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Draft Strategy for Achieving "Officially Bovine Tuberculosis-Free" Status for England

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Secretary of State's Foreword: Achieving a Bovine Tuberculosis-Free England

Bovine tuberculosis (bTB) is the most pressing animal health problem in the UK. The crisis facing our cattle farmers, their families and their communities cannot be overstated. Bovine tuberculosis is a devastating disease which threatens our cattle industry and presents risks to other livestock, wildlife species such as badgers, domestic pets and humans.

This was once a disease isolated to small pockets of the country; in 1972 only 0.01 per cent of cattle in Great Britain tested as infected. It has now spread extensively through the West of England and Wales. The number of new herd breakdowns has doubled every nine years and in the last decade we have slaughtered 305,000 cattle across Great Britain. In 2012 in England alone, over 5.5 million bTB tests were performed, leading to the slaughter of 28,000 cattle with the disease costing the taxpayer nearly £100 million. Last year, 26 per cent of herds in the South West and West Midlands were placed under movement restrictions at some point. In the last ten years bTB has cost the taxpayer £500 million. It is estimated that this will rise to £1 billion over the next decade if the disease is left unchecked.

If we do not get on top of the disease we will see a continued increase in the number of herds affected and further geographical spread. It is therefore vital that industry and government work together to free England of bTB and build a thriving and sustainable cattle sector in England, which trades internationally and delivers economic growth for the country.

The current surveillance and control scheme is based on the traditional approach applied across the EU: routine skin testing of cattle, removal and slaughter of test reactors combined with post-mortem surveillance at slaughter and movement controls placed on infected herds. In the absence of a major wildlife reservoir, this approach has been successful in allowing many EU countries and regions, for example Scotland, to achieve Officially bTB-Free (OTF) Status. It has also been successful at preventing the establishment of disease in many counties in the North and East of England where the reservoir of infection in wildlife is not significant. It has reduced the spread of the disease in the endemic areas where bTB is established but on its own it is not enough.

While most of England currently remains free of bTB, we are continuing to see a rising trend in endemic areas, where 55 per cent of all English dairy herds and 44 per cent of all English beef herds are situated. There has been an increase in the geographic spread of the disease north and east into new counties. Tackling this disease will require long-term solutions and considerable national resolve. I intend to reverse this trend well before the end of this decade, achieve OTF status for parts of England on the same timescale and thereafter progressively rid the whole of England of bTB over 25 years. To do this we need a control and eradication strategy with this clear aim at its heart. It will be dynamic,

adapting to the tools available and tailored geographically to the sources of disease and the potential for eliminating it, moving from control to eradication.

In achieving this aim, we must learn the lessons from those countries that have succeeded in tackling bovine TB where there has been a reservoir of the disease in wildlife.

I have visited Australia, Michigan (in the USA) New Zealand and the Republic of Ireland, talked to the Ministers, farmers and officials involved. I intend to apply the lessons of their success in England:

- Australia achieved official freedom from bTB in 1997 after a sustained campaign over nearly three decades.
- Michigan has successfully reduced the average annual number of livestock herds affected with bTB to single figures since 2005.
- New Zealand achieved a reduction in the number of infected herds from 1,700 in the mid-1990s to less than 66 in 2011/12.
- The Republic of Ireland reduced the proportion of herds affected annually from 9.6 per cent in 1995 to 7.4 per cent in 2010. In the same period it increased from 0.8 per cent to 9 per cent in England.

The vital lesson I've taken from these countries is the importance of stringent cattle control measures in combination with tackling the primary wildlife reservoir, be it the water buffalo in Australia, the white-tailed deer in Michigan, the brush-tailed possum in New Zealand or, closer to home, the badger in the Republic of Ireland. An additional factor which has contributed to their success is the fact that their programmes are either led by industry or delivered by industry and government working in partnership, with both parties contributing to the cost.

The conditions in some of these countries and the types of wildlife hosts in them differ from England, so we need to be smart in how we adapt and apply the key elements of their eradication strategies to our conditions. However, the common thread is the sustained and adaptive application of a control programme that addresses significant reservoirs of infection in cattle and wildlife.

The Government's new bTB Strategy for England will go out to public consultation this summer. For the first time it:

- combines all the tools we need to address the disease including those currently available and those under development, but not yet available, such as cattle vaccines or those being piloted like the badger culls that will take place this summer;
- explicitly moves away from a one size fits all approach, recognising the need to apply different tools in different areas depending on local circumstances and disease risk;

- sets targets and a timescale by which we expect to have made significant progress; and
- uses a risk-based adaptive management approach.

The Strategy is comprehensive and risk-based, using all available tools to:

- contain the disease in the high risk area and progressively reduce its size by reversing its spread and increasing the number of herds disease free in the long term;
- support the commercial viability of herds in the high risk areas by risk-based policies, while maintaining consumer confidence and exports without dis-incentivising the detection and control of disease;
- reduce the risk of spread of the disease to currently free geographical areas and freeing cattle herds in affected areas;
- rapidly find and eliminate disease in cattle when it occurs in free areas or herds, thus reducing the risk of spread to cattle and wildlife;
- reduce the spread of bTB between cattle both within and between herds;
- minimise the exposure of cattle to infected badgers, a key risk factor for the spread of the disease;
- reduce and eliminate the spread of disease from the badger wildlife reservoir to cattle;
- deal promptly with any other epidemiologically significant reservoirs of bTB infection that are discovered;
- pursue all available measures, including vaccination for both cattle and badgers when they become available in the future;
- identify and apply cattle management practices for different herd/husbandry types that minimise transmission risk within cattle herds, and between badgers and cattle; and
- deploy market measures, regulation, incentives and deterrents to reduce the risk of disease spread due to cattle movements.

As well as using available tools, I am determined to develop new ones to support the Strategy. Government will continue to invest in the development and licensing of bTB vaccines for both cattle and badgers. I have already achieved a major success in securing a concrete route-map from Commissioner Tonio Borg (DG-SANCO) on the application of a cattle vaccination programme. I am committed to meeting the minimum timescale for its implementation, but that is at least 10 years away. Based on first veterinary principles one would expect a badger vaccination strategy to be far more effective if the wildlife reservoir

of the disease has been dramatically reduced in the meantime; that is my intention. We have not yet identified a suitable oral badger vaccine candidate to take forward for licensing. Government will also continue to invest in the development of improved diagnostic tests for both cattle and badgers such as DNA-based technologies. We will look at novel tools to control the disease in both species.

A key element for success drawn from other countries is a partnership approach to governance, funding and delivery of eradication programmes with farmers making the key implementation decisions and significantly contributing to the costs of these. In New Zealand an independent, farmer-led body, jointly funded by industry and government has been responsible for oversight and implementation of the eradication strategy. This includes decisions on compensation rates, conditions, testing requirements including who pays, and rules for cattle movements. I am absolutely clear that if we are to tackle this disease successfully, we need to work together, whilst recognising respective responsibilities for Government and Industry both in terms of what we do and how we pay for it. We need dialogue with industry on this. The consultation we are launching provides a perfect opportunity to have this dialogue.

I am extremely grateful for the work of the Animal Health and Welfare Board for England (AHWBE) and the Bovine TB Eradication Advisory Group for England (TBEAG). The Strategy, in which they have played a key role, recognises that achieving OTF Status in England will be a long haul. However, it has been done under more difficult physical circumstances elsewhere in the world. I am confident that it is not beyond the wit of industry and government to achieve it for England on similar timescales. We will aim for England to be free of bTB in 25 years. Our cattle industry and countryside deserve no less.

The Rt Hon Owen Paterson MP
Secretary of State for Environment, Food and Rural Affairs

Executive Summary

1. This Strategy aims to eradicate bovine tuberculosis (bTB) achieving "Officially Bovine Tuberculosis-Free" (OTF) Status for England incrementally, whilst maintaining a sustainable livestock industry. The targets are ambitious: by 2025, the Strategy aims to achieve OTF status[1] for much of England and to have made significant advances in reducing the prevalence of bTB in the worst affected areas. We will aim for the whole of England to be free of bTB in 25 years. Success will be dependent upon a number of interdependent, increasingly farmer-led activities: the effective application of disease control measures in cattle, securing best practice in livestock farming, addressing the reservoir of disease in wildlife whilst maintaining biodiversity, and ensuring that costs are spread fairly between the general taxpayer, the food and farming industry and other stakeholders. The approach will be comprehensive, risk-based and staged embracing support for farmers, partnership working with a range of stakeholders, a fair balance of costs and supported responsibility, as well as working effectively in the European Union (EU). The Strategy draws upon demonstrably successful approaches to address bTB from around the world, including Australia, New Zealand, Michigan (USA) and the Republic of Ireland. To this end, the Government will develop proposals for governance, delivery and funding of the Strategy in partnership with stakeholders.

2. Bovine tuberculosis is one of the most significant problems affecting animal health and sustainable farming in England. It is a chronic infectious disease of cattle caused by *Mycobacterium bovis*. While cattle are particularly susceptible to infection, *M. bovis* can infect other mammals. Before the introduction of milk pasteurisation and bTB testing of cattle herds, *M. bovis* infection in humans was much more common. *M. bovis* can also be transmitted to humans through direct contact with infected animals. The European Food Safety Authority (EFSA) has advised that there is no evidence suggesting that *M. bovis* is a meat-borne hazard for humans in the EU. Today, the vast majority of cases of TB in humans in the UK are caused by human-to-human transmission of *M. tuberculosis*.

3. England has struggled to control bTB in cattle for decades, but hope can be taken from the success of other countries and the two decades up to 1979, when the prevalence of bTB in cattle in GB declined steadily to 0.018% of all cattle tested as a result of voluntary and compulsory cattle testing and slaughter schemes. The badger was first identified as a possible wildlife reservoir of infection for cattle in the early 1970s in parts of South West England where a high prevalence of bTB persisted despite enhanced herd control measures. A series of different strategies were

[1] For an EU Member State or region to achieve OTF status as defined in Council Directive 64/432/EEC, the percentage of OTF status withdrawn herds must not have exceeded 0.1 % per year for 6 consecutive years.

developed throughout the 1970s, 1980s and 1990s to tackle this wildlife source of bTB along with further cattle-based measures. However, by the mid 1980s progress had stalled with bTB incidence in the South West remaining three times higher than elsewhere despite annual testing of cattle. It has been estimated that some 50% of cattle herd breakdowns in high incidence areas were caused by badgers. Despite the introduction of additional cattle testing and movement controls, by 2008 England reached a historical peak of 6.4% of herds experiencing bTB.

4. Today, whilst most of the North and East of England have a very low and sporadic incidence of breakdowns, bTB is endemic in large areas of the West, South West and a pocket in East Sussex. Significant cost and effort is spent in surveillance for infection, managing breakdowns and preventing disease. While Scotland achieved OTF status in 2009, the prevalence of bTB in England contributes to an unacceptably high prevalence in the UK cattle herd as a whole. Many other EU Member States are already OTF.

5. The Strategy recognises that much more must be done to reverse the trends of the preceding 30 years: firstly, stop bTB spreading and then to make steady progress in achieving OTF status for England whilst maintaining a sustainable livestock industry. Significant and renewed efforts will be required. Although it will be neither easy nor cheap to achieve OTF status for England, the costs will be more than offset by the benefits. These include a reduction in the long term disease control costs both to farmers and to other taxpayers, increased ability to trade internationally and alleviation from the social impacts on those suffering the direct consequences of the disease.

6. Government has a clear obligation to take a strong lead on achieving OTF status for England. Whilst there are a number of actions that individuals can take to improve their own situation, achieving OTF status for England cannot be solved by individuals acting alone, especially without full understanding of the science and the implications of their actions, and a coordinated approach. Some local actions can even make the situation worse, underlining the importance for the Government to provide a clear lead. The Government's responsibility is to set out how the disease can be tackled holistically, to ensure that the UK meets its legal obligations and to reduce the financial strain on public finances and industry through increased partnership working, industry-led delivery and a fair sharing of the costs involved in putting the sector on a more sustainable footing.

7. The Strategy summarises the comprehensive programme[2] of measures currently applied across England, including surveillance in cattle and other animals, additional controls in bTB breakdown herds and measures to address the reservoir of infection in badgers.

[2] Bovine Tuberculosis Eradication Programme for England, July 2011 (PB13601) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69443/pb13601-bovinetb-eradication-programme-110719.pdf

8. A key component of the Strategy is developing our risk-based approach and it defines three different risk areas in England: the Low Risk Area, the Edge Area and the High Risk Area.

9. The Low Risk Area (LRA) currently extends across the North and East of England. The prevalence of bTB is very low with most cases linked to animals being introduced from higher risk herds. Breakdowns tend to be relatively short. There is not a recognised reservoir of the disease in wildlife in the LRA. The objective of the LRA strategy is to continue to protect it from the spread of the disease through strengthened measures, immediately deal with any isolated outbreaks and obtain OTF status as soon as possible in a phased approach.

10. The Edge Area covers the boundary of the High and Low Risk Areas. It marks the area where infection is spreading outward from the High Risk Area. The objective of the Edge Area strategy is to focus effort on containing the spread of bTB and then reversing it to achieve OTF status. This will involve cattle measures coupled with research to determine the role of badgers in spreading bTB in the Edge Area. The results of this research will inform future evidence-based action.

11. The High Risk Area (HRA) is concentrated in the South West, West Midlands and East Sussex. In the HRA, bTB is endemic with a relatively high proportion of herds experiencing breakdowns, including repeat breakdowns, and a reservoir of infection in badgers. The objective of the HRA strategy is to halt and then reverse the increasing prevalence of bTB by addressing the disease in cattle and in badgers, and ultimately to achieve OTF status.

12. The Strategy sets out a comprehensive range of options for the control of bTB in each risk area based on scientific knowledge and existing tools. These options would be deployed in addition to existing measures. The Government has decided to deploy some of these options as part of on-going policy development and they will be rolled out as soon as possible. For each risk area, the Strategy presents a preferred package of options, which is most likely to achieve OTF status over time whilst maintaining a sustainable livestock industry. Other options are also considered: the most rigorous options would have the greatest impact on bTB but would also impose impossible costs and render the livestock industry unsustainable; the least rigorous approaches would do little other than increase the grip of the infection and would also risk contravening EU law, jeopardising both the EU financial contribution and trade.

13. The Strategy also indicates options for developing cross-cutting measures applicable to all areas. The first of these is improving biosecurity by developing voluntary risk-based trading in response to the recommendations of an industry-led Risk-Based Trading Group and by deploying measures at farm level. The Strategy considers options for adjusting compensation to provide the necessary incentives to reward risk-reduction and to penalise risky practices. The Strategy also considers options for improving advice for farmers, improving compliance and enforcement, and tackling TB in non-bovine species such as South American camelids.

14. Another key component of the Strategy is developing new tools. The Government has spent over £155 million since 1991/92 on a wide-ranging bTB research programme. The Strategy acknowledges that we need to address gaps in our understanding of bTB and its spread, and that we must continue to develop new tools to combat the disease. The research programme will continue to evolve under the Strategy bringing together epidemiology, veterinary science, modelling, statistics and social science to generate integrated and innovative approaches to tackling the disease. The Strategy is designed such that as the evidence and science develops, the approach to managing the disease will be adapted. Additionally, the Strategy proposes the roll out of new and innovative tools when they are available, subject to an assessment of costs and benefits.

15. The Strategy considers ongoing work to increase understanding of the disease and support the development of new tools such as diagnostic tests, vaccination and badger population control methods:

    a. The Strategy summarises the diagnostic tests available for use in cattle, their limitations, and potential future developments. It also describes ongoing research to develop new diagnostic tests, such as PCR, for use in badgers to support alternative control strategies.

    b. The Strategy recognises that cattle vaccination is likely to be a valuable additional tool in the eradication of bTB and considers the steps necessary to be able to deploy cattle vaccination in England. It also describes work underway to develop an oral badger vaccination, which may overcome some of the limitations of deploying the existing injectable badger vaccine.

    c. The Strategy summarises research into alternative badger population control methods, both lethal and non-lethal.

    d. Finally, the Strategy summarises the latest state of evidence on genetic resistance in cattle to bTB and explains the barriers to using therapeutics to treat bTB in cattle.

16. The Strategy includes a consideration of governance, delivery and funding. The New Zealand experience in particular, shows that an alternative governance model can really enhance bTB control. The Government will develop proposals for an enhanced partnership approach to the governance of the Strategy.

17. The Government will continue to review delivery to ensure that it is appropriate, proportionate and provides essential support whilst building on the efficiency savings delivered to date and sustaining quality. The Strategy considers options for maximising efficiencies with existing delivery approaches, for example on bTB testing, and slaughter and salvage of bTB reactor carcases. It also considers new options such as developing an enhanced role for veterinary businesses providing local services.

18. Tackling bTB carries significant costs to farmers and other taxpayers. The average cost of a bTB breakdown is estimated at £12,000 to a farmer and £22,000 to Government. The Government alone is forecasting spending over £95 million on bTB measures in 2014/15. These costs are not sustainable. Additional investment will be required to bring the disease under control and reduce the costs in the long term.

19. The Government will develop proposals for a sustainable funding model for the Strategy. The experiences of both New Zealand and the Republic of Ireland provide evidence of the success of innovative delivery and co-financed bTB control strategies. The Strategy considers possible options such as stakeholders paying for some bTB measures such as testing and vaccination, government reviewing its role in compensation and carcase salvage, developing options for commercial insurance, and establishing a mutual fund co-financed by government and stakeholders linked to partnership-based governance.

20. The Strategy acknowledges that the correct tools must be used to monitor and evaluate its effectiveness drawing from a wide range of relevant sources including epidemiological, economic and social analyses. Adequate monitoring, review and adaptation of the approach will be critical to the Strategy's long term success, which will be achieving OTF status for England.

Background

Bovine tuberculosis

Bovine tuberculosis (bTB) is a chronic infectious disease of cattle caused by the bacterium *Mycobacterium bovis* (*M. bovis*). While cattle are particularly susceptible to infection, *M. bovis* can also infect a range of other mammalian species.

The current risk posed by *M. bovis* to human health in the UK is considered very low. The European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC)[3] have advised that the main transmission routes of *M. bovis* to humans are through drinking raw milk or eating raw milk products from bTB-infected cows. Historically, before the introduction of milk pasteurisation and tuberculin testing of cattle herds, *M. bovis* infection in humans was much more common. *M. bovis* can also be transmitted through direct contact with infected animals; if bTB is left unchecked, we could potentially see more cases of *M. bovis* infection in humans associated with spillover of infection into non-bovine species that have close contact with humans. EFSA[4] has also advised that there is no evidence suggesting that *M. bovis* is a meat-borne hazard for humans in the EU.

Today the vast majority of cases of TB in humans in the UK are caused by human-to-human transmission of *M. tuberculosis*.

History of bovine tuberculosis in England

Efforts to eradicate bTB from Great Britain were initially driven by public health concerns and the desire to increase the productivity and welfare of the national cattle herd. The voluntary herd schemes up to the 1950s were replaced by compulsory schemes. The whole of GB became 'attested' on 1st October 1960 i.e. each cattle herd was certified as being subject to regular tuberculin testing with immediate slaughter of any reactors.

For the next two decades there was a steady decline in the incidence of reactor cattle, clinical cases and infected herds detected and every year new counties would be

[3] EFSA (European Food Safety Authority) & ECDC (European Centre for Disease Prevention and Control), 2013. The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2011; EFSA Journal 2013;11(4):3129, 250 pp. doi:10.2903/j.efsa.2013.3129 http://www.efsa.europa.eu/en/efsajournal/doc/3129.pdf

[4] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2013. Scientific Opinion on the public health hazards to be covered by inspection of meat (bovine animals). EFSA Journal 2013;11(6):3266, 261 pp. doi:10.2903/j.efsa.2013.3266 http://www.efsa.europa.eu/en/efsajournal/doc/3266.pdf

designated bTB-free areas in which the herd testing frequency could be gradually relaxed to reflect the improved situation. In 1979 the lowest bTB prevalence was recorded in GB, with 0.49% of all herds tested having a reactor, which equated to 0.018% of all cattle tested.

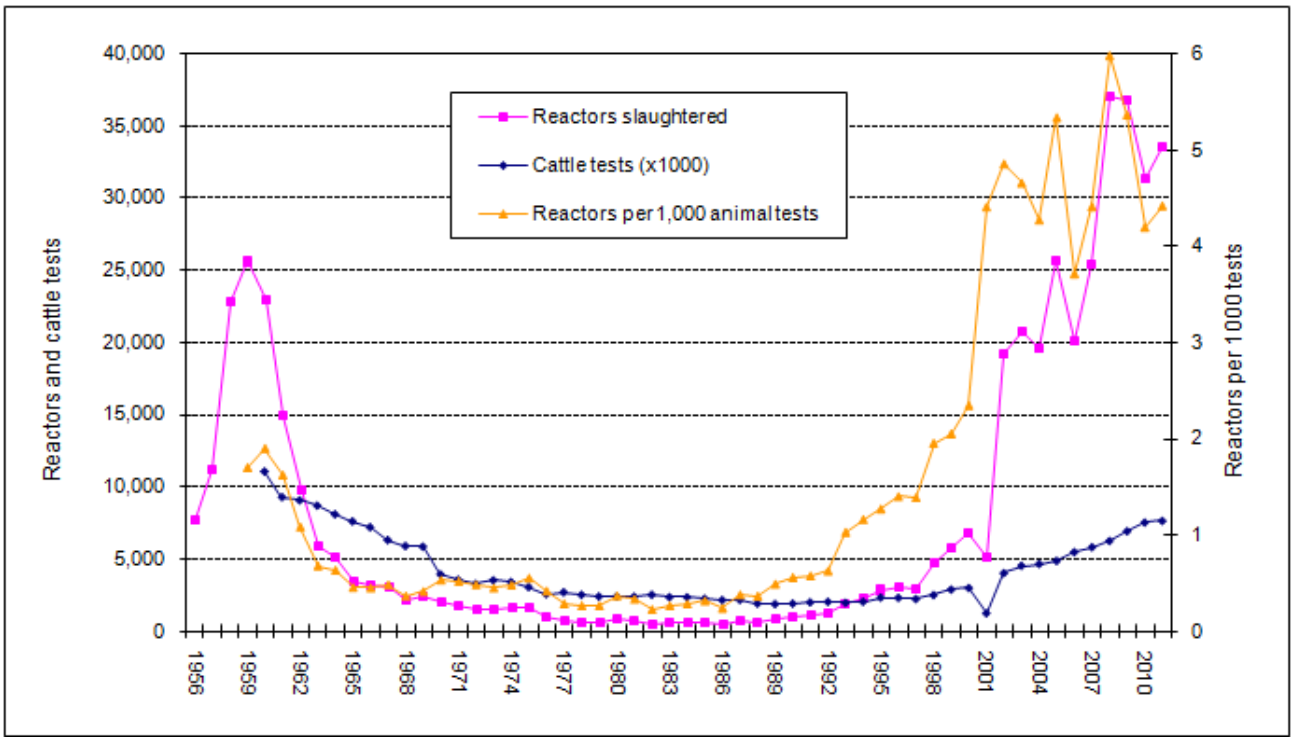
The badger was first identified as a possible wildlife reservoir of infection for cattle in the early 1970s in parts of South West England where a high prevalence of bTB persisted despite enhanced herd control measures. A series of different strategies were developed throughout the 1970s, 1980s and 1990s to tackle this wildlife source of bTB along with further cattle-based measures. Gassing (1975-1982) and "clean ring" (1982-1986) strategies were used prior to an "interim" badger culling strategy in place between 1986 and 1997, whereby badgers were removed only from farms where a bTB incident had been confirmed by *M. bovis* culture and where, following investigation, it was thought that badgers were the most likely source. **Annex A** provides further information.

The progressive reduction in bTB incidence stalled in the mid-1980s. Bovine TB herd incidence in South West England had remained about three times higher than in the rest of Great Britain, despite the retention of an annual (and occasionally more frequent) tuberculin herd testing regime in those areas.

The Krebs report published in 1997 concluded that "the sum of evidence strongly supports the view that, in Britain, badgers are a significant source of infection in cattle". The main recommendation was to set up a controlled field experiment (the Randomised Badger Culling Trial (RBCT)) overseen by the Independent Scientific Group on cattle TB (ISG) to quantify the impact of culling badgers on TB incidence in cattle. Immediately after the publication of the Krebs report, the Government suspended all badger removal operations outside the RBCT pending its outcome.

In 2001, the national bTB testing programme was severely disrupted due to a major outbreak of Foot and Mouth Disease, which led to anomalous bTB statistics from 2001 to early 2003. This led to a marked fall in the number of bTB breakdowns and reactors detected in 2001, followed by a sharp increase in 2002 as tuberculin herd testing resumed (**Figure 1**). Another consequence of the outbreak was the geographical spread of bTB to new areas of England through the restocking of depopulated herds.

Figure 1 – The evolution of the bTB epidemic in Great Britain



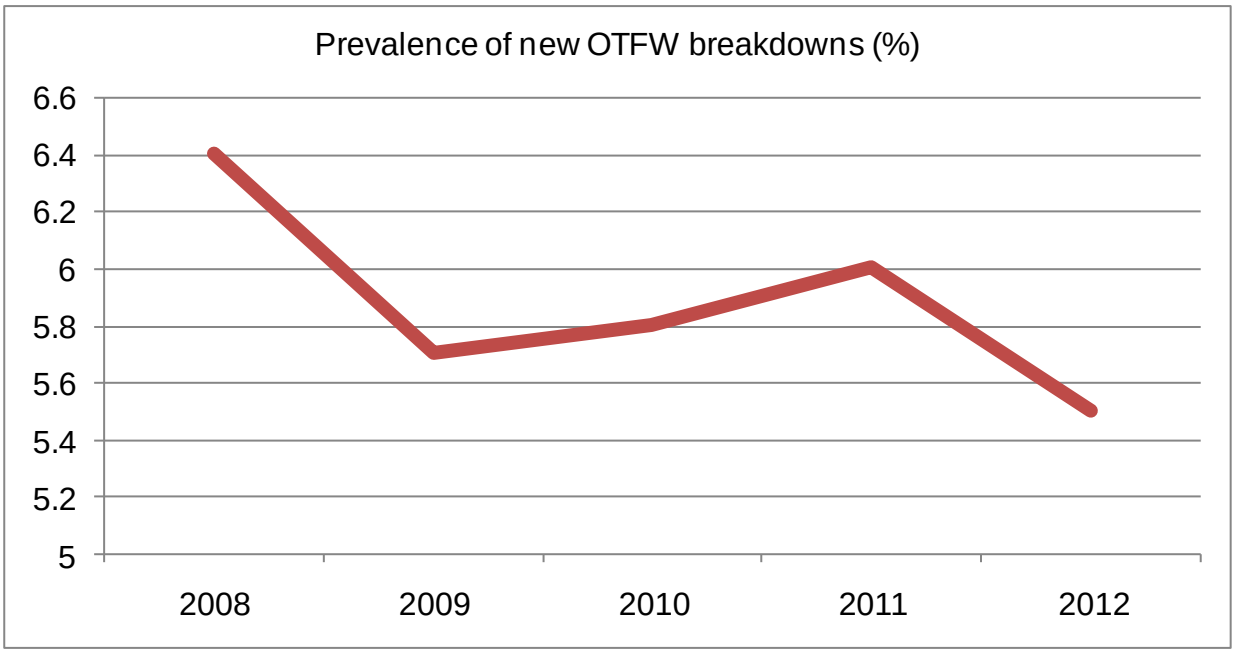
The Final Report of the ISG published in 2007 included the findings of the RBCT (1998-2005). It has been estimated that some 50% of cattle herd breakdowns in high incidence areas were caused by badgers.

From 2006, a range of additional cattle surveillance testing and movement controls were introduced in England, including a compulsory pre-movement tuberculin testing of cattle moving out of herds in high risk areas and the use of the interferon-gamma test to supplement the skin test in certain circumstances. In 2006, a new compensation system for TB reactor cattle was introduced, using monthly tables of values that reflect the average sales price of different categories of cattle. The most recent packages of additional cattle measures came into effect in 2012 and in 2013[5].

By 2008 England reached a historical peak of 6.4% of herds experiencing new Officially TB Free status withdrawn (OTFW) breakdowns. Between 2008 and 2012, the average annual prevalence of new OTFW breakdowns was 5.8%, with some variation from year to year (**Figure 2**). More detailed data is included in **Annex B**.

