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Bovine Tuberculosis: The Government's approach to tackling the disease and consultation on a badger control policy

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Contents

Executive Summary

1. The Coalition Government has committed, as part of a package of measures, to develop affordable options for a carefully-managed and science-led policy of badger control in areas with high and persistent levels of bovine TB.

TB is one of the biggest challenges facing the cattle industry

2. Bovine TB is a pressing animal health problem. The incidence rate of bovine TB in cattle in England and Wales has been rising for 25 years and has worsened since the 2001 foot and mouth disease outbreak. The area affected by bovine TB has spread from isolated pockets in the late 1980s to cover large areas of the West and South-west of England and Wales. 6.4% of herds in England were under bovine TB restriction at the end of 2009. The figure was 14.3% in the South West. In England, in 2009, bovine TB cost the taxpayer £63m[1] and over 25,000[2] cattle were slaughtered for bovine TB control.

3. It is estimated that the average cost of a confirmed TB incident in cattle is around £30,000. About £20,000 of this falls to Government, mainly compensation for animals compulsorily slaughtered and costs of testing. This leaves about £10,000 in costs to farmers from losses of animals, farm costs of testing, and disruption to business through movement restrictions. The costs of control are rising year by year and are becoming unaffordable.

Eradication is a long term goal but additional measures are needed now to stop the disease spreading and start to reverse the upward trend

4. The Government's long term goal is to eradicate the disease in cattle, but this is likely to take several decades. We need a progressive approach to tackling bovine TB which first aims to stop the disease getting worse and then to reduce the spread and prevalence of the disease to a point where eradication becomes an achievable goal. The farming industry, veterinary profession and Government need to work in partnership to achieve this.

[1] 2009/10 figure, excludes research and development

[2] 2009 figure

There is no single solution to tackling bovine TB – we need to use every tool in the toolbox

5. The Government is committed to putting in place a balanced package of measures to tackle bovine TB.

6. Bovine TB is predominantly a disease of cattle but can affect a range of species; there is a significant reservoir of infection in badgers. The disease is transmitted between cattle, between badgers, and between the two species.

7. Cattle measures will continue to be central to our bovine TB control programme but we will not succeed in eliminating the disease in cattle unless we also tackle the disease in badgers. No other country in the world has managed to eradicate bovine TB in cattle without addressing the reservoir of the disease in wildlife.

Badger culling and vaccination both have a role to play

8. Badger culling has the potential to reduce bovine TB in cattle by rapidly reducing the overall number of infected badgers, thus reducing the rate of transmission of the disease to cattle. The main body of evidence on the impact badger culling has on incidence of bovine TB in cattle is the Randomised Badger Culling Trial (RBCT). The results of this trial demonstrate that badger culling, done on a sufficient scale, in a widespread, coordinated and efficient way, and over a sustained period of time, would reduce the incidence of bovine TB in cattle in high incidence areas.

9. In areas with high and persistent levels of bovine TB in cattle, vaccination would not reduce the weight of infection in the badger population as quickly as widespread, effective and efficient culling. However, it is still likely to reduce disease risk and have greater disease control benefits than taking no action to tackle bovine TB in badgers. Vaccination could reduce the prevalence and severity of bovine TB in a badger population, could reduce the rate of onward transmission of disease to cattle and, by using it in combination with culling strategies, could maximise the benefits of both options.

10. However, vaccination does not guarantee that all badgers are fully protected from infection and it would take some time for herd immunity[3] to develop. In addition, the first injectable badger vaccine was only

[3] In a badger population, herd immunity from vaccination will be needed to decrease transmission and decrease TB prevalence in badgers. Herd immunity occurs when enough individuals are immune in a population to protect the remaining unvaccinated animals.

licensed in March 2010. Since then, the vaccine has been available for use on prescription, subject to a licence from Natural England for trained operators to trap badgers to inject the vaccine. This means that there is only very limited experience of using vaccination in the field and no hard evidence on the contribution badger vaccination would make to reducing the disease in cattle. Much of the scientific evidence on the role of vaccination in disease control relies on laboratory testing or computer modelling.

The Government's proposal

11. The Government's proposal is to issue licences under the Protection of Badgers Act 1992 to enable farmers and landowners to cull badgers, at their own expense and subject to strict licence criteria. Under existing arrangements farmers and landowners are already able to apply for licences to vaccinate badgers. Under the new proposal, they will be able to use vaccination either on its own or in combination with culling. This approach will empower farmers to take control of reducing the risks of transmission from the wildlife reservoir at the local level.

12. In order to obtain a licence to cull badgers, applicants will be expected to satisfy a series of criteria to ensure that the cull is justified and is likely to contribute to controlling bovine TB in cattle in their area. It is expected there will be a single licence application for each culling area (of at least 150km^2). The application will need to meet strict licence criteria (set out in Section 4 of this Consultation Document) and demonstrate how the applicants, collectively, propose to control the disease in badgers.

13. Farmers and landowners will be expected to cover the costs of culling and/or vaccination themselves. Government will put in place arrangements to issue licences in response to applications meeting the criteria, and will take responsibility for monitoring the effectiveness, humaneness and impact of badger control measures.

14. Where appropriate, the use of vaccination will be encouraged to mitigate against the negative effects of culling brought about by perturbation[4]. Farmers and landowners will be able to apply for licences, individually or collectively, to vaccinate badgers as part of an approach coordinated locally with culling activity. This will allow them to cage-trap and vaccinate badgers within an area specified by the licence.

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[4] Badgers typically live in social groups of 4-7 animals, with defined territorial boundaries. Culling disrupts the organisation of these social groups, which causes surviving badgers to range more widely than they would normally and come into contact more often with other animals- called perturbation

15. A decision on this policy will be made early in 2011, taking into account views provided during this consultation, the available scientific and economic evidence, and the results of the spending review.

This document

16. This consultation document invites views on the key elements of this proposal, including:

    - whether you agree with the Government's proposed approach;
    - whether you agree that this approach, of issuing licences to farmers/landowners, is the most appropriate way to operate a badger control policy;
    - whether you agree with the proposed licensing criteria;
    - whether you agree that the proposed methods of culling are effective and humane;
    - whether you agree with the proposed use of vaccination, particularly its focus on mitigating the perturbation effects of culling;
    - whether more should be done to encourage the use of vaccination; and
    - whether you agree with the proposed monitoring.

17. This document has been developed in consultation with the Bovine TB Eradication Group for England (TBEG), which advises Ministers on the control and eradication of bovine TB. The membership of the group includes representatives from Defra, Animal Health, the farming industry and the veterinary profession.

18. Responses to this consultation will inform the Government's approach to tackling the reservoir of bovine TB in badgers in areas with high and persistent levels of TB in cattle.

19. Animal health and welfare is a devolved responsibility. This consultation therefore relates to the management of bovine TB in England only. The Scottish Executive, Welsh Assembly Government and Northern Ireland Executive are responsible for developing bovine TB control strategies within their own jurisdictions.

20. This document consists of two parts, each divided into two sections. The first part gives an overview of bovine tuberculosis (TB) (section 1), and outlines the Government's approach to tackling the disease through a balanced package of measures (section 2). The second part is the consultation on badger control: it describes policy options for badger control (section 3) and sets out the Government's proposed approach

(section 4). The consultation questions are set out alongside the proposal in Section 4.

Section 1: Background on bovine TB

21. Bovine TB is a serious infectious disease of cattle, caused by the bacterium *Mycobacterium bovis (M. bovis).* It can be transmitted to humans and other mammals. Badgers are known to maintain the disease and thus serve as a potential cause of disease outbreaks in kept animals and act as a reservoir of the infection in parts of England.

22. In Great Britain a large proportion of cattle herds were found to be infected with *M. bovis* in the early parts of the 20th century. In 1935 a voluntary GB-wide testing programme for cattle herds was introduced with a test-and-slaughter programme for cattle becoming compulsory in 1950. By 1960, the disease was confined to a few pockets in the South-west of England. However, despite continuous compulsory cattle testing and slaughter, levels of bovine TB in cattle in England have been rising since the 1980s and have worsened since the 2001 foot-and-mouth disease outbreak, when routine testing was significantly disrupted. TB now covers large parts of the west Midlands and South-west England, while other parts of England are effectively disease free (**Figure 1**).

