to demonstrate that that is the case to date, but obviously we have to keep a very close eye on this.

Ms Edwards: What it is worth saying is that most of those cases are either cases of latent infection in elderly people reactivating who would have been exposed to unpasteurised milk in their youth, or cases of people coming in from abroad. The cases which look like infection in younger people are very low.

Hilary Benn: I should just say that the figures were for England. There are also, of course, figures available for Great Britain.

Q52 Miss McIntosh: Obviously, the figures at the moment are highest in the West Country and Wales. You must be aware that the Thirsk Auction Mart is one of the largest fatstock marts in the country and just a case of one rogue animal coming from the West Country or Wales could have devastating consequences. Are you keeping an eye on that?

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Mr Simmons: If you were talking about foot and mouth disease I would be wholeheartedly in agreement with you. We are dealing with a disease which is much more slowly moving, is less infectious and has less capability of spreading the disease quite so quickly. What is important is that we use measures to prevent the spread as far as practicable out of the areas that are badly affected by routinely testing at the right frequency and pre-movement testing and then, when it does happen we find that animals have moved off the farm and have gone elsewhere and potentially are infected, we trace those forward and test them at the premises of destination. Of course, if that animal is infected you can do the necessary measures on those farms and in the low incidence areas we would frequently, particularly for confirmed disease, apply the gamma-interferon test with the expectation that that will pick up early disease. The only way to do any more, I believe, would be to draw a line across the country and, of course, that would have quite an economic impact on the movement of animals.

Q53 Mr Rogerson: This question of the bacterium travelling into pets is one thing that certainly concerns me and obviously it has received a lot more coverage recently because cases have emerged. You were talking about the fact that when one tests more one finds more of a disease, so the fact that we have a few cases that have been reported may mean that because there is no regime to try to look for it there may be many more cases out there. Is this something that you think the Eradication Group should consider or is this just something that the department could consider, because obviously there are questions there about what routes the bacterium is taking in getting into our pets, and what risks that may present, as Miss McIntosh was saying, to human health? That means that a greater number of people are potentially exposed to infection than might have been directly working in the industry.

Hilary Benn: Obviously, we should seek to understand what the rise in the figures tells us, bearing in mind the point I made a moment ago about changing the reporting requirement. Mr Simmons may want to comment from a vet's point of view, looking at domestic cats and dogs and forming a view about how that information is reported. I do not know whether you are suggesting, Mr Rogerson, that we should perhaps look at a more extensive screening programme, but I would have said, going back to your question about the group, that the focus of its activities is going to be the impact on cattle, for obvious reasons.

Mr Simmons: We have, as you have pointed out, confirmed more disease in cats in recent years. Some of that is almost certainly through better ascertainment. In other words, we have detected more disease because awareness is higher and more submissions have been made. In addition to that, one of the cat charities working with us has been doing further investigations on that and that has almost certainly identified more disease results. It is also worth remembering that only a relatively small proportion of those submissions get confirmed. Of

animals with chronic lesions suggestive of TB in cats only a proportion get confirmed as that, so there is, if you like, a background level of chronic disease that looks like TB but turns out not to be. Investigation will pick up more of those, but I think it would be fair to say that if you have a lot of disease in cattle then one could argue that there will be a greater risk of transmission to other domestic species, albeit a relatively low one, but it is moving up from a slightly lower base.

Q54 Mr Rogerson: I think it is just this question also then about saying it is going from cattle into pets. That is not necessarily so?

Mr Simmons: Not necessarily, no, that is absolutely right.

Q55 Mr Rogerson: That is part of what I am saying. It may be that, as we have, particularly in cats, animals that are roaming around over an area where there may be other species that are carrying it, does this not warrant some investigation as well, perhaps with the Department of Health, if we are talking about the potential risk to humans?

Hilary Benn: It is a point I am happy to go and put to both the Department of Health and the Health Protection Agency but, as I indicated a moment ago, the current assessment of the risk to humans is indeed that it is low.

Q56 Mr Cox: Secretary of State, Anne McIntosh, my colleague, asked you a question which I do not think you answered, which was should you not have a target for reducing the disease in hotspot areas? You have a target for the PSA9 to prevent it spreading to new parishes but should you not have a target for reducing it in hotspot areas and does not the absence of such a target really imply that you have no policy for reducing the disease in hotspot areas and no clue how to do it?

Hilary Benn: I do not think that follows, Mr Cox, at all. You could have a range of targets if you wanted. The question is, would it lead you to do things that otherwise would not happen? I come back to my earlier response to the question about the Eradication Group. It seems to me we have now got a structure in place which I have wanted and the industry is now supporting, as I say, showing great leadership, which I would have said gives us all, if you like, the target and incentive that we require to get on with trying to deal with this. If the group says yes, it would be helpful to have a target or a range of targets which would enable us to monitor the impact of the steps that are then taken subsequently as a result of the group's work, I would be very happy to consider that.

Q57 Mr Cox: But what is your policy for reducing the disease in a hotspot area? At the moment we have a marked increase in new herd breakdowns. The disease is out of control and, whatever you say, Secretary of State, you have no grip over it in these hotspot areas. What is your policy for reducing the disease?

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Hilary Benn: The policy is to use all the tools that we have available to us to try and deal with the impact of the disease, including in the hotspot areas, recognising that infection from badgers is a source.

Q58 Mr Cox: It is the main vector in the hotspot area which I represent and you know it. It is well established. It is a significant if not the main vector in a densely infected area such as the Torridge and West Devon areas that I represent. What is the policy for reducing the disease in areas such as that?

Hilary Benn: In the medium to the long term it is vaccination, if it can be made to work, is the answer to the question.

Q59 Mr Cox: It is a pipedream, is it not?

Hilary Benn: No, with respect, I disagree, Mr Cox, with your description of vaccination as a pipedream.

Q60 Mr Cox: You yourself have said on record that it is 10 years away.

Hilary Benn: It is some years away but I have spoken to the scientists, you have spoken to the scientists as well. What they are advising currently is that we think there will be an injectable vaccine available in 2010. Obviously, the purpose of the deployment project is to see how it might be used in that form and we want to take a reasonable size area in which to do it and part of the answer to your question might be, would one of the hotspot areas be interested in helping a deployment project to take place? That is one thing which the group itself can look at for the cattle vaccine. The earliest date for a badger vaccine for an oral version is 2014 probably.

Q61 Chairman: Can I just ask a little question? If you have got a hotspot area with a high disease incidence can you just wade in and vaccinate willy-nilly and get rid of the disease? Do you have to have a clean cattle area to vaccinate as a starting point? I thought that one of the arguments when we had foot and mouth was that you could not vaccinate unless you got ahead of the disease. The hotspot area of the disease seems to be well ahead of you.