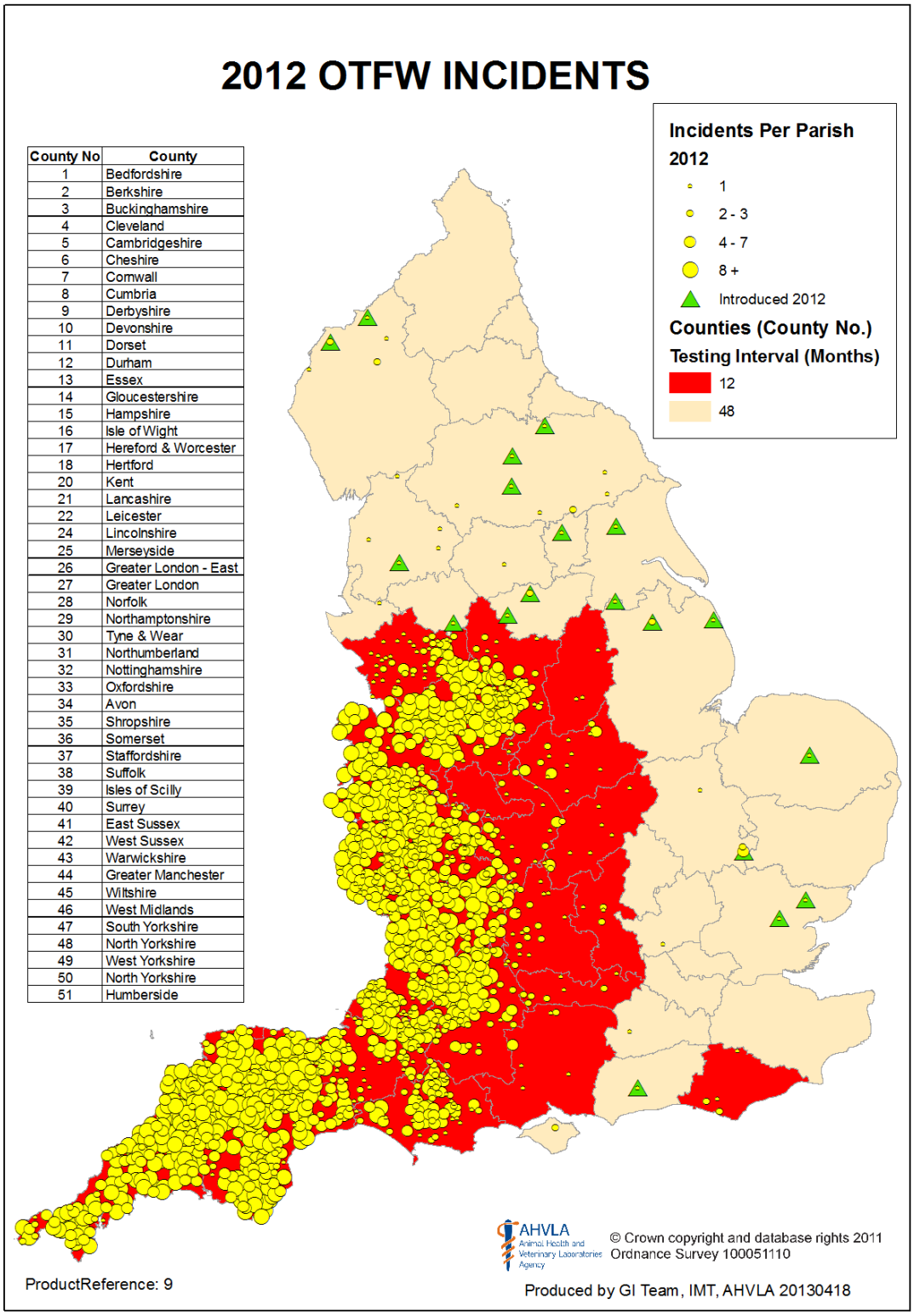
[5] Information Notes on changes introduced in 2012 and 2013
http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/publications/

Figure 2 – Prevalence of new OTFW breakdowns over the period 2008-2012



In 2012, most bTB breakdowns in England were in the South West and West Midlands (**Figure 3**) which correlated to the recognised wildlife reservoir of bTB in badgers. By contrast the North and East of England had a very low and sporadic incidence of breakdowns. Less than 1.5% of bTB breakdowns in previously unaffected herds occurred in the areas of the country at low risk of the infection. Of these, at least half could be traced directly to the movement of infected cattle from areas at high risk of the infection into herds in the low risk area. The other half represented cases where the likelihood of spread with cattle movements was high but this could not be established as the index animal had moved on or been slaughtered without being detected as bTB-infected. These isolated cases in the low risk area created individual breakdowns with occasional but limited subsequent secondary spread.

Figure 3 – Map showing the uneven geographic distribution of bTB in England. New bTB herd breakdowns, or clusters of breakdowns, with OTFW (Officially bTB Free status withdrawn) that were identified in England during 2012 are shown as yellow dots. Counties shown in red correspond to the current annual testing area of England that has been in force from 1 January 2013. (Source: AHVLA)



Key facts

The Natural Science and Social Science Evidence Statements at **Annexes C and D** provide a summary of the evidence base on bTB. In some areas, further research is required to improve the evidence base.

Strategy Aim

The aim of the Strategy is to eradicate bTB, achieving Officially bTB Free (OTF) Status[6] for England incrementally, whilst maintaining a sustainable livestock industry[7].

The Strategy sets out how the aim will be achieved through greater partnership working, increasingly industry-led implementation and a fair sharing of the associated costs. It draws upon the demonstratively successful approaches taken by other countries around the world, for example in:

- Australia, where the national eradication programme spanning almost three decades achieved official freedom from bTB in 1997 through a comprehensive package of measures to tackle the disease in domestic cattle and wildlife. This included rigorous culling of feral water buffalo, which were introduced into Australia in the nineteenth century;

- Scotland, which in the absence of a wildlife reservoir successfully applied a package of conventional cattle measures to achieve OTF status in 2009;

- Michigan in the United States of America, where the bTB eradication project includes cattle and wildlife controls. Since the mid 1990s, Michigan State has made significant progress in lowering the apparent prevalence of *M. bovis* in free ranging white-tailed deer in the endemic area by over 60% through reduction of deer densities by hunting and restrictions on public feeding and baiting of deer. This strategy has been implemented with the cooperation of local hunters. Livestock herd breakdowns averaged 3-4 per year from 2005 to 2011;

[6] For a Member State or region to achieve OTF status as defined in Council Directive 64/432/EEC, at least 99.9% of the herds within it must have been or remained OTF for at least six consecutive years. OTF status allows for residual levels of the infection to remain, whereby less than 0.1% of herds experience the infection annually in a region defined as OTF, whilst eradication would represent elimination of the infection

[7] The Strategy's aim complements Defra's strategic objectives of supporting and developing British farming and encouraging sustainable food production, enhancing the environment and biodiversity, and managing the risk of animal disease. These support Government's overarching objective of achieving economic growth.

- New Zealand, where a farmer-led organisation has taken the lead in formulating, implementing and raising funding for a comprehensive and successful package of measures to eradicate bTB. The primary wildlife reservoir of *M. bovis* is in brush-tailed possums, introduced into New Zealand in the nineteenth century. Wildlife control measures include aerially- or ground-deployed poison bait and trapping. The number of *M. bovis* infected cattle and deer herds has reduced from over 1700 in the mid 1990s to 66 (0.1%) in 2011/12; and

- The Republic of Ireland, where cattle bTB testing and compensation are co-funded by industry. The comprehensive bTB eradication programme, which includes targeted capture and culling of badgers, has seen the proportion of bTB herd breakdowns fall from 9.6% in 1995 to 7.4% in 2010, compared to an increase from 0.8% to 9.0% in England over the same period.[8]

Achieving the aim will be dependent upon:

- Effective application of disease control measures in cattle;

- Best practice in livestock farming achieved through advice and appropriate use of rewards and penalties;

- Addressing the reservoir of *M. bovis* in wildlife[9] whilst maintaining biodiversity[10] to enable a healthy cattle population to live alongside a healthy wildlife population; and

- Ensuring a fair balance of costs falling to the general taxpayer, the food and farming industry and other stakeholders.

The Strategy focuses on keeping the Low Risk Area free of bTB, halting and then reversing the spread of bTB at the Edge of the High Risk Area, and radically reducing the prevalence of bTB in the High Risk Area, progressively achieving OTF status for England.

[8] Standardised annual herd prevalence as defined in Abernethy, D.A. *et al* (2013) Bovine tuberculosis trends in the UK and the Republic of Ireland, 1995-2010. Veterinary Record (2013) doi: 10.1136/vr.100969

[9] Further information is available in the Government's Policy on Bovine TB and badger control in England, December 2011 (PB13691) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69463/pb13691-bovinetb-policy-statement.pdf

[10] **Annex A** provides a summary of evidence of the potential ecological consequences of changes in the badger population

Rationale for intervention

The Government wants to see a thriving and sustainable livestock sector in England, one that, along with the rest of the agricultural sector, helps to support the resilience of the entire food chain.

bTB is one of the most pressing challenges facing the industry today. Based on current expenditure, the forecast cost to Government alone without additional intervention will exceed £1 billion over the next decade; this level of expenditure is unsustainable. If bTB is left unchecked we risk impacting the productivity and capability of the industry threatening our ability to trade and grow our exports into new and emerging markets. We also risk undermining confidence in our food and more cases of human infection.

bTB can spread from animal to animal and from farm to farm. Whilst there are a number of measures that individuals can and should take to help reduce the risk of bTB, achievement of OTF status and then eradication of bTB in England requires collective action. Individuals are unlikely to consider the potential costs and benefits to others when deciding how and when to invest to limit the spread of the disease. For this reason their decisions are unlikely to be optimal from the perspective of the industry or society. Certain activities can actually worsen the spread of infection, so a coordinated and strategic approach is essential if we are to prevent the spread, bear down on, and ultimately eradicate the infection.

The UK is required to have a plan[11] for accelerating the eradication of bTB which meets minimum criteria (Council Directives 77/391/EEC and 78/52/EEC). The EU provides co-financing, up to an annual maximum agreed under Council Decision 2009/470/EC, to support the UK's bTB Eradication Plan. Failure to comply would pose a risk of loss of EU co-financing, infraction proceedings and financial penalties, and a risk of trade sanctions.

The Government's responsibility is to set out how the disease can be tackled holistically. In doing so it needs to ensure that the UK meets its legal obligations and to reduce the financial strain on public finances and industry through increased partnership working, industry-led delivery and a fair sharing of the costs involved. In so doing it will help put the sector and public financing of disease control on a more sustainable footing.

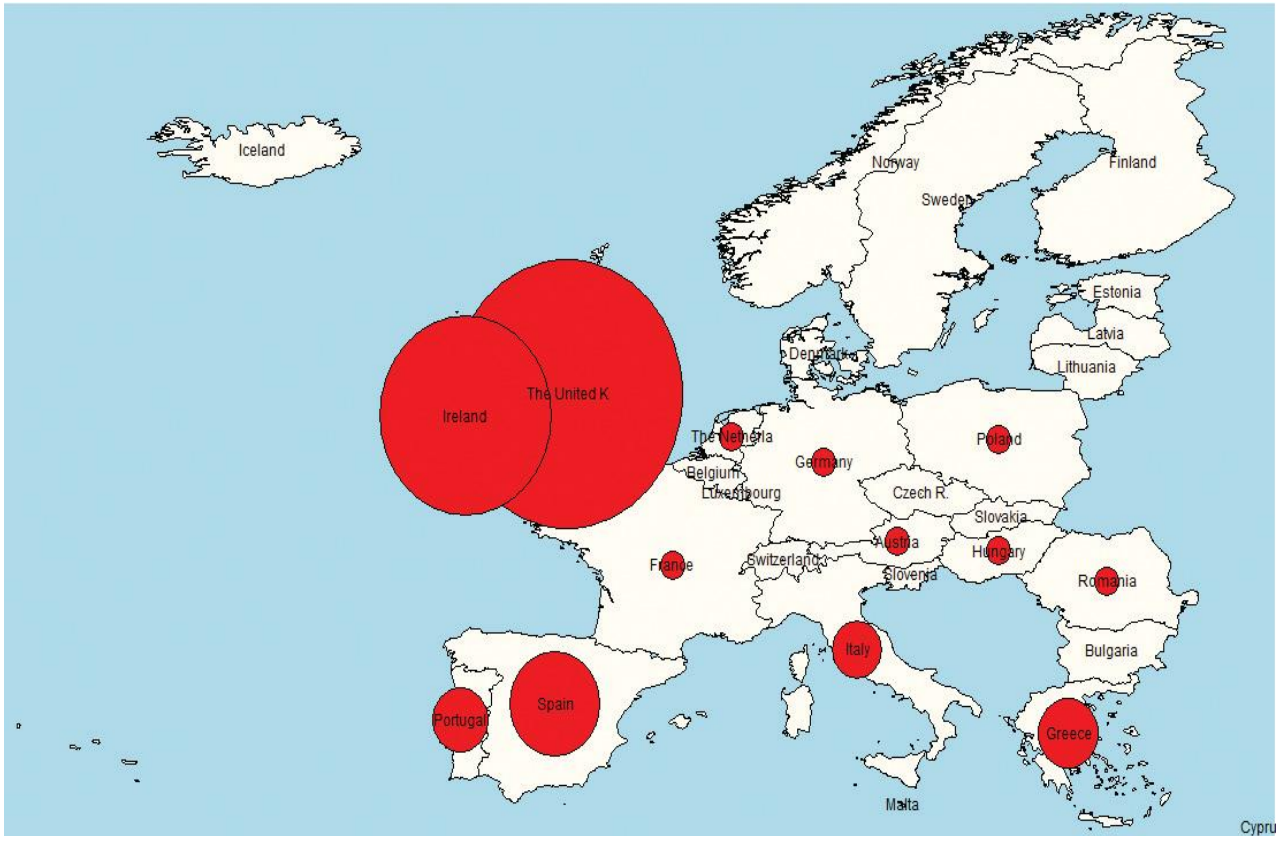
Achieving OTF status for England will provide tangible benefits for the cattle industry, rural communities and Government. These include significant savings in combating the disease

[11] Working document on eradication of bovine tuberculosis in the EU accepted by the Bovine tuberculosis subgroup of the Task Force on monitoring animal disease eradication (SANCO/10067/2013) http://ec.europa.eu/food/animal/diseases/eradication/tb_workingdoc2006_en.pdf

both to Government and to industry, increasing the ability to trade within the EU and internationally[12] and alleviating the social impacts.

While Scotland achieved OTF status in 2009, the prevalence of bTB infection in England contributes to an unacceptably high prevalence of bTB in the UK herd as a whole **(Figure 4)**. Many other EU Member States are already OTF. A map showing the OTF status of EU Member States can be found at **Annex E**.

Figure 4: National herd prevalence[13] for bovine TB in European Member States[14]



The Government does not envisage disadvantages arising from the achievement of OTF status for England. Nevertheless, the Government proposes working with the Agricultural and Horticultural Development Board to assess any market impacts which might arise as a

[12] The World Organisation for Animal Health's (OIE) Terrestrial Animal Health Code lays down animal health standards for international trade. These include requirements for qualifying for official freedom from bTB. http://www.oie.int/

[13] Prevalence proportions have been calculated as the percentage of cattle herds infected with or positive for *M. bovis* during 2010. The red symbol size is proportional to the prevalence of *M. bovis* in cattle herds

[14] Source: Ru,G. *et al* (2013) Bovine TB Control: valuable insights from countries on steps toward eradication. Veterinary Record 2013 172: 310-311 doi: 10.1136/vr.f1347 citing EFSA & ECDC (2012) The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2010. EFSA Journal 10, 2597

consequence of pursuing a staged approach (i.e. by counties or groups of counties) to achieving OTF regional status for England.

Strategy Approach

The Strategy reflects the Government's commitment to tackle bTB in a comprehensive and balanced way, with achievement of OTF status for England. The approach will be:

- **Comprehensive**, tackling *M. bovis* infection in cattle, other farmed animals and wildlife, addressing all transmission routes to tackle bTB in cattle, making best use of all available tools whilst funding research to address evidence gaps and develop new tools;

- **Risk-based**, with controls targeted according to risk of infection and based on scientific and veterinary advice; and

- **Staged**, to provide the means to stop the spread of infection, bring it under control, and bear down on it to achieve and maintain OTF.

To achieve a balanced approach, the Strategy embraces:

- **Supporting farmers**: Government will work with those at the forefront of the disease to support farm businesses in taking more responsibility for disease control, for example by appropriate use of rewards and penalties to encourage best practice.

- **Partnership working**: Many individuals and groups have a direct involvement in controlling the disease and will benefit from England achieving OTF status. The Government, the farming and food industry, the veterinary profession, local authorities, wildlife interest groups and other stakeholders will need to collaborate effectively to deliver the Strategy's aim. The Government will maintain open dialogue on bTB policy development guided by the Strategy. It will work closely with devolved administrations, particularly in the context of the evolution of the UK's bTB eradication plan.

- **Fair balance of costs and supported responsibility**: Government will ensure that farmers have the right incentives for tackling bTB. Government will explore innovative governance arrangements and delivery models.

- **Working effectively in the EU**: Government, as the competent authority, will ensure that England complies with EU bTB legislation, while pushing for a more flexible, risk-based EU legal framework under a new Animal Health Law[15]. Government will also

[15] On 6 May 2013, the European Commission adopted a package of measures to strengthen the enforcement of health and safety standards for the whole agri-food chain. The main elements include Animal Health and Official Controls. The package is subject to consideration by the European Parliament and the Council with possible entry into force in 2016, followed by a proposed three-year transition period. http://europa.eu/rapid/press-release_IP-13-400_en.htm

work through the EU to ensure that the World Organisation for Animal Health (OIE) animal health standards for international trade are aligned as far as possible with rules for intra-EU trade.

Targets and Timeline

Targets

The initial Strategy targets - proposed up to 2025 - are set out in **Table 1,** below. The targets will be used to monitor and evaluate the Strategy (see Monitoring and Evaluation of the Strategy).

Table 1 – Initial targets

Basic measures of performance	Targets	Delivery scale	Indicators of success
Annual proportion of OTF herds Annual proportion of OTFW herds	Progressive attainment of OTF status for **individual counties** (or groups of counties) within the current **low risk area**[16]	Between 2018 and 2025	1. The achievement of OTF status for individual counties in England 2. The reduction in the geographical coverage of the High Risk and Edge Areas in England 3. In longer term, the achievement of OTF status for England
	Achievement of OTF status for **all** counties in the current **low risk area**	By 2025	
	Maintain herd prevalence below 2% overall in the **edge area**[17]	By 2019	
	Reduce herd prevalence below 1% overall in the **edge area**	By 2025	
	Achieve OTF status for the lowest prevalence counties in the **edge area**	By 2025	

[16] Cumbria, Durham, Lancashire, Northumberland, Yorkshire, Humberside, Lincolnshire, Cambridgeshire, Norfolk, Suffolk, Essex, Hertfordshire, Bedfordshire, Greater London, Surrey, Kent, West Sussex and Isle of Wight

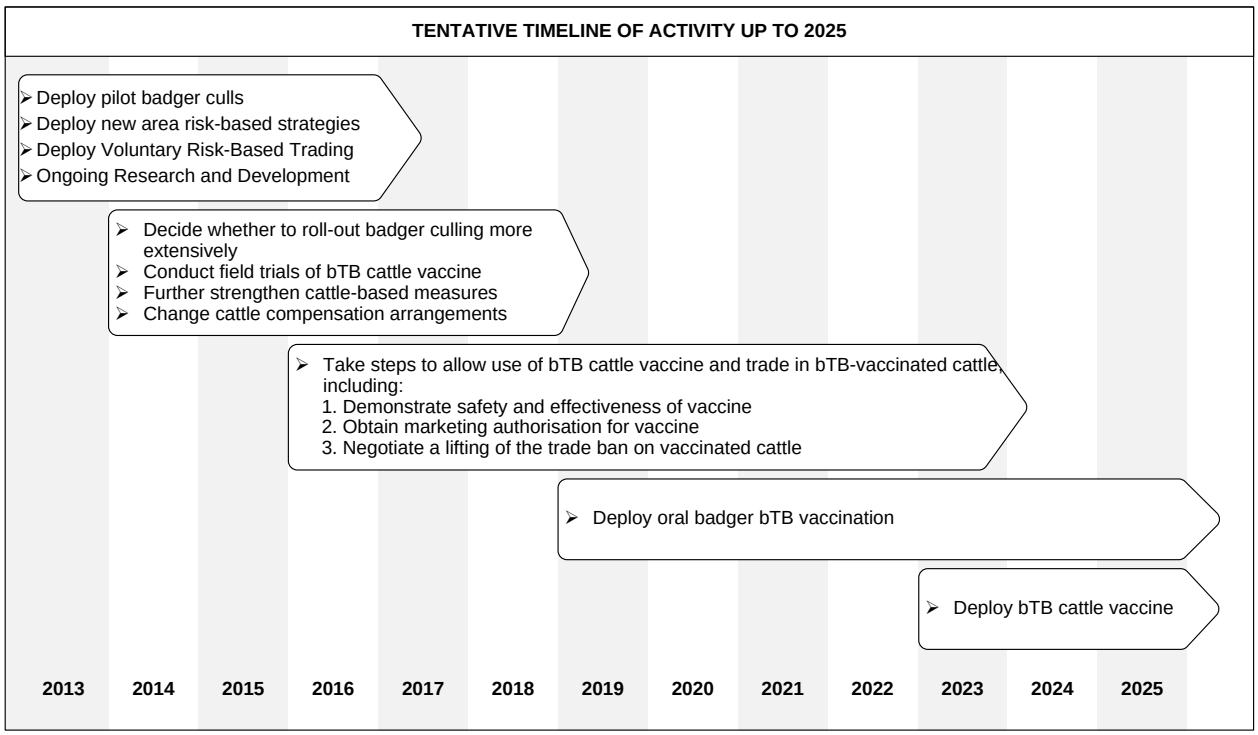
[17] As defined in 2013

	The Government proposes setting targets for individual counties within the **high risk area** with the aim of achieving OTF status for the whole of England in 25 years	

Timeline

Figure 5 illustrates the tentative timeline for potential deployment of measures until 2025 to achieve the targets in the preceding section.

Figure 5 – Tentative timeline of activity up to 2025



Ongoing monitoring and evaluation will be carried out (see Monitoring and Evaluation of the Strategy).

Key Elements

Current bTB control measures applied in England

The current bTB control measures in England are directed primarily to controlling *M. bovis* infection in cattle. Some measures address the disease in other animals, such as badgers and South American Camelids (SAC) in order to reduce the risk of TB transmission to cattle. The current measures are a mixture of:

- measures that fulfil the minimum legislative requirements established by the EU in order a) to entitle herds and regions of a country to be OTF and to be able to trade with other Member States and b) to entitle the UK to EU co-financing of certain bTB control measures (testing, laboratory analysis, compensation);

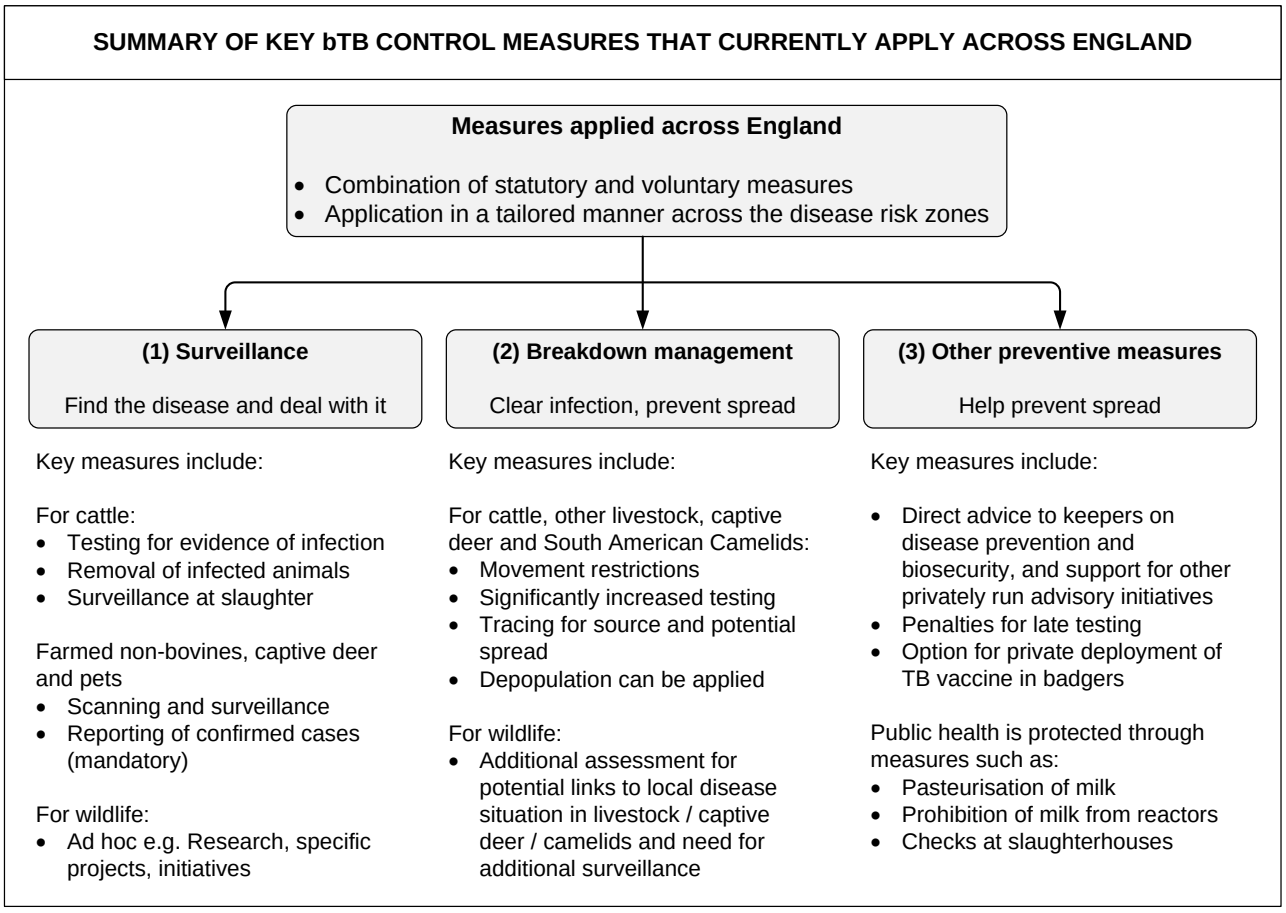
- measures that are statutory (in domestic legislation) and apply to all keepers, irrespective of a particular situation;

- measures that are statutory (in domestic legislation) but are only applied on a discretionary basis, depending on a particular situation; and

- voluntary measures such as private deployment of badger vaccines.

They can be categorised under the following headings: disease prevention; surveillance; and breakdown management (**Figure 6**). The measures, both statutory and non-statutory, are applied in a tailored manner across the different disease risk zones. The precise deployment reflects the predictive diagnostic or disease control value of each measure in a particular disease situation.

Figure 6 – Summary of key bTB control measures applied currently in England



The measures that are currently applied across all areas in England are:

(1) Surveillance for bTB infection:

- In cattle, surveillance for bTB is based on using the comparative tuberculin skin test (the single intradermal comparative cervical test (SICCT)). In areas that have endemic bTB or are otherwise considered to be at high risk of bTB spread, there is annual whole herd testing of cattle. In the low risk area (LRA) of the country, four-yearly testing of breeding stock (routine herd testing) is carried out. This herd based surveillance is statutory, EU law dictates minimum frequency levels for surveillance testing, depending on disease prevalence (lower prevalence = less frequent testing). It is not possible to reduce the surveillance testing frequency below the four-yearly pattern until a country or a region has gained OTF status. Some high risk herds in the LRA are surveyed annually with a whole herd test (a discretionary statutory measure). All commercially slaughtered cattle are surveyed throughout the country for signs of bTB at slaughter (a statutory measure) and this is of critical importance in detecting herd infection, especially in the LRA. Statutory scanning surveillance by reporting and investigating suspect clinical cases applies to cattle but has little value currently, as active surveillance tends to remove all infected animals before clinical signs appear;

- Surveillance in other livestock and in captive deer is carried out by statutory slaughterhouse and scanning surveillance, as in cattle;

- Surveillance in SAC and pets is carried out by non-statutory scanning surveillance. Reporting of confirmation of bTB in private laboratories is a statutory requirement; and

- Surveillance of wildlife is not statutory and is only carried out as part of research or specific projects/initiatives (e.g. localised deer surveys in 2006, Road Traffic Accident surveys of badgers in the past; current research by AHVLA/Fera in Gloucestershire; investigations of unknown breakdown origins in the LRA).