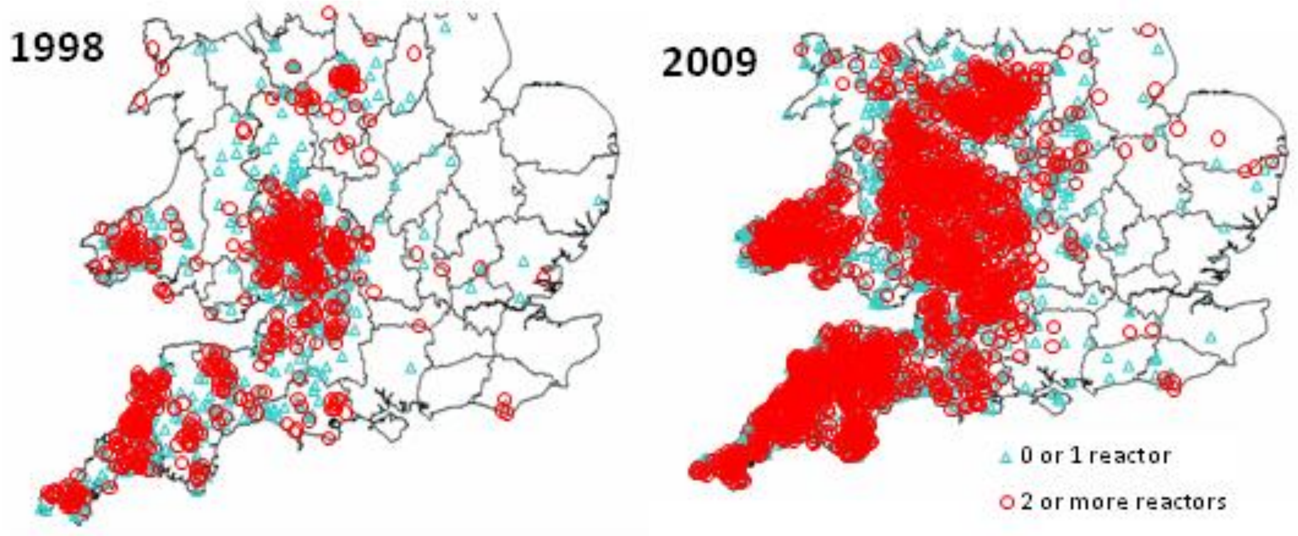


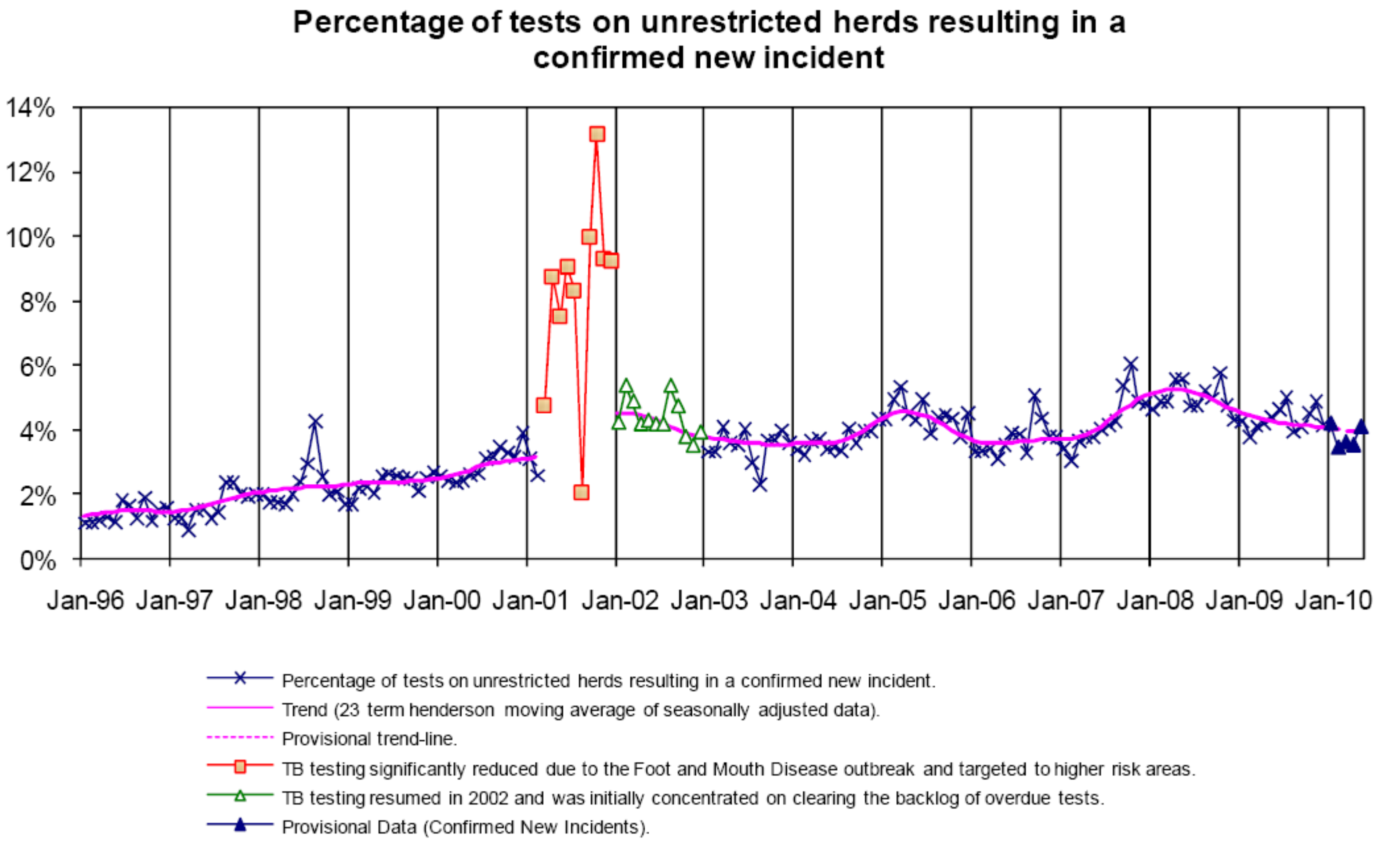
Figure 1: Geographical distribution of confirmed new breakdowns of bovine TB in 1998 and 2009 (source VLA). If an animal has failed the tuberculin skin test for TB is it called a reactor. If reactors are found in a herd, this is known as a herd TB breakdown.

23. Bovine TB is a pressing animal health problem and is one of the biggest challenges facing the cattle farming industry today. In England, in 2009, bovine TB cost the taxpayer £63m[5] and over 25,000[6] cattle were slaughtered for bovine TB control. By continuing with the current approach, the cost to the taxpayer and the industry will increase further as the disease situation worsens and the cost of control measures increases.

24. In the first half of 2010 there has been a welcome fall in the number and incidence of new bovine TB breakdowns in Great Britain, and the number of cattle slaughtered, relative to 2008 and 2009. However we have observed similar declines over the last nine years, only then to see bovine TB incidence rise again **(Figure 2)**. It is not currently possible to know with any certainty what may be causing this reduction, and whether it is just a temporary phenomenon or the beginning of a sustained long-term downward trend. The reasons for the observed decline could be a genuine fall in the underlying prevalence of infection in cattle (due either to more intensive bovine TB surveillance and controls in cattle herds over the last few years, or other epidemiological factors), a statistical anomaly, or a combination of these factors. Despite the overall decline in the national incidence, the number of bovine TB breakdowns and reactors in certain parts of England has continued to increase and the area of England under more frequent TB testing is expanding. Therefore the recent figures must be treated with caution and not detract from the fact that the incidence of bovine TB in Great Britain (and the West of England in particular) is still unacceptably high.

[5] 2009/10 figure, excludes research and development

[6] 2009 figure



25. For the overwhelming majority of people in the UK, the risk of contracting *M. bovis* infection from animals is very low as a result of the pasteurisation of milk (which kills *M. bovis*), meat inspection at slaughterhouses, and the cattle testing programme. In the early parts of the 20th century before milk pasteurisation was introduced, consumption of infected milk was thought to have led to over 2,500 human deaths and over 50,000 new cases of bovine TB per year in the human population. Today, the number of cases of humans contracting bovine TB is very low. While the risk to the general population is low, there is still a risk of infection to certain groups of the population, in the form of continued on-farm consumption of unpasteurised cows' milk, and to farmers, vets, slaughterhouse workers, etc. from occupational exposure to *M. bovis* in aerosols from animals or carcases infected with bovine TB.

26. While maintaining vigilance over public health risks, the main focus of the Government's efforts today is on mitigating the economic impact of the disease on farmers and taxpayers, and meeting European Union legal requirements for trade purposes.

27. The Government's long-term goal is to eradicate the disease in cattle. However, this is likely to take several decades. We therefore need a

progressive approach to tackling bovine TB which aims firstly to stop the disease getting worse, and then to reduce the geographical range and prevalence in affected areas, to a point where eradication becomes an achievable goal.

Section 2: A package of measures to tackle bovine TB

28. The Government is committed to putting in place a package of measures to tackle bovine TB which adds up to a balanced programme, with measures deployed in a flexible way to address TB risks at the local level. There is no single solution, so we need to use every control tool in the toolbox to reduce the disease in cattle, in a proportionate and cost-effective way. We envisage that a balanced programme should include the following key elements, many of which are already in place:

- cattle surveillance and control measures;
- controlling the disease in badgers;
- enhanced biosecurity and husbandry practices by cattle owners;
- advice and support to farmers;
- dealing with bovine TB in non-bovine kept species (including camelids and goats); and
- focused research and development (including development of a cattle vaccine and an oral badger vaccine).

29. Scientific evidence indicates that, in areas with high incidence of bovine TB in cattle, it will not be possible to eliminate the disease in cattle without addressing the transmission of disease from badgers. Countries and regions outside Great Britain with a known wildlife reservoir, i.e. where the wildlife population can sustain bovine TB infection on its own, regardless of bovine TB levels in cattle, include Northern Ireland[7], the Republic of Ireland[8,9], Spain[10], and New Zealand[11]. These places have not been able to eradicate TB, although New Zealand has made substantial progress towards this. Of those countries which have successfully eradicated bovine TB from cattle, only Australia is known to have had a longstanding feral buffalo reservoir. Australia achieved

[7] Abernethy, D. A., Denny, G. O., Menzies, F. D., McGuckian, P., Honhold, N., Roberts, A. R. (2006). The Northern Ireland programme for the control and eradication of *Mycobacterium bovis*. *Veterinary Microbiology 112,* 231-237.

[8] Good, M. (2006). Bovine Tuberculosis eradication in Ireland. *Irish Veterinary Journal 59*, 154-162.

[9] More, S. (2009). What is needed to eradicate bovine tuberculosis successfully: an Irish perspective. *The Veterinary Journal 180*, 275-278.

[10] Naranjo, V., Gortazar, C., Vicente, J., and de la Fuente, J. (2008). Evidence of the role of European wild boar as a reservoir of Mycobacterium tuberculosis complex. *Veterinary Microbiology 127*, 1-9

[11] Ryan, T. J., Livingstone, P. G., Ramsey, D. S. L., de Lisle, G. W., Nugent, G., Collins, D. M., Buddle, B. M. (2006). Advances in understanding disease epidemiology and implications for control and eradication of tuberculosis in livestock: The experience from New Zealand. *Veterinary Microbiology 112*, 211–219.

bovine TB eradication[12,13] through stringent cattle controls, combined with a control programme targeting the buffalo reservoir. In other countries, such as the USA and Canada, a significant wildlife reservoir only became evident when bovine TB was nearing eradication, making it necessary to introduce further control measures in certain regions[14,15]. France succeeded in eradicating bovine TB in 2000, but localised wildlife reservoirs of the disease have since emerged[16].

30. We therefore regard addressing the wildlife reservoir in badgers as the most pressing issue if we are to make progress on tackling the disease in cattle.

31. However, badger control is only one part of the programme. We are committed to a balanced package of measures which includes all the key elements above and which will be reviewed regularly as we progress towards the long term goal of eradication. Cattle measures will continue to be central to our bovine TB control programme.

32. Over the coming months, in parallel with the consultation on badger control, we will be further developing other elements of the package of measures. This will include considering potential changes to cattle measures.

33. Existing bovine TB control measures and potential changes are described below. We plan to publish a comprehensive and balanced bovine TB eradication programme early in 2011.

Cattle surveillance and control measures

34. Compulsory bovine TB controls in cattle have been in place in England since 1950. In line with the approach taken in other developed countries, surveillance and control continue to form the basis of our eradication programme.

35. Measures already in place to tackle bovine TB can be divided into surveillance measures (designed to identify animals with *M. bovis*

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[12] Radunz B. (2006) Surveillance and risk management during the latter stages of eradication: experiences from Australia. Vet Microbiol. 112, 283-290.

[13] Cousins DV et al. (1998) Eradication of bovine tuberculosis from Australia: key management and technical aspects. CSL Limited, Melbourne, Australia.

[14] O'Brien, D. J., Schmitt, S. M., Fitzgerald, S. D., Berry, D.E., Hickling, G.J. (2006). Managing the wildlife reservoir of Mycobacterium bovis: the Michigan, USA, experience. *Veterinary Microbiology 112*, 313–323.

[15] Nishi, J. S., Shury, T., Elkin, B. T. (2006). Wildlife reservoirs for bovine tuberculosis (*Mycobacterium bovis*) in Canada: strategies for management and research. *Veterinary Microbiology 112*, 325–338.

[16] Zanella, G., Durand, B., Hars, J., Moutou, F., Garin-Bastuji, B., Ducauchelle, A., Ferme, M., Karoui, C., Boschiroli, M. L. (2008). Mycobacterium bovis in wildlife in France. *Journal of Wildlife Diseases 44*, 99-108.

infection) and control measures (designed to tackle infection and prevent its further spread, once it has been found).

Cattle surveillance

36. Bovine TB surveillance testing in cattle is by the comparative tuberculin skin test. Details of the tests and the circumstances in which they are used can be found on Defra's website[17].

Routine testing	On-farm surveillance for bovine TB is carried out primarily through a programme of risk-based 'routine testing', with cattle herds tested every one, two, three or four years depending on the level of risk of infection with *M. bovis* and historic incidence of infection in the local area. The incidence and risk of *M. bovis* infection are reviewed annually on an area basis to confirm or change the frequency of routine testing. This annual review has resulted in year on year increases in the proportion of herds tested annually and the total number of herds and animals tested. Changes made for 2010 aimed to get ahead rather than trail behind the disease by placing a greater number of herds, in higher bovine TB risk areas, on a more frequent testing regime and introducing two-year testing buffer areas around annual testing areas.
Pre movement testing	Cattle in herds that are tested annually or every two years are also tested before moving to other farms to reduce the risk of disease spread. All owners of cattle intended for export, regardless of testing frequency, must ensure the animals test clear before being moved.
Slaughterhouse surveillance	Cattle carcases are inspected by the Food Standards Agency for suspect bovine TB lesions during commercial slaughter. Around 17% of all confirmed bovine TB herd breakdowns in Great Britain are detected this way.
Check-testing herds cleared of bovine TB	Before reverting to regular routine testing, a herd cleared of *M. bovis* infection will be retested 6

[17] http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/control/index.htm

	months after the last animal to test positive has been removed.