Ms Edwards: In an ideal world, obviously, you would use vaccination where there was a very low level of disease. Vaccination on its own will never be the magic bullet that sorts TB out. Vaccination as part of a wider control programme would have a much more significant impact. If you are vaccinating against a background of high levels of disease in the badger population it will take longer for a vaccine to have an effect, particularly in the badger population, because if you vaccinate animals that already are infected with TB you will not have an impact, so effectively you have to get the cubs, you have to get them early, and so you have to keep vaccinating for a number of years and you would expect the disease load in the population to go down over time.

Q62 Mr Cox: So is that not an argument manifestly for vaccine being by itself not an answer and therefore the only way is to consider it alongside a programme of culling?

Hilary Benn: I do not agree, with respect.

Q63 Mr Cox: But you have not looked at the issue as to whether or not alongside vaccination it might make sense. All you have looked at is a particular method of proactive culling, and there is a question I want to ask about whether you have considered the latest results of Rosie Woodroffe on that, but you have not looked at whether you may need it alongside vaccination, have you?

Hilary Benn: We have looked at it over a 10-year study, so it is not as if the Government has said, "Yes, we are not going to think about it at all". John Krebs proposed the trials, they took place. We invested a very considerable amount of money and the ISG report, as you know only too well, Mr Cox, came out and reached the conclusion that it did.

Q64 Mr Cox: You told my colleague that you were not ruling anything out for the Eradication Group. I assume that would mean looking at culling again in different contexts.

Hilary Benn: I said to the House of Commons when I made my oral statement in July that I had made my decision on culling. I have, and I have not changed my mind, but in answer to the question what about other circumstances, clearly two sensible things to have an open mind about are, first, does the scientific evidence change, although I would just make the point (and that is why the Eradication Group in its terms of reference says that is one of the things it can look at) that in answer to the earlier question I said the group can look at anything that it wants to. I am clear also that I took a decision, having thought long and hard about it and weighing, of course, very heavily in the balance the result of 10 years of trying it, and it is really important to remember that. It was 10 years of trying it to see what impact it would have, but it is not just a question of what the science shows. You also have to consider the practicality and the impact of practicality on achieving the result when someone might say if you just look at the science and if you could do all of those things then it might have this impact.

Q65 Mr Cox: Did you consider when you were doing it that the fact that it appears that the post-trial effects mean that now in the proactive areas it is 54% lower, not 23%, and in the areas neighbouring where there had been a perturbation effect it is 23% lower, not 24% greater? In other words, what she found was that in the post-trial period there was a radical decrease in the incidence not only in the proactive cull area but also in the neighbouring and adjacent land.

Hilary Benn: Yes, I have been aware, as I think the Committee has, of the developing research. Indeed, we are funding it as a department, and it is a trend that has been emerging and it is something that the former members of the ISG have been aware of. However, as I was saying a moment ago in answer to your question, Mr Cox, it is a combination of what the trials and the scientific results show and a judgment, and in the end I had to make a judgment, about the practicalities.

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Q66 Mr Cox: But your own experts say this could lead to showing that in fact culling has beneficial effects and they last. How can you rule it out when your own experts that you are funding are telling you that the beneficial effects may last?

Hilary Benn: What I said was that we asked the ISG to do its work. The ISG came back and, in the words of John Bourne, he said to me that in his view badger culling could not—

Q67 Mr Cox: This has come afterwards.

Hilary Benn: I am well aware of that. John Bourne has been aware of the emerging results, but he said when he published the report in the summer of 2007 that badger culling “could not meaningfully contribute”. Those were the words. I think it is right and proper that one should give that due weight, and that is exactly what I did, but I also make the point, Mr Cox, about the practicality of doing this. This was the difference in the argument between David King and John Bourne, because David King said, “If you did this over a large enough area you would have this effect”, and David King said, “But I have not looked at the practicality of making it happen”, and it is absolutely right and proper that you weigh in the balance—and that is what I said to the NFU conference just under a year ago—that there is a range of things that you have to look at, the tests you have to apply, what the science says, what the practicality is, what the effectiveness is, and (and I got booed for it) public acceptability because that does have an impact potentially on the practicality of the course of action. The final point I would make, Mr Cox, is this. As I think you recognise, most people agree that culling could only potentially make a contribution if all of those conditions could be met and then only in some parts of the country, in the end I formed the view that you could not take the risk. It is not something that would work anywhere.

Q68 Mr Cox: I completely agree with you. It might work in an intensely infected hotspot area. I do not accept, frankly, the fact that you can rule out culling as an instrument alongside other things, and what surprises me most of all is that you are shutting it out for the future, having set up an Eradication Group, even when vaccine may come in and be required to be used alongside it to be an effective tool. That has the hallmarks to me not of a weighed and balanced and objective decision but of a political decision.

Hilary Benn: With respect, I do not agree with you, and I thought very long and hard about the decision that I reached and I took into account all of the considerations that I have just described to the Committee.

Mr Cox: But, Secretary of State, forgive me. I am not actually—

Q69 Chairman: Let the Secretary of State give us his answer.

Hilary Benn: Thank you very much, Chairman.

Q70 Mr Cox: It is only going to be the same one as the last time.

Hilary Benn: I am sorry, Mr Cox, if you do not like the answer that I give but I have come to be absolutely straight with the Committee about the process that I went through in reaching the decision that I did. I have been at great pains throughout to say that the science, yes, but you also have to weigh in the balance the practicality of the course of action. I just also want to be straight: having taken a year to consider carefully, to meet a lot of people, to listen, to weigh it in my mind, I am not going to come before the Committee today and say, “Yes, I have changed my mind”, because I have not changed my mind and I have got to be straight about that, and, as you know, I said that to the farmers that I met.

Q71 Mr Cox: Absolutely.

Hilary Benn: And I think it is important that I do that and, as we know, if I wanted a really quiet life, of course, I would not have—

Q72 Mr Cox: Yes, but, Hilary, what I am asking you is the future. You are a reasonable and intelligent man.

Hilary Benn: I am glad that is going to be on the record.

Q73 Mr Cox: As you know, I have said that many times.

Hilary Benn: You have also said one or two other things.

Q74 Mr Cox: I have indeed, and I am going to say it again. The reality is that if you are looking ahead into the future you have set up this group. If you want to be even-handed and fair for the farming community you have at least to say to them, surely, “There may be circumstances in the future in which developing vaccine and alongside vaccine we may need to look again at this question of whether in a limited area, like the densely infected hotspot areas we are talking about, it may need to be used alongside it”. That is just good policy, is it not, not to shut something out completely when new developments like vaccine may come along that may require it?

Hilary Benn: If I could just draw your attention, Mr Cox, to what the work of the group is going to include, there is a long list which I do not know whether you have seen, and one of the things it says is “considering any exceptional circumstances”, which by definition are rather hard to define, “or new scientific evidence that might arise relating to the established policy on badger culling for control of TB”. That is why nobody could sit and say they have closed their minds to anything that may happen in the future. That would clearly not be a sensible policy, but I also want to be absolutely straight with the Committee. Having had the 10-year study, having had the ISG advice, and, let us be frank, a lot of people were surprised when it came to the conclusions that it did—

Q75 Mr Cox: But those conclusions are developing, are they not?