(2) Breakdown management:

- Bovine TB breakdowns in cattle herds are managed with the aim of preventing further spread of disease and clearing the infection from the herd as quickly as possible. The following controls are applied uniformly across the country: (i) preventing movements from the herd (statutory; EU), other than to slaughter or to other herds in some specific circumstances; (ii) short interval testing with the SICCT (at a 60-day interval) until one or two clear tests (statutory; EU) and (iii) tracing and testing both the potential source and spread of the infection (statutory; under domestic legislation). Statutory use of interferon gamma assay as an additional breakdown test, is applied to all breakdowns where OTF status has been withdrawn in the LRA and to some breakdowns in the Edge Area;

- The Government pays statutory compensation to cattle farmers for cattle compulsorily slaughtered for bTB control purposes. Compensation is determined primarily using monthly table values, which reflect 100% of the average sale prices of bovine animals in 51 different categories. The categories are based on the animal's age, gender, type (dairy or beef) and status (pedigree or non-pedigree). The default position is to use table valuation although individual valuations may be used in defined circumstances.

- Statutory depopulation of a cattle herd can be applied in cases where repeated testing does not, or is suspected not, to clear a herd of infection, although it is rarely applied in practice. Contiguous risk in breakdown situations is addressed in the annual testing area and in the LRA; in the former, by applying contiguous testing on a discretionary basis; in the latter, by testing all herds within a 3-km radius of the index farm. All testing relating to local risk from a breakdown is enforced under domestic legislation;

- Laboratory confirmation of *M. bovis* infection in all other livestock species, such as captive deer herds, pigs, goats, sheep and SAC normally triggers statutory movement restrictions and repeat TB testing (or, in the case of animals reared for their meat, depopulation) of the remaining animals on the infected premises in order to lift the restrictions. AHVLA also instigates spread and source tracings, as well as testing of any cattle herds that may be co-located with (or contiguous to) the infected premises. In the LRA, any incidents of TB in non-bovine species caused by *M. bovis* infection result in enhanced bTB surveillance (targeted testing) of cattle herds situated within a 3km radius of the index premises; and

- In pets and wildlife, confirmed cases of *M. bovis* are reported to AHVLA (statutory) and private deer stalkers are trained and encouraged to submit suspect samples from deer. The confirmed cases are epidemiologically assessed in terms of potential links to local disease situation in livestock/deer/camelids and need for additional surveillance.

- In 2012, Natural England issued badger control licences[18] in the HRA in Somerset and Gloucestershire. Each licence has a four-year term and authorises control operations to be conducted over a continuous six-week period each year. No control operations can take place during specified close seasons. Each licence sets a minimum target to ensure that enough badgers (at least 70% of the local population) are culled to control bTB and a maximum number to prevent local extinction. Two pilot culls will start in summer 2013 and an Independent Expert Panel will assess the humaneness, effectiveness (in terms of badger removal) and safety of controlled shooting of free-ranging badgers. The results will inform a decision on a wider roll out (up to ten new licences per year) of the policy in England from 2014.[19] Unlicensed culling of badgers or interference with their setts is illegal under the Badger Protection Act 1992, may increase the risk of perturbation, and may therefore increase the likelihood of geographical spread of bTB to cattle and other badgers. Unlicensed taking of, possession or selling of badgers is also illegal.

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[18]Further information is available http://www.naturalengland.org.uk/ourwork/regulation/wildlife/species/badgertb.aspx

[19] Further information is available in the Government's Policy on Bovine TB and badger control in England, December 2011 (PB13691) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69463/pb13691-bovinetb-policy-statement.pdf

(3) Other disease prevention measures:

- AHVLA provides disease prevention and biosecurity advice to keepers. Defra also supports financially various initiatives to provide such advice to keepers and finances substantial research effort into biosecurity measures, particularly to address spread from badgers to cattle. Whilst some disease control measures (see below) are statutory, there are no statutory measures relating to on-farm biosecurity;

- All surveillance and breakdown testing (including trace and contiguous testing) has to be carried out within a given time window. There are statutory and financial sanctions that apply to overdue testing across the country, such as movement restrictions, reduced compensation levels and enforced testing;

- All cattle over 42-days of age, moving from annually tested herds to live on another holding must be pre-movement bTB tested (statutory). There are some limited exemptions to this requirement. Keepers are also encouraged voluntarily to isolate and post-movement test any new stock they bring into their herd;

- Cattle moving from restricted herds can be moved to slaughter either directly or via a biosecure Approved Finishing Unit (AFU). In the LRA and Edge Area, AFUs are not allowed to graze their stock;

- Cattle keepers are not allowed to establish links between holdings in the HRA and holdings in the LRA; all movements of cattle between such holdings must be reported to Cattle Tracing System and cattle must be pre-movement bTB tested as appropriate.

- New Sole Occupancy Authorities (SOAs) are no longer permitted and new premises can no longer be added to existing SOAs; and

- The first injectable bTB vaccine for badgers (BadgerBCG) was licensed in 2010, since when it has been used on the Badger Vaccine Deployment Project[20] in Gloucestershire (outside the licensed culling area). The Project was established to learn practical lessons about vaccinating badgers and to train lay badger vaccinators. The vaccine is available on veterinary prescription and can be deployed by private individuals on their land, subject to a licence from Natural England and it being administered by a trained and competent person. The Government may support such vaccination projects through the Badger Vaccination Fund[21], a competitive grant scheme which can provide match-funded grants of up to 50 per cent of the first year costs of badger vaccination[22].

[20] The budget for the Badger Vaccine Deployment Project is £416,000 in 2013/14

[21] The budget for the Badger Vaccination Fund is £250,000 in 2013/14

[22] For further information on badger vaccination see https://www.gov.uk/government/policies/reducing-bovine-tuberculosis/supporting-pages/vaccines-against-tb

The deployment of the injectable badger vaccine raises issues of practicality (a spectrum of protection is seen in uninfected badgers with no benefit in infected animals; annual deployment is required to target newly emerged badger cubs) and cost (estimated at £2000-£4000 km^2/year) and the effects on bTB in cattle are unknown.

Developing our risk-based approach

Introduction to Area Risk-Based Strategies

This section sets out the Strategy's risk-based approach. Since January 2013, geographical areas of England have been assigned one of three bTB risk-based classifications: Low Risk, High Risk or Edge of High Risk ("Edge"). The Low Risk Area (LRA) is demarcated by the four yearly cattle herd testing counties in the North and East of England. The annual cattle herd testing zone includes the High Risk Area (HRA) and the Edge Area. The inner boundary of the Edge Area has been determined based on research and surveillance data, and local knowledge. **Figure 7** illustrates the coverage of each area in 2013. The aim of the Strategy is incrementally to extend the LRA to the whole of England and eventually to achieve OTF status. The boundaries of all three zones will be subject to regular review and will change over time as we move towards achieving this aim.

The Strategy proposes sub-strategies for each risk area. Cross-cutting tools such as biosecurity, advice, compliance and enforcement will underpin the approaches. The Government also needs to ensure that proportionate measures are in place to address the risk posed by bTB in other non-bovine species. The underlying approach is common for all risk areas, i.e. prevent bTB breakdowns, detect bTB breakdowns early, and deal with bTB breakdowns rigorously. Whilst some control measures will apply across all risk areas, others will be tailored as part of individual packages to suit the disease profile of each area. For example, in the HRA particular emphasis is placed on addressing the reservoir of *M. bovis* in badgers alongside conventional cattle-based measures. **Figure 8** summarises the objectives for each of the area risk-based strategies.

It is important to note that the level of bTB risk and incidence within each risk area is not uniform and stable. Even in the LRA, individual herds may pose greater risks of infection than others because of their location, size, bTB history, cattle husbandry and trading practices. The Government therefore also wants to move towards better definition of bTB risks on an individual herd basis to address this. AHVLA is working to generate a bTB risk rating for every herd in the country, which could be used to support risk-based trading decisions and to enable the application of the principle of 'earned recognition' whereby best practice is rewarded with fewer burdens.

Figure 7 – Geographical location of the three risk areas in 2013

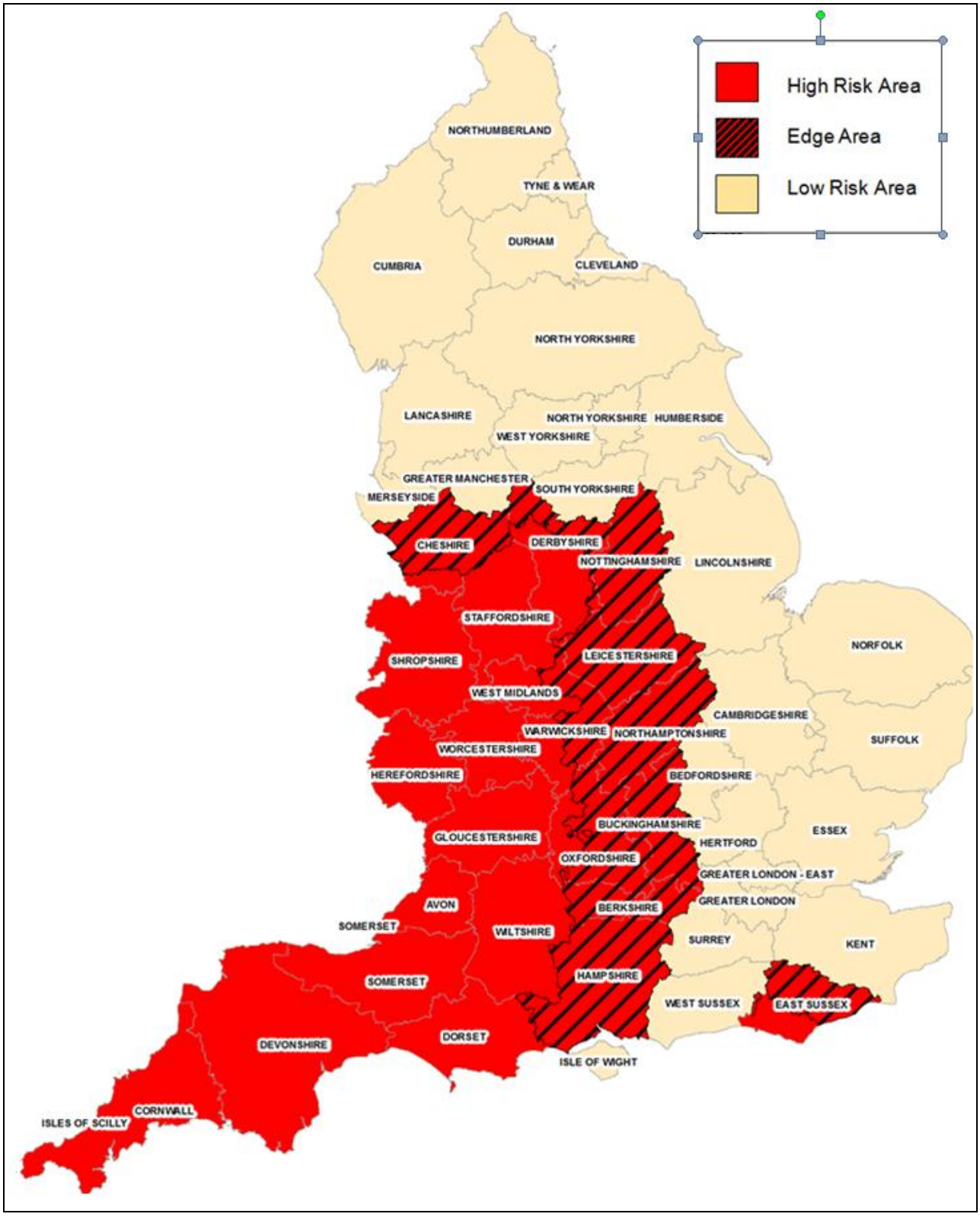

Figure 8 - Summary of objectives of Area Risk-Based Strategies

For ALL areas (of England)		
The **aim** of the Strategy is to eradicate bTB, achieving Officially bTB Free (OTF) Status for England incrementally, whilst maintaining a sustainable livestock industry. Delivery will be supported using an area strategy for each of the High Risk Area, Low Risk Area and Edge (of High Risk) Area, with appropriate measures tailored to each area.		
For the HIGH RISK AREA	**For the EDGE AREA**	**For the LOW RISK AREA**
General characteristics: • Infection appears to be endemic • Infection in wildlife (badger population) • High incidence and repeat breakdowns (in area as a whole) At present the High Risk Area is concentrated in the South West and West Midlands, and East Sussex. We want to see this area contract.	**General characteristics:** • Infection is potentially currently spreading from High Risk Area • Incidence varies from place to place therefore approach will be tailored to local conditions Currently covers the edge/boundary of the High Risk Area, and is defined along county boundaries.	**General characteristics:** • Low incidence rate, mostly due to bringing in diseased animals • Low reoccurrence • Relatively short breakdown duration • No recognised wildlife reservoir Currently extends across the North and East of England. We want to see this area grow.
Main objectives In the short term to: • Reduce incidence rate, and • Improve epidemiological understanding In the medium term to: • Address the disease in livestock and in wildlife • Reduce herd incidence • Introduce targeted and localised strategies with clear prevalence targets In the long term to: • Achieve continuous and sustained reduction • Then Achieve OTF status • Eliminate need for wide scale intervention	**Main objectives** In the short to medium term to: • Stop geographical spread of the disease and the High Risk Area • Begin to reduce the incidence rate within the Edge Area In the longer term to: • Reverse spread of the disease • Reduce the incidence rate of the Edge Area, working towards an OTF status for the counties involved	**Main objectives:** In the short to medium term: • Continue to protect the current Low Risk Area, halting the spatial spread of the disease • Deal immediately with an incursions of disease • Further reduce the very low and sporadic incidence rate • Expand the current OTF coverage

The remainder of this section explains:

- Cross-cutting bTB control measures to apply in all risk areas
- The LRA strategy
- The Edge Area strategy
- The HRA strategy

For each of these sub-strategies, this section explains in turn the epidemiological rationale, objectives and package of measures.

Cross-cutting bTB control measures in all risk areas

Cross-cutting measures which may be applicable to all risk areas include:

- Risk-based trading;
- On-farm biosecurity;
- Using compensation to reward good practice on biosecurity;
- Improved advice to farmers;
- Improved compliance and enforcement; and
- Tackling TB in non-bovine farmed species.

The individual cross-cutting measures are explained at the bullet points below.

- **Risk-based trading**

  The way in which livestock is traded can have a direct impact on the risk of spreading disease as well as implications for surveillance. Incomplete information in decision making is a well established form of “market failure” that sometimes can require Government intervention, and this is no less true for controlling bTB in cattle. Introducing cattle from higher risk herds e.g. herds which have recently experienced a bTB breakdown, increases the disease risks for the importing herd. Achieving OTF status for the LRA and expanding it into the current HRA is a key aim of the Strategy; actions which jeopardise this need to be discouraged with the costs of consequences of risky decisions falling on those who take them. Making more bTB history information available to buyers would enable them to make informed decisions on the disease risk of purchased stock and would enable farmers to take appropriate action to reduce the risk of spreading bTB.

  The substantive recommendation of the industry-led Risk-Based Trading Group[23] was the development and introduction of a comprehensive, accessible database as the ideal solution to support a successful risk-based trading scheme. This would be used by farmers, veterinary surgeons and auctioneers to inform purchasing decisions and post-purchase behaviour. As the development of such a database is not a quick or simple task, the group recommended a phased introduction of risk-based trading measures whilst the requirements and costs of the database can be scoped. In the shorter term, the group recommended the introduction of other measures such as making herds’ bTB history available at the point of sale; the production of buyer and seller best-practice guidance and for AHVLA to continue its work aimed at generating a bTB risk rating for every herd in the country, which could be used to support risk-based trading decisions.

  The Group strongly favoured the voluntary approach to the introduction of risk-based trading, and emphasised that the Government and industry working in partnership was the way forward. However, it cautioned that if this was not successful, a mandatory approach must be considered to ensure the adoption of risk-based trading and to facilitate informed decision making by farmers when they trade cattle to help minimise the risk of spreading the disease by riskier trading practices. There are other tools (e.g. compensation levels) that can be used to encourage farmers to take advantage of risk-based trading.

- **On-farm biosecurity**

[23] In 2012 Defra set up an industry-led group to consider options for risk-based trading to help tackle the spread of bTB. Further information is available in the report of the Risk-Based Trading Group: Empowering Farmers to Manage TB Trading Risks
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/193647/rbtg-final-report.pdf

Biosecurity measures aim to prevent cattle-to-cattle and badger-to-cattle spread of bTB[24]. For example, the risk of cattle-to-cattle spread of bTB may be tackled through timely herd bTB testing, pre- and post-movement testing, isolation of new animals prior to their introduction into a herd and separating cattle from neighbouring cattle herds. Other on-farm biosecurity measures are aimed at reducing contact between cattle and badgers, for example by fencing off badger latrines and setts and preventing badgers from accessing cattle feed and water troughs; these are of particular importance in areas where there is a reservoir of *M. bovis* infection on the badger population. Many on-farm biosecurity measures are voluntary, but there is scope to build on the approach introduced in 2012 which reduced reactor compensation levels for herds whose bTB tests were significantly overdue.

- **Using compensation to reward good practice on biosecurity**

  Compensation rates for bTB reactors in England are relatively high and it is important to consider the extent to which paying compensation at 100% of average market value is in excess of EU requirements and is a disincentive for some farmers to manage effectively their bTB risks. In countries with successful control strategies such as New Zealand and Spain, compensation is paid at 65% and 75% of market value respectively.

  In reviewing bTB compensation the objective would be to reward risk-reduction and penalise risky practices, for example by ensuring that farmers receive salvage value as a default with a premium paid to farmers who comply with specified 'best practice' on biosecurity (e.g. risk-based trading). Possible options include:

  - Paying only salvage value for reactors disclosed in cattle brought into TB breakdown herds. To date, re-stocking in many TB breakdown herds has been licensed following a veterinary risk assessment i.e. for business sustainability reasons new cattle are brought into herds with a known (and sometimes long-running) TB problem. Sometimes the brought-in animals become TB reactors and are compulsorily slaughtered with government compensation paid.
  - Paying only salvage value for reactors disclosed in herds in the LRA, if cattle have been introduced from higher risk herds.
  - Using privately funded assurance schemes, audited by Government, as a basis for certifying 'best practice' on biosecurity (e.g. risk-based trading) to enable the payment of compensation above salvage value.

The Government will consult further on detailed proposals and carry out impact assessments as appropriate.

Improving advice and guidance to farmers

[24] Further information on biosecurity measures is available on the AHVLA website at http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/animal-keepers/biosecurity/

The Government is committed to exploring ways to provide effective advice and guidance to farmers, in partnership with the food and farming industry, levy bodies and the veterinary profession.

Previous examples of biosecurity advice and guidance include films funded jointly by Defra, the National Farming Union, the Welsh Government and the National Animal Disease Information System, AHVLA leaflets, and biosecurity workshops for farmers in the HRA area. The Government is planning to offer further biosecurity workshops in the Edge area in 2013.

Previous examples of compliance advice include bTB Information Notes summarising details of changes to bTB rules, and guidance produced by AHVLA. The Government will continue to work in partnership with stakeholder representatives to ensure that such advice is fit for purpose and is disseminated effectively.

The Government will also continue to provide funding for and work with the Farming Community Network (formerly Farm Crisis Network) to ensure that its volunteers are kept up to date with bTB policy developments so that they can provide effective support and business advice to those farmers most in need.

There may be an opportunity for industry to apply for Rural Development programme for England (RDPE) funding towards training and information exchange activities.

Improving compliance and enforcement

It is crucial that the currently high levels of farmer compliance with bTB controls are maintained. The small minority of farmers that contravene or ignore disease control rules jeopardise their own business and undermine the efforts of others. The Government recognises that non-compliance is not always deliberate, but can be due to the complexity of the rules and/or poor guidance. Therefore a high priority is to help farmers to comply by better understanding what guidance material they need. The Government has commissioned a review to consider the multiple sources of available guidance on bTB rules, find out what works well and not so well, and act on recommendations made. It also plans to work with industry partners to publicise the importance of compliance.

The Government will work with the farming industry and delivery partners (including local authorities) to monitor compliance levels and find practical, proportionate and effective ways to improve them. A project board comprising industry and government representatives is in place to oversee and direct bTB-related compliance and enforcement activity. For example, the Government will build on the existing approach whereby owners of bTB affected herds that fail to test on time receive reduced compensation for bTB reactors by tightening the single farm payment cross-compliance rules for bTB; maximising existing levers to encourage timely testing is more effective than penalising those that have already increased the risk of spreading bTB through late testing.

Resources will be focused on areas where non-compliance could be most damaging. Where significant, damaging and deliberate breaches of bTB controls are identified the

Government will encourage and support robust enforcement action by local authorities. To that end it is considering trialling, in 2013/14, a new approach: a dedicated bTB enforcement team with knowledge and experience of bTB controls will be established by a group of Local Authorities in the West Midlands to identify and deal with non-compliance.

Tackling TB in non-bovine species

Many species of non-bovine farmed (e.g. South American Camelids (SAC), captive deer, goats, pigs and sheep) companion (e.g. cats, dogs and ferrets) zoo and wild mammals are susceptible to *M. bovis* infection. Only a relatively small number of animals are identified as infected each year through scanning surveillance (**Annex F)**. Evidence suggests that with the exception of the badger, these species are generally 'spillover' hosts and appear to pose a very small risk of spreading *M. bovis* to cattle and badgers.

All confirmed cases in SAC are investigated by AHVLA to assess epidemiological links and disease links to cattle or other SAC premises. The evidence from this work suggests that they often act as sentinel species to local cattle or badger infection; there are no known cases where a cattle bTB breakdown has been caused directly by transmission from SACs.

Wild mammals other than badgers can act as maintenance hosts for *M. bovis* and vectors of the infection for cattle, as illustrated by the experiences of New Zealand (brush-tailed possum) Australia (Asiatic water buffalo) Michigan (white-tailed deer) South Africa (Cape buffalo) the Central and Southern Iberian Peninsula (wild boar and red deer) and some departments of France (wild boar and red deer). However, the existing evidence from wildlife surveys and quantitative risk models carried out by the Food and Environment Research Agency (Fera) in GB indicates that in this country the badger remains the principal and possibly the only wildlife maintenance host of *M. bovis*. Whilst *M. bovis* infection has been found in other wild mammals in England (notably deer and more rarely wild boar, fox and some rodents) the data on the prevalence of infection, pathology, abundance and ecology suggest that fallow deer and possibly muntjac and red deer are the only other wild mammals that could act as potential sources of *M. bovis* for cattle in the South West of England and Wales. Even in these deer species the effect is localised and the risk of transmission to cattle much lower than that posed by badgers.[25] [26] [27]

The Government's response to *M. bovis* infection in non-bovine species will be evidence-driven and proportionate to the risk, in order to target efforts in areas where risk

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[25] Delahay *et al.* (2002) The status of *Mycobacterium bovis* infection in the UK wild mammals: a review. The Veterinary Journal, 164, 90-105

[26] Delahay *et al.* (2007) Bovine tuberculosis infection in wild mammals in the South West region of England: a survey of prevalence and semi quantitative assessment of the relative risk to cattle. The Veterinary Journal, 173, 287-301

[27] Ward *et al.* (2009) Estimating the risk of cattle exposure to tuberculosis posed by wild deer relative to badgers in England and Wales. Journal of Wildlife Disease, Vol. 45 No. 4,1104-20

management will make a real impact on bTB. Additional measures for badgers are discussed elsewhere. Any additional measures proposed for other non-bovine species are explained below:

- South American Camelids:

There is ample empirical evidence from Great Britain and other countries that the tuberculin skin test has limited sensitivity in SACs. As a result of research undertaken for the SAC sector, the Government intends to introduce mandatory single intradermal tuberculin testing supplemented by a combination of two antibody tests (in parallel interpretation) as a condition for lifting movement restrictions from all SAC herds with confirmed *M. bovis* infection. The Government plans to work with the sector to encourage voluntary pre/post movement testing of animals and routine voluntary TB surveillance of camelid herds using skin and blood tests.

There are no compulsory registration and identification requirements for SACs. As SACs are considered spillover hosts for *M. bovis*, the Government's position remains that these arrangements are proportionate to the risk. There are therefore no plans to introduce compulsory identification and registration requirements for the control of TB in SACs in the short term. In the longer term, however, it is possible that a new EU Animal Health Law may include a requirement for Member States to regulate the registration and identification of SACs. The Government will review the case for including SAC within such a requirement in the context of negotiations on the European Commission's Animal Health Law proposal published in 2013.

- Other farmed mammals (e.g. captive deer, goats, pigs and sheep):

M. bovis infection in other farmed mammals is a relatively rare occurrence and improved slaughterhouse surveillance introduced in 2011 has helped identify new TB outbreaks, which will continue to be handled on a case by case basis using the tuberculin skin test as required. All confirmed holdings will carry on being placed under movement restrictions until testing or slaughter surveillance has demonstrated absence of infection. Contiguous or radial surveillance around these cases will continue. The Government will also continue to work with the various sectors to raise awareness among farmers of the risks of *M. bovis* infections in non-bovine species and the measures that can be taken to reduce these risks.

- Companion and zoo mammals

M. bovis infection in companion and zoo mammals is a relatively rare occurrence and AHVLA and Public Health England will continue to monitor the results of scanning surveillance and work with the sectors to raise awareness of the risks and of the measures that can be taken to reduce these risks. AHVLA will continue carrying out epidemiological investigations into all companion animal cases to assess any connection with local cattle epidemics. Zoos and animal collections with confirmed incidence will continue to be placed under movement restrictions until considered free of disease.

- Wild mammals (other than badgers)

Wild deer surveillance is carried out by private stalkers who are aware of the need to submit suspicious lesions for bacteriological examination. Where there is a suspicion of deer-related infection in cattle, this surveillance can be intensified and additional radial surveillance of cattle in an area can be initiated by AHVLA when considered appropriate. AHVLA will continue to monitor the results of scanning surveillance in wild mammals.

Low risk area (LRA) strategy

Epidemiological Rationale

The rationale for the LRA strategy is based on the following evidence and assumptions:

- The area has a low bTB incidence. Where bTB does occur, it tends to result from infected cattle that have been brought in from other parts of the UK. An analysis of the prevalence of OTFW herds over the past six years (up to 2012) demonstrated that, if only the 'indigenous' breakdowns of bTB are included in the calculation, the crude annual herd prevalence for the area remained below or equal to 0.1% throughout the period. The proportion of OTF herds remained above 99.9% throughout the period. These figures demonstrate that the area has great potential to gain OTF status as defined in Council Directive 64/432/EEC. See **Item 1** in **Annex G.**

- There is evidence to support the non-endemic nature of bTB in the LRA:

    - The analysis of the genotypes of the mycobacteria involved in herd breakdowns in England carried out on a continuous basis since 1996 by AHVLA, shows that there are no established areas of specific genotypes of *M. bovis* isolated from cattle within the LRA or near it (see map in **Item 2** within **Annex G**);

    - there is little evidence of local spread between cattle herds (this analysis continues and is strengthened by the radial surveillance measures implemented in the LRA from 2013);

    - recurrence figures are low and associated with re-introduction of disease by stock brought in from the endemic area (a total of four recurrent breakdowns, within a three year retrospective window, in 2009-2011; three of these were attributable to a new genotype introduced by new stock purchased from the endemic area; one had an unknown origin);

    - breakdown duration is shorter than in the endemic areas (14% of LRA breakdowns ending in 2011 lasted more than 240 days; the same figure for GB was 33% and for Wales 53%; see **Item 3** in **Annex G**); and

    - whilst previous analysis has found badgers infected with *M. bovis* in the past, there is currently no recognised badger reservoir of *M. bovis* anywhere in the area in spite of AHVLA carrying out special surveillance measures, whenever unexplained bTB incidence in the LRA is detected.

- With the non-endemic nature of the disease in the LRA, it is considered important to maintain the status quo, seek further and sustained reduction in breakdown incidence and to seek OTF status for the whole or parts of the area as soon as this can be justified within the current EU legislation. The target in the Strategy is to achieve OTF status progressively starting in 2018. This would allow the LRA to be better protected from disease occurrence, to align its cattle movements and marketing with other OTF regions of the UK and to reduce the surveillance burden on cattle keepers and Government. The resultant resource or financial savings could then be directed to achieving OTF status for other areas.