Cattle controls – once *M. bovis* infection has been identified

Movement restrictions	Cattle movement restrictions are applied immediately when bovine TB is suspected through testing or slaughterhouse inspection, or when the disease status of the herd is unknown because a bovine TB test is overdue.
Short interval testing	Bovine TB breakdown herds undergo a series of tuberculin skin tests, at minimum intervals of 60 days. Depending on post-mortem findings, breakdown herds must have one or two consecutive clear tests before they regain their bovine TB free status. Skin testing may also be supplemented by gamma interferon blood testing in some circumstances. Details of the tests and the circumstances in which they are used can be found on Defra's website[18].
Gamma interferon testing	The gamma interferon blood test is mainly used in breakdown herds in areas of the country with a lower risk of bovine TB where post-mortem evidence of bovine TB has been found, and in certain herds in the high-risk areas of the country with persistent and severe bovine TB problems.
Cattle tracing	Cattle may have been moved from herds infected with *M. bovis* before the disease was identified. For every bovine TB breakdown herd, Animal Health completes an epidemiological risk assessment. Where there is post-mortem evidence of bovine TB lesions (and hence the animal is likely to have been infectious to others), Animal Health trace back to any source herd of infection and trace animals moved out of the herd since the last clear bovine TB herd test, to identify any further disease spread.
Testing contiguous (neighbouring) herds	The risk of spread of *M. bovis* infection to or from cattle neighbouring a bovine TB breakdown herd is assessed by Animal Health and where necessary

[18] http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/control/index.htm

	check testing of neighbouring herds is carried out.
Removal of *M. bovis* infected cattle	Cattle that test positive and those identified as high risk contacts to established *M. bovis* infection must be removed from the herd and slaughtered. Compensation for these animals is paid by Defra.

Possible changes to cattle measures

37. As part of our commitment to a package of measures to tackle bovine TB we are considering a number of changes to existing cattle measures. Some current control measures are applied too generally and are not sufficiently targeted on the basis of disease risk. We will also take this opportunity to review those areas where controls may be disproportionate in order to reduce the burden on both farmers and taxpayers where possible, while maintaining vigilance and control over the disease. This section provides a brief summary of some of the options being considered. The Bovine TB Eradication Group for England (TBEG) has already identified some of the measures detailed below as a high priority[19].

38. We are currently carrying out the annual **review of routine TB testing intervals** which will be completed to inform the 2011 testing programme. This follows a substantial expansion of the area under more frequent routine TB testing in 2010. Areas of high and persistent bovine TB will remain on annual testing. We will be considering whether the area on annual testing and the two-year testing buffer area should be expanded further. In the longer-term we will also be considering the potential for a more risk-based approach to setting routine TB testing intervals.

39. We have just completed the first stage of a **review of pre-movement testing** that has confirmed the effectiveness and value of this measure in reducing the risk of disease spread. The full report is available on the Defra website[20]. The next stage of this review will consider whether the policy could be improved further, including any changes to current exemptions.

40. We are planning to introduce immediately some **minor changes to TB testing** that will help us to focus our testing efforts on high-risk herds more effectively and reduce the testing burden on herds where there is a lower TB risk. These changes include reducing the testing requirements for re-stocking herds (introduced as a precaution after the foot and

[19] Progress report: Developing a Bovine TB Eradication Programme for England
http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/partnership/eradication-group/index.htm

[20] http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/premovement/index.htm

mouth disease outbreak in 2001 but now obsolete); stopping testing young calves (except where they are considered at high risk of infection) since the skin test is unreliable in young animals; rationalising post-breakdown testing in low-risk herds where TB is not confirmed; and rationalising and reducing the amount of contiguous testing (i.e. of herds neighbouring a confirmed TB breakdown) through a more risk-based approach. These changes are set out in more detail on the Defra website[21]. Over the coming months we will also be looking at whether we can reduce the number of unnecessary tracing tests carried out and whether we can provide further opportunities for TB restricted farm businesses to see surplus stock, without increasing disease risk.

41. We are planning to **increase controls in some higher-risk herds** where TB is not confirmed at post-mortem examination or on bacterial culture of tissue samples. This is likely to focus on herds which have a history of confirmed bovine TB and/or which are contiguous to other herds under TB restrictions. The current approach to such herds can perpetuate the misunderstanding that a lack of post-mortem confirmation of disease means the herd does not have TB and thereby risks greater spread of infection within the herd or onward spread by allowing resumption of normal trading too soon. We are therefore planning to extend the period that the herd is kept under TB restrictions, so that it has to clear two consecutive short-interval tests (rather than the current one) to help ensure it is truly clear of the disease.

42. We are planning to introduce a **change in terminology**, moving from using "unconfirmed" or "confirmed" breakdown to using terminology which describes the situation more accurately:

- Herd officially TB-free (OTF);
- Status suspended (OTF-S); or
- Status withdrawn (OTF-W).

43. The use of the term "unconfirmed" can cause confusion as it is often incorrectly taken to mean that an animal which tested positive was not truly infected. This is not the case, since diagnostic tests are more sensitive and reliable than routine post-mortem examination of carcases or culture of animal tissue. This change will also align us with the terminology used in EU legislation, and help farmers to understand better the infection status of their herd.

44. In some parts of the country, for some herds, the risks and weight of bovine TB infection in cattle and wildlife may mean it is unlikely that they

[21] http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/premovement/index.htm

are truly TB-free. Further to the changes to controls and terminology set out above we are planning a more detailed **review of TB-free status** to see if the current rules for herds to qualify and be able to trade as officially TB-free (OTF) are still appropriate. We will also look at how long it takes herds to regain officially TB-free status following a bovine TB breakdown (this can be as little as two months for some) and the most appropriate interval for breakdown testing to give the best assurance that the herd is clear of bovine TB before OTF status is regained.

45. The **gamma interferon blood test** is mainly used in areas of the country with a low incidence of bovine TB in cattle and where post-mortem evidence of bovine TB has been found. It is more sensitive (detects a greater proportion of truly infected animals), but less specific (is more likely to identify some animals as infected when they are not) than the routine tuberculin skin test read at standard interpretation. As in other countries, it is not used for routine TB surveillance. The gamma interferon blood test can be repeated as often as necessary without the need to wait at least 60 days between tests, as is required with the skin test. We plan to make increased use of the gamma interferon test to enhance TB controls in low-incidence areas. We also need to communicate more clearly the effectiveness of the test and the associated benefits for herds/farmers in different circumstances (in particular regarding its role in clearing infection from herds more quickly).

46. We will be looking for ways in which we can improve the quality and consistency of bovine **TB surveillance at slaughterhouses**. Such surveillance plays an important role in identifying disease (particularly in areas of lower disease risk).

47. Animal Health and local authorities are working together to **strengthen enforcement activity**. The large majority of cattle owners comply with bovine TB controls. However, the few that do not comply present unacceptable risks to others and take up considerable resources.

48. Our longer-term objective is to continue the move to a more **risk-based approach** to improve the way in which controls are targeted so that we are in a better position to tackle the disease. This would also help reduce the burden on farmers and get better value for money for taxpayers. By making interventions much more responsive to specific risks in this way (for example focusing more on high-risk herds), control of bovine TB would be more consistent with the approach to managing other animal diseases. Some of this may require a re-negotiation of EU legislation to allow greater flexibility to make changes to controls as knowledge and capabilities increase.

Biosecurity and husbandry

49. Following good biosecurity and management practices is important in reducing the risk of bovine TB transmission from wildlife and between cattle. Advice on this is available on the Defra website[22]. Many of the cattle controls described above are biosecurity measures. However, there are additional approaches that could be shared and applied as appropriate to a particular farm. In addition to the current measures we will look at:

- how to promote and incentivise best practice;
- learning lessons from farmers with consistently uninfected herds in high-incidence areas;
- disseminating the latest research findings as practical, easy to follow guidance for farmers;
- introducing isolation units for animals imported into the herd. This would allow farmers with bovine TB-restricted cattle to buy, sell or move cattle, achieve a more competitive price and avoid some of the problems created by having to keep cattle in one place; and
- whether action on biosecurity and husbandry could be linked to compensation payments (for example, if it were considered (on veterinary advice) that serious failings were not being addressed, then compensation payments could be reduced).

Advice and support to farmers

50. Bovine TB can have a significant economic and social impact on farmers. This was brought into focus by the Farm Crisis Network's 2009 report on the impact of bovine TB on farming families[23]. The report concluded that dealing with bovine TB causes considerable stress among farmers and their families. Farmers' reactions ranged from feeling the pressure but coping, through to actual physical illness caused by stress, and in some cases feelings of not wanting to carry on. The greatest impact was in relation to farm finances. Suggestions were made for wider improvements to official communications and a need to tackle the disease in badgers was identified.

51. The Farmer Advice Project was established in 2009, after the bovine TB Eradication Group for England (TBEG) highlighted the importance of providing enhanced support to farm businesses affected by bovine TB in

[22] http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/abouttb/protect.htm.

[23] FCN (2009) Stress and Loss: The impact of bovine TB on farming families at http://www.farmcrisisnetwork.org.uk/

the form of professional and focused advice on biosecurity, veterinary and business issues. The initiative (funded by Defra and delivered in partnership with the industry) is aimed at livestock owners experiencing their first bovine TB breakdown and those under long-term restrictions.

52. Two pilot on-farm events on biosecurity were held in spring 2010 and provide information to livestock keepers on reducing the risks of transmitting bovine TB between cattle, and from wildlife to cattle. This initiative is being reviewed and will be rolled out more widely before the end of this year. Also, the Farm Crisis Network will provide business advice aimed at minimising the financial impacts of bovine TB breakdowns.

53. Since January 2010, Animal Health has also been delivering enhanced veterinary advice for farmers experiencing their first bovine TB breakdown, through extended disease investigation visits. We are working with the veterinary profession to deliver focused veterinary advice (through private vets) to owners of long-term breakdown herds.

Other non-bovine species

54. Although relatively rare, other non-bovine kept species such as goats, pigs, sheep, farmed deer and South American camelids (including llama and alpaca) are susceptible to *M. bovis* infection. Infection can occur from a number of sources, including other members of their own species, wildlife (particularly badgers), or cattle.

55. The majority of these cases have been detected in areas where disease is endemic in cattle and wildlife. Infection of non-bovine farmed animals is not considered to be significant in determining the levels of bovine TB in cattle. This is because the number of cases is small, these animals do not appear to provide an ongoing reservoir of the disease, and most have limited contact with cattle. As with cases in cattle, transmission of *M. bovis* from other species to people is a possibility, and the risk needs to be assessed by healthcare professionals when disease is discovered in animals.

56. We propose to review the existing policy on camelids and other non-bovine species to ensure there is an effective disease-control system in England which is proportionate to the problem. This will look at how to secure effective control and enforcement, considering the respective roles and responsibilities of industry and Government.

Research and Development

57. Defra funds a wide-ranging bovine TB research and development programme which covers many branches of science (including immunology, microbiology, epidemiology, ecology and genetics), as well as social science and economics. Between 1991/92 and 2009/10 Defra funded over 90 individual research projects, and invested approximately £86 million in bovine TB research and development. In recent years, an increasing proportion of this research budget has been directed towards developing vaccines and associated diagnostic tests.

58. In addition to this research programme, Defra also funded a large-scale project to examine the effect of badger culling strategies on bovine TB incidence in cattle, costing £49 million – the Randomised Badger Culling Trial (RBCT)[24]. The trial ran from 1998 to 2007 and involved culling operations in ten areas ('triplets', each consisting of two areas where culling took place and one control area where no culling took place) across England. Defra continues to fund analysis of cattle TB data collected from proactively culled and control areas. The results of this trial are described in further detail from paragraph 78 and in **Annex B**.

59. Despite substantial investment, and a growing evidence base, there is still a need to improve our understanding of bovine TB. Defra's priorities in this area include:

- continuing to develop badger and cattle vaccines;
- improving diagnostic tests for use on both cattle and badgers; and
- epidemiological studies and developing mathematical models to understand better the spread of the disease and estimate the effect of various control policies.