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Hilary Benn: Indeed, they are developing, but I have not changed my mind about the decision that I reported to the House of Commons in July. I just want to be clear.

Q76 Lynne Jones: Can I say that I for one believe that your decision on culling was in line with our Committee's recommendations and we will be, I believe, exploring that later so I will not dwell on that. If we have got a risk-based approach, could I just go back to the point about the number of herds where the testing is overdue? Why is it that the situation is even worse in the hotspot areas? It is bad enough that there are so many tests overdue but it is even worse that the problem is greater in the south west and in Wales.

Hilary Benn: Obviously, there are more tests to do in those circumstances.

Mr Simmons: There are more tests to do and it is worth remembering that—

Q77 Lynne Jones: As a proportion though it is greater as well.

Mr Simmons: But the numbers have come down in the last couple of months. The figures show a fall in the number of overdue tests.

Q78 Lynne Jones: So we are on track to have a zero tolerance policy, are we?

Mr Simmons: We are dealing with farming and we are dealing with a degree of human nature and a number of other circumstances that mean a zero overdue test is extremely unlikely. I would have said it is almost impossible to get. If farmers fall over and break a leg or the machinery breaks or the vet is ill then tests will become overdue, no matter what we do.

Ms Edwards: We do have a zero tolerance policy in terms of movement restrictions on farms where the test goes overdue but the responsibility for fixing the test rests with the farmer.

Sir Peter Soulsby: Perhaps I can begin by saying that, like Lynne, I am entirely convinced that your decision on culling was consistent both with our report and the advice you and we received.

Mr Cox: But you did not read it.

Chairman: Just a minute. If you want to have a say you can have it in a minute.

Q79 Sir Peter Soulsby: I certainly did read it and also heard the evidence, and I have read very carefully how the Government responded, but I just want to take up the issue of culling because a very powerful case was made by the NFU that it did have a role to play in particular areas and there was a particular argument for what was described as VLA9, the proposal for a large-scale cull in the south west of England. I would just like to explore with you why you felt that did not meet the criteria and why that one was ruled out.

Hilary Benn: When the NFU came to see me as part of the series of meetings that I held with all of those who had an interest in reaching my decision, they brought along those who had been involved in putting together the proposal for the VLA9 cull, and

indeed I met some of those involved again when I had the opportunity to visit Mr Cox's constituency recently. I listened, of course, very carefully to what they had to say. As I recall, and Mr Cox will correct me if I have got it wrong, they said that they thought that they had around 75%, maybe a bit more, of the land area, I think, rather than landowners.

Q80 Mr Cox: Over 70% of the landowners and 75% of the land area.

Hilary Benn: It is very clear to me that a huge amount of work has gone into that. Look: I understand, given how desperate and difficult it is for the farmers in that area in particular and the other hotspot areas, why, if you think that this is one of the ways in which you can deal with the disease, all of that effort has been put in. However, the judgment that I reached was this, and I discussed the question of culling over an area with John Bourne, and I did refer to this in my statement to the House: one would have to be confident not just that there was a huge commitment (which self-evidently there is) to start it now, you would also have to be confident that you could sustain it over a considerable number of years. In the face of such decisions that landowners may or may not reach subsequently about continuing to participate, or farmers themselves, in the face of what may be public protest about the process of culling, if you cannot be absolutely sure that it could be sustained over the period of time, then you run the risk that it might end up making matters worse. That is what John Bourne said to me about the broad principle of taking this approach. You have to be certain about all of those things because if you are not certain about all of those things then you do run the risk of making matters worse, and in the end you have to make a judgment and you have to weigh those two things in the balance. That is what I did and I took the view that it was a risk that we should not take, but I do not for one second underestimate the determination, indeed the desperation, of those who are affected in seeking to try and find a way of dealing with the problem that they are facing.

Q81 Sir Peter Soulsby: Is there any point at all in the NFU and their members continuing to work on that proposal? Is there any prospect you could see at all of them being able to overcome the objections you have outlined to it and perhaps elaborating their proposals further?

Hilary Benn: No, not really, I do not, because having weighed that all up I took the decision that I did which I told the House of Commons about and the thought process that led up to that decision is the one that I have tried to describe to you here.

Q82 Mr Cox: At some point they are going to take you to court. You know. You will be in the court and you will be facing a judge and what the judge will ask is, "Why have you made a decision before the application is made?". They have not made their licence application yet and yet you have told them even before they make it, without seeing the evidence they are going to put forward, without seeing the contracts that they have signed to show it is

sustainable over five years, that you are not going to do it. That sounds like pre-emption to me of an application.

Hilary Benn: We will not attempt to have the legal argument here before the Committee.

Chairman: He is a good lawyer.

Q83 Mr Cox: As you know, I practise in field.

Hilary Benn: I know, Mr Cox, you practise.

Q84 Mr Cox: And the reality is that you have pre-empted a perfectly legitimate licence application and told them, even before they make it, that they are not going to get it granted.

Hilary Benn: I have taken a decision in the light of the scientific evidence that has been given to me on the basis of culling, and, do not forget, we have had 10 years of culling under the ISG, 11,000 badgers were culled in the course of trying to find out whether it worked, and the conclusion of that 10-year scientific study was, in the words of John Bourne, “badger culling cannot meaningfully contribute”. It seems to me that that is a reasonable basis on which to take the decision that I did.

Q85 Chairman: It is something I just observe from a personal standpoint.

Ms Edwards: The general policy has been set out in guidance for Natural England, but Natural England still have to consider every licence application, when it comes in, to consider whether or not it is an exception to that policy.

Q86 Mr Cox: Well, I know the judge will read your remarks with interest.

Hilary Benn: Yes, that is an extremely important point.

Q87 Mr Cox: What I would remind you, Secretary of State, if I may, is that Rosie Woodroffe and the scientists have said as follows: that the beneficial effects may last. Now, that is what they concluded in their recent report, having shown that post-trial, two years post-trial, it is going down in the neighbouring areas and it is 54% lower in the proactive area. In other words, you have shut the door before the evidence has had properly time to mature.

Hilary Benn: Well, I think in fairness to myself, I was urged actually to take a decision on this question.

Q88 Mr Cox: It depends what decision you take.

Hilary Benn: Well, I know, and I know some people approved of it and some people detested it.

Q89 Mr Cox: Well, you could take a decision that says, “We’re going to watch this for now”, but you said, “No, except in exceptional circumstances, you are not able to define it”.

Hilary Benn: I do not think that is a wholly fair characterisation of the decision that I have reached, and I stand by what I said to the House of Commons both about the decision that I have reached and about exceptional circumstances and new scientific evidence, and clearly it would not be sensible to rule culling out in perpetuity. You have got to keep an

open mind, but, on the basis of what we know now, that is the decision that I have reached and I stand by it.

Q90 Mr Williams: If I remember correctly, when you made the statement to the House, you did say that you ruled out a cull, but were always open to further scientific evidence, and I think I asked you would you be commissioning any more work that would give rise to that, but it seems to me that the evidence that Mr Cox has brought forward has almost come passively, in the sense that no extra work has been done, but the evidence has come. I think that now it is open to you to look at that decision again.