- The creation of the uniform four-yearly testing area in 2013 removed pockets of more frequently tested areas. Farmers may not therefore be aware of disease levels occurring in this area and we need to guard against a perception that there is no disease threat in this area. Low risk does not mean no risk and the impact of an increase in breakdowns could lead to whole counties being placed on more frequent testing.

Objectives

- To maintain or further reduce the very low incidence of sporadic OTF Withdrawn (OTFW) breakdowns in the counties of the North and East of England (LRA) and deal quickly and effectively with any incursions of disease in these areas, through the application of proactive, risk-based surveillance and breakdown management;

- To expand the current OTF region of the UK by moving towards similar OTF status recognition for those counties (or groups of counties) in the North and East of England that have maintained over a six-year period a very low incidence of ‘indigenous’ (not clearly introduced) OTFW bTB breakdowns, which is below the threshold set out in Council Directive 64/432/EEC (0.1% annual herd incidence); and

- To continue to protect the LRA of England, by introducing additional measures to halt the spatial spread of the disease (see below) and by introducing risk based cattle trading strategies.

Options

A detailed explanation of the options which could be deployed in addition to the current measures is set out in **Annex H**. The preferred “package” of options is listed below.

- Voluntary risk-based trading
- Link top-up compensation to biosecurity, which includes for example risk-based trading
- Stricter biosecurity conditions for AFUs that introduce large numbers of cattle from the HRA
- Establish voluntary local eradication boards to coordinate progress towards OTF status
- Compulsory post-movement testing of cattle moved from the HRA (except to slaughter)
- Reduce exemptions to pre-movement testing from higher risk herds
- Additional surveillance testing for herds regularly importing stock from the HRA

- Enhanced slaughterhouse surveillance by monitoring slaughterhouse performance
- Treat all OTFS2 breakdowns as OTFW in terms of breakdown management

Edge area strategy

Epidemiological Rationale

The rationale for the Edge area strategy is based on the following evidence and assumptions:

- There are advancing disease fronts where bTB is spreading spatially across the entire annually tested area of England, including within the HRA. The Edge Area strategy will focus on those disease fronts that face the non-endemic areas of England. The disease fronts, or areas where geographic spread of bTB has occurred, threaten areas of high cattle density, such as in north Cheshire, Derbyshire and South Yorkshire. It makes good disease control sense and is likely to be cost effective to apply additional disease control measures and increase farmer awareness of the disease spread risk in the Edge Area in order to:
    - identify where disease is emerging and publicise this information locally;
    - take effective measures to stamp out the disease when found; and
    - prevent the disease from re-emerging by addressing the causes of breakdowns.
- The Edge Area strategy will be applied to areas where the infection is potentially spreading geographically and to areas that are at short term risk from such spread.
- It is important to define the Edge Area where the control measures are applied in order to deploy the measures and to measure their success in halting the spread.
- The outer boundary of the Edge Area is a county boundary for administrative and EU legal reasons. The inner boundary of the Edge Area is set based on previous research work, surveillance data and knowledge of the local situation provided by the AHVLA staff working within the Edge Area. This boundary will be subject to change, reflecting the changing disease situation in the area. While there are local differences in the disease occurrence in the Edge Area, it differs from the LRA and the HRA in disease prevalence. In the past six years there has been an increasing number of OTFW breakdowns in the Edge Area and the crude prevalence of herd breakdowns is just over 1% (see further details in **Item 4** in **Annex G**).
- As the rate of disease movement is not uniform across the Edge Area and the areas affected differ in their characteristics, a successful strategy to target disease spread needs to be tailored to the local conditions. This flexibility can be achieved by using a mixture of compulsory and discretionary control measures which can be applied with local evidence-based veterinary discretion.

Objectives

The **short to medium term** objectives for the edge area are to:

- stop the geographic spread of the HRA; and
- begin to reduce the incidence rate within the Edge Area.

The **longer term** objectives are to:

- reverse the spread of disease; and
- reduce the incidence rate of the Edge Area, working towards an OTF status for the counties involved.

Options

A detailed explanation of the options which could be deployed in addition to the current measures is set out in **Annex H**. The preferred “package” of options is listed below.

- Voluntary risk-based trading
- Link top-up compensation to biosecurity, which includes for example risk-based trading
- AHVLA support for local farmer advice meetings; Defra-funded advice and support events to increase awareness and highlight how bTB risks can be mitigated
- Deploy enhanced epidemiological investigations for bTB breakdowns; AHVLA data monitoring and analysis; and AHVLA publication of quarterly/annual reports of local situation
- Establish voluntary local eradication boards to coordinate progress towards OTF status
- Encouragement for local badger vaccination initiatives; e.g. prioritise the deployment of the Badger Vaccination Fund
- Targeted, risk-based surveillance for *M. bovis* in badgers
- Enhanced slaughterhouse surveillance by monitoring slaughterhouse performance
- Additional surveillance in a 3km radius around OTFW breakdowns, with 6 month follow-up testing of clear herds
- Mandatory interferon gamma assay parallel testing in new OTFW breakdowns and discretionary interferon gamma assay testing in OTFS breakdowns
- Check testing at severe interpretation of OTFS breakdowns six and 12 months after restrictions are lifted
- Remove CTS links between holdings in the Edge Area and holdings in the High Risk Area

High risk area (HRA) strategy

Epidemiological Rationale

The rationale for the HRA strategy is based on the following evidence and assumptions:

- The South West and West Midlands have been recognised as a HRA for bTB. A separate and epidemiologically distinct HRA is located in East Sussex. There is evidence to indicate that bTB is endemic and that the badger plays a key role in bTB epidemiology in these areas;

- Due to the limitations of any single disease control measure, a multiple approach to disease control in both the major hosts of bTB infection in the area, the cattle and the badger, is required;

- The epidemic in the HRA can be defined by home ranges of different genotypes of *M. bovis*, suggesting a pattern of clusters that tend to expand and overlap;

- Recurrence of herd breakdowns is another key epidemiological feature of the epidemic in the HRA. In England and Wales, herds with a 36-month history of breakdowns were 6.3-8.5 times more likely to have a breakdown in 2011 than herds without such a history. Around 56% of herds with OTFW breakdowns in 2011 had a history of a breakdown in the previous 36 months[28];

- There is evidence to suggest that a substantial proportion of herds have residual infection left in the herd at the end of a breakdown. Recently published data indicate that, in the worst-case scenario, up to 21% of cattle herds may be harbouring at least one infected animal when movement restrictions are lifted[29]. Furthermore, depending on the modelling assumptions, the researchers estimated that 50% (33–67, 95% CI) or 24% (11–42, 95% CI) of recurrent bTB breakdowns could be attributed to infection missed by the short-interval skin testing regime. This is likely to play a substantial role in the epidemiology of bTB in the HRA, contributing to the high recurrence rate. This suggests improved breakdown management will be important for disease eradication;

- Whilst the contribution of cattle movements to the epidemiology of bTB in the HRA is not quantified in the same manner as in the LRA, it must be assumed that it contributes to disease spread in the HRA as well. Most (over 90%) movements of cattle from holdings in the HRA to live on other holdings are within the HRA. Thus there is a need to apply risk based trading practices in the HRA;

- A small proportion of often prolonged breakdowns with high numbers of reactors are responsible for a disproportionate share of breakdown costs in the HRA. Evidence suggests that, in any one year, 40% of breakdown costs arise in 10% of breakdowns;

- In spite of the relatively high county level herd prevalence across the HRA, there is a marked variation in this prevalence (0.7-15.7%; see county map of proportion of herds affected with OTFW breakdowns in 2011 in **Item 5** of **Annex G**), and a large proportion of cattle herds in the HRA have not, or not for a number of years, experienced a breakdown (40% of all herds alive in the HRA in the past 10 years have not had breakdown in those 10 years). We do not fully understand the reasons for this; and

[28] AHVLA (2013) Bovine tuberculosis, infection status of cattle in GB, Annual Surveillance Report for the period of Jan 2011 to Dec 2011 http://www.defra.gov.uk/ahvla-en/files/pub-survreport-tb11.pdf

[29] Conlan *et al.* (2013) Estimating the Hidden Burden of bovine tuberculosis in Great Britain. PLoS Comput Biol 8(10): e1002730. doi:10.1371/journal.pcbi.1002730.

- As OTF status in the HRA will take decades to achieve, it is important to ensure that the epidemic is closely monitored, the approach to eradication is flexible and short and medium term targets are in place. It is also important that a flexible and adaptive approach to the management of the strategy is adopted.

Objectives

The **short term objectives** for the HRA are to:

- maintain a stable incidence rate within this area; and
- establish an improved understanding of the epidemiology of bTB in the area in order to introduce a more tailored approach to control measures.

The **medium term** objectives for the HRA are to:

- turn the current trend of increasing herd incidence into a decline by addressing the wildlife reservoir, strengthening and targeting cattle control measures, introducing vaccination of both cattle and badgers and moving towards greater stakeholder engagement on all control fronts; and
- introduce targeted and localised strategies with clear prevalence targets.

In the **longer term**, the objectives are to:

- achieve a continuous and sustained reduction in both herd and animal incidence of bTB in all areas of the HRA, and
- ultimately, to achieve OTF status.

Options

A detailed explanation of the options which could be deployed in addition to the current measures is set out in **Annex H**. The preferred “package” of options is listed below.

- Voluntary risk-based trading
- Link top-up compensation to biosecurity, which includes for example risk-based trading
- Enable cattle keepers to deal with identified bio-security weaknesses
- Wider roll out of badger culling subject to successful pilot culls
- Enhanced use of depopulation and controlled restocking of herds with on-going and recurring breakdowns
- Improved epidemiological investigations to establish approaches that address local and herd level risk factors more appropriately
- Local eradication strategies
- Improved breakdown management measures to identify and address the most likely causes of recurrent or persistent breakdowns
- More sensitive breakdown control regimes in areas where badger infection is controlled; e.g. introduce parallel interferon gamma assay in all OTFW breakdowns
- Extend time between short interval tests and/or do not allow the short interval test to be used as a pre-movement test

- Treat all OTFS2 breakdowns as OTFW in terms of breakdown management
- Deploy cattle vaccination as soon as vaccine available
- Deploy oral badger vaccination as soon as vaccine available

Developing new tools

Introduction

This section outlines the research programme and new tools under development, with a view to deployment as part of the ongoing implementation of the Strategy. It also explains why the Government is not developing therapeutics for treating bTB.

Defra's Evidence and Investment Strategy

Defra's Evidence and Investment Strategy[30] summarises the work that it is doing to develop research programmes to support the development of policy. Defra's Evidence Plans provide a clear reasoning as to why Defra invests in evidence and how it makes best use of all available evidence.

The bTB Research Programme

The Government has spent a significant amount (over £155 million since 1991/92) on an ongoing and wide-ranging bTB research programme. The content and direction of the research programme is described in further detail in the Bovine Tuberculosis Evidence Plan 2013/14 – 2017/18.[31] Further information is available in **Annex I**. The portfolio comprises projects to increase understanding of the disease epidemic and to support the development of new tools such as vaccination and diagnostics that can be used to tackle the disease. Evidence needs to be multidisciplinary to provide a comprehensive understanding of the disease epidemic. The research programme will continue to bring together epidemiology, veterinary science, modelling, statistics and the social sciences to generate integrated and innovative approaches to tackling the disease.

Developing new diagnostics tests for surveillance

(i) Tests to detect bTB in cattle

- Tuberculin Skin Test

[30] Defra's Evidence and Investment Strategy is available at https://www.gov.uk/government/publications/defra-s-evidence-investment-strategy-2010-to-2013-and-beyond-2011-update

[31] The Bovine Tuberculosis Evidence Plan 2013/14 – 2017/18 is available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181866/pb13909-evidenceplan-bovine-tuberculosis.pdf.pdf

Under Council Directive 64/432/EEC, the cervical (i.e. applied to the neck) tuberculin skin test is the only official EU test for bTB in live cattle. If performed correctly it remains the most practical and cost-effective tool for detecting bTB. However, no diagnostic test for bTB is perfect and the tuberculin skin test is no exception.

For the routine programme of surveillance testing of cattle herds, we have used the **comparative tuberculin skin test** (the single intradermal comparative cervical test (SICCT)) which measures the animal's immune reaction to injections of both avian and bovine tuberculin. At standard interpretation, fewer than 1 in 1,000 bTB-free cattle give a false positive result (99.9% specific) but the test misses 1 in 5 bTB-infected cattle (80% sensitive). The sensitivity of the comparative tuberculin skin test increases when it is deployed as a herd test, especially as the number of infected animals in the herd increases. Using a **severe interpretation** of the comparative tuberculin skin test marginally reduces the likelihood of false negatives (i.e. increases the sensitivity to 85%) whilst slightly increasing the likelihood of false positives (i.e. decreases the specificity).

A further option is to use the **bovine tuberculin skin test** (the single intradermal cervical test (SICT)) which measures the animal's immune reaction to injections of bovine tuberculin only. The bovine tuberculin skin test increases the likelihood of detecting bTB-infected cattle and the Government has therefore taken the decision to use it for pre-export testing to safeguard trade. However cattle are exposed to a wide range of (non-*M. bovis*) environmental mycobacteria which can potentially interfere with the assessment of reactions to the bovine tuberculin skin test so use of the bovine tuberculin skin test for routine or whole herd testing would be at the expense of a high proportion of false positives. For example, a retrospective analysis carried out by AHVLA, of 1 million cattle tested in 2005 concluded that only one in every twenty-one additional cattle which would have been removed by applying the bovine tuberculin skin test, would have progressed to develop detectable bTB in the following four years; this would have resulted in the slaughter of 24,100 cattle in addition to the 30,000 cattle slaughtered for bTB control in 2005. While some countries (e.g. New Zealand) apply the bovine tuberculin skin test in the caudal fold of the tail (rather than in the neck) which allows for a quicker and safer application of tuberculin, this technique is not permitted for trade purposes under EU law.

- **Interferon-Gamma (IFNg) Assay**

Council Directive 64/432/EEC also allows the slightly more sensitive interferon-gamma assay (which is a blood test) to be used in parallel with the tuberculin skin test. Since 2002 the Government has applied the interferon-gamma assay (which also uses tuberculin) in bTB-infected herds in low risk areas to detect and remove additional infected cattle. The Government is considering the possibility of widening its use.

A European Food Safety Authority (EFSA) scientific opinion[32] on the use of the interferon-gamma assay for the diagnosis of bTB published in 2012 concluded that the tuberculin-based interferon-gamma assay could be included among the official tests, but protocols for use should first be harmonised across the EU. This opinion may result in EU negotiations on the future approval of the tuberculin-based-interferon-gamma assay as another official test for bTB in live cattle although no changes are envisaged before 2017.

- **Other Tests**

In the opinion cited above, EFSA advised that other tests reviewed (e.g. antibody detection tests) should not yet be considered for use as official tests for the purpose of granting official bTB-free herd status.

Given the limitations of current cattle diagnostic tests and the need to develop improved tests, the Government will consider funding research when potentially useful new methods become available. As new diagnostic tests become available, the Government will make an assessment of their costs and benefits before deciding whether or not to deploy them.

(ii) Tests to detect *M. bovis* infected badgers

Ongoing research aims to develop additional diagnostic tests for use in potential surveillance programmes. This includes tests to detect infection either in individual infected badgers or areas containing infected badgers. These tests have many potential applications including: supporting a selective cull strategy; measuring TB prevalence in badgers to support surveillance scanning or to monitor the effect of interventions such as vaccination; and increasing our understanding of the epidemiology of the disease and the relative importance of different routes of transmission.

- Detection of infected, individual badgers can be done by post mortem examination of dead badgers (identification of lesions and/or culture of *M. bovis* from lesions or of certain predilection site organs). These techniques are highly developed and moderate to high sensitivity and specificity of testing can be achieved. However, healthy badgers may need to be killed for this methodology to be used for surveillance and representative meaningful sampling is not straight forward. In live badgers, testing for an immune response associated with exposure to *M. bovis*, such as the BrockTB StatPak[33] or interferon gamma assay testing can be carried out. The former test could be carried out in field conditions but has a relatively low sensitivity, meaning it would not pick out many of the infected individuals. The latter test has moderate to high sensitivity but requires laboratory analysis. Both these immunological tests require blood sampling of live, captured badgers which can currently only be done under sedation by trained and licensed staff. Defra is funding a research project which aims

[32]EFSA Panel on Animal Health and Welfare (AHAW); Scientific Opinion on the use of a gamma interferon test for the diagnosis of bovine tuberculosis. EFSA Journal 2012;10 (12):2975 [63 pp.] doi:10.2903/j.efsa.2012.2975 http://www.efsa.europa.eu/en/efsajournal/doc/2975.pdf

[33] Commercial name for *M. bovis* serology test for badgers

to develop methods of taking clinical samples such as blood and urine from badgers without the need for anaesthetic. This would simplify the sampling of trapped badgers and could be used in conjunction with new serological diagnostic[34] methods and methods for testing urine samples that are being developed. In the Republic of Ireland, polymerase chain reaction (PCR) methodology is currently tested to assess its sensitivity in individual badgers by sampling culled badger faeces.

- Efforts to develop a suitable tool for testing badger setts have concentrated on developing tests which can detect *M. bovis* in environmental samples taken in the vicinity of setts, including from latrines. The analysis and interpretation of environmental sampling is challenging. Infected badgers shed *M. bovis* intermittently. The presence of bacteria in latrines, soil or air will depend on whether infected badgers have been shedding bacteria in the sample type collected, in the location being sampled from, and in the sample that is taken. The methods being assessed include PCR and immuno-magnetic separation (IMS)[35] coupled with a lateral flow device. Defra has been funding the development of a PCR-based test to detect *M. bovis* in environmental samples at Warwick University since 2007. While the test performs well at identifying spiked samples in the laboratory and is reproducible, so far it has been less sensitive at detecting known infected social groups from faecal samples collected in the field. Warwick is currently leading on Defra-funded research to optimise the sampling regime with the aim of improving the performance of the test in the field. The IMS technique has the potential to increase the sensitivity of environmental sampling strategies. Defra is funding a project at Queens University, Belfast to develop this method.

Developing deployable bTB vaccines

We have a licensed injectable vaccine for badgers. There are no bTB vaccines licensed for use in other animals. Vaccination of cattle to control bTB is prohibited under EU law (Council Directive 78/52/EEC) as it is not compatible with the provisions for testing and herd qualification for OTF status (Council Directive 64/432/EEC).

(i) Cattle Vaccination

A cattle bTB vaccine is likely to be a valuable additional tool (see **Annex B**) in the fight to eradicate bTB but vaccination of cattle with a vaccine such as BCG (Bacillus Calmette-Guerin) will reduce but never eradicate bTB from the national herd if there remains a constant reservoir of *M. bovis* in badgers.

The best candidate vaccine to protect against TB in cattle is based on BCG. Like vaccines for other diseases, BCG does not offer complete protection from infection with *M. bovis.*

[34] "Serological diagnostics" is testing for antibodies in serum (serum is a component of blood)

[35] Using antibody-coated magnetic particles to separate microbe cells from the rest of the sample in order to concentrate them for better detection

Research to date suggests that the proportion of cattle protected or partially protected may be in the order of 50-70% although further research is needed to verify this. Vaccination of cattle with BCG can cause them to test positive to the tuberculin skin test, the backbone of our bTB control policy. This is the main reason for the EU ban on bTB vaccination in cattle. EU law meets OIE standards for international trade. The OIE Terrestrial Manual 2012[36] advises that cattle vaccination should not be used in countries where control or trade measures based on tuberculin skin tests are in operation.

To use such a vaccine, a diagnostic test is required that can differentiate infected from vaccinated animals (DIVA). Development of this DIVA test forms part of the ongoing Defra-funded research programme and a candidate diagnostic test has been developed. This is a modified version of the currently used interferon-gamma test.

In January 2013 the European Commission set out a tentative timeline[37] of the steps to be able eventually to deploy a cattle BCG vaccine and associated DIVA. These steps include a field trial of the vaccine and DIVA test under EU conditions. Work to define the objectives and consider the design of such a trial is in progress. Cattle vaccination could only be deployed if it is demonstrably safe.

An additional step in this process is licensing of the vaccine. In January 2012 AHVLA submitted an application for a provisional Marketing Authorisation (MA) for a BCG-based cattle TB vaccine (CattleBCG) to the Veterinary Medicines Directorate (VMD) for assessment. During the course of their assessment VMD identified data shortfalls in the application which are largely concerned with the lack of opportunity (to date) to conduct field trials in the UK. These data gaps must be filled before further consideration could be given to the application.

Subject to successful trials, the European Commission has estimated that it is unlikely that the EU ban on intra-EU trade in bTB-vaccinated cattle would be lifted before 2023; the European Commission's tentative timeline includes the need to amend OIE animal health standards for international trade.

In the intervening period the European Commission has indicated that it may be possible to allow the vaccine to be used under controlled conditions in the UK but that live cattle would not be able to be traded within the EU until the wider ban was lifted.

Research to develop other cattle vaccines (i.e. that are better than BCG or that do not sensitise cattle to the tuberculin skin test) to improve the sensitivity of the DIVA test, and to

[36] Chapter 2.4.7, Bovine tuberculosis (version adopted May 2009) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2012 http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/

[37] Letter from European Commissioner for Health and Consumer Protection to the Secretary of State for Environment, Food and Rural Affairs, 14 January 2013 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/183229/bovinetb-letter-paterson.pdf

develop DIVA tests using alternative methods is ongoing but these are long-term goals and will require scientific breakthroughs to achieve.

(ii) Badger vaccination

The Veterinary Medicines Directorate licensed an injectable BCG-based bTB vaccine for badgers (BadgerBCG) in 2010 and vaccination of badgers is permitted subject to a licence issued by Natural England. Defra is funding research to investigate farmer and veterinary attitudes to injectable badger vaccination, and identify barriers and levers to its potential uptake. There is scope to use data from the Badger Vaccination Deployment Project in England and the Badger Vaccination Project in the Intensive Action Area in Wales[38] to understand better the long-term costs and benefits of deploying injectable badger vaccination.

Further research is underway both to identify an effective and affordable oral badger vaccine which could make the vaccine much simpler to deploy than the currently available injectable vaccine. A lead candidate to take forward to licensing has not yet been identified. Progress is dependent on scientific breakthroughs so we cannot predict when an oral vaccine could be taken forward for licensing and therefore might be available to use in the field.

Research into alternative badger control strategies

In parallel to research to develop diagnostic tests to detect infected badgers and/or their setts, consideration is being given to how such tests might best be used to support the development, delivery and monitoring of bTB badger control strategies, e.g. targeted culling, understanding local epidemiology and monitoring the effectiveness of a vaccination campaign at reducing infection. This work will inform where future research effort should be targeted.

Further research into alternative population control methods (e.g. sett-based culling methods and non-lethal methods) is also under consideration. This includes a potential investigation into the use of anoxic gas or gas-filled foam as a sett-based means of humane culling. Proof-of-principle research into the application of fertility control using an injectable contraceptive is ongoing.

Research into genetic resistance of cattle to bTB

In the UK there is no clear evidence of differences between breeds in terms of susceptibility to bTB. While there is evidence that dairy farms are more likely to experience a breakdown than beef farms, this is not necessarily due to breed differences.

[38] The Welsh Government's Bovine TB Eradication Programme, IAA Badger Vaccination Project Year 1 Report is available at http://wales.gov.uk/docs/drah/publications/130129iaareport2012en.pdf

Pedigree analysis has shown evidence of genetic variation to bTB susceptibility within UK Holstein Friesians. Another study identifying genetic markers linked to susceptibility saw no significant differences in the distribution of these markers across UK breeds. This remains an active area of research, but it is unlikely that genetic selection of cattle on its own will be a major element in the eradication of bTB.

The Government believes that it is for cattle farmers to make business decisions on which bulls they choose to use, taking into account genetic merit for resistance to diseases and other desirable traits which may or may not be correlated with bTB susceptibility.

Why we do not use therapeutics to treat bTB in cattle

Therapeutic treatment of cattle to control bTB is prohibited under EU law as it is not compatible with the provisions for testing and herd qualification for OTF status. There are no drugs licensed in the UK for the treatment of bTB in animals.

To date, antimicrobial therapy of cattle believed to be infected with *M. bovis* has not been a realistic option for the reasons set out below.

- Treatment of TB with antibiotics is not universally successful, even in humans receiving multiple drug therapy for several months.

- *M. bovis* is naturally resistant to one of the first-line drugs used for the treatment of TB in humans. In order to eliminate the risk of antibiotic-resistant strains of *M. bovis* infecting the human population, where multiple-drug resistant strains of *M. tuberculosis* are already a significant public health problem, it is critical to ensure that such strains of *M. bovis* are not artificially selected in animal populations.

- Most drugs used to treat TB in humans are inherently toxic and are poorly tolerated by animals.

- Therapeutic treatment of cattle for bTB would interfere with the detection of infected animals, by suppressing the immunological reactions that are measured by the tuberculin skin and interferon-gamma tests.

- During treatment it would be necessary to consider infected cattle contagious for the duration of treatment and to observe milk and meat withdrawal times during and following treatment.

Governance, Delivery and Funding

The Government will develop proposals for governance, delivery and funding of the Strategy in partnership with stakeholders. It will consult further on detailed proposals and carry out impact assessments as appropriate. Any changes to governance or delivery would need to comply with EU law[39] and take account of wider impacts on the Government's capability to respond to animal disease outbreaks. Any changes to funding would need to comply with HM Treasury rules on managing public money[40].

Governance

Defra Ministers have policy responsibility for bTB policy in England. In 2011, the Government established the Animal Health and Welfare Board for England (AHWBE) in response to the recommendations of the England Advisory Group on Responsibility and Cost Sharing[41]. The AHWBE is the principal source of Departmental advice to Defra Ministers on all strategic health and welfare matters relating to all kept animals in England[42]. It comprises appointed external members with the confidence and support of major stakeholder interests, and senior government officials. The AHWBE is an innovative approach to bringing those affected by government decisions into the heart of the process in order to create a more direct link between those making Defra policy and those experiencing the delivery of that policy. Establishing the AHWBE marked an important step in sharing responsibility for animal health and welfare with animal keepers and other interested parties. It aims to build trust between government and animal keepers and strengthen arrangements for working together to develop a true partnership. Agreement on how best to achieve practices that collectively and cost effectively reduce disease risk leads to greater adherence to responsible practices and then to reduced animal disease risk and improved standards of health and welfare. This benefits government, the public and animal keepers. The Bovine Tuberculosis Eradication Advisory Group (TBEAG) is an AHWBE sub-group, which brings together a range of interested parties who share the desire to tackle bTB. This Strategy has been developed in partnership and discussion with TBEAG.

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[39] Regulation (EC) No.882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. On 6 May 2013, the European Commission adopted a proposal to amend this legislation. The package is subject to consideration by the European Parliament and the Council with possible entry into force in 2016, followed by a proposed three-year transition period. http://europa.eu/rapid/press-release_IP-13-400_en.htm

[40] Managing Public Money, HMT http://www.hm-treasury.gov.uk/psr_mpm_index.htm

[41] Responsibility and Cost Sharing for Animal Health and Welfare – Final report (PB13450) http://www.defra.gov.uk/publications/2011/04/08/pb13450-rcsag-report/

[42] Animal Health and Welfare Board for England's terms of reference http://www.defra.gov.uk/ahwbe/about/terms-of-reference/

Developing a new governance model

The Government will develop proposals for an enhanced partnership approach to the governance of the Strategy. The New Zealand experience shows that an alternative governance model can really enhance bTB control. There, control of bTB has been fully devolved to an industry-led body[43]. The bTB control budget has been co-financed by industry and government with funding from central and local government, from beef and dairy sector levies, and from dairy and deer sector grants[44].

Delivery

Delivery of bTB controls rests with government agencies such as AHVLA, local authorities and the private sector e.g. veterinary and farming businesses. Delivery approaches include services funded and provided by Government, services funded by Government and procured from the private sector, and services funded and provided by the private sector.

Reviewing delivery

The Government will continue to review delivery to ensure that Government is delivering those services that only it can deliver and to build on the efficiency savings delivered to date whilst ensuring quality. Options may include:

- **Re-tendering salvage contracts to secure a better deal for bTB reactors**. Farmers receive compensation from the Government for compulsorily slaughtered bTB reactors. Bovine TB reactors are sent for slaughter to contracted slaughterhouses in line with food safety rules and Government receives salvage payments which help offset the cost of compensation paid. In 2011/12 Defra paid £31.5 million in compensation and received £10.5 million in salvage. Government will seek to maximise the returns from salvage when new tenders are invited.