60. The Bovine TB Science Advisory Body (TB SAB) was set up in January 2008 to provide independent advice to Defra's Chief Scientific Advisor and Chief Veterinary Officer on bovine TB-related research. The TB SAB consists of four sub-groups focusing on specific areas of Defra's bovine TB research portfolio[25]:

<u>Cattle vaccines research</u>

61. Although there is currently no cattle vaccine available, work to develop one demonstrates that cattle vaccination could have potential benefits in reducing prevalence, incidence and spread of bovine TB in the cattle population and could also reduce the severity of a herd breakdown

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[24] Bourne, J., Donnelly, C.A., Cox, D.R., Gettinby, G., McInerney, J.P., Morrison, W.I., & Woodroffe, R. (2007). *Bovine TB: the scientific evidence.* Defra. www.defra.gov.uk/animalh/tb/isg/pdf/final_report.pdf, London

[25] http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/tb-sab/subgroups/index.htm

regardless of infection being introduced by wildlife or cattle. However, a cattle vaccine will not guarantee that all cattle vaccinated are fully protected.

62. Defra had invested £18 million by the end of the last financial year on the development of cattle vaccines and associated diagnostic tools. We aim to have a licensed cattle vaccine by 2012. This vaccine is BCG (*Bacille Calmette-Guérin*, the human TB vaccine) which sensitizes cattle to the mandatory tuberculin skin test for some time after vaccination and can lead to a positive result when an animal is not infected with *M. bovis* (a 'false positive'). Therefore Defra is also developing a diagnostic test to differentiate infected from vaccinated animals (known as a 'DIVA' test) that could be used alongside the tuberculin skin test, where necessary, to confirm whether the animal is indeed infected. Our aim is also to have the DIVA test approved by 2012.

63. However, there is currently an EU ban on vaccinating cattle against *M. bovis*[26] and only cattle which test negative to the tuberculin skin test can be traded in the EU[27]. These restrictions also have consequences for trade in cattle products. Hygiene rules for food of animal origin[28] stipulate that raw milk must come from cows belonging to a herd which is officially TB-free (OTF). Milk from non-OTF herds can still be used but must be pasteurised, and milk from cows that give a positive reaction to a bovine TB test cannot enter the food chain. Once a licensed cattle vaccine and effective DIVA test are available, the basis for declaring herds tuberculosis-free will need to change. As part of the ongoing consultation on the new EU Animal Health Law, we will be using the strong scientific and technical evidence on the efficacy and safety of the cattle vaccine and the role of a DIVA test to request the necessary changes to EU legislation to lift the requirement for the skin test to be the only test to confer OTF herd status. Due to the need to change EU legislation, which is a lengthy process, we anticipate that a cattle vaccine and DIVA test could not be used in the field before 2015 at the earliest. In parallel with discussions at EU level we will be working with the food industry and regulators to provide the necessary reassurance about the safety of meat and other animal products entering the human food chain where they derive from animals which tested clear of bovine TB but which had been vaccinated.

[26] EU Directive 78/52/EEC

[27] EU Directive 64/432/EEC) and implementing domestic legislation (Tuberculosis (England) Order 2007)

[28] Regulation (EC) No 853/2004

Badger vaccines research

64. Defra and its research agencies are among the leaders internationally in developing TB vaccines for badgers, working particularly closely with researchers and Governments in the Republic of Ireland, New Zealand, Spain and the USA. Since 1999, Defra has invested over £11 million on research into badger vaccines, and the injectable BCG badger vaccine is now available. It is currently being used in a Government-funded Badger Vaccine Deployment Project in one area in Gloucestershire. This project involves training operatives to use the vaccine in the field and seeks to increase confidence in the use of injectable badger vaccines, while looking at the practicalities of the vaccination process.

65. An oral badger vaccine, which may be a more practical option in terms of field deployment, is still at the research stage and will not be available until 2015 at the earliest. Compared to an injectable vaccine, an oral vaccine is technically more difficult to formulate. It also requires the selection of a bait which encourages ingestion of the vaccine by badgers but minimises the potential for other species to eat it. The efficacy of potential oral vaccine formulations is currently being tested by the Veterinary Laboratories Agency (VLA).

Section 3: Options for a badger control policy

66. This section sets out the policy options for badger control, discusses the benefits and limitations of both culling and vaccination and describes how they could be used in combination.

67. The key pieces of work which form the scientific evidence base on the effects of culling on TB incidence in cattle are listed below. Further details on these reports are in **Annex B** and on Defra's website[29].

- The 1997 Krebs Review on Bovine TB in Cattle and Badgers;
- The Godfray review (2004), set up in 2003 to look at progress in the RBCT after the disruption caused by the 2001 FMD outbreak;
- Peer-reviewed papers published by the Independent Scientific Group on Cattle TB (ISG) and summarised with wider-ranging conclusions drawn in their 2007 Final Report;
- The 2007 report by the former Chief Scientific Advisor to the Government, Sir David King and the ISG's response to this report;
- Updated post-culling analyses from Imperial College London, published in two papers by Jenkins et al in International Journal of Infectious Diseases (2008) and PLoS ONE (2010); and
- The independent review of Jenkins et al (2010) carried out by the TB Science Advisory Body at the request of Defra's Chief Scientific Adviser.

68. Badger culling has been part of bovine TB control in the past, through a variety of policies (see Annex A). However, it is not possible to compare the effectiveness of most of these different policies or compare any of them with the impact of not culling badgers at all, because they were not scientific trials. The RBCT is the only one of these that was conducted as a rigorous scientific trial. There is however some evidence to suggest that culling policies involving complete or near complete removal of badgers from an area appear to be more effective at reducing cattle herd breakdowns[30].

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[29] http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/publications/index.htm#krebs

[30] Krebs, J.R., Anderson, R., Clutton-Brock, T., Morrison, I., Young, D., Donnelly, C., Frost, S., & Woodroffe, R. 1997. *Bovine tuberculosis in cattle and badgers.* H.M.S.O., London

69. Areas of England with a high incidence of bovine TB in cattle also tend to have high numbers of badgers, and the scientific evidence demonstrates conclusively that badgers contribute significantly to bovine TB in cattle[31]. This evidence comes from the RBCT, in which there were positive and negative changes in the incidence of bovine TB in cattle as a result of badger culling. However, the relationship between bovine TB in badgers and in cattle is highly complex, and the rate of transmission between the species is not in direct proportion to badger density.

70. Badgers are able to live for several years while infected with *M. bovis*, breeding successfully and transmitting the disease to other badgers and cattle. The prevalence of bovine TB in badgers varies greatly locally and across the country and is difficult to estimate precisely. In areas of England where bovine TB is endemic, during previous badger removal operations carried out between 1978 and 1982[32] estimates of prevalence in badgers ranged from 6.9% to 34.5%, and 33% to 80% of social groups were found to be infected. During the RBCT, an average of 16.6% (within a range of 1.6% to 37.2%) of badgers in proactively culled areas were found to be infected. However, this is likely to be an underestimate of true prevalence – when a sample of these badgers were subjected to extended post-mortem examination, prevalence was found to be almost twice as high[33]. As badgers are territorial and live in social groups, within endemic areas, it is quite possible to have some social groups which are infected and other neighbouring groups which are free from bovine TB.

71. There is evidence to suggest that without addressing the reservoir of disease in the badger population, it will not be possible to eradicate bovine TB in cattle in England. This evidence comes both from scientific studies (including studies of the effects of badger culling in Great Britain and elsewhere), and from comparison with other countries' attempts to eradicate TB.

72. Studies of the effects of badger culling operations have been able to establish that a certain percentage of cases of cattle TB occur due to

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[31] Bourne, J., Donnelly, C.A., Cox, D.R., Gettinby, G., McInerney, J.P., Morrison, W.I., & Woodroffe, R. (2007). *Bovine TB: the scientific evidence* Defra www.defra.gov.uk/animalh/tb/isg/pdf/final_report.pdf, London.

[32] Krebs, J.R., Anderson, R., Clutton-Brock, T., Morrison, I., Young, D., Donnelly, C., Frost, S., & Woodroffe, R. (1997). *Bovine tuberculosis in cattle and badgers.* H.M.S.O., London.

[33] Crawshaw, TR., Griffiths, IB & Clifton-Hadley, RS. (2008). *Comparison of a standard and a detailed post-mortem protocol for detecting Mycobacterium bovis in badgers*. Veterinary Record 163: 473-477

infection from badgers[34, 35, 36, 37]. No matter how stringent a programme of cattle testing was applied, these cases could not be reduced without reducing the rate of transmission from badgers to cattle.

73. Of those countries which have successfully eradicated TB from cattle, only one, Australia, is known to have had a longstanding reservoir of the disease in wildlife/feral species. Australia's TB control programme included a substantial element of feral buffalo control. Other countries with a known wildlife reservoir have not been able to eradicate the disease; although New Zealand has made substantial progress towards this (again through a control programme that includes wildlife control measures). These issues are covered in more detail in paragraph 29.

74. In addition to biosecurity measures, both culling and vaccination are options for controlling transmission of bovine TB from badgers to cattle. Each of these methods would have to be employed in a manner authorised by or compliant with current legislation, and the Government would wish to ensure that they were also employed in a manner consistent with the obligations of the UK and the EU under the Bern Convention.

75. Badgers are not an endangered species in the UK, but are protected by UK legislation. The Protection of Badgers Act 1992 (PoBA) and the Wildlife and Countryside Act 1981 (WCA) protect badgers and their setts, but make provision for licences to be granted to kill or trap badgers (using a specified method) or to interfere with their setts for the purpose of preventing the spread of disease, provided the methods of capture and dispatch are humane.

76. Badgers are also a protected species under the Bern Convention on the Conservation of European Wildlife and Natural Habitats, which requires contracting parties to take appropriate legislative and administrative measures to ensure their protection. Exceptions can be made for various purposes, which include the prevention of serious damage to livestock, but only provided that there is no other satisfactory solution and that the exception will not be detrimental to the survival of the population

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[34] Griffin, J. M., Williams, D. H., Kelly, G. E., Clegg, T. A., O'Boyle, I., Collins, J. D., More, S. J. (2005). The impact of badger removal on the control of tuberculosis in cattle herds in Ireland. *Preventive Veterinary Medicine 67*, 237-266

[35] Donnelly, C.A., Woodroffe, R., Cox, D.R., Bourne, F.J., Cheeseman, C.L., Wei, G., Gettinby, G., Gilks, P., Jenkins, H., Johnston, W.T., Le Fevre, A.M., McInerney, J.P., & Morrison, W.I. (2006). *Positive and negative effects of widespread badger culling on cattle tuberculosis*. Nature, 439, 843-846

[36] Donnelly, C.A., Wei, G., Johnston, W.T., Cox, D.R., Woodroffe, R., Bourne, F.J., Cheeseman, C.L., Clifton-Hadley, R.S., Gettinby, G., Gilks, P., Jenkins, H.E., Le Fevre, A.M., McInerney, J.P., & Morrison, W.I. (2007). *Impacts of widespread badger culling on cattle tuberculosis: concluding analyses from a large-scale field trial.* International Journal of Infectious Disease, 11, 300-308

[37] Donnelly, CA & Hone, J. (2010). *Is there an association between levels of bovine tuberculosis in cattle herds and badgers?* Statistical Communications in Infectious Diseases 2 (1).

concerned. Signatories to the Bern Convention must report to the Standing Committee established under the Convention every two years on any exceptions they have made.

Badger culling as a bovine TB control measure

77. Badger culling has the potential to reduce bovine TB in cattle by reducing the number of infected badgers, and thus reducing the rate of transmission of the disease to cattle.