Hilary Benn: Well, having just made the decision back in July, I am not coming before the Committee to say, “Okay, I’ll have another think” because that is not my position. We are paying for that research precisely because it is important that we continue to understand what is going on and, yes, I absolutely recognise, Mr Cox, it says—what was the phrase that you described from it—that it may—

Q91 Mr Cox: That the effects are lasting and may continue to last.

Hilary Benn: And “may continue to last”. Well, the reason we are paying for the research is of course to see whether in fact that is the case or not, but we also have a great—

Miss McIntosh: You said, Secretary of State, that in the first two years the results are beneficial and lasting.

Q92 Mr Cox: Yes, post-trial. They are down 54% in the proactive area and you based your decision in your statement, Secretary of State, on the fact that there was a perturbation effect. You said in terms to the House that this may make things worse in the adjoining areas. What this piece of work shows is that in the adjoining areas it is making it better now and has done for the last 12 months and may go on to.

Hilary Benn: But, as I have said to the Committee twice already today, it is not the only factor that we have to take into account in reaching a decision on—

Q93 Mr Cox: But it was the main factor. Perturbation was your main factor.

Hilary Benn: Well, it is one of the factors and it led the ISG to reach the conclusion that it did, but it is not the only one because you also have to have regard to the practicality of a course of action, and I would be failing in my duty, as the Secretary of State, if I did not take that into account alongside the scientific evidence that has been put before me.

Chairman: Well, perhaps one of the things that the Eradication Group will be able to do is to evaluate the economics of all of the options, including a potential cull, because I refresh my memory of the final report of the ISG and they came to the conclusion that you mentioned for the first time of taking fully into account the economics that were involved. If I recall in their previous reports, they effectively said that there was a reduction in the incidence of bovine TB in the proactively culled

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area, that that was a provable scientific conclusion, irrespective of the costs of achieving it, so I am sure that the NFU will have noted the line that you have taken, as a participant to the Eradication Group, and will want perhaps to look at that matter again.

Q94 Mr Williams: It may be that evidence will emerge from activities that are going to take place in Wales of the effectiveness of a cull and that might help the Secretary of State in looking at this issue again. If a cull in Wales were to go ahead, would that be evidence that would lead you to look again at this issue?

Hilary Benn: As I have already indicated to the Committee, we will continue to look at all of the evidence and information that is available, but let us just be clear about a cull in Wales. Elin Jones announced that this was going to be part of the approach that the Welsh Assembly Government was going to take. We are still waiting obviously to see what form it will take and where it will happen and, as the scientific evidence has already indicated, it is going to take some years, is it not?

Q95 Mr Drew: Some.

Hilary Benn: Well, it could be four, five or more to know what the impact is and, therefore, we have things that we have got to get on with now and, who knows, in four or five years' time we will obviously need to look at what that demonstrates. I do not know what the answer will be, nor does anybody else, but it is some years off.

Q96 Mr Rogerson: Very briefly on that is this question of what the group is for if things are being ruled out at this stage, so you have quite rightly, Secretary of State, said that it is right that you get on and look at things now. On this issue of VLA9 where there was a proposal to do something, it just seems crazy to me that you can say "No, never" rather than say that, if the measures that the Eradication Group look at, bearing in mind the future evidence, if there would possibly be a case for doing something in a clearly defined local area where, if the practicalities are a key consideration, the other one that you have pointed to as well as the perturbation effect, if the perturbation effect can be overcome through emerging evidence, is practicalities, if there is an area where there is clear support from the local community for something to take place, it strikes me that that could be overcome as well and that there might then be a case for you to review the decision.

Hilary Benn: Well, it depends on what public objection and protest there may be. We have not discussed this much, but we might as well at this point in relation to that question. There is a very, very large number of people in the country, and we have talked a lot about those who are convinced that culling is the right thing to do, but there is a very, very, very large number of people who are absolutely clear in their minds that it is the wrong thing to do—

Q97 Mr Rogerson: In unaffected areas maybe.

Hilary Benn: Well, I would not say that. I have had a very large number of postcards since I took the decision in July, and I have not read them all, but they seem to me to come from right across the country, from towns and cities and rural areas as well. The question that I have to consider, and did consider in reaching my decision, is how would we deal with the consequence of that and what impact would that have, public protest and the need to police it and all of those things, on the ability to actually do what those who are promoting the idea of a cull would seek to do. It seems to me that that is a really legitimate consideration.

Q98 Mr Drew: Could we move on to vaccinations, and I think it is fair to say that it was always our Plan B and Plan B may be nearer to Plan A now. There is a great deal of ignorance about the role that vaccination could play. To what extent do you think that part of your role through the Eradication Group will be to try and explain how vaccination could be taken forward?

Hilary Benn: I think it is an important responsibility for all of us because, if it can be developed and made to work, then, as I think we would all agree, it would be a much better way of trying to deal with this over time than the tools that we have got at the moment, recognising that we would have to work alongside them. Secondly, because there is no absolute certainty about the timetable, of course there is a difficulty because people say, "Well, when is this thing going to turn up?" and the purpose of the vaccination deployment project is indeed to say, "Look, we're going to have before very long, we think, an injectable badger vaccine. Let's take an area or a number of areas and try it out to get those, in the end, for whose benefit the vaccine is being developed", and a considerable amount of money is being put in, "to be a part of that process, to be able to see". It would not be a scientific trial in the same way as the RBCT was, but you would hope to take a big enough area and say, "Well, let's give it a go and then let's look at the figures in relation to that area in relation to others". It is about really building confidence and of course seeing how practical it is, and I think the general view is that, the prospect of trapping and then injecting badgers on an ongoing basis, is going to be pretty tough and you would have to train people to try it, which is why we are putting money into the oral vaccine because, if that can be made to work, that is a better delivery mechanism than trying to catch and to inject. Similarly, with cattle vaccine, part of the timetable is not the development of the vaccine, but getting all of the evidence ready to then have the really important conversation with the European Union, and I did raise this briefly at a discussion with Commissioner Vassiliou recently, and obviously European Union law currently prohibits vaccination. Now, in order to demonstrate, you have got to say, "We've got a vaccine. This is its effectiveness and here is a DIVA test which is going to enable you to differentiate vaccinated from infected animals". If and when we get all of those things in place, well, then I think all

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of us would have a shared interest, the industry, the Select Committee and certainly myself, in saying, "Well, come on, can we agree to allow this to happen?" and we are putting a considerable amount in because I think it is an investment that is well worth making.