- **Introducing more competition for bTB testing, whilst ensuring quality**. The New Zealand experience demonstrates the benefits of effective deployment of bTB testing. The Government recognises the need to modernise its commercial relationship with veterinary businesses and is seeking to introduce more competition for bTB testing, while ensuring quality. As a consequence of previous findings of non-compliance with bTB testing operating protocols and a need for enhanced auditing, the Government will further tighten the audit arrangements and take robust action where there is evidence

[43] On 1 July 2013, the role of management agency for New Zealand's National Bovine Tuberculosis Pest Management Plan transferred from the Animal Health Board to a new limited-liability company, TBfree New Zealand Limited http://www.biosecurity.govt.nz/media/14-06-2013/new-agency-national-tb-management-plan

[44] Further information is available at http://tbfree.org.nz/

of fraud or other non-compliance. It will also drive efficiency savings, for example, by increasing the e-reporting of results of tests carried out by Official Veterinarians (OVs).

- **Exploring alternative delivery approaches**
    - **Enhanced Role for Veterinary Businesses (the 'TB Plus' option)**. The Government will also explore ways in which OVs in veterinary businesses could take on bTB services currently delivered by AHVLA, for example providing local advice, licensing cattle movements or carrying out veterinary risk assessments.
    - **Extending the use of approved lay bTB testers**. Under an exemption from the Veterinary Surgeons Act 1966, the Government may deploy approved lay bTB testers employed by AHVLA and acting under the direction of an authorised veterinary surgeon. Lay bTB testers are successfully deployed in New Zealand and feedback from farmers in England has been positive about their use. The Government will therefore consider the possibility of extending the current exemption to approved lay bTB testers employed by veterinary businesses and acting under the direction of an authorised veterinary surgeon. Wider roll of lay bTB testing out would be subject to having robust training and auditing systems in place and it would release OV resources to provide additional bTB services as outlined above.

Funding

Tackling bTB carries significant costs to farmers and other taxpayers. These costs are not sustainable. At the same time, it is clear that additional investment is required to bring the disease under control and reduce the costs in the longer term. Furthermore, the Government must demonstrate value for money in public funding as well as acting where there are clear advantages and a need for Government intervention to overcoming market failure. **Table 2** provides a contemporary breakdown of state-funded and privately funded areas.

Table 2: Contemporary breakdown of state-funded and privately-funded areas

State-funded areas	Privately-funded areas
• Routine bTB surveillance testing and breakdown testing, mainly delivered by veterinary businesses • Laboratory testing (e.g. bacterial culture and gamma-interferon blood testing) • bTB breakdown investigations • Procuring transport and disposal of TB	• Handling facilities, staff and time away from business for bTB testing • Pre-movement testing and export testing • Consequential losses (e.g. from movement restrictions and compulsorily slaughtered cattle) • Biosecurity measures (e.g. badger proofing

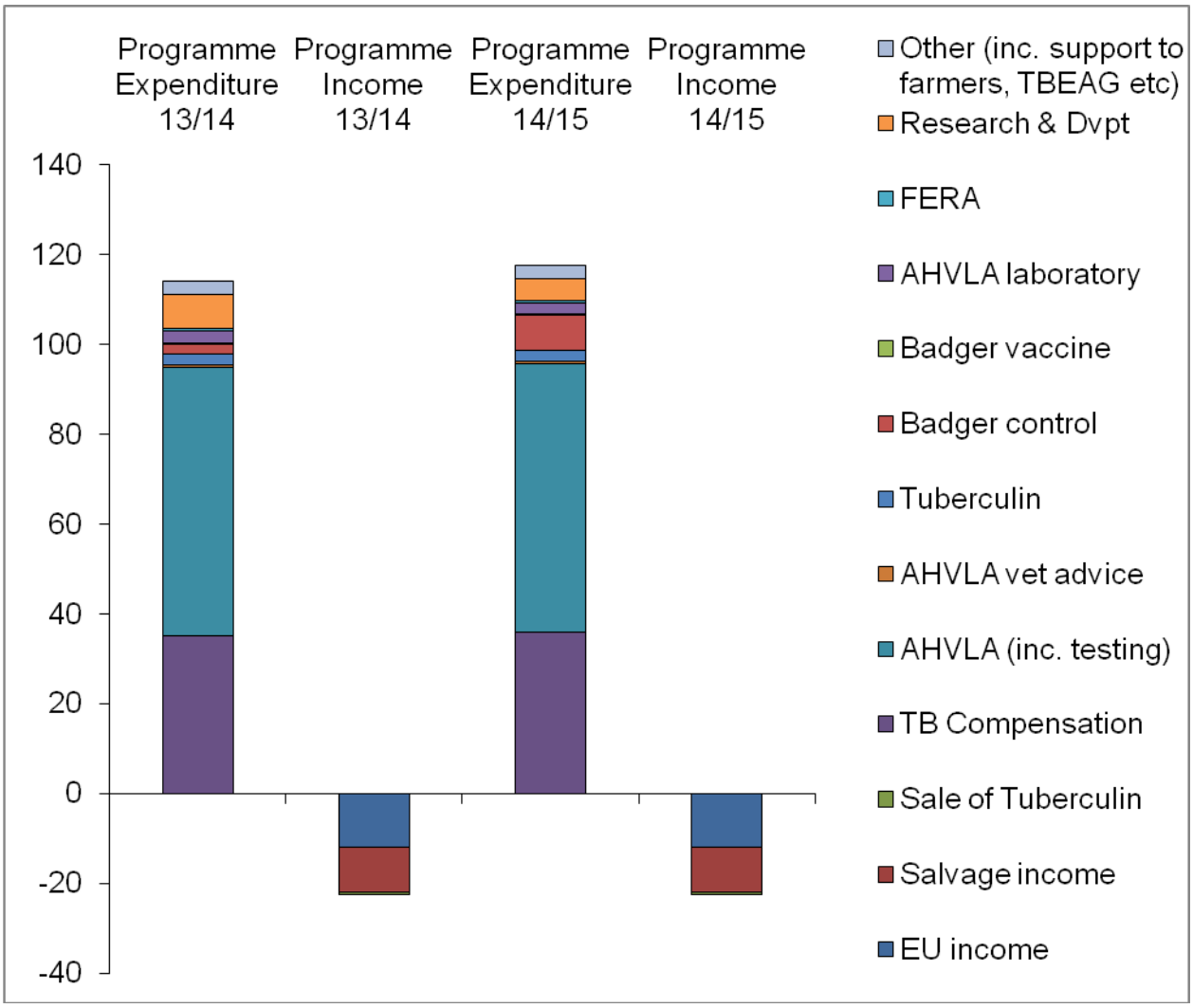
reactors • Compensation for bTB reactors (above the minimum carcase salvage value) • Badger Vaccination Deployment Project and Badger Vaccination Fund • bTB research and development • Advice and guidance • Competent Authority functions (including policing)	or double fencing) • Local badger vaccination deployment • Advice and guidance • Deployment of badger culling licensed by Natural England

For the costs which fall to Government, Defra's animal health and welfare budget, which includes bTB, reduced from £244 million in 2011/12 to £199 million in 2014/15 as a result of the 2010 Spending Review[45]. Defra is forecasting[46] spending £95 million on bTB measures and research in 2014/15, against an allocated budget of £75 million. This takes account of co-financing income (to Defra) of £12 million from the EU's Veterinary Fund (**Figure 9**). The budgetary pressure is expected to increase in future years through a combination of increasing costs and declining budgets; EU financial support at current levels is not guaranteed to continue indefinitely.

[45] The Defra resource budget reduced from 2.6 billion in 2011/12 to 2.2 billion in 2014/15.

[46] This forecast is subject to change and does not include Defra policy development costs.

Figure 9: Defra TB Programme forecast costs (£ million) for 2013/14 and 2014/15[47]



Most of the Government's bTB budget is spent on AHVLA (covering costs of bTB testing and breakdown management, including some £18 million forecast to be paid to OVs in 2013/14) and on reactor compensation. Almost 80% of testing and compensation costs are related to managing bTB breakdowns. The cost of breakdowns is concentrated in a minority of affected herds: about 40% of breakdown costs arise in 10% of breakdown herds. Actions that significantly reduce the likelihood, duration and extent of these breakdowns would have a major effect in reducing the overall cost of bTB management.

Farmers also bear financial costs of bTB both in terms of taking steps to minimise risk and also when a breakdown occurs. These financial costs can be significant to individuals. As an example, **Table 3** sets out high level, indicative average costs of bTB breakdowns and routine bTB testing to farmers and Government. These are simple averages and do not reflect individual circumstances which will vary.

[47] These forecasts are subject to change and do not include Defra policy development costs.

Table 3: Estimated average costs of a bTB breakdown and a routine bTB test

	Average cost to farmer	Average cost to Government
TB breakdown (estimated average of OTFW and OTFS cost)	£12,000	£22,000
Routine TB test (estimate of average cost for 100 animals)	£350	£770

The costs to Government are based on actual costs devolved to England for the year ending 2011/12.

Developing a new funding model

The Government will develop proposals for a new funding model for the Strategy. The experiences of both New Zealand and the Republic of Ireland provide evidence of the success of co-financed bTB control strategies. Irish farmers are responsible for arranging annual herd bTB tests with their veterinary practitioners and for payment of testing fees. They also contribute towards 50% of the cost of the bTB compensation via statutory Bovine Disease Levies collected in respect of each animal slaughtered or exported from the country, and in respect of each unit of milk delivered to creameries.

Funding options for the Strategy may include:

- **Stakeholders paying more for bTB measures**. For example farmers could pay their OV for other types of bTB testing (i.e. not just pre-movement and pre-export testing) and various stakeholders could pay for deployment of cattle and badger vaccination.

- **Government reducing its intervention in the market**. For example Government could increase the uptake of private slaughter of bTB reactors by reducing the differential between statutory compensation and salvage value and guaranteeing compensation for any carcases condemned at slaughter. One of the first actions that New Zealand's Animal Health Board took was to reduce compensation payments.

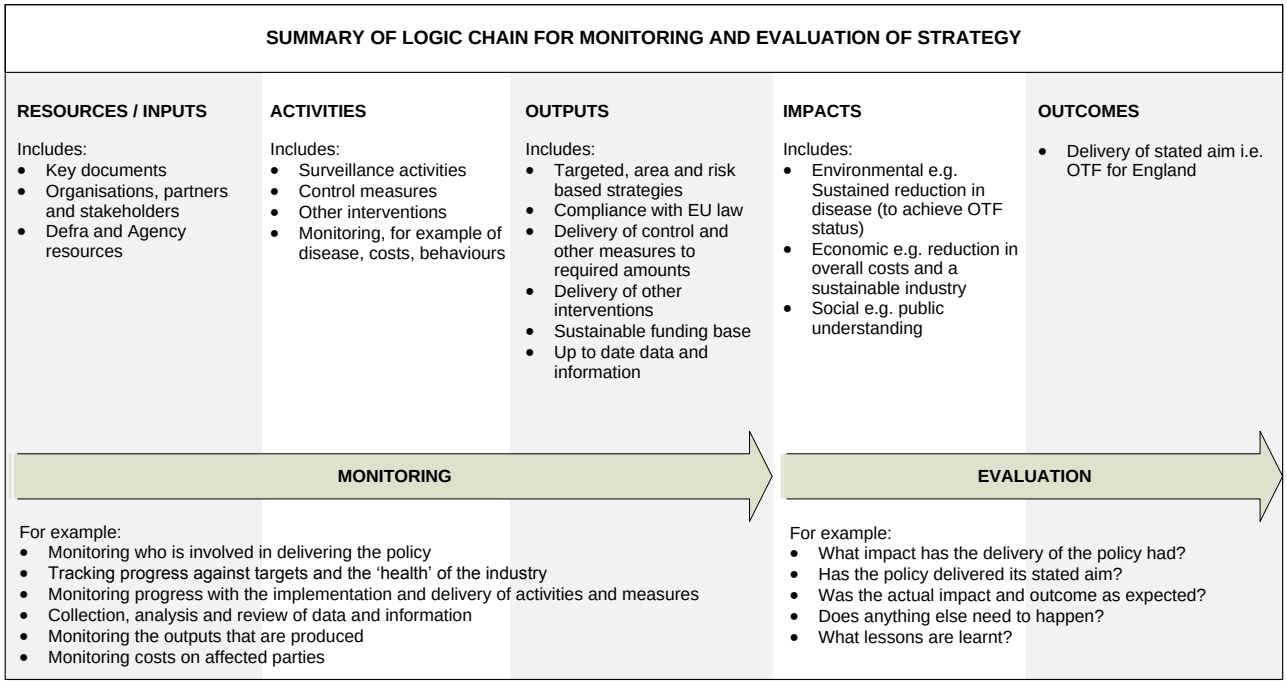
- **Developing insurance options**. Insurance offers the opportunity to reward risk-mitigating practices via differentiated premiums. However, there is a limited commercial insurance market covering bTB. This is partly because a lack of compulsion and partly because statutory compensation impacts on the viability of the market. Government will continue to work with the insurance sector to explore options for deploying insurance against bTB.

- **The establishment of a mutual bTB control fund co-financed by Government**. For example, the food and farming industry could fund cattle controls as the main beneficiary and Government and other stakeholders could fund wildlife controls including vaccination. Other areas such as research could be co-funded. Government would need to explore whether contributions to any such mutual fund should be compulsory or voluntary. Eligibility for a compensation premium could provide an incentive for farmers to contribute to a voluntary fund. Any new compulsory contribution would need to ensure commensurate benefits for those paying.[48]

Monitoring and evaluation of the Strategy

Figure 10 illustrates the monitoring and evaluation that can be applied to various strands of the Strategy. It is a critical part of measuring progress made towards the stated aim (and the various targets, outputs and activities that lead toward it) and allows action to be taken as and when the disease situation changes and alternative approaches become available.

Figure 10 – Logic chain



[48] Long standing statutory levies (e.g. on beef and dairy) are collected annually by the Agriculture and Horticulture Development Board – under the National Environment and Rural Communities Act 2006 – to promote livestock sector competitiveness and sustainability. Compensation during the successful eradication of Aujeszky's disease in the 1980s was funded by a statutory levy on pig farmers collected under the Pig Industry Levy Act 1983. However these are not directly comparable in terms of incidence of costs and benefits, statutory basis or history.

The Government will retain lead responsibility for monitoring progress and evaluating the overall impact and outcome of the Strategy. In particular, focus will be placed on progress and delivery of the specified targets and outputs that work toward the overall aim of OTF. The correct tools must be used to monitor and evaluate the effectiveness of the Strategy, including epidemiological, economic and social analyses. The use of epidemiological expertise is particularly important to better inform ongoing decisions on tackling disease at the national, regional and local level. Local action will be guided by the Strategy and further intelligently tailored to the local situation.

Key tools include:

- Using best available information to review the impact in terms of:
- The health and sustainability of the sector
- Media and social coverage
- Behaviours and attitudes of farmers and the public
- Trade patterns, for example the number of cattle exported
- Monthly laboratory testing result reports
- Genetic typing home range alert system
- Quarterly and annual epidemiological reports from regions
- Monthly publication and analysis of national bTB statistics
- Quarterly publication and analysis of non-bovine TB statistics
- Annual surveillance reporting and associated analysis of outcomes

The impact of activities will be carefully monitored and fully evaluated and the approach and forward use of the tools will be adapted based on experience in the field and as new tools become available.

Glossary

AFU – Approved Finishing Unit, a biosecure unit used to channel cattle from bTB restricted herds to slaughter

AHVLA – Animal Health and Veterinary Laboratories Agency, an executive agency of Defra

AHWBE – Animal Health and Welfare Board for England

BCG – Bacillus Calmette-Guérin, which is used to manufacture tuberculosis vaccines

Biosecurity – security from transmission of infectious diseases

Bovine tuberculosis – an infectious disease in cattle caused by *Mycobacterium bovis*

Breakdown – detection of exposure to *M. bovis* infection in a herd (e.g. detection of a bTB reactor or signs of possible bTB at post mortem). This is followed by breakdown control procedures; the duration of a breakdown depends on the successfulness of the breakdown measures to clear the infection from the herd

bTB – bovine tuberculosis

Defra – Department for Environment, Food and Rural Affairs

Depopulation – slaughtering all the animals in a herd for disease control purposes

DIVA – a test used to **d**ifferentiate **i**nfected from **v**accinated **a**nimals

Edge Area – the edge of the HRA where the disease is not yet considered to be endemic and disease prevalence is lower than in the HRA but there is a great likelihood of further geographical spread of bTB out of the HRA

ECDC – European Centre for Disease Prevention and Control

EFSA – European Food Safety Authority

Endemic – a disease which is typically present in a specific geographical area

Epidemiology – a study of disease in a population

EU – European Union

Fera – Food and Environment Research Agency, an executive agency of Defra. Fera's Wildlife Team transferred to AHVLA in April 2013.

FSA – Food Standards Agency

GB – Great Britain, comprising England, Wales and Scotland

Genotype – a genetically distinct strain of a specimen or species

Herd prevalence – can be expressed in different ways but depicts the proportion of herds that are affected by a disease/condition in a defined area

High Risk Area for bTB– an area defined geographically in which cattle herds have a greater likelihood of experiencing a bTB breakdown. It includes geographical areas in which there is a relatively high herd prevalence of bTB

Home range – the specific geographic area where a specific genotype of *M. bovis* is typically detected

Host – animals which can routinely become infected with *M. bovis* if exposed

HRA – see High Risk Area

Incidence – reflects the number of cases of infection or disease.

Inconclusive reactor – an animal which gives an inconclusive reaction to the tuberculin skin test as defined in Council Directive 64/432/EEC

Index – the first infection in a herd or area.

Interferon Gamma Assay - a rapid (24 hour) whole blood in-vitro assay to detect immune response to *M. bovis* infection for the diagnosis of bTB

IR – see Inconclusive reactor

ISG – Independent Scientific Group, which supervised the Randomised Badger Culling Trial

Test Interval – the period of time between tuberculin tests

Low Risk Area - An area defined geographically in which cattle herds have a lower likelihood of experiencing a bTB breakdown. It includes geographic areas with very low herd prevalence of bTB and where the disease is not believed to be maintained by badgers and is primarily caused by cattle movements

LRA – see Low Risk Area

MAFF – Ministry of Agriculture, Food and Rural Affairs, replaced by Defra in 2001

Mycobacteria – a family of bacteria which includes *Mycobacterium bovis*

***Mycobacterium bovis* (*M. bovis*)** – the bacterium which causes bovine tuberculosis

***Mycobacterium tuberculosis* (*M. tuberculosis*)** – one of the bacteria which causes tuberculosis in humans

Natural England - an executive non-departmental public body responsible to Defra, which administers applications for licences under the Badger Protection Act 1992

OIE – World Organisation for Animal Health

OTF – "Officially Bovine Tuberculosis Free" as defined in Council Directive 64/432/EEC. OTF status may apply to herds, regions or Member States

OTFS – "Officially Bovine Tuberculosis Free" status of herd suspended as defined in Council Directive 64/432/EEC. This status is used for those cattle and herds where the infection is not confirmed by culture of *M. bovis*

OTFS 2 - a small subset of OTFS herds considered at greater epidemiological risk

OTFW– Officially Bovine Tuberculosis Free status of herd withdrawn as defined in Council Directive 64/432/EEC. This status is used for those cattle and herds where the infection is confirmed by culture of *M. bovis* or by finding typical lesions in a carcase of an animal

OV – Official Veterinarian, a private veterinarian permitted to undertake official controls such as tuberculin skin testing

PCR – See Polymerase Chain Reaction

Perturbation - disruption of badger social groups causes 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

Polymerase Chain Reaction - technology to amplify a single of a few copies of a piece of DNA in order to allow easier detection of a particular pathogen by its DNA

Post Movement Test – a tuberculin skin test applied to an animal after it has moved between premises

Pre Movement Test – a tuberculin skin test applied to an animal before it has moved between premises

Prevalence – see Herd Prevalence

R&D – research and development

RBCT – Randomised Badger Culling Trial, a scientific study carried out from 1998-2005 to quantify the impact of culling badgers on TB incidence in cattle

Reactor – an animal which gives a positive reaction to the tuberculin skin test as defined in Council Directive 64/432/EEC

Reservoir Host – animals which can routinely harbour *M. bovis* infection

Routine herd testing – the programme of routine surveillance testing of breeding cattle in herds using the tuberculin skin test in line with Council Directive 64/432/EEC. Routine herd testing is applied to four-yearly tested herds

RTA – road traffic accident

SAC – South American camelids, for example alpacas and llamas

Severe interpretation – a more rigorous interpretation of the tuberculin skin test (than the "standard interpretation") in line with Council Directive 64/432/EEC

Short interval test - the intensive testing of all cattle in breakdown herds using the tuberculin skin test in line with Council Directive 64/432/EEC

Standard interpretation – the routine interpretation of the tuberculin skin test in line with Council Directive 64/432/EEC

SICT – single intradermal cervical test. See tuberculin skin test

SICCT – single intradermal comparative cervical test. See tuberculin skin test

Spillover Host – animals which do not normally become infected with *M. bovis* unless they are exposed to relatively high levels of infection

Surveillance – an effort to detect disease in a population by using diagnostic or clinical methods. For bTB in England, formal surveillance is carried out with frequent whole or routine herd testing, by pre-movement testing of all cattle over 42-days of age leaving premises in the HRA and by inspecting all cattle carcases slaughtered commercially for post mortem signs of bTB

TBEAG – Bovine Tuberculosis Eradication Advisory Group for England, a sub-group of AHWBE

Therapeutics – pharmaceutical agents (drugs) licensed for use in treating human or animal diseases

Tuberculin – mycobacterial proteins used in tests to detect bovine tuberculosis

Tuberculin skin test – measuring an animal's reaction to injections of tuberculin carried out in line with Council Directive 64/432/EEC. The single intradermal cervical test involves a single injection of bovine tuberculin in the neck; the single intradermal cervical comparative test involves single injections of bovine and avian tuberculin in the neck

UK – United Kingdom, comprising Great Britain and Northern Ireland

VMD – Veterinary Medicines Directorate, an agency of Defra

Whole herd testing – the testing of all cattle in herds using the tuberculin skin test in line with Council Directive 64/432/EEC. Whole herd testing is applied routinely to annually tested herds and to breakdown herds

Annexes

ANNEX A – BADGER CONTROLS & ECOLOGY

A chronology of badger controls

1971	***M. bovis* first isolated in badgers** *M. bovis* first isolated in a badger in Gloucestershire.
1973	**The Badgers Act** Made it an offence to take, injure or kill badgers and commit offences of cruelty.
1975-82	**Gassing strategy** By 1975 there were concerns about the lack of controls on who could kill badgers, so MAFF decided that only its own staff, or people under its control, could cull. Gassing using hydrogen cyanide was permitted under The Conservation of Wild Creatures and Wild Plants Act 1975.
1980	**Zuckerman Review** Concluded badgers were probably a significant source of bTB infection and that high density and close proximity of cattle and badgers in parts of South West England made disease spread easy. Because disease seemed to have spread since controls stopped at the start of the review, it advised that control measures start again. As gassing was considered inhumane, cage trapping, followed by shooting, became the culling method.
1982-86	**'Clean-ring' strategy** Zuckerman advised that areas should be cleared of infected badgers and kept clear. Under this strategy, social groups of badgers on and around breakdown farms were identified, trapped and a sample of carcases from these groups were examined. Where infection was found, all badgers in the social group were removed. The 'ring' extended out until groups with uninfected badgers were found. Trapping took place in the cleared area for a further six months to keep the area 'clean'.

1986	**Dunnet Review** Concluded that some form of badger control was unavoidable. Recommended the use of an interim strategy until there was sufficient data from research and badger removal operations for a further substantive review, and development of a reliable live diagnostic test for TB in badgers.
1986-96	**'Interim' strategy** Removal and culling of badgers only from farms where a bTB incident had been confirmed and where, following investigation, it was thought that badgers were the most likely cause of the disease. During the operation of the interim strategy, the annual incidence of bovine TB increased in south west England and occurred in other areas with no recent history of infection, including the West Midlands and south Wales.
1991	**The Badgers (Further Protection) Act** Conferred additional powers on a Court, where a dog had been used in or was present at the commission of certain offences under the Badgers Act 1973.
1992	**The Protection of Badgers Act** Consolidated and built on the 1973 & 1991 Acts. Made it a serious offence to kill, injure or take a badger, or to damage or interfere with a sett unless a licence is obtained from a statutory authority.
1994-96	**Live test strategy** Trial of live badger diagnostic test, stopped due to poor sensitivity of test and problems with trial.
1997	**Krebs Review** Concluded that despite there being "compelling" evidence badgers were involved in transmitting *M. bovis* to cattle, the development of a control policy was made difficult because the effectiveness of badger culling could not be quantified with the data available. Recommended a large-scale field trial be set up to quantify the impact of culling badgers on incidence of TB in cattle, and to determine the effectiveness of strategies to reduce the risk of a TB cattle herd breakdown.

1998-2005	**Randomised Badger Culling Trial (RBCT)** Saw both beneficial and detrimental effects of culling during culling period. Hypothesised that culling disrupts badger behaviour to increase ranging and therefore potential for infectious contact ('perturbation') increasing disease prevalence in badgers and subsequently that in cattle (the 'perturbation effect'). On-going post-trial analysis showed that once culling stopped, the detrimental effects diminished quickly.
2013	**Pilot of Badger Control Policy** Licensed badger culling pilots in Somerset and Gloucestershire to assess the humaneness, effectiveness (in terms of badger removal) and safety of controlled shooting of free-ranging badgers. Licences also permit cage trapping and despatch. Each licence has a four-year term and authorises control operations to be conducted over a continuous six-week period each year. No control operations can take place during specified close seasons.

Changes in the British badger population

A national badger survey[49] commissioned by the Peoples Trust for Endangered Species estimated that the British badger population increased by 77% between 1988 and 1997. Of this, 47% was due to an increase in the size of social groups and 30% was due to the establishment of new social groups. There were regional differences in the amount of change. In order to provide updated estimates of the badger population, Defra is funding a badger survey of England and Wales (Defra Project SE3129). This is complemented by a Defra-funded project to generate estimates of typical badger social group size in different landscapes (Defra Project SE3132). These projects are scheduled for completion in 2013 and 2014 respectively.

Scientific evidence on potential consequences of badger culling on other wildlife populations

Badgers are the UK's largest carnivorous terrestrial mammal and as such are an important component of the ecosystem. Additionally, they occur at relatively high densities in most bTB hotspot areas, hence significant and sustained reduction of their numbers over large areas is likely to have consequences for the ecosystem. An assessment of the consequences of badger removal for the populations of other species was carried out in the context of the Randomised Badger Culling Trial (RBCT)[50]. Badger culling undertaken

[49] Wilson G, *et al*. (1997) Changes in the British badger population, 1988 to 1997. PTES, London. http://www.ptes.org/files/2067_changes_in_the_british_badger_population_1988_to1997_fullsearcable.pdf

[50] Defra Project report ZF0531: The ecological consequences of removing badgers from the ecosystem. http://www.defra.gov.uk/animalh/tb/research/summary/zf0531.htm

at such scales, is likely to result in higher fox densities[51], which raises potential issues relating to the economic costs of predation on livestock and game, and the ecological impact of foxes as predators of birds and mammals. Badger predation limits hedgehog populations and hedgehog numbers may increase as a result of widespread badger culling[52]. The reviewed evidence suggests that the prevalence of birds in the diet of badgers is generally low[53]. However, the impacts of badger removal on the species of ground nesting bird populations studied remain uncertain. It is likely that the ecological consequences of culling badgers will vary depending on the location, effectiveness, scale and duration of culling, and characteristics of the ecosystem.

[51] Trewby, I. D., Wilson, G. J., Delahay, R. J., Walker, N., Young, R., Davison, J., Cheeseman, C. L., Robertson, P.A., Gorman, M. L. & McDonald, R. A. (2008) Experimental Evidence of Competitive Release in Sympatric Carnivores. Biology Letters 4, 170–172.

[52] Trewby, I. D., Young, R., McDonald, R. A., Wilson, G. J., Davison, J., Walker, N., Doncaster P. & Delahay, R. J. (submitted) Experimental badger culling leads to mesopredator release of hedgehogs. Biology Letters.