78. Evidence for the effect of badger culling on bovine TB incidence rates comes principally from the RBCT. This trial ran from 1998 to 2007 and was overseen by the Independent Scientific Group on Cattle TB (ISG). The trial took place in thirty 100km^2 areas of England, which were grouped into ten sets of three areas ('triplets'). In each triplet, one area received repeated culling across all accessible land (proactive culling), one area received culling in response to bovine TB outbreaks in cattle (reactive culling), and the third area received no culling (survey only). Proactive culling operations took place for between four and seven years (averaging 5 years).

79. The RBCT showed that the effects of proactive culling could be split into two areas: an inner core area where culling took place ('culling area') and an approximately 2km-wide ring just outside the cull area where no culling took place, but effects on bovine TB incidence in cattle were seen (2km ring). 'Survey-only areas' are areas used for comparison, with efforts made to make them similar in most respects except for the fact that culling did not take place there.

80. During the lifetime of the trial, annual proactive culling over 4-7 years (this range is due to the gradual recruitment of study areas and the interruption from the 2001 FMD outbreak) on accessible land in ten 100km^2 areas was associated with a 23.2% decrease (95% Confidence Interval (CI[38]): 12.4% decrease to 32.7% decrease) in confirmed TB herd incidence inside culling areas when compared with survey-only areas. However, proactive culling was also associated with a 24.5% increase (95%CI: 0.6% decrease to 56.0% increase) in confirmed TB

[38] A 95% confidence interval for a particular figure is the range of values within which one can be 95% confident that the 'true' figure lies. Whether zero is included in the interval is used to judge whether the figure is significantly different from zero. For example, if the figure is an estimation of the size of a beneficial effect, the benefit can be said to be statistically significant if the 95% confidence interval does not include zero.

herd incidence in the surrounding 2km ring around the culling area when compared with survey-only areas [39, 40, 41].

81. The ISG hypothesised[42] that the increase in TB incidence observed in the 2km ring around the culling areas was a result of changes in badger behaviour brought about by culling. Badgers typically live in social groups of 4-7 animals, with defined territorial boundaries. Culling disrupts the organisation of these social groups, which causes surviving badgers to range more widely than they would normally and come into contact more often with other animals (including both cattle and other badgers). This is called perturbation. This increased ranging is thought to be behind the increase in bovine TB prevalence in badgers in the 2km ring adjacent to proactively culled areas. Therefore, although total badger numbers were significantly reduced by culling in the trial, the probability of bovine TB being transmitted from the remaining infected badgers to cattle increased in the short term, particularly at the edge of a culled area. This is known as the 'perturbation effect'.

82. Ongoing monitoring since the end of the RBCT shows that the positive effect of culling on herd breakdowns is maintained for at least 5 years after culling stopped and that the negative effect on confirmed herd breakdowns on surrounding land disappeared relatively quickly[43, 44]. We cannot be sure exactly when this happened, but the first data-point in the post-trial period is calculated from cattle incidence data from 12-18 months after culling stopped and shows no detrimental effect.

83. Overall, from the first cull to five years after the last cull (i.e. up to July 2010)[45] there was a 28.3% reduction (95%CI: 20.9% decrease to 35.0%

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[39] Bourne, J., Donnelly, C.A., Cox, D.R., Gettinby, G., McInerney, J.P., Morrison, W.I., & Woodroffe, R. 2007. *Bovine TB: the scientific evidence* Defra www.defra.gov.uk/animalh/tb/isg/pdf/final_report.pdf, London

[40] Donnelly, C.A., Woodroffe, R., Cox, D.R., Bourne, F.J., Cheeseman, C.L., Wei, G., Gettinby, G., Gilks, P., Jenkins, H., Johnston, W.T., Le Fevre, A.M., McInerney, J.P., & Morrison, W.I. (2006). *Positive and negative effects of widespread badger culling on cattle tuberculosis*. Nature, 439, 843-846

[41] Donnelly, C.A., Wei, G., Johnston, W.T., Cox, D.R., Woodroffe, R., Bourne, F.J., Cheeseman, C.L., Clifton-Hadley, R.S., Gettinby, G., Gilks, P., Jenkins, H.E., Le Fevre, A.M., McInerney, J.P., & Morrison, W.I. (2007). *Impacts of widespread badger culling on cattle tuberculosis: concluding analyses from a large-scale field trial.* International Journal of Infectious Disease, 11, 300-308

[42] Woodroffe, R., Donnelly, CA., Woodroffe, R., Cox, DR., Bourne, FJ., Cheeseman, CL., Delahay, RJ, Gettinby, G., McInerney, JP., Morrision, WI. (2006). *Effects of culling on badger Meles meles spatial organization: implications for the control of bovine tuberculosis*. Journal of Applied Ecology. 43: 1-10

[43] Jenkins, HE., Woodroffe, R., Donnelly, CA. (2008). *The effects of annual widespread badger culls on cattle tuberculosis following the cessation of culling.* International Journal of Infectious Disease 12: 457–465

[44] Jenkins, HE., Woodroffe, R & Donnelly, CA. (2010). *The duration of the effects of repeated widespread badger culling on cattle tuberculosis following the cessation of culling*. PLoS ONE. 5(2): e9090, DOI:10.1371/journal.pone.0009090

[45] Donnelly, CA., Jenkins, HE & RW Woodroffe. 2010. *Analysis of further data (to 2 July 2010) on the impacts on cattle TB incidence of repeated badger culling.* PLoS ONE comment. http://www.plosone.org/annotation/listThread.action?inReplyTo=info%3Adoi%2F10.1371%2Fannotation

decrease) in TB confirmed cattle herd incidence in the 100km^2 proactively culled areas when compared with 100km^2 survey-only areas. Confirmed TB herd incidence on the land 2km outside the culling area was comparable with that in survey-only areas (9% increase in incidence, 95%CI: 15.5% decrease to 40.7% increase). Table 1 describes the effects of culling on TB cattle herd breakdowns seen (a) during the culling period and one year thereafter, (b) for five years after the last cull and (c) from the first cull to five years after the last cull.

Table 1: Comparison of estimates of overall effects of proactive badger culling on the incidence of confirmed cattle TB breakdowns on lands inside and up to 2km outside trial areas derived from successive analyses of RBCT data reported in July 2010 (95%CI in brackets).

	During the trial[46]	Post-trial period[47]	During- and post-trial periods combined
Inside 100km^2 proactively culled trial areas	-23.2% (-12.4% to -32.7%)	-34.1% (-23.0% to -43.6%)	-28.3% (-35.0% to -20.9%)
Adjoining lands ≤ 2km outside culled trial areas (not culled)	+24.5% (-0.6% to +56.0%)	-5.6% (-31.0% to +29.1%)	+9.0% (-15.5% to +40.7%)

84. The results from the RBCT have been extrapolated to circular culling areas of different sizes. Assuming that the effects of culling are consistent throughout affected areas, Jenkins et al. (2010) shows that to be 97.5% confident that culling will be beneficial it must be carried out over an area of at least 141km^2. This figure is based on data up to July 2009 derived from existing data collected from the RBCT. There is no empirical evidence from an experimental study covering an area of this size.

85. By extrapolating from the results of the RBCT, it is possible to estimate the average net effect of culling on confirmed cattle TB herd breakdowns for a range of scenarios (i.e. by varying the size of the culled area, cattle herd density and annual herd incidence in both the culling area and adjacent ring). This is done by working out the number of breakdowns saved and gained over a nine year period (with five annual culls), described in detail in **Annex B**.

%2Fae30e6f1-2ad2-4b9d-88c1-cbb11a3d4619&root=info%3Adoi%2F10.1371%2Fannotation%2Fae30e6f1-2ad2-4b9d-88c1-cbb11a3d4619 Last accessed 22.07.10

[46] First cull to one year after the last cull

[47] One year after the last cull to 2 July 2010

86. A range of possible scenarios is considered in **Table 2** below. The overall size of the effect depends on the balance between the effects in the culled area and those in the adjacent 2km ring. In turn, each of these effects depend on the size of the area and background levels of TB, which may not be the same in the culled area and in the adjacent 2km ring.

87. It must be noted that these figures are derived from the effect observed in the RBCT and depend upon a number of assumptions. For example, it is assumed that the size of the average effect of culling over 100km^2 areas in the RBCT will scale to areas of a different size and that different herd densities and annual incidence are affected by culling in the same way, and that these effects are consistent across the entire culled area or adjacent ring. There is no empirical evidence from an experimental study investigating the effect of culling over these various scenarios.

Size of area	TB Confirmed New Incidents (CNIs) in the culled area per km per year/ *TB CNIs in 2km ring per km per year*[48]		
	0.10/*0.10**	0.15/*0.10***	0.085/*0.046*†
150 km^2 (*surrounding area is 99 km^2*)	-12.4%	-16.0%	-17.7%
300 km^2 (*surrounding area is 135.4 km^2*)	-15.9%	-19.0%	-20.4%

Table 2: The estimated average net effect of proactive badger culling on the incidence of confirmed cattle TB breakdowns culling over a range of scenarios. Figures in italics correspond to the 2km ring.

88. These estimates are based on the average effects observed in the RBCT (i.e. those listed in Table 1). What is seen in reality will of course

48 * As used in the example reported in Jenkins *et al.* (2010)
**VLA most recent estimates of incidence in the worst affected areas in England
†Average initial incidence observed in the RBCT

depend on a range of factors that have an influence on how effective the culling strategy is and how well the perturbation effect is controlled for, including:

- cattle herd size;
- density of badgers;
- badger TB prevalence;
- culling efficacy (number of badgers caught/time caught in);
- land access;
- coordination of the culling effort; and
- barriers to badger movement.

89. It should be noted that these figures are slightly different from those in the Impact Assessment which is included as an Annex to this document. The main reason for this is that the figures here are calculated for a nine year period (a five year culling period followed by four years with no culling). This reflects the period for which there is scientific data available from the RBCT areas. The figures in the Impact Assessment are calculated for a ten year period, comprising a five year culling period followed by five years with no culling. This makes the assumption that the beneficial effects seen in the RBCT areas will continue for one further year.

90. Greater net benefits from proactive culling would be expected if additional measures were taken to minimise the detrimental effects at the edges of the culled area and on inaccessible land within the culled area. These might include making use of existing barriers to limit badger movement, such as coastlines and major rivers and land without cattle, and/or using vaccination. This is reflected in the proposed licensing criteria detailed in Section 4 of this document.

91. **The scientific evidence from the RBCT suggests therefore that proactive badger culling, done on a sufficient geographical scale, in a widespread, coordinated and efficient way, and over a sustained period of time of at least four years, is likely to reduce the incidence of bovine TB in cattle in high incidence areas.**

92. Each triplet in the RBCT also included culling locally on and near farmland where recent outbreaks of TB had occurred in cattle (‘reactive culling’). However, the reactive culling component of this trial was stopped early by Ministers, as initial results from the reactively culled areas showed an increase in TB incidence in cattle. This increase was thought to be due to perturbation of badgers caused by the reactive

culling[49]. However, because reactive culling was stopped early there are limited results available, making it difficult to draw firm conclusions about its possible contribution to cattle TB control. Therefore, there is insufficient evidence to support the use of reactive badger culling as a TB control measure.

93. Ideally, a culling strategy would be selective, i.e. only infected badgers, or badgers in a sett where bovine TB has been detected, would be culled. However, this requires a diagnostic test that is sensitive enough reliably to detect a high proportion of infected animals. Any infected badgers that were not detected, and therefore left behind, could pose an increase in disease risk through perturbation. There is currently no diagnostic test available that is both sufficiently sensitive, and suitable for use in the field, so a policy of selective culling is not currently being pursued. We are continuing to fund the development of diagnostic tests and this position will be reviewed as tests improve.

94. PCR (polymerase chain reaction) has been put forward as a suitable diagnostic test to support a selective culling policy. Currently, the sensitivity of PCR-based tests for *M. bovis* is not high enough for them to be used in this way. We are continuing to fund the development of PCR, but it is possible that diagnostic tests such as PCR (which rely on detecting the TB organism itself, rather than the immune response to it) will never be sensitive enough. This is due to the chronic nature of the disease – infected badgers tend to excrete only very low detectable levels of *M. bovis*, and this excretion is intermittent. Defra's Chief Scientific Advisor chaired an expert group in July 2010 to consider whether a PCR test could be used to detect infected badgers and/or setts[50]. This group concluded that PCR was not a test that could be usefully used for detecting bovine TB in badgers based on the current state of knowledge, particularly in the field.