Q99 Mr Drew: In terms of the field trial, which you know I know something about because it is in my area, when we went to see the laboratory work at Weybridge, I suppose the question that really came up was: why can we not be looking to do more field trials? In a sense, I pose the question no more scientifically than to say it is a ruse at the moment. Given that it is all heat rather than light that seems to emanate around the issue of culling, why could we not actually replicate the vaccination trials in the terms of trying to see if an area could be used to dampen down the rate of increase of bovine TB? All I am saying is, to some extent, let us go with the hunch rather than a pure scientific proven outcome to see if we can dampen down an area by using the vaccination initially, injecting the badgers, because that is all we have got at the moment, we have not got the oral vaccine, we have not got the cattle vaccine, but we know, we have got some evidence, not yet proven, of whether you can dampen down TB in that area by using an injectable vaccine.

Hilary Benn: I would certainly be keen, it is obviously subject to advice that I receive, to try this out in hotspot areas. That would seem to be a really sensible and logical place to have a go. Now, you need the support and involvement of those who are terribly affected by the disease because this has to be done together. I do not know whether Gabrielle wants to add something on this.

Ms Edwards: It is probably just worth differentiating between the trials that are being done at the moment, which are scientific trials to get the safety data for the licensing of the injectable vaccine, and then what we are looking at in terms of the injectable deployment project, which, I would hope, would do the sort of thing that you are talking about because, as we do not see that as a rigorous scientific trial, we would be using it and we would be trying to see if there was some sort of impact on the disease in cattle as a result of using it. You will not be able to do something against controls in the same way as we did with the RBCT, but you may be able to see something in trends, and we also hope that you will learn more in terms of how you could actually go about getting groups of farmers together to deliver a vaccine. Whilst the work would be around the injectable vaccine, some of the problems you would have in delivering that would be very similar to those you would have with an oral vaccine, so there is quite a lot of learning you can do with an injectable vaccine. I think the other point that is worth making is that the analysis we have done so far suggests that the cost:benefit of using an injectable vaccine on a large scale would suggest that you are not going to be able to do it, it is just not economic, but we do not actually know until we go out there and try it. It may

well be that, by doing that work, particularly if there is some sort of delay in the oral vaccine, it might look more attractive than it does at the moment.

Q100 Mr Drew: Well, the parallel is what we have just done with bluetongue, that none of us quite knows what the implications are going to be of the vaccine trial because it is still a trial and we have got different strains of bluetongue. Now, I know we have got experience from what is happening in other countries, but, in a sense, what we have here is a lot in common. We suspect that it will be a lot better to trial, and I know there are issues about take-up which is an issue to do with it being voluntary versus making it compulsory, but, in a sense, if you compare that to foot and mouth where we had the arguments about whether we could vaccinate to get ahead of the disease, we chose not to do that and we chose a culling policy and at that time, personally, I felt it was right. I think that, if we were to run it now, we would have a hell of a lot of argument about whether we could cull to try and eradicate the disease.

Hilary Benn: I agree with that. In relation to foot and mouth, and we put, as you will know, the vaccination teams on standby when there was the outbreak last year, I think attitudes have shifted compared to where they were in 2001. I think the crucial point about the bluetongue example, okay, we developed a vaccine, we were the first northern European country to place the order, but the reason why the rollout of the vaccination programme has been a success is because the industry was absolutely committed to this and we did it together. The industry came and said, "Look, would you put the money upfront to order the vaccine?" I said, "Fine, I'll do that, but the deal is that farmers have to pay for the vaccine when it's used, sharing the cost", and that is exactly what has happened. They came and said, "We don't want a compulsory programme. We've thought about it and we want a voluntary programme, but we will give it all the support that we can. Don't hesitate, vaccinate". The take-up, okay, it has diminished a bit, but it has gone further north because actually we have just had a summer in which we have had no new cases, apart from those arising from the imports, and you could see, the further north it got, that farmers may have thought, "Well, there haven't been any further cases, so perhaps I'll wait and see", but the industry continues to be very strong in saying, "Why wouldn't you want to vaccinate your animals?" That is why you need the support of the areas in which we are going to have the injectable vaccine deployment because you build confidence, people need to participate, you are going to have to train people to actually do the trapping and the injecting, and then you see what the results are, but it is a shared endeavour and it is a much, much better way of doing it. I think we have got an opportunity here myself and, in the process, the aim is not scientific, as Gabrielle says, but it is a way of trying to build confidence and seeing will it hope to have an effect, as you described it very well, in damping down and then people will say, "Well, maybe vaccines have got something to offer".

Q101 David Taylor: You will have noticed that your July statement seems to have polarised the Committee more into jabbers and cullers, and I am a fully paid-up member of the jabbing tendency! I want to look at some of the practical difficulties that are associated with your vaccine time-line. As an accountant, I fell on this beautiful project plan with some relish and I was disappointed at some of the detail that I found. It is page 24 of your response to our tenth Report. You mention in the narrative of that response that European countries which are TB-free would be reluctant to see changes in the present control system, and I think that is undeniable, and, therefore, you said a moment or two ago that you wanted to have, in a sense, all of the ducks lined up before you took the plan to them and got the appropriate licensing endorsed. Do you not think that where you have placed the serious discussion with the European Commission, which is in 2013–14, that it seems sort of an unduly leisurely approach from where we sit here in 2008, even one demonstrating some sort of insouciance as well? Surely, (a) that should be earlier and (b) you will need more time anyway, will you not, from the serious discussion with the European Commission to the availability of a vaccine that is ready to use by 2015?

Hilary Benn: Well, I can assure you, Mr Taylor, being leisurely is absolutely not what we are about. In the end, you have to make a judgment of how long you think it might take, given that Europe's policy currently is that you cannot vaccinate and given that the Commission is likely to say, "Well, when you've got all of your bits ready" so that we can begin to have a conversation with them about their being sufficiently confident that all of these things are going to work to change the policy, "because, after all, there will be other Member States where it is not so big a problem and we will want to be absolutely convinced that you've got this right, otherwise why would we want to agree to a change in the arrangements". I am keen that we get on with this as quickly as possible. If that time-line can be shortened, then great, but—

Q102 David Taylor: But is it not too close, Secretary of State?

Hilary Benn: Too?

Q103 David Taylor: Too close. Are you even allowing enough time from the serious discussion, so-called, until the licensing of the vaccine and its availability for use because it will be on the critical path without a doubt and any delays at that point will push back the availability of the vaccine? What we have seen in some of the early statistics, and my colleague Mr Gray pulled it out very well indeed, is a doubling of the infection over a four-and-a-half-year period, that is the trend, I think that has been established, and it takes just simple arithmetic, two four-and-a-half-year periods, nine years from 2007, the last date that is available when you are into the first year when the vaccine is theoretically going to be available and you are going to have a quadrupling

of herd breakdowns to, on that trend, 16,000 herd breakdowns a year. How many herds are there, by the way, in the UK?

Mr Simmons: In GB about 85,000.

Q104 David Taylor: So another ten years really beyond that and every damned herd is broken down. In terms of animals slaughtered quadrupling, it would produce a figure of 100,000 animals slaughtered. Do you think that the British public, farmers and others could sustain that sort of level of loss, 300 cattle a day being slaughtered because of TB, which is a herd a day or whatever it might be? That is an astonishingly high figure which should really provoke, and stimulate, a perhaps rather more rapid reaction.