[53] Hounsome, T. D. & Delahay, R. J. (2005) Birds in the diet of the Eurasian badger Meles meles): a review and meta-analysis. Mammal Review 35, 199 – 209.

ANNEX B – SUMMARY OF BOVINE TUBERCULOSIS STATISTICS FOR ENGLAND IN THE PERIOD 2008-2012

The key headline statistics for bTB in England over the last five years can be summarised in the table below. This shows that, following a peak in 2008, the annual number of newly identified bTB breakdowns and test reactors went down in 2009 and then bounced back steadily to a level which is likely to exceed that of 2008. However, if these figures are expressed as a herd incidence rate (new herds with OTF status withdrawn divided by the number of OTF herds that were tested for bTB) and the rate of reactors disclosed per 1,000 animal tests, the annual indicators for 2009-2012 have remained more or less stable and below the historical high of 2008. There appears to have been a three-year cycle of herd incidence since the FMD outbreak of 2001.

	Herd-level statistics (1)						Animal-level statistics (1)				
Year (Jan-Dec)	Cattle herds registered at year end	Total herd tests	Total tests in officially TB freee (OTF) herds	New TB herd breakdowns (2)	New OTFW TB herd breakdowns (3)	TB herd incidence (4)	Total cattle tested	Test reactors	Direct Contacts (5)	Reactors per 1,000 tests	Slaughterhouse cases (6) confirmed by laboratory culture
2008	58,465	47,419	38,507	3,765	2,447	6.4	4,540,731	26,392	955	5.8	704
2009	57,495	50,140	40,332	3,362	2,282	5.7	4,829,190	25,539	635	5.3	621
2010	56,867	52,957	42,898	3,634	2,485	5.8	5,367,432	23,895	432	4.5	913
2011	54,295	54,118	42,823	3,763	2,565	6.0	5,493,311	25,879	322	4.7	956
2012	53,563	63,474	51,799	3,931	2,829	5.5	5,850,210	27,740	354	4.7	1,080

(1) Data for 2008-2012 extracted from AHVLA's new IT system (Sam). Data for earlier years were derived from the old IT system (VetNet), are not directly comparable and have not been included in this historical series.

(2) OTF herds that suffered a new TB breakdown as a result of animals reacting to a skin test or animals disclosed with TB during routine meat inspection at commercial slaughter.

(3) A subset of all new TB breakdowns, in which infection with *Mycobacterium bovis* (the bovine TB bacillus) was confirmed by detection of typical lesions in at least one TB test reactor or by laboratory culture.

(4) An approximate incidence estimate calculated as the number of new OTFW breakdowns divided by the number of tests carried out in OTF herds (as in the National statistics).

(5) Non-reactor animals slaughtered in the course of an OTFW breakdown because they were considered to have been exposed to the bovine TB bacterium.

(6) Cases of TB detected during routine meat inspection at commercial slaughter of test-negative animals with suspect lesions from which M. bovis was isolated in laboratory culture.

Note - In 2001, the TB testing and control programme was largely suspended due to the Foot and Mouth Disease (FMD) outbreak. When herd testing resumed in 2002, resources were concentrated on herds with overdue TB tests which would have had a longer period in which to contract the disease. Also the proportion of high risk herds tested post-FMDwas greater than that prior to the outbreak. Consequently, the number of TB incidents since 2002 are not comparable to those in previous years.

(Source: Defra bTB National Statistics)

ANNEX C – DRAFT NATURAL SCIENCE EVIDENCE STATEMENT: BOVINE TUBERCULOSIS

The following paper describing a project to provide a succinct summary of the natural science evidence base relevant to the control of bTB has been accepted for publication in the Proceedings of the Royal Society Biology http://rspb.royalsocietypublishing.org/

Godfray, H.C.J. *et al.* (publication pending) A restatement of the natural science evidence base relevant to the control of bovine tuberculosis in Great Britain

The project was commissioned and funded by the Oxford Martin School (part of the University of Oxford) and though many groups were consulted, the project was conducted completely independently of any stakeholder. Further information is available at http://www.futureoffood.ox.ac.uk/news/bTBevidence

ANNEX D – DRAFT SOCIAL SCIENCE EVIDENCE STATEMENT: BOVINE TUBERCULOSIS

Overview

Both the tools used to control bTB and the disease itself have significant social and economic impacts on livestock keepers, their businesses, families and communities, and the general public. The following statements describe the nature of these impacts along with the state of the evidence to support these.

In 2012 there were 3,900 new incidents of bTB in cattle herds across England, 28,000 cattle were slaughtered and 6,900 herds were placed under movement restrictions. The majority of cases were in the South and West of England, having a disproportionate impact on the region's livestock farming. 70% of bTB cases in 2012 were in the South and West region where 26% of herds were under restrictions at some point in the year. (1)

The impacts of bTB and its control

The Government spent £85m controlling the spread of bTB in England in 2011/12, excluding roughly £14m of EU co-funding. (2) Government spending was used to fund cattle testing, removal and disposal of reactors, compensation payments to livestock keepers along with R&D into cattle and badger vaccines with the EU co-funding cattle testing and compensation.

The routine testing of cattle herds across England for bTB places burdens on both Government and livestock keepers. On average, herd tests cost farmers £350 through additional resources and lost productivity. The average cost to government is around £770 per test[54]. (18) (3)

Cattle herd breakdowns lead to financial costs to livestock farmers and government through disruption to farm productivity and adherence to control measures. These costs include restrictions on cattle movements on and off the farm, resources needed for repeat testing and the removal and disposal of reactor cattle. (19, 17) The average financial cost of a bTB breakdown is estimated at £34,000 of which £12,000 falls to farmers. (3, 9)

bTB and its control has a significant impact on the health and wellbeing of farmers, their families and farming communities. The Farm Crisis Network found that bTB can cause stress within farming families. (14) Many farmers in high risk areas have become fatalistic about bTB, feeling a loss of control over their ability to prevent the disease (12, 13).

bTB controls have the potential to influence risk-based cattle trading behaviour. Research suggests that pre- and post-movement testing legislation has had a strong deterrent effect

[54] These averages are high level, indicative costs to farmers and Government. They are simple averages and we acknowledge that they do not reflect individual circumstances

on cattle import trade from high incidence regions of England and Wales into Scotland. (15)

The presence of bTB in England stifles trade, particularly in live animals and has even led to informal trade bans on UK live cattle exports. The cost of this is estimated at £1.3m per year to English producers. (17)

Defra estimates the direct costs of culling badgers at £1,000/km^2 using a combination of cage-trapping and controlled shooting (range: £300 – £2,500) compared with £2,250/km^2 for vaccination. (10) The Welsh Government's badger vaccination project has cost around £3,900/km^2. (20)

Cattle vaccination has been rated the most acceptable bTB cattle control measure (7) and farmers have been shown to have a substantial willingness to pay for a vaccine. (6)

A cattle vaccine could deliver a benefit of up to £250m over 15 years, through reduced cattle herd breakdowns. The extent of deployment and the need for repeat doses will determine whether benefits outweigh costs. (8)

Benefits of controlling bTB

The current risk posed by *M. bovis* to human health in the UK is considered very low. Prior to the introduction of effective controls through milk pasteurisation and tuberculin screening of herds to identify infected animals, *M. bovis* infection was much more common. There are relatively few recorded cases in England each year: 22 case notifications in 2011. The majority of these cases are likely attributable to reactivation of latent infection, probably acquired prior to more widespread implementation of controls. (5)

Controlling bTB continues to deliver benefits by protecting and enhancing the sustainability of the livestock sector and minimising any impacts on productivity.

Controlling bTB is essential for maintaining the UK's beef and dairy export markets valued at £1.7bn in 2011. (4) Based on existing trade, closing these markets could costs UK producers £700m per year as trade is diverted and prices lowered to sell on the domestic market. (11) Maintaining confidence in UK livestock products enables export growth and expansion into new markets. UK dairy exports alone grew by nearly 20% in 2011. (4)

Controlling bTB helps maintain consumer confidence in livestock products, benefiting the whole food chain. (16)

Estimates of the benefits of government intervention to tackle TB depend upon assumptions about what would happen in the absence of that intervention e.g. what would happen without the existing, or proposed, government policies. If we assume that government withdrew from current controls and an alternative model replaced it, with lower levels of compliance, this may be less effective at controlling disease. Under these assumptions the benefits of government intervention outweigh the costs 2.6 to 1. (16)

Defra, 2013

Statistics and resources

1. Statistics on TB: http://www.defra.gov.uk/statistics/foodfarm/landuselivestock/cattletb/national/

2. Defra annual accounts: https://www.gov.uk/government/publications?departments%5B%5D=department-for-environment-food-rural-affairs&publication_type=corporate-reports

3. Defra "A call for your views on strengthening our TB eradication programme and new ways of working": http://www.defra.gov.uk/ahwbe/files/ahwbe-btb-callforviews-120910.pdf

4. Trade data: https://www.gov.uk/government/statistical-data-sets/overseas-trade-in-food-feed-and-drink

5. M. *bovis* in humans data: http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Tuberculosis/TBUKSurveillanceData/EnhancedMycobacteriumBovisSurveillance/TBMbovis01countryregion

Literature, reports and analysis

6. Bennett R & Balcombe K (2012). Farmers' willingness to pay for a tuberculosis cattle vaccine. Journal of Agricultural Economics, 63 (2). pp480-424

7. Bennett R, Cook R, & Ijpelaar A (2005). Economic assessment of bovine tuberculosis and alternative policies. Cattle Practice, 13. Pp235-238

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12. Enticott G. (2008). The ecological paradox: Social and natural consequences of the geographies of animal health promotion. Transactions of the Institute of British Geographers, 33**,** 433-446.

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14. Farm Crisis Network (2009). Stress and Loss: a report on the impact of bovine TB on farming families. Available at: http://www.tbfreeengland.co.uk/assets/4200

15. Gates MC, Volvoka W & Woolhouse ME. (2013). Impact of changes in cattle movement regulations on the risks of bovine tuberculosis for Scottish farms. Pre Vet Med 108, 125-36

16. Scanlan S, Mitchell I & Young R. (2013) Animal Disease Risk: An Economic Framework for Policy. Defra (awaiting publication)

17. Scottish Government (2009). An assessment of the costs and consequences of Scotland having Officially TB Free Status. (Link not known)

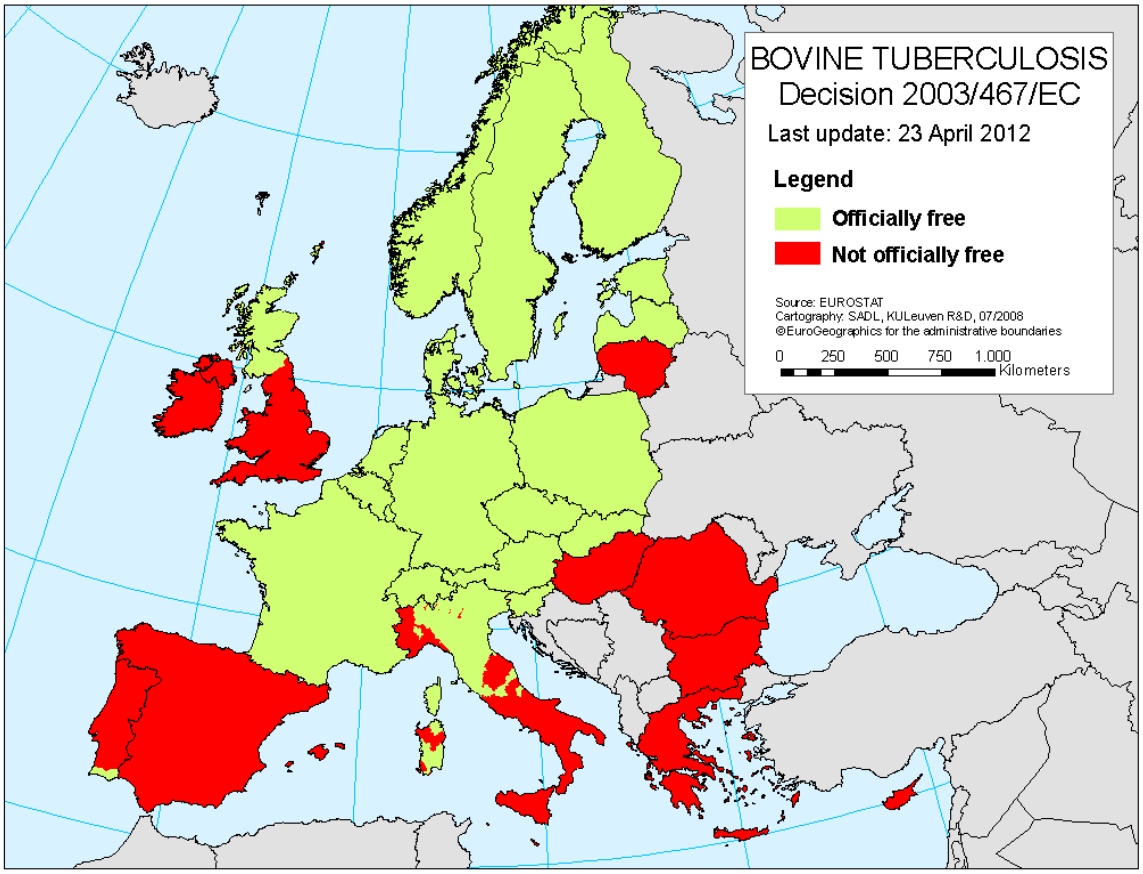
18. University of Exeter, ADAS (2008). Investigate the longer-term effects on farm businesses of a bTB breakdown. Available at: http://randd.defra.gov.uk/Document.aspx?Document=SE3120_9221_FRP.pdf

19. University of Reading (2004). Assessment of the Economic Impacts of TB and alternative control policies. Defra. Available at: http://randd.defra.gov.uk/Document.aspx?Document=SE3112_1428_FRP.doc

20. Welsh Government (2013). Bovine TB Eradication Programme: IAA Badger Vaccination Project, Year 1 Report. Available at: http://wales.gov.uk/docs/drah/publications/130129iaareport2012en.pdf

ANNEX E - BOVINE TUBERCULOSIS IN EUROPE

Figure 1: Official Bovine Tuberculosis status of EU Member States in April 2012



(Source: European Commission Annual Report Bovine and Swine Diseases 2011)

ANNEX F – BOVINE TUBERCULOSIS IN NON-BOVINE ANIMALS FROM 2010-2012

The tables summarise the testing of non-bovine animals for bTB between 2010 and 2012. Tests are only conducted where there is a high suspicion of disease.

Table 1: Number of bTB culture-positive animals by year and species

Species	2010	2011	2012[1]
Farmed Deer	1	6	2
Park Deer	6	0	0
Wild Deer	15	15	12
Domestic Cat	23	18	9
Domestic Dog	2	0	1
Domestic Pig	29	40	18
Alpaca	43	17	35
Llama	0	0	3
Sheep	13	35	16
Goat	1	0	2
Ferret	0	0	0
Farmed Wild Boar	1	1(2)[2]	0(1)[2]

Table 2: Number of animals examined

Species	2010	2011	2012[1]
Farmed Deer (Farmed/ Park/Wild)	46	51	29
Domestic Cat	86	70	63
Domestic Dog	9	8	4
Domestic Pig	340	275	196
Alpaca	151	108	342[3]
Llama	7	5	9
Sheep	39	70	36
Goat	11	10	9
Ferret	3	1	0
Farmed Wild Boar	1	1(2)[2]	0(1)[2]

[1] Data for 1 January to 31 December 2012 (data as at 4 April 2013)

[2] Number in parenthesis denotes non-farmed wild boar

[3] Approximately 160 of these alpacas originated from a single bTB outbreak and were not processed for culture, as *M. bovis* had already been identified on the premises - therefore AHVLA was only looking for the presence or absence of visible bTB lesions.

(Source: AHVLA TB Culture Database)

ANNEX G – RISK AREAS

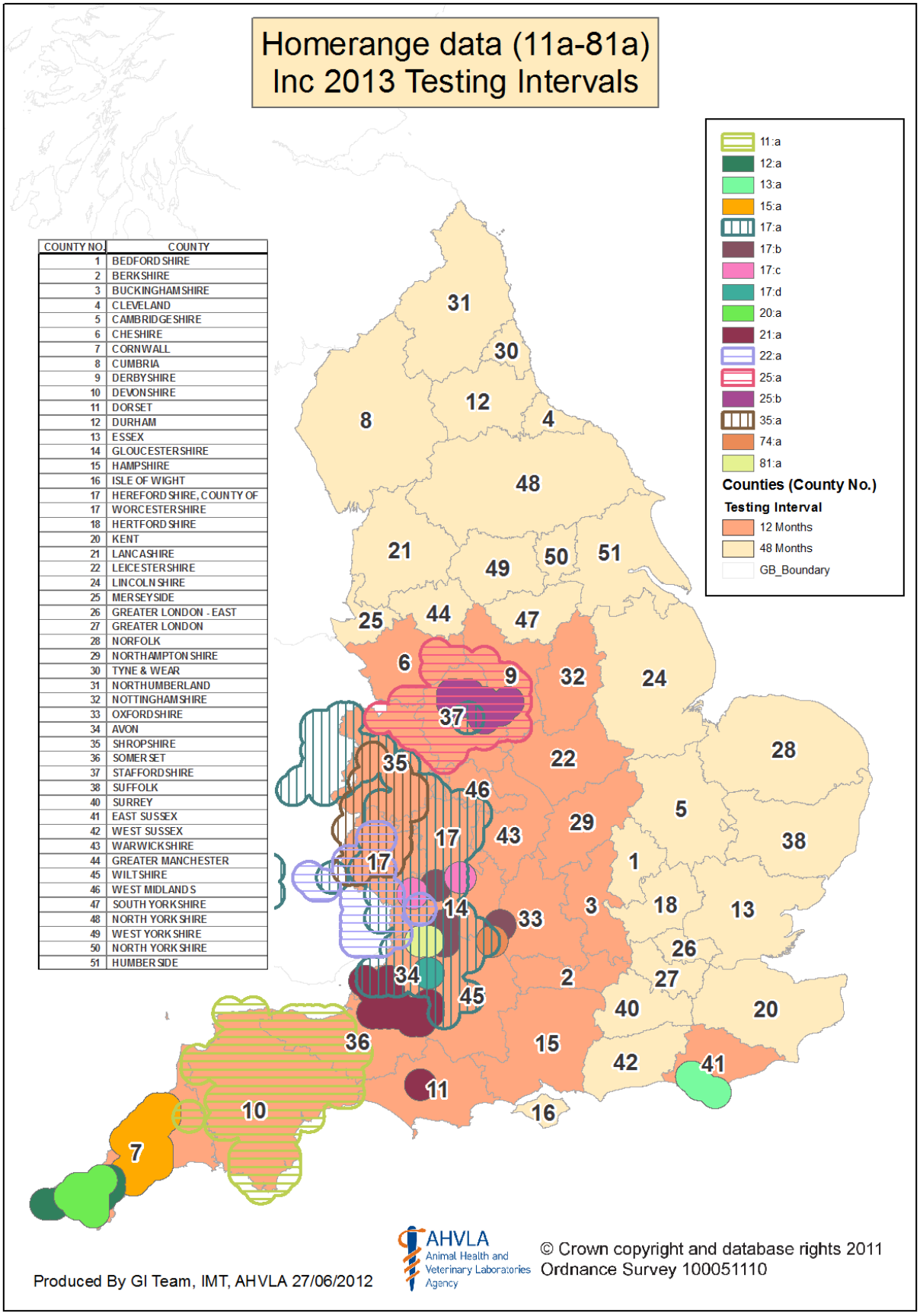
Low Risk Area

Item 1 – Table of OTFW Breakdowns

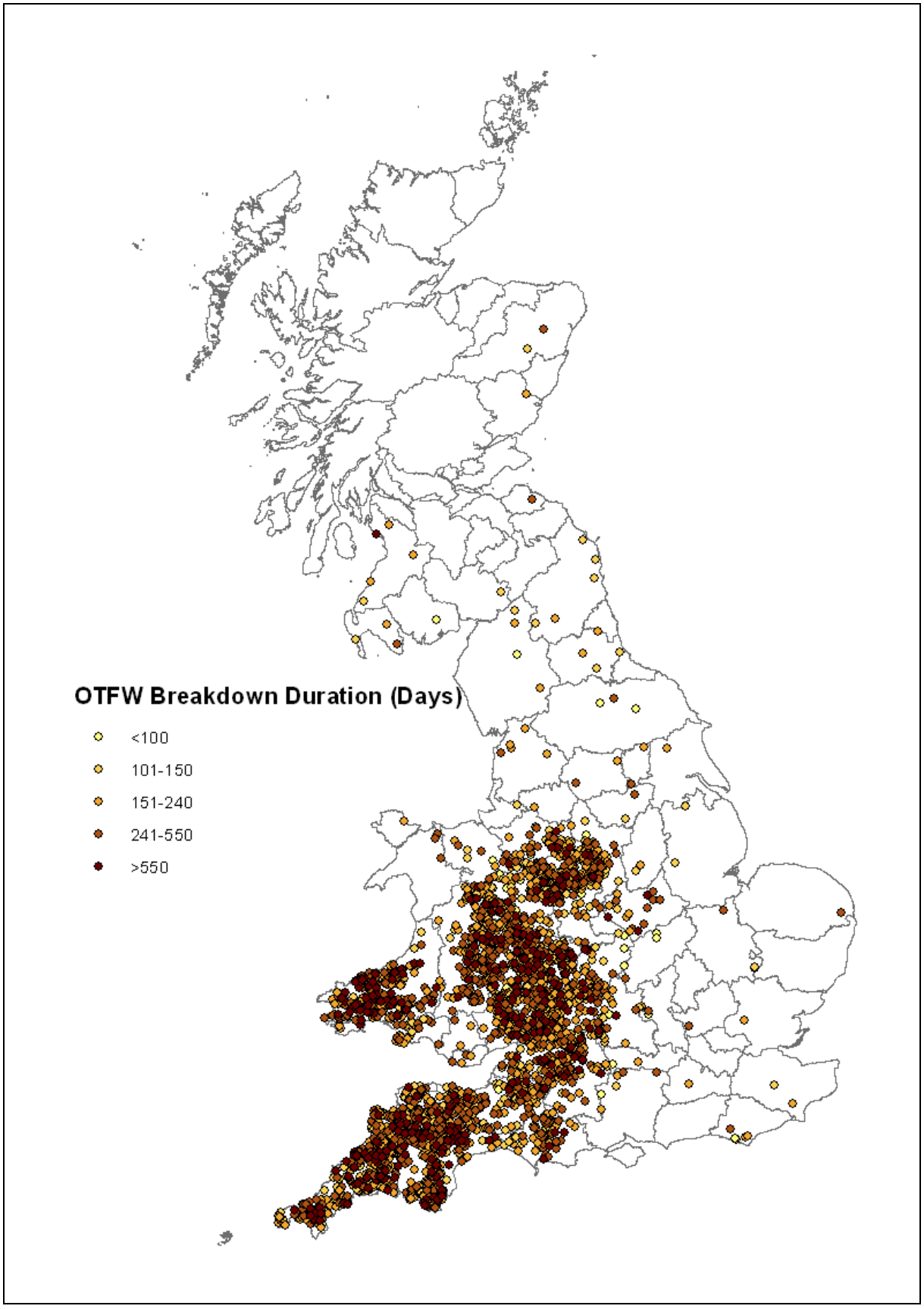
Year	Total number of OTFW breakdowns	Number of OTFW breakdowns that could be removed from 'indigenous' breakdown figure on the basis of home range and CTS analysis	Number of OTFW breakdowns that could be removed from 'indigenous' breakdown figure on the basis of local intelligence	Number of OTFW breakdowns removed by home range analysis but included based on local intelligence	Total number of 'indigenous' breakdowns retained for prevalence analysis	Total number of breakdowns removed from the prevalence analysis
2007- 2010	174	57	55	0	62	112
2011	37	12	5	1	21	16
2012	40	16	6	2	20	20
Total	**251**	**85**	**66**	**3**	**103**	**148**

The Table of OTFW breakdowns in the LRA during the period of 2007-2012, demonstrates the number of breakdowns that could be removed from prevalence calculation on the basis origin of the breakdown (not 'indigenous'). Preliminary analysis of these data shows that the TB crude prevalence of infected herds for the LRA for the period 2007-2012, a) without removing introduced infection breakdowns, is 0.1176% (i.e. above the 0.1% criteria for EU OTF status); and b) by removing introduced infection, is 0.0511% (i.e. below the EU criteria for OTF status).

Item 2 - Map demonstrating the 2011 homeranges of the major *Mycobacterium bovis* genotypes against current testing interval map of England



Item 3 - Geographic distribution of OTFW bovine TB breakdowns that ended in 2011, according to their duration



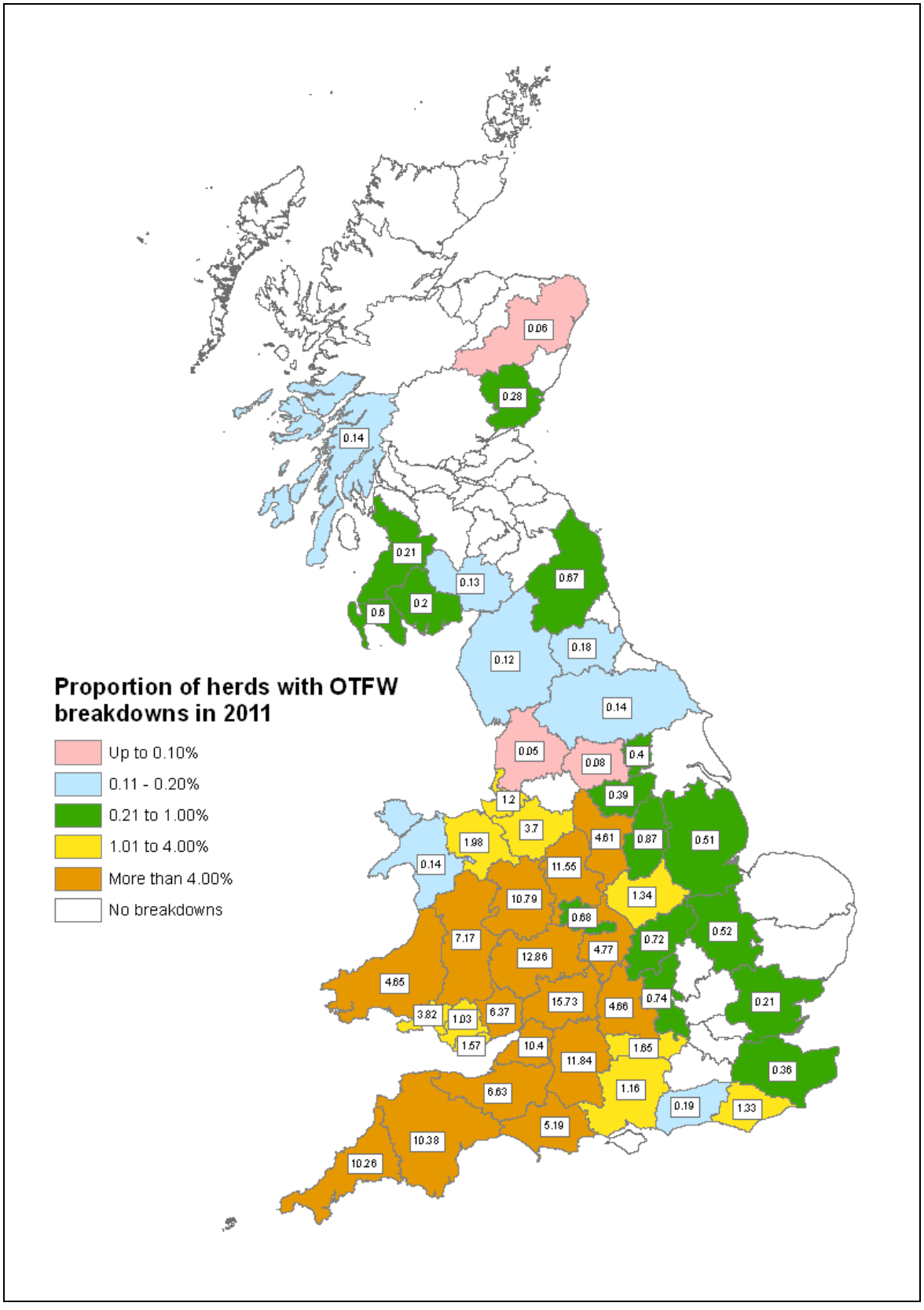
Edge Area

Item 4 - Crude prevalence and percentage of herds OTF at the end of each year for the proposed edge area in 2006-2011

Prevalence (%) of infected herds							
Year	**Number of bovine herds per year (2006-11) (a)**	**Number of new confirmed breakdowns (OTFW) (b)**	**Crude prevalence of infected herds (b)/(a) (%)**	**Adjusted herd prevalence**	**Confirmed breakdowns (OTFW) on 31 December (c)**	**Number of officially free herds at 31 December (a) - (c)**	**% of officially free herds (a) - (c) / (a)**
2006	8912	40	0.4		73	8839	99.2
2007	8575	37	0.4		51	8524	99.4
2008	8374	52	0.6		67	8307	99.2
2009	8333	53	0.6		71	8262	99.1
2010	8309	61	0.7		93	8216	98.9
2011	8318	89	1.1		109	8209	98.7

High Risk Area

Item 5 - Proportion of live herds with OTF-W bovine TB breakdowns by county between January and December 2011: Number of OTF-W new breakdowns of bovine TB per 100 live herds.