Badger culling techniques

95. Any culling technique must be supported by evidence that it is effective and humane for use on badgers. It would also need to meet the requirement for co-ordinated delivery, where culling is done as completely and efficiently as possible over a minimum area of 150 km^2 .

[49] Donnelly CA, Woodroffe R, Cox DR, Bourne J, Gettinby G, Le Fevre AM, McInerney JP, Morrison WI (2003). Impact of localized badger culling on tuberculosis incidence in British cattle. *Nature 426*, 834-7.

[50] http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/research/index.htm

Cage trapping and shooting

96. Cage traps have been used for many years by MAFF/Defra including in the RBCT. While they are unlikely to catch all badgers in an area (since some animals will be trap-shy), the RBCT showed that a high percentage of the local population (approximately 70%[51,52]) could be caught. In the majority of cases non-target species caught in the traps can be freed without causing harm.

97. Once caught, badgers would be killed by shooting. The use of frangible ammunition (bullets/shot which shatter on impact) reduces the risk from ammunition ricocheting against the cage.

98. Some landowners may be sceptical about the efficiency of cage traps. While we expect that about 70% of the local badger population would be caught, the actual number will depend on operator skill, effort and seasonal and weather-related variations in badger behaviour.

Shooting free ranging badgers

99. Shooting free-ranging wildlife is a technique already widely used by the rural and pest-control communities. It is commonly used to kill foxes (at night) and deer (day time), but it has not been used in any trial or field test on badgers. A report by the Game Conservancy Trust[53] concluded that "sighting frequency of badgers was sufficient to be an efficient form of badger control".

100. Badgers could be shot using rifles or shotguns as specified by the PoBA. Farmers or their contractors could carry out culling by this method and many already have or have access to the relevant weapons and training. Individuals carrying out the culling using rifles would need to apply to the police to have their Firearms Certificates amended to include badgers.

101. Death by shooting in most cases is humane and rapid, provided the animals can be dispatched quickly and cleanly. Free-shooting carries some risk of causing suffering if animals are shot and wounded and are not as a result dispatched cleanly. The actual level of this risk for free-shooting badgers is unknown as the technique has not been tested, but

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[51] Woodroffe. R., Gilks, P., Johnston, WT., Le Fevre, AM., Cox, DR., Donnelly, CA., Bourne, FJ., Cheeseman, CL., Gettinby, G., McInerney, JP., Morrison, WI. (2008). *Effects of culling on badger abundance: implications for tuberculosis control*. Journal of Zoology. 274:28-37.

[52] Smith G.C and Cheeseman C.L. *Efficacy of trapping during the initial proactive culls in the randomised badger culling trial*. 2007. Veterinary Record. 160:723-726.

[53] The Game Conservancy Trust. 2006. *Shooting as a potential tool in badger population control. Report to Defra*. http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/badger-gct0806.pdf. Accessed 24.06.10.

it is unlikely to be worse than for shooting deer or foxes, which is generally considered humane.

Gassing badgers in setts

102. Gassing with hydrogen cyanide has previously been permitted as a culling technique for badgers (1975-1980). A review in the early 1980s commissioned by Lord Zuckerman led to doubts being cast on the humaneness of this method because research showed that badgers did not die immediately underground.

103. Uneven distribution of a gas (carbon monoxide, carbon dioxide or inert gasses such as nitrogen and argon) in a badger sett carries a high risk of exposing badgers to sub-lethal doses which could lead to long-term and serious side-effects for the affected badgers and thus contravene the PoBA by the potential to cause 'cruel ill-treatment'. It is still not currently known whether it is possible to ensure distribution of a gas at a lethal concentration to all parts of a badger sett for the required length of time.

104. The use of vehicle exhaust to fumigate setts is not considered a viable option on the grounds that it is inhumane as it contains sub-lethal amounts of carbon monoxide and a large number of other toxicants to which badgers are known to be averse.

Snaring

105. Snares are currently used in the Republic of Ireland to catch and restrain badgers prior to shooting. A study[54] from Ireland concluded that the use of snares to catch badgers is effective, however it did not provide evidence on the humaneness of this technique.

106. In the past, only low capture rates were achieved by Government personnel using free-running body-snares during badger control operations. While higher capture rates have been achieved elsewhere, more data are required before an accurate assessment of efficacy can be made. Capture rates are known to be dependent on the skill of the operator. Trials by the Food and Environment Research Agency (Fera) in 2007 assessing the humaneness of a badger body-snare were stopped early because the trapping success was so low and because of concerns over the welfare of trapped badgers.

[54] Murphy, D., O'Keeffe, JJ., Martin, SW., Gormley, E & Corner, LAL. 2009. *An assessment of injury to European badgers (Meles meles) due to capture in stopped restraints*. Journal of Wildlife Diseases 45(2): 481-490.

Lethal injections

107. Lethal injections could be used in conjunction with cage-trapping. As the technique involves the administration of medicines that are restricted to veterinary surgeons, it is not practicable or economic for use in the field. However, this is considered to be one of the most humane methods of killing badgers.

Oral Poisons

108. A report for Defra concluded that there are currently no poisons that would be effective against badgers without causing deaths that would be considered markedly inhumane and/or pose significant risks to non-target wildlife.

109. **Our assessment of the available culling techniques is that cage-trapping and shooting and shooting free-ranging badgers are currently the only practicable techniques which have the capability to kill badgers humanely in line with the criteria suggested by the scientific evidence and without posing a risk to non-target wildlife. We have ruled out gassing, snaring, lethal injections and oral poisons for the time being on grounds of humaneness, effectiveness, costs or risks to other wildlife. We will consider the case for further research and development into alternative culling methods.**

Badger vaccination as a bovine TB control measure

110. Since the first injectable badger vaccine was licensed in March 2010, it has been available for use on prescription, subject to a licence from Natural England for lay operators to trap badgers to inject the vaccine. In common with other prescription-only medicines, BadgerBCG must be prescribed for use by a veterinary surgeon. Vaccination can be performed by a vet, or by a non-veterinary ‘lay vaccinator’, provided he or she has completed an approved training course. Under existing arrangements, farmers and landowners, individually or collectively, can apply for a licence to trap and vaccinate badgers.

111. The aim of badger vaccination would be to reduce the prevalence and severity of *M. bovis* infection in a badger population, with the intention of reducing the likelihood of transmission from badgers to cattle. Laboratory studies have demonstrated that vaccination is efficacious in badgers, but while we would expect it to result in reduced transmission of bovine TB to cattle, we currently have no hard evidence on this. Therefore the precise contribution vaccination could make to reducing

disease in cattle is unknown. Further information on the badger TB vaccine is at **Annexes C and D**.

112. The fact that the first badger vaccine has only recently been licensed is the reason why only very limited scientific evidence exists on the disease control benefits vaccination would provide. As vaccination begins to be used, the evidence base will grow. But currently, in contrast to the RBCT, much of the available evidence on the contribution vaccination can make to tackling TB relies on laboratory studies and computer simulated models, rather than field trials, with the inherent increased uncertainty they provide. While modelling provides an important contribution to our understanding of the benefits vaccination could provide, the results cannot be considered conclusive and can vary significantly depending on the assumptions used. Defra's TB Science Advisory Body (TB SAB) have also advised against over-reliance on modelling in policy development if just one model is available and recommend developing separate independent models to inform policy.

113. The aim of a sustained vaccination campaign would be, over time, to achieve 'herd immunity' in the badger population – a state in which a large enough proportion of the badgers was protected such that the disease could not be sustained in the badger population. This will take time to develop, particularly as BCG vaccination is not 100% effective in preventing TB in badgers. This is for two reasons: the vaccine will not fully protect or prevent infection in all uninfected badgers that are vaccinated and, as far as we are aware, the vaccine will not benefit badgers that are already infected.

114. Benefits from vaccination would therefore be expected to accrue incrementally during a vaccination campaign, as the number of badgers immunised successfully increased and as infected badgers died off naturally. The larger the proportion of infected badgers within the population, the longer it would take to build up herd immunity. Modelling work carried out by the Food and Environment Research Agency (Fera) indicates that longer badger vaccination campaigns could give better TB control in both badgers and cattle, and are more likely to be economically justified than short campaigns, but this has not been tried in the field[55].

115. One of the main benefits of vaccination is that it would not disrupt badger social groups and therefore this method of controlling bovine TB in badgers does not have the potential risks arising from perturbation associated with culling. Moreover, the stable social structure of badger

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[55] Badger (Meles meles) oral vaccination to reduce cattle-herd TB breakdowns in Britain – model with cattle and cost benefit analysis. D. Wilkinson, G.C. Smith, R. Bennett, I.McFarlane. 2008.

populations may actually enhance the efficacy of vaccination. Similarly, although the positive benefits of fragmented vaccination would be lower than those achieved by vaccinating over contiguous areas, as badger herd immunity would be harder to establish, nevertheless unlike culling, there would be no detrimental effect from vaccinating in this manner.

116. It is unlikely that vaccinated badgers will be tagged or marked permanently because this requires anaesthetisation, which is costly and requires specialist skills. However, animals can be temporarily marked with e.g. a stock marker to prevent re-vaccination of animals in the same trapping session. Re-vaccination poses no safety risk to the animal; avoidance of it is only desirable to save the cost of the vaccine.

Comparing culling and vaccination

117. The aim of both vaccination and culling is to reduce disease transmission in badgers and hence the total number of badgers infected with bovine TB that could transmit the disease to cattle. The Chief Veterinary Officer's advice[56] is that in areas of high and persistent cattle TB, badger culling is likely to achieve this more quickly than badger vaccination, assuming culling is sufficiently widespread, effective and efficient. This is because, as outlined above, with vaccination the infected animals would take a period of years to die off naturally, vaccination does not protect already infected animals, vaccination does not reduce the size of the badger population, and a sufficient proportion of badgers in a population need to be vaccinated to develop badger herd immunity.

118. Although the available evidence on the effects on bovine TB in cattle is currently very limited, vaccination does still have value, as it reduces the prevalence and severity of disease in the badger population and has greater disease control benefits than taking no action to tackle the disease in badgers. For some farmers and landowners, using vaccination may be the preferred option for tackling bovine TB in badgers. But given its early stage in development, many farmers and landowners are unlikely to feel sufficiently confident in using vaccination, especially as the cost of using vaccination is unlikely to be less than cage-trapping and shooting. We therefore anticipate that, for most farmers, culling is likely to be the preferred option, leading to higher uptake – which is an important consideration in the context of any policy options which would require the industry to bear the direct costs of badger control.

[56] Conclusion of a Veterinary Risk Assessment conducted by Defra at Annex D

119. In addition, there are ways in which vaccination and culling might usefully be combined, to maximise the benefits of both strategies. Possible options for this include:

i. using vaccination to try to reduce the potential negative effects of culling due to perturbation, e.g. by surrounding culled areas with a ring of vaccination, or vaccinating in any ‘gaps’ in a culled area where culling is not possible;

ii. using vaccination as an ‘exit strategy’ from culling, e.g. by following culling with a programme of vaccination to establish an immune badger population in culled areas; and

iii. vaccinating in buffer areas at the border of high and low cattle TB incidence areas and/or in low incidence areas to reduce disease spread and prevent new hotspots becoming established.

120. Of these options, we believe that using vaccination to reduce the risks from perturbation in any gaps within culling areas and on land surrounding them has the greatest practical potential to support wider disease control objectives in the short term.