Hilary Benn: Well, I am listening very carefully to what you have got to say, Mr Taylor. If anyone can say, looking at this time-line, "We think you can speed it up", and I have asked the question in relation to the development of the vaccine, "If I put yet more money in, will it speed it up?", I asked that very specifically when I met the scientists and the answer was, "No, it won't, but, if you put more money in, you increase the likelihood that you'll produce something that is going to work". If there is any way in which, because there are certain processes you have to go through, and Gabrielle may no doubt wish to comment, and you cannot hurry up in terms of licensing and accreditation and so on and so forth, but, if we can squeeze a bit of the time, and in the end that is a judgment as to how long we think any incorporation into a legal framework any EU negotiations are going to take, if we can squeeze that, great.

Q105 David Taylor: You are starting the serious discussions, but that is five years away.

Hilary Benn: Well, when I met Commissioner Vassiliou recently, I did—

Q106 David Taylor: It is five and a half years away, those serious discussions starting.

Hilary Benn: Well, it is the first time I had had a discussion with her and one of the things that I did raise was indeed this point. I said, "Look, we are investing more money in vaccination and, if and when we get to the point where we've got something, I hope very much that the European Union will say, 'Right, we can change the rules so that we can use it in order to deal with the disease'".

Ms Edwards: I think there is a difference between serious discussions and formal negotiations because we are actually starting the process of discussing with the European Commission now and we will try to share the information with them, but there are some things and, I would absolutely agree, there is not much room for slippage in that timetable, it is very tight, and it is our most optimistic timescale.

Q107 Chairman: But the European Union are giving you a hard time as it is now. They have suddenly got themselves involved in this whole business of the work of the Eradication Group, they do not seem to be wildly happy with the strategy you are currently

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following and there are all kinds of rumblings and noises off as to whether there might be trade measures because of the high incidence in certain areas of bovine TB. You are not getting on terribly well with the European Union on this at the moment, are you?

Hilary Benn: On the trade measures, SCoFCAH, as you know, has been looking in particular at the case of the calves which are exported and there is the informal trade ban that Belgium and the Netherlands have put in place.¹ In that case, the system worked in that, as soon as we discovered that the calves had come from a farm that subsequently turned out to have a case, we let the Netherlands know, and the Commission is in the process of deciding what it is going to do about this and it has been having kind of a number of goes during the course of the autumn. The EU Task Force, they will come and they will give some advice to support the work of the Eradication Group, but, as Gabrielle was just saying, it is not as if we are saying that we are going to go away and do all this work on vaccines and then suddenly we will turn up to the Commission and say, "Hey, we've done all this". Clearly, the sensible thing to do is to keep them informed about the process as we go through the stages because it is about building confidence in what we hope in the end to produce, which is a usable vaccine alongside a DIVA test that can give the confidence that you can distinguish, and then to try and get the process of changing the current laws to permit vaccination, because it is a better way of dealing with it, as soon as possible.

Q108 David Taylor: Well, my final question relates to the discussion we have been having which has been, in essence, about a cattle vaccine. Now, during your rapprochement with the European Commission people that you have been talking to, do you get the similar feeling, that there will be difficulties in winning their acceptance of a badger vaccine when that might appear?

Hilary Benn: We do not need to get their approval because the cattle vaccine is for trade measures and we are not exporting badgers.

Ms Edwards: We have actually got to clarify that.

Q109 David Taylor: The badger vaccine would need to be licensed, would it not?

Hilary Benn: Yes, under the normal process, but we would do that.

Q110 David Taylor: But there is no further approval needed?

Hilary Benn: No, it does not require their approval, but the cattle vaccine would.

Q111 Mr Drew: Really, the crux of this is that it is a bit of madness, is it not, because we have got here a situation whereby the two countries that have got a real problem with bovine TB are ourselves and the Irish Republic, yet the rest of the EU are pontificating on this. They are not pontificating on

whether it is good science or bad science, what we are doing, but they are looking at it in terms of the pure economics, as a trade measure. At a whim, they could take away our TB-free status. I have never understood how—

Ms Edwards: We do not have TB-free status.

Q112 Mr Drew: Well, exactly, so it is all a wonderful ruse. What we really want is the EU to be helpful to us, to recognise that we are at the front end of trying with other countries in the world who happen to be outside of the EU, like New Zealand and, the classic case, Australia. Is this not rather limiting? What we want is just their help, as we have had in other areas, to go back to our earlier discussion of foot and mouth and bluetongue, where they have been helpful in the type of things we have tried to do. Surely they should be more helpful in this and say, "Look, if you can find a way forward, we're not going to use economic measures" because they are merely, let us say, trade-related to try and block what will be a perfectly sensible way if we can find a cattle vaccine. If we can prove that it is safe to eat, and to draw from, the cattle, why would they still not want to take our animals?

Ms Edwards: It is about trade in live cattle, the issue. The relevant European legislation is a trade directive, and their concern is that they would not be able to identify which cattle were infected with TB and which were vaccinated, so it is just inconsistent with the trade measures.

Q113 Mr Drew: But that is true of other species at the moment. We still have pigs, for example, and the Dutch presumably would be paranoid if we were to take the sort of measures, which we could have taken against us in terms of bovine TB, against Swine Vesicular Disease because of the difficulty with that disease growing around Europe at the moment.

Hilary Benn: Of course we need all the assistance that we can get and the reason why I have raised it with the Commissioner, why the discussions that Gabrielle has just described have begun and why we will keep them closely in touch with progress is that we want to be in the best position when we get to the formal stage of saying, "Now, will you change the rules because we've got", fingers crossed, "a vaccine that works and we've got a DIVA test?" to try to minimise the time, but in the end you have to make a judgment because you have got to be straight with people. It is not a question of the Commission saying, "That's fine. Right, you can start next Tuesday", which is why in the time-line, which is where the question began, we built a period into the time-line for making that happen, recognising that it may not be easy to get the support of other Member States, but the more we can build confidence, the better chance, I hope, we will have.

Q114 David Lepper: Can we move away from culling and from vaccination. One strand, Secretary of State, of the Welsh Assembly's strategy is improved biosecurity measures. The ISG say that it is very difficult to know what to recommend in terms of biosecurity, but, as I understand it, Dr Enticott's

¹ SCoFCAH: The Standing Committee on Food Chain and Animal Health

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evaluation into the South Wales Biosecurity Intensive Treatment Area did suggest that there were gains to be made from improved biosecurity. Indeed, you had said, I think, in your statement in July that it is something you would be willing to look at. Do you feel that Defra should be considering measures like those that were evaluated by Dr Enticott in Wales and, in particular, the Welsh view of linking compensation to biosecurity, is that something that you would wish to consider?