ANNEX H – RISK AREA STRATEGIES

Introduction

Each Risk Area Strategy sets out a preferred package of options which could be applied in addition to the current measures. A summary of the options for each of the Low Risk, Edge and High Risk Areas is explained in turn. The preferred package of options is presented alongside alternatives classified as “most rigorous” and “least rigorous”. In most circumstances the least rigorous options would do little or nothing to stop the spread of the endemic area and increase adverse consequences. The most rigorous options are not always the best. The precise reasons are situation-specific but will include potential drawbacks such as insufficient benefit compared to cost, legal issues, or practical limitations. Different interventions are considered for each risk area, which is largely attributed to the role of badgers in spreading disease and the shift in focus from predominantly cattle-based measures to measures addressing the disease problem in cattle and badgers.

Over time, the approaches will evolve. For example, additional evidence may come to light, especially where there are acknowledged weaknesses in contemporary understanding. The extent of the disease and its geographical coverage will also change over time, thereby requiring adjustments in the deployment of measures. New tools may become available or be able to be delivered more cost effectively than is the case at the present time. The Strategy emphasises the importance of monitoring, reviewing and adapting the approach taken.

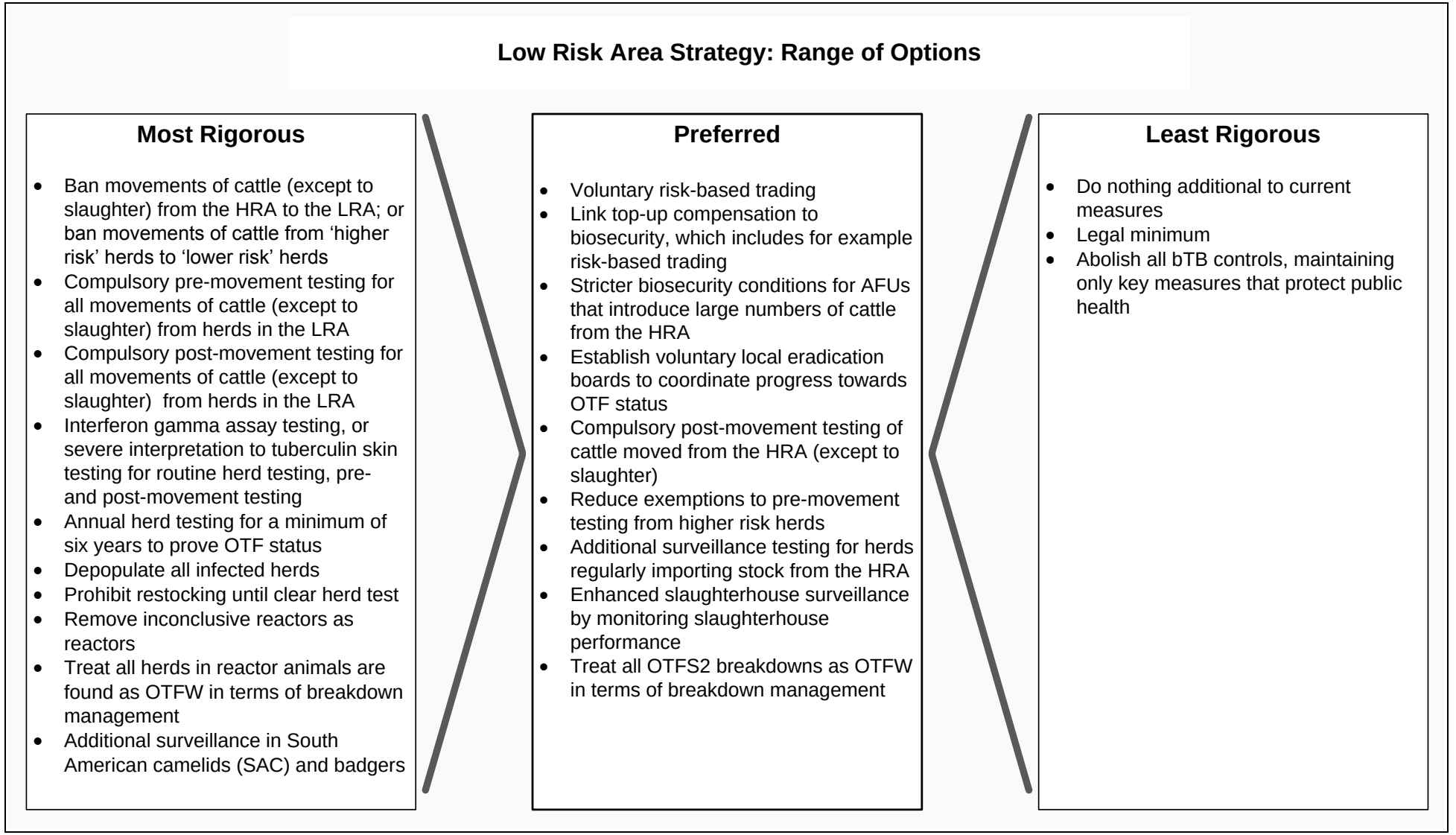
This document sets out options that are being considered as part of the sub-strategies covering each of the risk areas. The Government is keen to encourage the update of appropriate voluntary measures wherever possible and as soon as practicable. **The Government has decided to deploy some of these options as part of on-going policy development and they will be rolled out as soon as possible; such items are clearly marked within the text**. For other options, the Government will consult on detailed proposals and carry out impact assessments as appropriate. Deployment of some options is subject to securing additional funding.

Low Risk Area Strategy

Options

The various options for the Low Risk Area have been grouped into packages of measures classified as “most rigorous”, “least rigorous” and “preferred”. The preferred options are those that the Government is minded to develop. These are illustrated in **figure 1** (overleaf) and explained in turn.

Figure 1 – Potential options for the Low Risk Area



"Least Rigorous" Options for the Low Risk Area

- **Do nothing additional to current measures**

  Evidence from Scotland suggests that achieving and maintaining OTF status will be unattainable without deploying additional measures to reduce the risk of bTB outbreaks in the LRA. Doing nothing additional to current measures is therefore not compatible with the Strategy aim.

- **Legal minimum**

  The rationale for not adopting this option is similar to that for "Do nothing additional to current measures". Reducing measures to EU legal minimum, would for instance, remove pre-movement testing and interferon gamma assay testing, which are important measures in tackling bTB. Additionally, the Bovine Tuberculosis Subgroup of the EU Task Force for Monitoring Animal Disease Eradication has recommended[55] measures in addition to the legal minimum so applying this option would risk failing to secure EU approval for co-financing the bTB Eradication Plan in England.

- **Abolish all bTB controls, maintaining only key measures that protect public health**

  The abolition of all bTB controls and surveillance would increase the likelihood of bTB outbreaks within the Low Risk Area and is therefore not compatible with the Strategy aim. It would carry implications for trade, contravene EU law, risk the loss of EU co-financing, risk EU infraction proceedings and potentially bring animal welfare problems. Although controls on milk and meat are the main public health protection measures, a reduction in cattle surveillance and the prompt removal of bTB reactors could increase public health risks, particularly in terms of occupational health for those in close contact with exposed animals.

"Most Rigorous" Options for the Low Risk Area

- **Ban movements of cattle (except to slaughter) from the HRA to the LRA; or ban movements of cattle from 'higher risk' herds to 'lower risk' herds**

  Within the LRA, most bTB herd breakdowns result from the import of infected cattle from the HRA. Although banning such moves would reduce risks, the Government's initial assessment is that the benefit would be relatively low. Only 2% of movements from herds in the HRA are to the LRA. Most of these are to finishing units. The actual disease risk is therefore relatively low. Banning cattle movements from OTF herds in the HRA could be perceived as unfair and a restriction on trade. Risk levels within the

[55] Report of the Bovine TB subgroup of the Task Force for Monitoring Animal Disease Eradication meeting held in UK, 27-28 March 2012 http://ec.europa.eu/food/animal/diseases/docs/tb_subgroup_uk_2012_en.pdf

HRA are not homogenous; 40% of herds in the HRA have not had bTB for ten years. Banning cattle movements to the LRA in England would result in the anomalous situation in which OTF herds in the HRA could continue to sell cattle to other regions of the UK and to other Member States (including those with OTF status). Options such as risk-based trading would be more proportionate and offer a risk-based approach for herd-owners without recourse to an outright ban on movements.

- **Compulsory pre-movement testing for all movements of cattle (except to slaughter) from herds in the LRA**

  Pre-movement testing is currently required for cattle moved from herds in the HRA and herds identified as higher risk in the LRA. Requiring the pre-movement testing of all cattle moved from LRA herds, irrespective of the actual status of the individual herd, would not improve the disease situation. There would likely be minimal additional cost to Government from being more rigorous. Legislation would be required and the cost to herd-owners, who would have to pay for the additional tests, would be difficult to justify in an absence of clear benefits for individuals or for disease control overall.

- **Compulsory post-movement testing for all movements of cattle (except to slaughter) from herds in the LRA**

  Requiring the post-movement testing of all cattle moved from LRA herds, irrespective of the actual status of the individual herd, would not improve the disease situation. There would be minimal additional cost to Government from being more rigorous. Legislation would be required and the cost to herd-owners, who would have to pay for the additional tests, would be difficult to justify in an absence of clear benefits for individuals or for disease control overall.

- **Interferon gamma assay testing, or severe interpretation to tuberculin skin testing for routine herd testing, pre- and post-movement testing**

  No test is 100% accurate, but the tuberculin skin test (the SICCT) is widely considered the best test currently available for detecting bTB in live animals. To improve the sensitivity of the test to detect infected animals a more severe interpretation of the test could be used when the epidemiological probability of *M. bovis* infection is high. However, used as the primary screening test in low risk areas, the severe interpretation of the skin test would be expected to lead to a substantial rise in the number of bTB-free herds misclassified as infected (due to non-specific cross reactions with bovine tuberculin).[56]

[56] In the EU, reactors to the SICT may be re-tested 42 days later with the more specific SICCT to reduce the probability of false positive results and enhance specificity. However, EU law does not yet provide for the option to negate a positive SICT by a negative interferon gamma assay test ('serial' skin and blood testing) although this approach is used routinely in New Zealand and occasionally in France. In GB we employ the serial interferon gamma assay test in a small number of herds where AHVLA suspects fraudulent interference with the SICCT test results, or to help resolve suspected cases of non-specific sensitisation to bovine tuberculin in persistent OTFS breakdowns in low TB risk areas.

In order to clear out bTB more quickly, the interferon gamma assay is used as a supplementary test once OTFW status is applied to a herd in the Low Risk Area. It is a sensitive test and will identify more infected animals than the skin test. It may also identify a slightly different cohort of infected cattle, in particular those that are in the earlier stages of infection. As a result the risk of the disease being undetected in a herd is less than if the skin test is used.

For the same reasons, if interferon gamma assay is used as a pre- or post-movement test, the risk of moving an infected animal would be less than only using the skin test. The Government could choose to use the interferon gamma assay for these discretionary tests but because the interferon gamma assay is not approved in EU law for use as a standalone test or as a primary test for screening for bTB, its use for herd level screening can only be in addition to the tuberculin skin test.

The trade off for a more sensitive test such as the interferon gamma assay is a reduction in specificity. This means that whilst the test identifies more infected animals than the skin test, a higher proportion of those will be false positive results. A relatively high number of false positives could be considered an acceptable consequence of taking a rigorous approach to clearing a herd of disease. However, it could also be considered to be unfair to expect herd-owners to destroy the high number of potentially healthy animals if the interferon gamma assay were to be used before all movements, or in all routine herd testing. This would also add to the cost of compensation payments. These costs would be further compounded if herd restrictions were imposed on the basis of false positives. False-positives cannot be distinguished from true-positives.

In addition to requiring a change in EU law, which in itself would be a big undertaking, there are also the issues of laboratory capacity and the cost of the additional tests. Interferon gamma assay is a more expensive test than the tuberculin skin test (largely due to the requirement for blood samples to be drawn and delivered to the laboratory in temperature controlled packaging for testing). Whilst the tuberculin skin test may be delivered privately, the interferon gamma assay is carried out only by AHVLA staff and samples tested at AHVLA laboratories at Government expense. Any increase in the use of interferon gamma testing would have to be at farmer expense. Establishing a private market would be complex and expensive.

Voluntary use of the test could be considered as part of industry best practice, particularly where high value stock is involved and the implications of a breakdown are perhaps at their highest. This would require the setting up of a cost-recovery system within AHVLA.

- **Annual herd testing for a minimum of six years to prove OTF status**

  Most herds within the LRA are tested once every four years. In each of the four years an equal proportion of herds in the area are tested. This is consistent with EU law and the Government’s view has been that more frequent testing is not necessary for areas that are genuinely low risk.

More frequent testing might help provide greater assurance when declaring a herd or an area free of TB. However, rolling out annual testing would be very expensive (estimated at an additional £10 million per year) with little additional disease control benefit. Most breakdowns in the LRA are caused by infected cattle sourced from the HRA. There is little evidence of disease spread beyond these herds. Putting these isolated cases to one side, the incidence rate for the LRA remains below 0.1%, as per the EU threshold for maintaining four-yearly testing.

Since 2013, other measures agreed with the European Commission are in place as part of a surveillance strategy for the low risk area. 3km radial testing (with herds required to pre-movement test whilst on radial testing) is deployed to provide assurance that disease has not spread in an area. Annual testing is already required for higher risk TB herds e.g. bull hire herds, heifer rearing herds, producer-retailers of raw drinking milk, regular purchasers of cattle from high incidence countries or counties. Defra has commissioned research to develop criteria for identifying high risk herds which should be targeted with more frequent testing.

- **Depopulate all infected herds**

  In infectious disease control, depopulation of entire infected herds is used in certain circumstances. Depopulation may be used where the disease is very fast spreading (e.g. foot and mouth disease virus) and diagnostic testing would slow down disease control too much to allow effective control. It may also be used where the disease prevalence is very low in a country or a region and depopulation would substantially and cost-effectively speed up the achievement of disease free status.

  In the LRA, depopulation is currently used where testing has failed to clear a herd of infection. However, this is very rare as the current testing measures in the LRA appear to clear the infection from herds and recurrence in the same herd is rare, unless brought in with in-coming cattle. Targeting depopulation in this way is relatively cost effective.

  Depopulation would be expensive if rolled out widely. Depopulating an average sized cattle herd in England (120 cattle) at the current average compensation rate (£800/head taking account of salvage income) would cost the taxpayer £96,000. Using these estimates, the total cost of depopulating the 40 new breakdowns in the LRA in 2012 would have cost the taxpayer £3.8 million.

  In the LRA, the indiscriminate depopulation of infected herds is unnecessary and not cost effective because most herds have purchased in infection from elsewhere, sometimes repeatedly. Measures targeted at the riskiest practices would therefore have the greater chance of having a positive effect on the disease.

- **Prohibit restocking until clear herd test**

  Currently policy is to allow owners of bTB breakdown herds to re-stock following the first breakdown test even if reactors are disclosed at that test, subject to a satisfactory

Veterinary Risk Assessment although under Council Directive 78/52/EC, a herd is not permitted to restock until cattle over six weeks in the herd have passed an official tuberculin test. Under this option re-stocking would only be permitted following a clear TB test. There would potentially be some disease control benefits as the existing incentives for cattle keepers to invest in additional bio-security and consider safe cattle purchasing practices would be increased. There is also evidence[57] from the Republic of Ireland to demonstrate that restocking a herd during a breakdown prolongs the breakdown duration. However, preventing restocking until a clear test could jeopardise the viability of the business, particularly in the rare event of a prolonged breakdown in the LRA where breakdown duration is typically markedly shorter than in the HRA.

- **Remove inconclusive reactors as reactors**

  Where the result of the comparative skin test for an animal is inconclusive (known as an inconclusive reactor (IR)) the standard policy in accordance with EU law is to re-test the animal after 60 days. If the animal fails to pass the second test, it is removed from the herd with movement restrictions applied (if not already in place). In serious OTFW cases an IR can be removed by AHVLA, or on a voluntary basis at the owner's expense.

  Requiring the immediate removal of an IR would increase the probability of quickly removing infected animals from herds. The disadvantage is that it would result in large numbers of additional bTB-free cattle being slaughtered and would potentially place many additional bTB-free herds under movement restrictions[58]. The gain in disease surveillance and control terms would be relatively small, with a low benefit: cost ratio. It would be a disproportionate response in the LRA because only a low proportion of cattle that give an IR result for the first time are truly infected with *M. bovis*.

  A more logical approach in the LRA would be to advise farmers to remove IRs immediately where there is particular risk of infection, including:

  - in herds undergoing short-interval testing due to an OTFW breakdown,
  - in unrestricted herds with a history of bTB breakdowns, or
  - at tuberculin skin tests of animals traced from OTFW breakdowns.

  These are all situations where we can be more certain that cattle have been exposed to *M. bovis* and consequently, the predictive value of an inconclusive test result will be higher.

[57] Clegg TA, Blake M, Healy R, Good M, Higgins IM and More SJ. (2013) The impact of animal introductions during herd restrictions on future herd-level bovine tuberculosis risk, Prev Vet Med. 2013 May 1;109(3-4):246-57. doi: 10.1016/j.prevetmed.2012.10.005. Epub 2012 Nov 13.

[58] We do not have exact figures, but it would be in the order of hundreds of animals and herds.

- **Treat all herds in which reactor animals are found as OTFW in terms of breakdown management[59]**

  Evidence from the Republic of Ireland and GB[60] indicates that classifying a bTB breakdown as OTFW (rather than as OTFS) is not a reliable predictor of the risk of breakdowns in the future. This may be explained by the assumption that a number of OTFS breakdowns represent true *M. bovis* infections. Mathematical modelling[61] which considered all breakdowns (both OTFW and OTFS) suggested that up to 21% of herds may be harbouring infected animals when movement restrictions are lifted. Increasing the sensitivity of the TB testing during a breakdown will increase the likelihood that all infected animals are removed from the herd during the breakdown.

  At present all OTFS herds must undergo one short interval test (SIT) with negative results at standard interpretation to regain OTF status. However, since 2011 a small subset of OTFS herds considered to be at greater epidemiological risk (OTFS2) have to undergo two SITs with negative results. The identification of OTFS2 herds is based on a previous study, which showed that those OTFS herds that had their status withdrawn in the previous three years or were contiguous to another herd with its OTF status currently withdrawn, were more likely to suffer future OTFW breakdowns in the following four years[62].

  Currently, only a proportion of breakdowns, about two thirds, are treated as OTFW or OTFS2 breakdowns, meaning that the clearing test in the herd is carried initially at severe interpretation and two clear tests are required to gain OTF herd status. The remaining breakdowns are not considered confirmed and only one clear herd test is required to lift the movement restrictions. It could be argued that all breakdowns should be treated as OTFW/OTFS2, considering the low ability of the post mortem examination to detect *M. bovis* and the difficulties with culturing the organism.

  In the LRA, epidemiological evidence on recurrence and duration of OTFS breakdowns (i.e. only one test required for clearance) suggests that the current mechanism of applying a risk based approach and classifying some unconfirmed breakdowns as OTFS2 and applying more rigorous testing to clear these is working, and there is no need to tighten controls. Further justification is provided in the “Treat all OTFS2

[59] Two clear test under severe interpretation, interferon gamma assay parallel testing, 6- and 12-month subsequent testing and contiguous testing

[60] Karolemeas et al. Recurrence of bovine tuberculosis breakdowns in Great Britain: risk factors and prediction. Preventive Veterinary Medicine 102 (2011) 22– 29.

[61] Estimating the hidden burden of bovine Tuberculosis in Great Britain. Conlan et al., 2012 PLoS Computational Biology, In press.

[62] Downs and Sayers (2009, unpublished). Should a different TB control strategy be applied to unconfirmed breakdowns in GB herds based on the number of reactors that occur during unconfirmed breakdowns? Internal AHVLA report to Defra.

breakdowns as OTFW in terms of breakdown management" option in the Preferred Package for the LRA.

- **Additional surveillance in South American camelids (SAC) and badgers**

  SAC

  Camelids are a spillover host for *M. bovis*. There is no evidence that they contribute to the spread of bTB in cattle or wildlife although anecdotal evidence suggests that statutory rules on testing camelids as for cattle would be welcomed by the livestock industry. Relatively speaking, testing cattle is likely to be more effective than testing camelids because identifying infected camelids can require additional antibody testing. Costs of mandatory surveillance in the LRA and Edge Area, over and above the present surveillance arrangements that would continue to operate in the HRA, would be around £1.5 million excluding the costs of setting up and running a national camelid registration scheme.

  Badgers

  We do not know what the infection status of badgers in the LRA is. No systematic surveillance of TB in badgers has ever been carried out in these areas. Currently, badger surveillance in the LRA is carried out only in cases where breakdowns of obscure origin occur and re-occur and/or appear to be spreading locally. This surveillance is based on collecting badger carcases from Road Traffic Accidents (RTA) on a voluntary basis in a given location. Such surveillance is limited to a small area and carried out very rarely. Deer stalkers are legally required to submit suspect samples from shot deer to AHVLA for culture. If *M. bovis* infection is confirmed in such samples, radial cattle herd testing is carried out, particularly in the LRA. In the past six years, none of the above wildlife surveillance has produced evidence of wildlife related spread of bTB in the LRA.

  If considered necessary, wider wildlife surveillance in the LRA could be used for further reassurance of the apparent absence of wildlife involvement in the bTB incidence in the area and to support the relatively low frequency routine surveillance testing of cattle in the LRA. RTA badger surveillance is probably the only feasible way of badger surveillance in the LRA, as all other methods would involve capturing of badgers and sampling them live or killing them. It would be difficult to know whether the likely effort and cost involved in collection of RTA badgers in the LRA would yield useful information and how to interpret whatever information is collected. Any such 'scanning surveillance' would have to be carried over a long period of time to yield any meaningful results.

Preferred Package for the Low Risk Area

The preferred package of options would entail continuing with existing measures and potentially to introduce the measures outlined below.

- **Voluntary risk-based trading**

  The Government has decided to deploy this option, which is covered in more detail elsewhere.

- **Link top-up compensation to biosecurity, which includes for example risk-based trading**

  The option is covered in more detail elsewhere.

- **Stricter biosecurity conditions for AFUs that introduce large numbers of cattle from the HRA**

  Cattle finishers, some of whom are based within the LRA, provide a crucial link between cattle farmers and the major meat buyers. For good reason – it is where a large proportion of the national herd is located – finishers will regularly source cattle from the HRA. Finishers in the LRA will be invited to register with the AHVLA and bring their bio-security up to the high standards currently set for non-grazing Approved Finishing Units – for example cattle will have to be housed and the units made 'wildlife-proof'. The Government would then stop bTB surveillance testing within these units. This option would reduce the risk of *M. bovis* spread from higher risk herds in the LRA. Finishers would need to invest more in bio-security, but this cost would be more than offset by the savings from no longer having to support TB surveillance testing.

  The Government has decided to deploy this option.

- **Establish voluntary local eradication boards to coordinate progress towards OTF status**

  The establishment of voluntary industry-led local eradication boards in the LRA could prove useful to tackling TB and achieving OTF status. Costs should be fairly low, for example incurring secretariat and meeting costs. The engagement of local stakeholders and their willingness to work together is essential. An example already exists. A local eradication board has been set up in Cheshire in the Edge Area and it provides a model for local organisations taking charge of their local disease situation and working together to integrate services and respond effectively to the disease situation in the county. The board comprises a wide range of representatives from farming sectors, veterinarians, auctioneers, wildlife groups, local authorities and AHVLA. It was established to provide a regional and local perspective as part of the Edge Area action plan which in turn is part of the wider package of measures to achieve OTF status. Early experiences will help inform wider rollout.

- **Compulsory post-movement testing of cattle moved from the HRA (except to slaughter)**

  Post movement testing is currently encouraged in all risk areas and is applied voluntarily by farmers when introducing new animals into their herd. Compulsory post-

movement testing is currently required in all risk areas for cattle purchased from the Republic of Ireland and from Northern Ireland.

Under this option post-movement testing would be compulsory in the LRA, so that all stock brought into a herd from the HRA to live for more than 120 days would have to be privately tested 60 days[63] after leaving the HRA. Preferably, the purchased animals would have to be kept isolated for 60 days and tested before joining the rest of the new herd. This would impose some additional costs (but only for those not already voluntarily testing) which are appropriate given the risks involved.

Whilst the use of post-movement testing of cattle purchased from the HRA to live on a holding in the LRA will not prevent the translocation of infection from the HRA into the LRA, it can be beneficial in helping to detect the infection early in an area where surveillance testing is carried out only every four years and, thus, helping to prevent the spread of the infection within the herd, to other herds by cattle movements and to local wildlife.

Additionally, experiences in Scotland[64] provide evidence that compulsory pre- and post-movement testing for cattle moved from a HRA to a LRA has a strong deterrent effect on these riskier movements.

- **Reduce exemptions to pre-movement testing from higher risk herds**

  Only a small number of herd owners in the LRA are required to pre-movement test their cattle. Most exempted movements are to slaughter either direct or via a finishing unit i.e. very low risk. Reducing the exemptions to pre-movement testing would therefore have, at best, only small disease control benefits in the LRA. However the Government will be reviewing the exemptions to pre-movement testing policy, with particular focus on the exemption for higher risk movements to/from common land.

- **Additional surveillance testing for herds regularly importing stock from the HRA**

  Additional surveillance testing based on risk assessment is already carried out in the LRA. Herds that can be classified as dealer herds, with frequent movements on and off the holding, and herds with frequent imports from the Republic of Ireland and Northern Ireland are subject to annual surveillance testing.

[63] Which reflects the point in time at which the skin test is capable of detecting infection

[64] Gates, M.C, Volkova, VV and Woolhouse, M.E. (2013) Impact of changes in cattle movement regulations on the risks of bovine tuberculosis for Scottish farms. Prev Vet Med. 2013 Feb 1;108(2-3):125-36. doi: 10.1016/j.prevetmed.2012.07.016. Epub 2012 Aug 13.

It is proposed that this risk based surveillance is further strengthened by identifying additional herds that have a pattern of cattle movements or other risk factors (e.g. do not send animals to slaughter often, so are not subject to slaughterhouse surveillance) that would justify annual surveillance testing.

Defra has commissioned a research project by Glasgow University to develop a system of identifying these herds. This project is due to report in autumn 2013.

Whilst the use of more frequent surveillance testing of high risk herds will not prevent the translocation of infection from the HRA into the LRA, it can be beneficial in helping to detect the infection early in an area where surveillance testing would otherwise be carried out only every four years and, thus, helping to prevent the spread of the infection within the herd, to other herds by cattle movements and to local wildlife.

- **Enhanced slaughterhouse surveillance by monitoring slaughterhouse performance**

  Notification is required if signs of an animal having bTB are suspected at commercial slaughter. Post-mortem inspection of all cattle entering the human food chain (about 2.2 million a year) allows bTB to be detected in OTF infected herds missed by skin testing, or where infected in the time between two sets of tests. Meat inspection is a cost-effective surveillance tool for bTB, although its utility is limited by the inspector's skill and time spent inspecting each carcase for lesions and the fact that only a proportion of infected cattle will present with visible lesions.