121. It has been suggested that vaccination could be combined with a selective culling strategy, such that individual badgers or social groups are tested for bovine TB, and then test-positive badgers are culled and test-negative animals are vaccinated. However, as noted in paragraphs 93 and 94 we currently do not have the diagnostic tests available to enable efficient selective culling of infected animals, so for the time being selective culling and vaccination is not considered a viable option.

122. **Based on veterinary advice and the available scientific evidence our assessment is that vaccination will not be as effective as culling in quickly lowering the weight of infection in the badger population. We also do not know how effective vaccination would be in reducing bovine TB in cattle in high-incidence areas. However, while we acknowledge that the uptake of vaccination by farmers and landowners may be lower than for culling, as part of an overall approach to badger control, vaccination could have a role to play in helping to reduce the total number of badgers infected with bovine TB that are available to transmit the disease to cattle. It could also be effectively used in combination with culling to reduce perturbation.**

Costs and benefits of addressing the disease in badgers

123. It is estimated that the overall cost of an average confirmed TB incident in cattle is around £30,000[57]. About £20,000 of this falls to Government, mainly compensation for animals compulsorily slaughtered and costs of testing. This leaves about £10,000 in costs to farmers from losses of animals, farm costs of testing, and disruption to business through movement restrictions. There are also stress and health costs to farmers and their families but these cannot be quantified or valued.

124. The benefits of addressing the disease in badgers are:

- avoiding, and thus saving the cost of, cattle TB breakdowns;
- broader savings by avoiding the cost of the cattle TB epidemic spreading across a wider area and into the future; and
- benefits to members of the public who may value reductions in the level of bovine TB in the cattle population.

125. The main costs of culling are:

- the cost of the culling operation itself including disposal of badger carcases;
- the cost of the licensing process;
- the cost of monitoring the impacts of culling to ensure compliance with licence conditions and to safeguard badger welfare and ecosystems;
- the cost of increased bovine TB in cattle in neighbouring areas; and
- a cost in terms of any inherent non-monetary value attached to badger populations and badger welfare.

126. As previously explained, for any area where culling took place, the results from the RBCT suggest that the benefits of culling, i.e. reductions in incidence of bovine TB in cattle within the culled area, may not be seen for 1-2 years after culling begins but could continue for at least 5 years after culling stops. The results also suggest that there could be an increase in incidence of bovine TB in cattle on farms neighbouring the culled area during the culling period, although this increase is likely to disappear 12-18 months after culling stops. Figure 3[58] shows the results of the RBCT over the culling and post-trial periods.

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[57] This figure is an average of a very wide range from a large number of small breakdowns to a few very large, costly and long-lasting incidents.

[58] Figure produced from data in Donnelly, CA., Jenkins, HE & RW Woodroffe. 2010. *Analysis of further data (to 2 July 2010) on the impacts on cattle TB incidence of repeated badger culling.* PLoS ONE comment. http://www.plosone.org/annotation/listThread.action?inReplyTo=info%3Adoi%2F10.1371%2Fannotation%2Fae30e6f1-2ad2-4b9d-88c1-

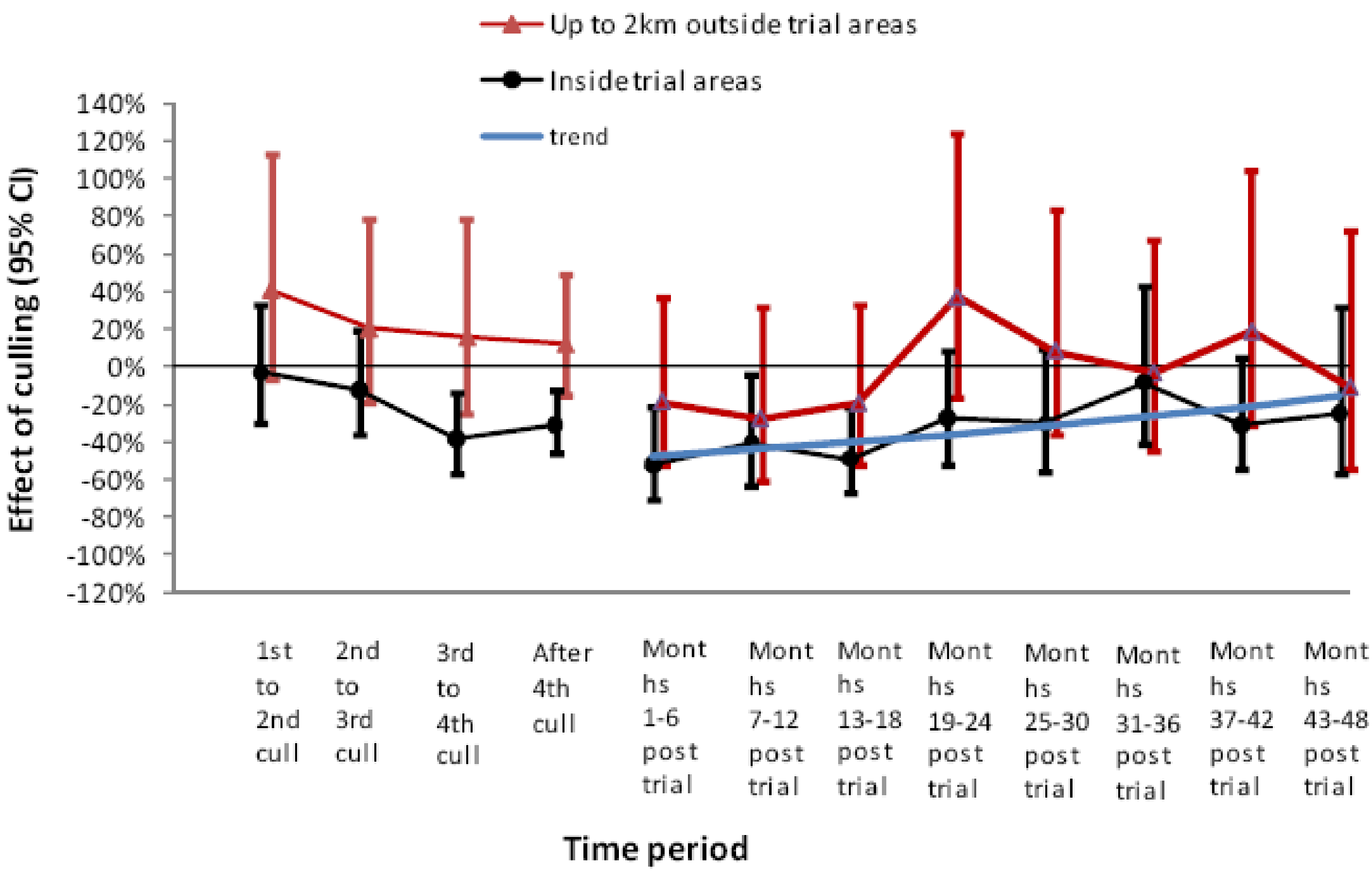

Figure 3: Estimated effects of proactive culling on the incidence of confirmed cattle TB breakdowns inside trial areas and up to 2 km outside trial area boundaries. The estimated effects of proactive culling are stratified by time periods defined by the timings of the culls during the trial, and by 6-month periods from 1 year after the last proactive cull (post-trial period). The black line shows the effects inside the trial areas and the red line shows the effects in the neighbouring areas. There were insufficient breakdowns in the second half of the fourth year post-trial as of 2 July 2010 to calculate estimates.

127. The economic case for badger control is strongest when used as part of a sustained package of control measures applied in the areas of high TB incidence which together have the potential to turn around the rising trend of the epidemic over the long term.

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cbb11a3d4619&root=info%3Adoi%2F10.1371%2Fannotation%2Fae30e6f1-2ad2-4b9d-88c1-cbb11a3d4619 Last accessed 22.07.10. Figure used with the authors permission and subject to the conditions of the Creative Commons Attribution Licence (http://creativecommons.org/licenses/by/3.0/).

128. The costs and benefits of the approaches considered are described in detail in the accompanying Impact Assessment, at **Annex F**. The Assessment demonstrates that if Government delivered a policy of badger control through either culling or vaccination, the costs would be too high to justify the benefits. If farmers and landowners are responsible for badger control then there is a stronger economic case. However, none of the options result in a large cost saving and, because the Government bears much of the cost of dealing with TB breakdowns, most of the benefits of any cost-savings accrue to the taxpayer. The success of the preferred option depends on a commitment and willingness from the industry to accept the costs of operating the policy for the marginal financial benefits that badger control offers and the non-financial benefits of freedom from TB in cattle.

Options considered for controlling bovine TB in badgers

129. We have considered six policy options for the control of bovine TB in badgers:

- Option 1: continue with the current policy (i.e. no additional control measures;
- Option 2: a Government-led policy of badger culling under the Animal Health Act 1981;
- Option 3: a Government-led policy of badger vaccination under the Animal Health Act 1981;

A partnership approach between the farming industry and Government, based on any or all of:

- Option 4: Issuing licences under the Protection of Badgers Act 1992 (PoBA) to cull badgers;
- Option 5: promoting greater use of licences under the PoBA to vaccinate badgers;
- Option 6: issuing licences under the PoBA to cull, vaccinate or carry out a combination of culling and vaccination.

130. **Option 1** would be to continue with the current policy. The current control strategy is primarily focused on cattle measures with no measures to address the disease reservoir in badgers. This control strategy however has failed to stop the spread of bovine TB to wider geographical areas and to more herds and animals within the infected areas. This current control policy incurs costs that are rising year by year and is therefore considered unaffordable. We also know that we

must address the disease reservoir in badgers in order to be able to control the disease in cattle.

131. **Option 2** involves a policy of culling badgers, managed and delivered by Government, or contractors acting on behalf of Government. A Government-led approach means the taxpayer ultimately bears all the costs in delivering a culling operation. The approach incurs higher costs associated with government overheads, for example, estate costs, vehicle costs, and travel and subsistence expenses to reach areas of operation.

132. **Option 3** involves a policy of vaccinating badgers, managed and delivered by Government, or contractors acting on behalf of Government. As for Option 2, a Government-led approach leaves the taxpayer bearing all costs incurred.

133. **If Government delivered a policy of badger control through either culling, vaccination or a combination of the two, the costs would be too high to justify the benefits (the benefits achieved in the RBCT of culling, and the estimated benefits of vaccinating, or culling and vaccination in combination).**

134. **Option 4** would involve the farming industry delivering culling in line with a set of strict criteria developed by Government in consultation with the industry. Natural England would assess and issue licences to those applicants meeting the criteria.

135. **Option 5** would involve encouraging farmers and landowners making greater use of vaccination to tackle TB, using the newly available injectable badger vaccine. It is already possible to apply to Natural England for licences to trap and vaccinate badgers.

136. **Option 6** is a combination of options 4 and 5 whereby groups of farmers or landowners would be able to apply for a licence to tackle TB in badgers through culling, vaccination, or a combined strategy of culling and vaccination. For those undertaking culling either on its own or in combination with vaccination, the full criteria for culling as proposed in section 4 of this consultation document would always need to be met.

137. In options 4 to 6 the farming industry would co-ordinate and implement culling and/or vaccination in line with the criteria developed by Government. Natural England would assess and issue licences (on behalf of the Secretary of State) to those applicants meeting the criteria. Government's role would be to ensure compliance with the licence criteria, to monitor the impacts of culling or vaccination, and to ensure adequate security.

138. **Our preferred approach is option 6**: to issue licences under the Protection of Badgers Act 1992 for industry to cull badgers, subject to a

specific set of licence criteria. Under existing arrangements farmers and landowners will also be able to apply for licences to vaccinate badgers. Under the new proposal, they will be able to use vaccination either on its own or for use in combination with culling. This approach will empower farmers to take control of the wildlife reservoir at the local level and decide for themselves which control measures to use. The approach will encourage farmers and landowners to fully consider the role of vaccination in support of a cull and increase the chance of successful disease control. It could also lead to greater participation from a wider range of farmers who may have different views on the most appropriate tool to use on their land. It also means that taxpayers will not be paying for significant additional disease-control measures. Options 2 and 3 are not affordable given the current pressures on public spending and could not be justified in cost-benefit terms.