Hilary Benn: The latter is an interesting idea. As I think I indicated earlier, we funded quite a lot of research on this front. We set up the Husbandry Working Group, as you will be aware, there have been leaflets and there have been roadshows. The circumstances of individual farmers of course differ enormously and I have seen some of the efforts that farmers have made to try and put physical measures in place. There is the evidence, the video which was done, which I think the Committee have seen, showing badgers coming into farm buildings in a way that surprised some of those who saw it. Therefore, the costs of doing something and the practicality of doing something are going to vary enormously from farmer to farmer. As I understand the research that has been done that you refer to, vets went out and gave advice and that was beneficial, but the question always is of course: if advice is given, is it followed? How do you communicate and, I suppose going back to the earlier point, how do you build confidence on the part of those who are suffering and are desperate that, if I take these steps, it is going to have some beneficial impact? Obviously that is going to weigh in the balance of individual farmers in deciding whether they think it is a sensible step to take, assuming that it is practical and they can afford it.

Q115 David Lepper: The ISG, I think, and more recently the Welsh Badger Trust described the sorts of measures that are being considered as just commonsense anyway. The Welsh Badger Trust said, "Why should we pay people to do what is merely commonsense and which they ought to be doing as a matter of course?" Is that a reasonable line to take?

Mr Simmons: If you consider there are lots of different measures, "biosecurity" is a term that gets used rather loosely by lots of different people. There is no silver bullet or even a magic bullet here, but there are measures you can take, particularly about how you source cattle, which obviously with pre-movement testing will be one of the things we will be forcing people to do, but, in addition to that, on the farm there are simple measures, such as closing feedstore doors or even putting a door on in the first place, but I think we have to recognise that, with some of the modern dairies we have now, we might have 300/400 cattle in them with open buildings and total mixed feeding and access which is probably pretty easy for wildlife, having controls on that which are going to eliminate the risk are going to be extremely difficult. The research that we have got at

the moment is looking at the measures that could be applied, although none of them is going to be something which is going to be extremely easy to apply to a large modern dairy farm, but there are simple measures people can take now, such as closing doors or installing doors, on relatively small farms which would be pretty cost-effective, in my view.

Q116 David Lepper: You did say, I think, in your response to the Committee's Report that you had not ruled out trialling something similar to the Welsh ITA trial in this country. Is that still the case?

Hilary Benn: As I have indicated earlier, the Eradication Group has the opportunity to look at anything which they think is going to help and I will look very carefully at the recommendations that they come forward with. I have got an open mind.

Q117 Chairman: Can I just probe you a bit more about biosecurity because, in the original reply you gave to the Committee, you sided alongside the words that we had used that there ought to be more information about the results of biosecurity research. Mr Simmons has just sort of ticked off a few things that he thinks might work, but one of the things that struck me about Dr Enticott's findings was the lack of a sort of list in his report of the things that had been tried and worked. I could not find what works and then I looked in his conclusion and he said, "As a result, the small changes that occurred to biosecurity levels represent a realistic level of change", so whatever happened in Wales was very small. Then I went a bit further and he conjectures that awareness is one thing, implementation is another. I am rapidly coming to the conclusion that biosecurity is a sort of sticking plaster concept, but nobody has actually really got a provable clue of what works. Dr Enticott says that, even if he did find something that did work, it is damned hard to get farmers to implement it, and yet it seems to me quite an important plank in your approach. Why are we still feeling in a sort of fog in the dark about biosecurity?

Mr Simmons: If you will forgive me, I would like to use an analogy about trying to reduce the cost of heating one's home, and I think it is probably quite relevant to Defra as well. If one takes a number of things that you could apply, which would be, say, lagging the loft or putting in cavity wall insulation, putting in better doors or a number of different things, you can get pretty good information as to which of those measures will provide you with the best return for your money and that might vary from house to house, but generally it is fairly well-established how much you can spend, so £500 spent on lagging your loft, you will recoup the cost in perhaps a couple of years. I think when one deals with biosecurity in respect of TB, because the measures vary from disease to disease, the benefits of various different measures are just not known and, in order to be able to get to that point where you had those measures, essentially you would have to do

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probably long-term intervention trials which would have farms on which you would deal with one area and probably apply a number of measures and then not apply them on other farms and then draw distinctions between them, long-term expensive and possibly inconclusive in the end. What is important though is that there are a number of sensible, relatively simple measures that people can be doing now which are relatively low-cost on many farms, and those ought to be applied now and the advice is available.

Q118 Chairman: I suppose I am just a bit cynical that we have heard a lot of this before and you, as a Department, make a lot about the information that is available to farmers to improve their biosecurity and you have got little pamphlets, lists and advice. In fact, it was all so good, as I understand it, that the lady who had a closed herd, a farmer in Devon who was one of the leading exponents of your approach on biosecure measures, actually got bovine TB in her herd. That somewhat seems to undermine the credibility of the work in this area. I am not saying for one moment that it is not important, but, given all the work that is supposed to have been done, given Dr Enticott's findings and given the weight that you, as a Department, seem to attach to it as a key ingredient in the non-cull part of the strategy to deal with bovine TB, at this stage given what you have spent on it, the fact that we do not know what works, that in Wales it makes a marginal difference, it does seem to sort of undermine its credibility, does it not? Is the answer not yes?

Hilary Benn: Well, it is not an unreasonable point, but the fact is that, just because we cannot know for certain what impact all of these things are going to have, I do not think it was wrong to have invested the time, effort and energy in trying to identify what biosecurity measures might work, but it is a theme that we have touched on earlier in this evidence session. Even in the absence of certainty, and that is clearly the case in relation to this as other matters, is the conclusion that is drawn that you should go off and do something else and not promote this further? I am not sure that that is the conclusion that I would draw. We have to give the knowledge and the understanding that we have currently, recognise the difficulties, a number of which Alick has just talked about, and in the end farmers are going to have to make a judgment.

Chairman: Secretary of State, I am going to draw things to a conclusion and you have, as always, been generous with your time, but here we are at the end, and Mr Drew, who, I think, eats, breathes and sleeps bovine TB, he looks at all of it and he made the point at the beginning about the volume of work, the reports and everything else, that has been done and here we are some years on and this Committee has done two, three, four inquiries into it—

Mr Drew: And the rest!

Q119 Chairman: Your Department has had plans, strategies and now it has for the first time an

Eradication Group, yet we start off from the premise that here we are now in 2008, coming towards the end of the year, the incidence of bovine TB continues to rise, the measures of biosecurity, we are not certain what might work, there are still great uncertainties about the time-lines, the effectiveness, the application of the vaccine procedures, and we still have to convince Europe. You have for the time being, for the reasons stated, ruled out an intervention with culling and we seem to be significantly behindhand in terms of the basics of testing cattle. It does not add up to a particularly effective approach to a policy that is costing your Department currently £70 million a year and, as one of my colleagues said, by admission, I think, of the 2005 Bovine TB Strategy, one of the annexes at the back projects that by 2012 you will have blown £1 billion of public money without showing very much for it. It does not add up much to a row of beans, does it?

Hilary Benn: With respect, I would not agree with that.

Q120 Chairman: Well, I would not expect you to, but there we are!