139. Section 4 of this document describes the Government's proposal for this new policy and invites your views.

Question 1: Comments are invited on the options, costs and assumptions made in the Impact Assessment.

Question 2: Do you agree with the preferred option?

Section 4: The Government's proposal

Summary of the proposal:

Our proposal is to issue licences under the Protection of Badgers Act 1992 and the Wildlife and Countryside Act 1981 to farmers and/or landowners to cull badgers for the purpose of preventing the spread of bovine TB in cattle. Licences to vaccinate badgers will also continue to be available. Applicants will have to demonstrate that they meet strict criteria in order to obtain a licence to cull, or cull and vaccinate badgers in combination. Government will take responsibility for monitoring the effectiveness, humaneness and impact of this badger control policy.

140. This section describes the Government's proposal in more detail and includes questions on specific elements of the proposal on which we would welcome views.

Licences to prevent the spread of bovine TB in cattle

141. Farmers and landowners will be able to apply for licences[59] to 'kill or take'[60] badgers for the purpose of preventing the spread of TB in cattle. This will allow them to cull or vaccinate badgers within an area specified by the licence by a means specified.

142. In order to obtain a licence to cull badgers, applicants will be expected to satisfy a series of criteria to ensure that the cull is justified and is likely to contribute to controlling bovine TB in cattle in their area. It is expected there will be a single licence application for each culling area (150km^2 or larger). The application will need to meet the proposed licence criteria described below and will set out how the applicants, collectively, propose to control the disease in badgers.

143. The farming industry/landowners will cover the direct costs of culling and/or vaccination. Government will put in place arrangements to issue licences in response to applications meeting the criteria, and will take responsibility for monitoring the effectiveness, humaneness and impact of badger control measures.

[59] Licences under the Protection of Badgers Act 1992 and, where appropriate (e.g. for the use of artificial light), the Wildlife and Countryside Act 1981

[60] from the Protection of Badgers Act 1992, http://www.opsi.gov.uk/acts/acts1992/ukpga_19920051_en_1

144. Where appropriate, the use of vaccination to mitigate the perturbation effects of culling will be encouraged. Farmers and landowners will be able to apply for licences, individually or collectively, to vaccinate badgers as part of an approach coordinated locally with culling activity. This will allow them to cage-trap and vaccinate badgers within an area specified by the licence.

145. To secure early disease control benefits, vaccination would focus on reducing disease risks on land surrounding a culling area and on land within the control area where culling would not, or could not, take place. In addition, as is already the case, applications for licences to vaccinate badgers as a sole control measure in a particular area could continue to be made. This is not limited to areas with high incidence of bovine TB in cattle.

Question 3: Do you agree that this approach, of issuing licences to farmers/landowners, is the most appropriate way to operate a badger control policy?

Proposed criteria for a culling licence

146. Section 3 of this document described the circumstances in which badger culling is likely to lead to a reduction in incidence of TB in cattle. We have used the scientific evidence to form the basis for the proposed criteria for culling licences. We propose that applicants for a licence will need to demonstrate that they satisfy the following criteria:

Criteria	Definition	Rationale
The area has high and persistent levels of TB in cattle	The area covered by the licence application is composed predominantly of 12-month test interval parishes and there is a recognised established reservoir of the disease in badgers	To ensure that only badger populations implicated in disease transmission to cattle are culled.
The area is at least $150km^2$ in size	Applications will be expected from groups of farmers/landowners where the area covered	The most recent estimate from the RBCT (using during- and post-trial data) suggest that

	by the group collectively is at least 150km^2	the size of area that would need to be culled to give a 97.5% confidence of an overall beneficial effect over the culled and edge areas in reducing cattle TB incidence is 141km^2. We have rounded this number up to 150km^2
There is land access for culling for over 70% of the area	Within the licence application, the area for which the group of farmers/landowners are responsible must have access to at least 70% of the total land area.	From the RBCT land access for culling was on average 70% of the total land area in the treatment areas. To achieve at least the same net benefits of culling as seen in the RBCT we have assumed that there must be land access of at least 70% in a licence application.
Where possible, the area will have boundaries or buffers to mitigate any possible negative effects in neighbouring areas caused by perturbation of badgers' social groups and increased disease transmission	Examples of boundaries may include sea coast, lakes and reservoirs, major rivers and estuaries, motorways, and large urban areas. Buffers may include arable areas, cattle-free areas, extensive upland/ blanket bog, or areas where badgers have been vaccinated	Geographical boundaries should surround the cull area as far as possible to minimise the disease risk from perturbation. This helps mitigate against any detrimental effects caused by culling. However, physical boundaries vary in their ability to deter/prevent badgers from crossing them.
Culling will be carried out effectively and humanely by competent operators. Culling will be permitted by cage-	Operators will need to demonstrate that they have the appropriate training and licences to carry out cage-trapping	Cage-trapping and shooting and shooting free-ranging badgers are currently the only techniques which have

trapping and shooting, and shooting free-ranging badgers	and shooting, and to shoot free-ranging badgers	the capability to humanely kill badgers in line with the criteria suggested by the scientific evidence without posing risk to non-target wildlife. Both methods would need to be carried out with due regard to animal welfare. Animals must not be left in cages for prolonged periods and must be dispatched cleanly and rapidly in a way that avoids any unnecessary excitement, pain or suffering as required under the Animal Welfare Act 2006.
A commitment to sustaining culling over the area at least annually for a period of at least 4 years	Culling in a licensed area must be carried out for a minimum of 4 years	In the RBCT, culling did not give a statistically significant benefit until the fourth annual cull had taken place. The beneficial effect appeared to increase with repeated removals (11.2% increase with each removal during the life of trial), suggesting that continuing to remove badgers beyond four years may increase the benefits further.
Culling will achieve badger densities low enough to reduce TB transmission, but not lead to local extinction	For a specific area badger removal rates will be calculated and monitored by licence receipts for badger carcass disposal.	The proportion of the badger population removed in each of the proactive removal trial areas during the RBCT was around 70%. To ensure the same

		benefits as seen in the RBCT, 70% of the badgers must be removed. Specific numbers to be removed from the area concerned can be estimated using field signs and modelling. Monitoring will be required to ensure there is not local extinction.
A closed season to protect dependent cubs will operate during late winter/early spring	Exact dates to be confirmed	To avoid abandoning and compromising the welfare of badger cubs that are underground and dependent on their mother
Arrangements are in place for carcases to be removed in accordance with legal requirements for animal by-products	All badger carcases are required to be collected, transported and identified without undue delay and either incinerated in an approved incineration plant or processed in an approved rendering plant, with the processed products being finally disposed of as waste by incineration or burial in an approved landfill.	Bovine TB is a zoonotic disease and therefore the carcases of any badgers suspected of harbouring the disease fall within the definition of Category 1 of the Animal By-Products Regulation (EC) 1774/2002 (Art. 4(1)(a)(v)), replaced as from 4 March 2011 by Regulation (EC) 1069/2009 (Art. 8(a)(v)). That is they "suspected of being infected with diseases communicable to humans or animals," and must be disposed of as described in the definition
Culling will be coordinated locally	A local area management plan must	Applications must demonstrate that they

across the area covered by the licence	be submitted as part of the licence application	have the capacity, competence and commitment to carry out a culling programme for a sufficiently long period to achieve effective disease control.
The role of vaccination in reducing the perturbation effects from culling has been fully considered and culling is coordinated locally with any vaccination taking place on neighbouring land	This would need to be detailed in the licence application	Vaccination could have a beneficial role in reducing the negative effects resulting from perturbation seen in culling and dealing with gaps in an area where culling is not possible. It could also have a role in an exit strategy from culling and at the borders of high/low incidence areas to reduce spread
Before a cull begins there is comprehensive awareness and compliance with existing TB control measures	This is to ensure that all other measures to control TB are also in place such as good biosecurity and husbandry	Culling is only part of the package of measures we have to control TB and all measures need to be used together to reduce the incidence of TB in cattle

Criteria that will need to be met to obtain a licence for using vaccination, either on its own or alongside culling:

147. Applicants for a licence to vaccinate badgers will need to demonstrate that:

- vaccination will be permitted only by cage-trapping and will be carried out effectively and with regard to animal welfare;
- vaccination will only be done by vets or trained lay vaccinators using the injectable badger vaccine (BadgerBCG) under prescription;

- before vaccination begins there is widespread understanding of, and compliance with any existing TB control measures;
- if vaccinating alongside culling, vaccination is coordinated locally with any culling. For example, to enable immunity to develop in vaccinated animals, this could include commencing vaccination ahead of any culling or alternatively designing control programmes so that culling and vaccination did not occur in adjacent areas at the same time. It may also include ensuring vaccination continued over a sufficient period of time to deal with the perturbation risks resulting from culling annually for at least four years.

Question 4: Do you agree with the proposed licensing criteria for culling and vaccination?

Question 5: Do you agree that the proposed methods of culling are effective and humane?

Question 6: Do you agree with the proposed use of vaccination, particularly its focus on mitigating the perturbation effects of culling?

Question 7: Should anything further be done to encourage the use of vaccination?

Government will take responsibility for monitoring the effectiveness, humaneness and impact of badger control

148. A policy to reduce the reservoir of disease in badgers will need to be monitored in terms of protecting animal welfare, sustainability of the local badger population and observing the effect of the control measures on the disease incidence in cattle. We propose monitoring of the following will take place:

- compliance with the licence criteria;
- badger welfare – spot-checking carcases to examine whether badgers are being culled in line with the licence criteria;
- monitoring the status (numbers) of the badger population to ensure effective control operations and that there will not be local extinction;
- incidence of bovine TB in cattle – this will be monitored through active surveillance as at present; and
- monitoring protected sites (e.g. Sites of Special Scientific Interest (SSSIs), Special Protection Areas (SPAs)).

Question 8: Do you agree with the proposed monitoring?

Policy review

149. No-one wants to see badger culling take place for any longer than is necessary. The scientific evidence shows us that, to be confident that culling reduces the incidence of bovine TB in cattle, it would need to be carried out for at least four years. We therefore propose that:

- licences to cull badgers will cover a fixed period, but not less than 4 years.
- licences will be revoked if at any time the criteria are not met;
- the impact of badger control will be reviewed after 4 years. The policy will also be reviewed in the light of any monitoring data showing unexpected results; and
- the policy will be reviewed in the light of new evidence or control tools becoming available (such as an oral badger vaccine and/or cattle vaccines).

Summary of Questions

Question 1: Comments are invited on the options, costs and assumptions made in the Impact Assessment

Question 2: Do you agree with the preferred option?

Question 3: Do you agree that this approach, of issuing licences to farmers/landowners, is the most appropriate way to operate a badger control policy?

Question 4: Do you agree with the proposed licensing criteria for culling and vaccination?

Question 5: Do you agree that the proposed methods of culling are effective and humane?

Question 6: Do you agree with the proposed use of vaccination, particularly its focus on mitigating the perturbation effects of culling?

Question 7: Should anything further be done to encourage the use of vaccination?

Question 8: Do you agree with the proposed monitoring?

Consultation documents

Consultation letter

Consultation Document

Annexes

The above consultation documents may be found on Defra's website:

http://www.defra.gov.uk/corporate/consult/tb-control-measures/index.htm

Responses

We welcome your views and comments on any aspects of the consultation proposals,

Please send responses to:

- TBBC mailbox, c/o Nobel House, 17 Smith Square, London, SW1P 3JR or
- e-mail tbbc@defra.gsi.gov.uk or
- Fax 0207 238 6431

Annexes

A History of TB control in the UK

B Scientific evidence on culling

C Scientific evidence on vaccination

D Veterinary assessment on vaccination

E Veterinary assessment on culling

F Impact Assessment

G Q & A

H List of organisations invited to respond