Hilary Benn: First of all, it is right and proper that we should try and find the answers to the questions that we can, and we do not know everything, there is a lot of uncertainty, and it is certainly not for the want of trying. Now, with the exception of the argument about culling which we have spent some time discussing, if there are a load of other things that the Committee or somebody else thinks, "Well, that's blindingly obvious. Why haven't you done it?", I would very much like to hear it. What we can do is to continue to put time, effort and energy into trying to deal with this disease, recognising it is darned difficult.

Q121 Chairman: I suppose, Secretary of State, if you go to John Innes and they tell you they have cracked the DNA of plants, you go to other scientists, they seem to have done a lot of unbelievably difficult things, and, however complicated this disease is, here we are still feeling around trying to find some way to counter its spread and I think that is the frustration that we all feel.

Hilary Benn: We all feel it, yes. Of course, we all feel the frustration but, as I say, it is not for the want of trying, it is not for the want of effort. There are choices to be made in how we deal with this. The one big step forward that we have got now is that a lot of these questions, which the Committee have put very legitimately to us, are about is it worth doing this, should you try more of that, and now we have got the opportunity in discussion and in partnership, if you want to use that word, together with the industry to weigh those things up. I think that will be a step forward compared to where we have been up until now.

Chairman: Mr Drew is going to ask the postscript question and then we will call it a day. You have got one minute.

5 November 2008 Rt Hon Hilary Benn MP, Ms Gabrielle Edwards and Mr Alick Simmons

Q122 Mr Drew: It will be one minute. This is a plaintive plea from my farmers. The two aspects of this disease, I am sure, will be economics, and at the moment you are in court over the tabular system, so I hope you get a speedy resolution to that, but I am aware of the emotional side and how much people are under huge pressure at the moment. In an area like Gloucestershire with so many herds that are currently closed for all sorts of reasons, where you have got young stock which are difficult to feed, can we look at ways in which we can intervene to try and be as sympathetic as possible? I know it is about money but it is also about the care regime when you are losing so many animals on so regular a basis. If we can at least be sympathetic to that I think a lot of farmers would feel that Defra is listening to them.

Hilary Benn: Can I ask what in particular you have got in mind?

Q123 Mr Drew: When you take animals out and you have got young stock, you either shoot them, that is the reality, or you try and find ways in which you can keep those animals going. That is not easy when you cannot move stock because you cannot buy in. This is where the real crisis is, and Roger will know more than anyone as he is facing it. This is where the real emotional pull is at the moment.

Mr Simmons: There have been a number of ways in which we have tried to address the impact of TB on farms which are under restriction for some time. I am assuming you are talking about dairy calves which would normally be sold a week or so old.

Q124 Mr Drew: It is dairy. It is less so with beef.

Mr Simmons: It is a week-old dairy calf that would normally be sold on, marketed and sold off to someone else. We have got a number of ways in which we can address this through approved

finishing units, which are not really suitable for young calves because clearly the care that needs to be applied when they are unweaned is very different than it would be if it was weaned calves, for example, that were going off to finish off elsewhere. It seems to me if this Eradication Group is going to look at anything, what it needs to look at amongst some of the things the Secretary of State and the Committee has already mentioned is how best to get farmers to effectively live with the disease. I know that is a phrase that farmers do not want to hear but, in essence, in certain parts of the country, Gloucestershire in particular, it is a matter of learning to live with the disease and us facilitating people living with that disease and trying to reduce the economic impact without significantly impacting on the prevalence of the disease and on public health risks. That is a real tall order but I think that is what we need to be doing.

Q125 Chairman: Can I thank you all very much for your patience and your contributions to this inquiry. I have a funny feeling that however much we might have looked at it, it is a subject that we might well come back to. Secretary of State, it would be helpful if you could continue to keep us posted about the progress of the Eradication Group which is an important next step. We would be grateful if you would keep us up to speed on how things are going.

Hilary Benn: I would be delighted to do so, Chairman. Can I thank the Committee because we need to continue to work together on this, and I am sure it will not be the last occasion when we talk about the problem of bovine TB and how we are going to deal with it. Can I just say to Mr Drew, I absolutely understand the devastating impact because I have talked to enough farmers who are trying to live with this to know that.

Chairman: Thank you very much.

Further memorandum submitted by the Department for Environment, Food and Rural Affairs

I am writing in response to your letter of 10 November to provide you with the additional information requested by the Committee during the evidence session held on 5 November.

The Committee asked for further information on the number of herds, and number of cattle, that had been identified through slaughterhouse surveillance (meat inspection) rather than skin tests as having TB. The proportion of confirmed new TB incidents (CNI) first disclosed by slaughterhouse cases was 15.8% (391 out of 2,479) of all CNIs in 2007. The remaining 84.2% were detected by routine and targeted skin testing. Between 1997 and 2004, the overall proportion of CNIs disclosed by slaughterhouse cases in GB steadily increased, but the trend has stabilised since 2005. The more frequently testing is carried out, the smaller the contribution of slaughterhouse surveillance to the detection of new TB breakdowns.

I attach a table which gives figures for animals and herds from 2003 to 2007. By way of explanation, on-farm TB surveillance by skin testing of cattle herds is supplemented by meat inspection of cattle carcasses during commercial slaughter, followed by traceback of any carcasses that present with suspect TB lesions positive to *Mycobacterium bovis* (the bovine TB bacillus). A proportion of the infected animals listed in the table as detected during meat inspection may have been identified in herds already under TB restrictions and thus do not generate a new TB incident. In other cases, more than one infected animal will originate from the same herd. Therefore, the number of infected herds detected will be less than the number of infected animals detected by meat inspection.

I am also enclosing a note which sets out details on the availability of medicines for bees and issues surrounding the authorisation of medicines together with information on Defra's funding at Rothamsted Research.¹¹

I hope this is helpful.

Hilary Benn

27 November 2008

¹¹ Not printed. Copies of the note have been placed in the House of Commons Library and in the Parliamentary Archives. The note is also available on the Committee's website: www.parliament.uk/efracom

BOVINE TB: SLAUGHTERHOUSE DATA FOR GB 2003-08

	2003	2004	2005	2006	2007	Jan-Jul 2008
Herds: Number of confirmed new TB incidents (CNI) first identified at slaughterhouse in GB (out of total CNI)	211 (1,780)	266 (1,923)	335 (2,247)	378 (2,246)	391 (2,479)	(not yet available)
Animals: Number of TB slaughterhouse cases identified in GB (of which M. bovis-positive on culture)	Not available (data series began in 2004)	651 (380)	791 (508)	853 (560)	960 (631)	622 (491)

Notes:

Data for number of confirmed new TB incidents identified at slaughterhouse (herds) in GB from Veterinary Laboratories Agency, unpublished observations. This differs from published TB statistics because it distinguishes confirmed new TB incidents identified at slaughterhouse.

Data for animals from VLA laboratory data.

TB statistics are published on the Defra website at <http://www.defra.gov.uk/animalh/tb/stats/latest.htm>