  Despite the expansion of annual bTB herd testing in England and Wales there has been an increase in the rate of suspect bTB submissions from many abattoirs and an increase in the proportion of new breakdowns disclosed by routine meat inspection over the last 10 years. In 2011 abattoir surveillance led to the detection of nearly 1,000 infected cattle and 656 new OTFW breakdowns in England. This represents 24% of the new OTFW breakdowns and 17% of all breakdowns. The percentages were higher (64% and 26%) in the LRA. At the time of writing, the reason for this increase has not been determined. It is unclear whether there has been a genuine increase in the number of infected animals entering abattoirs (and hence undetected by bTB testing on farms) or if the increase is due to a heightened awareness by Food Standards Agency (FSA) meat inspectors as a result of enhanced training.

  However, other countries, such as the Republic of Ireland and Northern Ireland, where all cattle herds are tested annually, have reported higher TB slaughterhouse case detection rates than GB relative to the number of breakdowns detected by skin testing. Additionally, research conducted in the Republic of Ireland and GB shows that detection rates vary widely between slaughterhouses. Consequently, there appears to be some scope for improving this element of the bTB surveillance regime, although the true number of *M. bovis* infected cattle that are missed by meat inspection at routine slaughter is not known.

  A combination of measures could include:

- additional training of FSA meat inspectors to raise the awareness and ability to recognise bTB lesions in cattle and other ‘red meat’ species, particularly in those abattoirs with lower than expected rates of slaughterhouse case detections;

- enhanced audit of and more challenging performance indicators for the FSA Operations Group. This would have to be underpinned by regular data analysis of slaughterhouse cases; and possibly

- some system of financial incentives/rewards for each culture-confirmed tuberculous carcase identified by a team of meat inspectors in the course of commercial (routine) slaughter leading to the detection of a new OTFW breakdown.

Additionally, Defra has commissioned further research from Cambridge University into the effectiveness of slaughterhouse bTB surveillance.

- **Treat all OTFS2 breakdowns as OTFW in terms of breakdown management**

  The background to this option is provided in the “Treat all herds in which reactor animals are found as OTFW” option in the “Most Rigorous” Options for the LRA.

  Tuberculin test sensitivity in the LRA could be increased through the compulsory use of stricter control measures for all OTFS breakdowns, thereby treating them like OTFW breakdowns (except that OTF status would not be withdrawn unless post-mortem evidence of infection could be found). Herds suffering OTFS breakdowns in the LRA would need two successive short interval tests at the severe interpretation. Linked to the stricter breakdown control measures in OTFS breakdowns would be the mandatory use of the interferon gamma assay test.

  All herds that had suffered OTFS breakdowns in the LRA would then have a check test six and twelve months after restrictions had been lifted (this is not currently required for OTFS breakdowns in the LRA).

  The scientific evidence which supports the introduction of these two measures in the edge of the annual testing area is summarised in the Edge Area section.

  In principle, from a disease control point of view these measures would also help to reduce the probability of residual *M. bovis* infection when herd restrictions are lifted and would contribute to mitigate the risk of spreading bTB within the LRA. However, as in the Edge Area, this would be accompanied by an inevitable increase in the number of reactors removed during the management of these breakdowns and in the duration of such breakdowns. The cost-effectiveness of these additional measures depends on two factors:

  - The probability of an OTFS reactor herd representing a true *M. bovis* infection (this is much reduced in areas of low TB prevalence); and

- The likelihood of infection being reintroduced into the herd following de-restriction (i.e. through cattle movements or from infected wildlife in the locality).

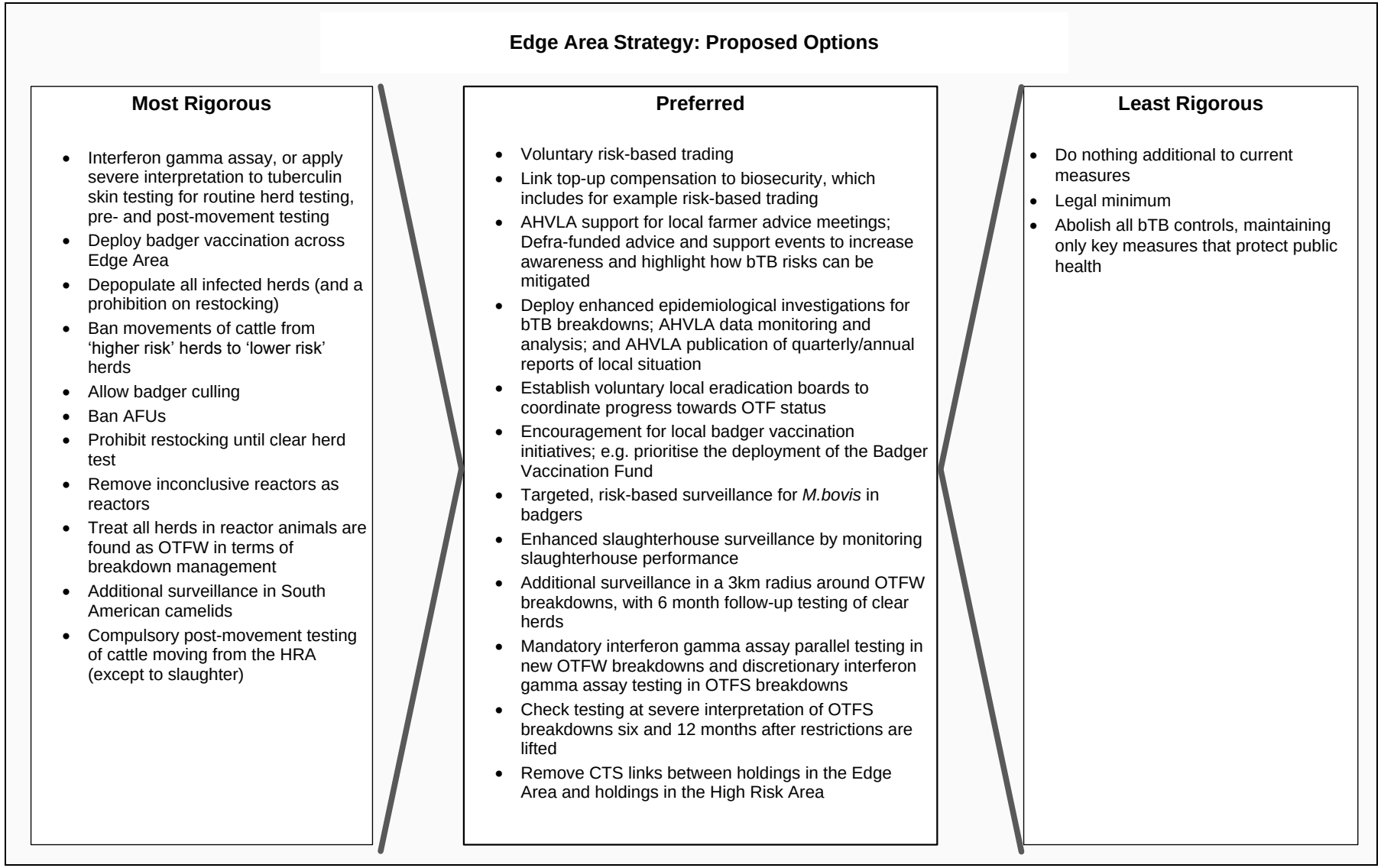
By virtue of their location, OTFS breakdowns in the LRA have a lower probability of being truly infected and would fulfil these criteria only under certain circumstances. Therefore, the additional breakdown control measures for OTFS breakdowns, whilst perfectly feasible, are hard to justify as a blanket policy throughout the LRA. It is, therefore, proposed that this policy is limited to the so-called OTFS2 breakdowns where a higher probability of infection is established and the few annually tested herds within the LRA.

Edge Area Strategy

Options

As with the Low Risk Area, the various options for the Edge Area have been grouped into packages of measures classified as “most rigorous”, “least rigorous” and “preferred”. The preferred options are those that the Government is minded to develop. These are illustrated in **figure 2** (overleaf) and explained in turn.

Figure 2 – Potential options for the Edge Area



"Least Rigorous" Options for the Edge Area

- **Do nothing additional to current measures**

  Evidence suggests that achieving OTF status for England will be unattainable without deploying additional measures in the Edge Area to stop and then reverse the spread of the endemic area. Doing nothing additional to current measures is therefore not compatible with the Strategy aim.

- **Legal minimum**

  The rationale for not adopting this option is similar to that for "Do nothing additional to current measures". Additional considerations are provided in the "Legal minimum" option in the "Least Rigorous" Options for the LRA.

- **Abolish all bTB controls, maintaining only key measures that protect public health**

  The abolition of all bTB controls and surveillance would increase the likelihood of the spread of bTB and is therefore not compatible with the Strategy aim. It would carry implications for trade, contravene EU law, risk the loss of EU co-financing, risk EU infraction proceedings and potentially bring animal welfare problems. Although controls on milk and meat are the main public health protection measures, a reduction in cattle surveillance and the prompt removal of bTB reactors could increase public health risks, particularly in terms of occupational health for those in close contact with exposed animals.

"Most Rigorous" Options for the Edge Area

- **Interferon gamma assay, or apply severe interpretation to tuberculin skin testing for routine herd testing, pre- and post-movement testing**

  This is not a preferred option for the legal and practical reasons given for the LRA.

- **Deploy badger vaccination across Edge Area**

  Injectable badger vaccination has been available since 2012 and may be used by vets and trained and competent lay persons. Vaccination has been trialled as part of the five-year Badger Vaccine Deployment Project in Gloucestershire and used by wildlife groups, the National Trust and as part of the badger control projects.

  Badger vaccination entails safely trapping the badger, administering the vaccine, and releasing it. It is an expensive process with the latest estimate of costs in the region of between £2,000 and £4,000 per km^2. If deployed across the whole region, annual costs would exceed £47 million.

Roll out on a large scale would pose very significant logistical challenges including coordinating the activity, securing consent of landowners, licensing and training a large number of people to administer the vaccine. An oral badger vaccination is still at the research stage and likely to be many years away from potential wide scale deployment. It is not possible to pre-empt the outcome and assess its effectiveness and cost.

- **Depopulate all infected herds (and a prohibition on restocking)**

  This is not a preferred option for similar reasons to those given in respect of the LRA. Depopulation is normally deployed as an additional means of clearing infection from a herd. In the Edge Area, indiscriminate depopulation of all infected herds is unlikely to be especially cost effective. In particular, there would have to be a careful assessment of causes of each breakdown to determine the potential origin of infection in order to avoid depopulating herds that will merely restock from higher risk herds. Additionally, in the absence of information about the level of *M. bovis* infection in the badger population in the Edge Area, it is not possible to assess the risk of infection from badgers for replacement cattle following restocking. Such risks could impact significantly on the cost effectiveness of this option. There should be more viable alternatives to tackle herds with the riskiest practices.

- **Ban movements of cattle from 'higher risk' herds to 'lower risk' herds**

  As for the LRA, options such as risk-based trading would be more proportionate and offer a risk-based approach for herd-owners without recourse to an outright ban on movements.

- **Allow badger culling**

  The Government is committed to evidence-based action to address the reservoir of *M. bovis* in wildlife. The current policy[65] is for Natural England to issue badger culling licences in high incidence areas only. If Ministers decide to roll out this policy following the pilot culls, this requirement could be relaxed to include the Edge Area within the licences. However, there is a lack of knowledge about the population and disease status of badgers in the Edge Area to make an informed decision on culling and the Government is commissioning research to address these knowledge gaps. Research into alternative badger population control methods is also in progress.

- **Ban AFUs**

  AFUs purchase and finish cattle from multiple bTB breakdown herds – they offer a potentially valuable marketing opportunity for bTB affected farm businesses. Currently

[65] Further information is available in the Government's Policy on Bovine TB and badger control in England, December 2011 (PB13691) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69463/pb13691-bovinetb-policy-statement.pdf

only a small number of non grazing AFUs are licensed to operate in the Edge Area, though more might be set up as a result of a decision to stop bTB surveillance testing in these units. Banning AFUs would reduce the number of cattle brought in from the HRA, though as the units have high biosecurity controls (including no grazing) disease control benefits are likely to be small and at the cost of reducing business opportunities for TB affected farms. As a result this measure could undermine the Strategy aim because it might do little to bear down on disease and reduce the sustainability of the livestock sector.

- **Prohibit restocking until clear herd test**

  This is not a preferred option for similar reasons to those given in respect of the LRA. There is a risk of closing down businesses if they have long-running breakdowns which will be higher than in the LRA, though not as high as in the HRA.

- **Remove inconclusive reactors as reactors**

  Whilst the higher prevalence of bTB within the Edge Area makes this a more appealing option than its potential deployment in the LRA, it is not a preferred option for similar reasons to those given in respect of the LRA. The preferred approach is to advise farmers to remove IRs immediately where there is particular risk of infection.

- **Treat all herds in which reactor animals are found as OTFW in terms of breakdown management**

  Currently, only a proportion of breakdowns, about two thirds, are treated as, OTFW or OTFS2 breakdowns, meaning that the clearing test in the herd is carried initially at severe interpretation and two clear tests are required to gain OTF status. The remaining breakdowns are not considered confirmed and only one clear herd test is required to lift the movement restrictions. It could be argued that all breakdowns should be treated as OTFW/OTFS2, considering the low ability of the post mortem examination to detect *M. bovis* and the difficulties with culturing the organism.

  In the Edge Area, a combination of alternative measures is proposed, bringing the treatment of OTFS breakdowns very close to OTFW breakdowns but retaining some of the risk-based approach (see the options of “Mandatory interferon gamma assay parallel testing in new OTFW breakdowns and discretionary interferon gamma assay testing in OTFS breakdowns” and “Check testing at severe interpretation of OTFS breakdowns six and 12 months after restrictions are lifted” in the Preferred Package for the Edge Area).

- **Additional surveillance in South American camelids**

  Camelids are a spillover host for *M. bovis*. There is no evidence that they contribute to the spread of bTB in cattle or wildlife although anecdotal evidence suggests that statutory rules on testing camelids as for cattle would be welcomed by the livestock industry. Relatively speaking, testing cattle is likely to be more effective than testing

camelids because identifying infected camelids can require additional antibody testing. Costs of mandatory surveillance in the LRA and Edge Area, over and above the present surveillance arrangements that would continue to operate in the HRA, are around £1.5 million excluding the costs of setting up and running a national camelid registration scheme.

- **Compulsory post-movement testing of cattle moving from the HRA (except to slaughter)**

  Voluntary post-movement testing is currently encouraged in all areas. The rationale for making it compulsory in the Edge Area is the same as elsewhere. However, it is assumed that the marginal benefits achieved by post-movement testing in the LRA, where 4-yearly testing makes the post movement testing more valuable, would be smaller in the Edge Area where annual whole herd testing is carried out.

Preferred Package for the Edge Area

The preferred package of options would entail continuing with existing measures and potentially to introduce the measures outlined below.

- **Voluntary risk-based trading**

  The Government has decided to deploy this option, which is covered in more detail elsewhere.

- **Link top-up compensation to biosecurity, which includes for example risk-based trading**

  The option is covered in more detail elsewhere.

- **AHVLA support for local farmer advice meetings; Defra-funded advice and support events to increase awareness and highlight how bTB risks can be mitigated**

  The Government is planning a series of events for farmers and veterinary surgeons in the Edge Area. These events will cover the Edge Area measures as well as an introduction to bTB and advice on how to prevent it from entering a herd and how to clear infection quickly without encouraging spread both within the herd and to local wildlife.

  The Government has decided to deploy this option.

- **Deploy enhanced epidemiological investigations for bTB breakdowns; AHVLA data monitoring and analysis; and AHVLA publication of quarterly/annual reports of local situation**

Annually, in the Edge Area, there are approximately 100 OTFW breakdowns (i.e. bTB is confirmed by typical lesions or by culture). We do not have a good understanding of the causes of each one of these breakdowns and the local disease dynamics.

In the LRA, the Government has introduced enhanced epidemiological assessment of each breakdown and intends to do the same in the Edge Area, with full epidemiological reports on all regional breakdowns summarised in a report every quarter. The epidemiological reports will then be published locally to improve local understanding of disease.

In the LRA, this approach has allowed a better understanding of the causes of breakdowns and the indigenous and non-indigenous nature of each case. The latter enables the exclusion of 'imported' or purchased infection from the calculation of disease prevalence, allowing the area to move towards OTF status, as indigenous, local disease spread diminishes or can be ruled out.

In the Edge Area, improved understanding of disease situation amongst the keepers is considered to be an even bigger benefit than in the LRA as there is a greater risk from disease spread than in the LRA, and farmer awareness can contribute to better disease control via additional biosecurity measures, such as preventing cattle to cattle contact between neighbouring farms.

The Government has decided to deploy this option.

- **Establish voluntary local eradication boards to coordinate progress towards OTF status**

  Management of TB in the Edge Area will include enhanced epidemiological reporting of the local disease situation. Industry-led local TB eradication boards would be a key audience for these reports and would be best placed to take action on their findings. The Cheshire TB Eradication Board is a model which the Government hopes will be replicated across the Edge Area.

- **Encouragement for local badger vaccination initiatives; e.g. prioritise the deployment of the Badger Vaccination Fund**

  In the Edge Area, injectable vaccine use could be encouraged by prioritising limited Defra funding through the Badger Vaccination Fund (£250,000 for 2013-14) in areas where badger related spread is most likely and where vaccination would have a real impact on the progress of the disease. The selection of suitable areas could be directed by research into badger risk in the Edge Area.

  The Government has decided to deploy this option.

- **Targeted, risk-based surveillance for *M. bovis* in badgers**

  There is a gap in our understanding of the role badgers play in the spread of bTB in the Edge Area. In order to address this gap, we need to find out the infection status of

badgers in the Edge Area and determine the role that badger infection plays in helping to drive the spread. The former is being addressed by on-going research that is identifying potential areas where more detailed badger surveillance could be implemented. We are also working on a sampling and analytical framework to assess *M. bovis* infection in these areas, once identified. The latter can potentially be addressed by whole genome sequencing of the *M. bovis* genome isolated from infected badgers and cattle in a particular area. The results of this research will enable evidence-based targeting of badger population control or vaccination in the Edge Area in the future. Research into alternative badger population control methods is also in progress.

The Government has decided to deploy this option.

- **Enhanced slaughterhouse surveillance by monitoring slaughterhouse performance**

  The rationale is the same as for the LRA.

- **Additional surveillance in a 3km radius around OTFW breakdowns, with 6 month follow-up testing of clear herds**

  Currently, surveillance around OTFW breakdowns in the annually tested areas is based on discretionary contiguous testing. On average, herds in GB have four contiguous neighbours with cattle, but not necessarily in conditions where nose to nose contact between cattle from different holdings is possible, and contiguous testing is not carried out. However, contiguous tests have a relatively high reactor detection rate and can find infection earlier than even annual whole herd testing. Also, as fragmentation of holdings and grazing areas and herd sizes increase, nose to nose contiguous testing may not be an adequate measure to detect local spread of the disease.

  It is, therefore proposed that radial testing in a 3km area around OTFW breakdowns in the Edge Area is carried out with an immediate check test followed by an additional test in 6 months time before reverting to the annual surveillance testing for the purposes of finding local spread early. As the combined cost of this measure to government and industry is relatively high (£2 million annually) and the rationale for its efficacy in preventing further spread of the disease edge is based on epidemiological analysis rather than trial results, it is proposed that initially radial testing would be carried out in the areas where the threat of spread is greatest, i.e. in Cheshire and Derbyshire, and the results monitored.

  The Government has decided to deploy this option.

- **Mandatory interferon gamma assay parallel testing in new OTFW breakdowns and discretionary interferon gamma assay testing in OTFS breakdowns**

  The Edge Area package includes mandatory interferon gamma assay testing for all OTFW breakdowns within the Edge Area. Additionally, to support further the efforts to

clamp down on the disease as early as possible, interferon gamma assay testing of OTFS herds will be made available as a discretionary measure when veterinary judgement suggests that its use would be beneficial in resolving a breakdown swiftly. This quick action will be essential in supporting the aim to stop disease spread at the edge of risk area.

The total annual cost of these measures is estimated at £1.1 million with £480,000 falling to industry due to testing and economic loss of culled animals. The cost to government due to testing is estimated at £197,000 which includes carrying out tests, analysing samples and reactor removal. Compensation costs are estimated at £452,000; however these costs may not be fully additional where reactors would have been found through alternative surveillance or a lower frequency of interferon gamma testing, albeit later and with potential negative disease implications.

The Government has decided to deploy this option.

- **Check testing at severe interpretation of OTFS breakdowns six and 12 months after restrictions are lifted**

  There is evidence to show that residual infection is often left in a breakdown herd after the restrictions are lifted. Early detection of such infection in OTFW breakdowns is attempted by using 6-month and 12-month tests post restriction removal. Under this option, these measures would also be applied to OTFS breakdowns in the Edge Area.

  It has been shown that OTFS breakdowns act as a precursor for endemic spread in the Edge Area, and many OTFS herds appear as OTFW breakdowns later on. The measure will add burden to the local farmers but only affect about 50 OTFS breakdowns annually in the Edge Area, so is expected to be cost effective.

  The Government has decided to deploy this option.

- **Remove CTS links between holdings in the Edge Area and holdings in the High Risk Area**

  Cattle keepers are not allowed to establish links between holdings in the HRA and holdings in the LRA; all movements of cattle between such holdings must be reported to Cattle Tracing System and cattle must be pre-movement bTB tested as appropriate. As a risk-based extension of this policy, cattle keepers would not be allowed to establish links between holdings in the HRA and holdings in the Edge Area.

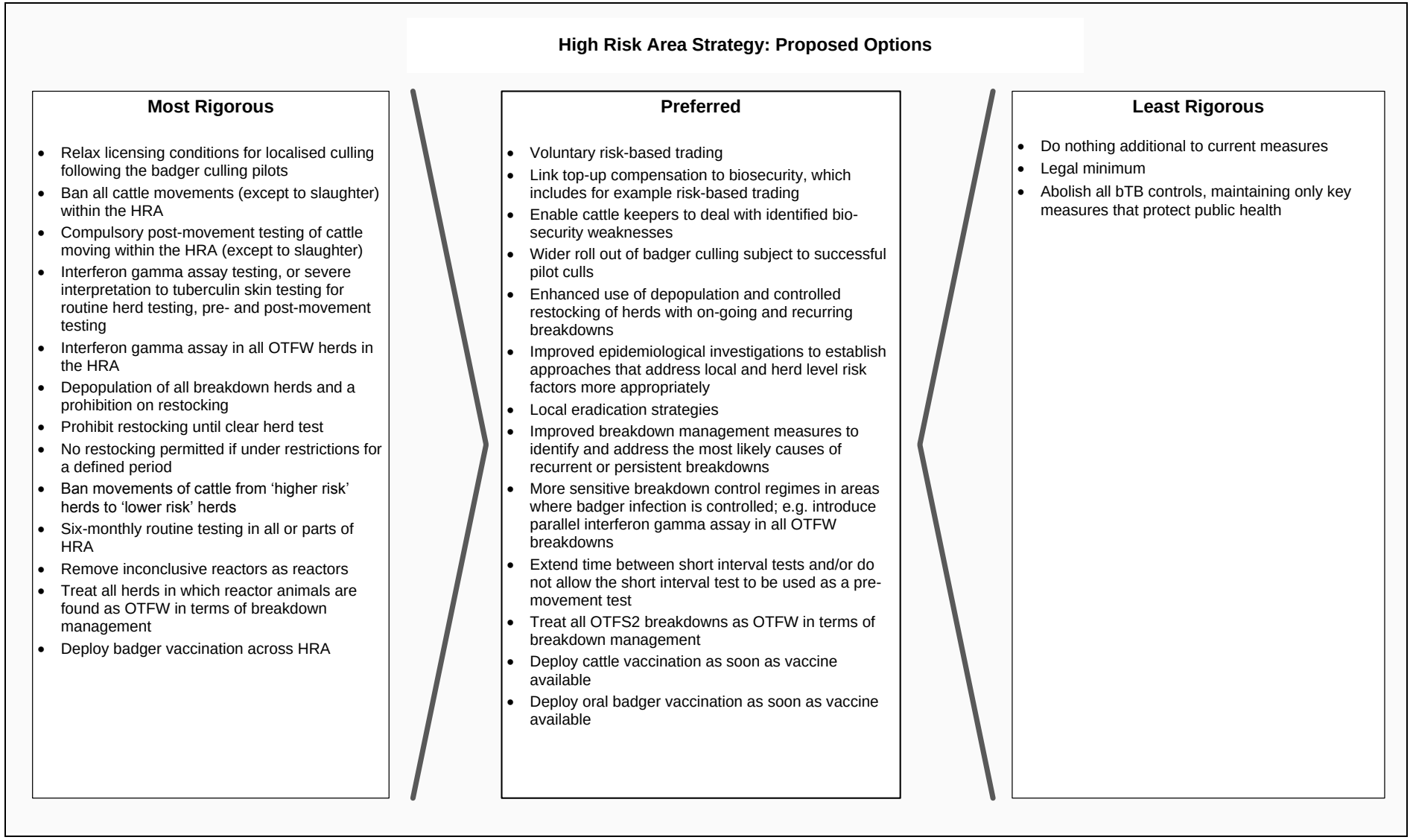
  The Government has decided to deploy this option.

High Risk Area Strategy

Options

As with the Low Risk Area and Edge Area, the various options for the High Risk Area have been grouped into packages of measures classified as “most rigorous”, “least rigorous” and “preferred”. The preferred options are those that the Government is minded to develop. These are illustrated in **figure 3** (overleaf) and explained in turn.

Figure 3 – Potential options for the High Risk Area



“Least Rigorous” Options for the High Risk Area

- **Do nothing additional to current measures**

  Evidence suggests that achieving OTF status for England will be unattainable without deploying additional measures in the High Risk Area. Doing nothing additional to current measures is therefore not compatible with the Strategy aim.

- **Legal minimum**

  One option for the HRA would be to deploy the minimum controls required under EU law to contain bTB in affected herds as far as possible. For example, affected herds would be placed under movement restrictions and limited to sending cattle to slaughter either directly or via Approved Finishing Units; herd surveillance testing could be reduced to the lowest possible frequency and compensation levels could be limited to salvage value. While this may enable resources to be prioritised on the Edge Area, the failure to tackle the disease proactively in the High Risk Area would increase the likelihood of the spread of the endemic area and of bTB outbreaks in the LRA. In the long term, it would undermine efforts to achieve OTF Status for England and would therefore not be compatible with the Strategy aim. Additional considerations are provided in the “Legal minimum” option in the “Least Rigorous” Options for the LRA.

- **Abolish all bTB controls, maintaining only key measures that protect public health**

  The abolition of all bTB controls and surveillance would increase the likelihood of the spread of bTB and is therefore not compatible with the Strategy aim. It would carry implications for trade, contravene EU law, risk the loss of EU co-financing, risk EU infraction proceedings and potentially bring animal welfare problems. Although controls on milk and meat are the main public health protection measures, a reduction in cattle surveillance and the prompt removal of bTB reactors could increase public health risks, particularly in terms of occupational health for those in close contact with exposed animals.

“Most Rigorous” Options for the High Risk Area

- **Relax licensing conditions for localised culling following the badger culling pilots**

  Badger culling is included in the package of preferred measures. Management of the wildlife reservoir will reduce the spread of *M. bovis* from badgers to cattle. The Government is not proposing any significant changes to the approach at this time. Following the conclusion of the pilot culls there will be an opportunity to revisit the policy statement and licence conditions. Research into alternative badger population control methods is also in progress.

- **Ban all cattle movements (except to slaughter) within the HRA**

  There are approximately 2.3 million cattle movements from one holding to another, for cattle to live, within the HRA annually. If all such movements were banned, there would have to be substantial changes to the industry structure which, unless great care was taken, would significantly impact on the sustainability of the sector. This measure would also establish an anomalous situation where OTF herds in the HRA could sell cattle outside the HRA, including to other Member States, but not to a neighbouring herd. Although it is assumed that cattle movements within the HRA contribute to the severity of the disease, the precise split between wildlife-to-cattle and cattle-to-cattle spread is not known making it difficult to assess accurately and compare costs and benefits of such an intervention. Particularly if coupled to new tools such as risk-based trading, this risk is mitigated by compulsory pre-movement testing of all cattle over 42 days of age from all holdings in the HRA to live. Annual whole herd testing of all cattle herds in the HRA and tracing of all cattle moved from infected herds further mitigates this risk by providing early detection of infection.

- **Compulsory post-movement testing of cattle moving within the HRA (except to slaughter)**

  Voluntary post-movement testing is currently encouraged in all areas. The rationale for making it compulsory in the HRA is the same as elsewhere. However, it is assumed that the marginal benefits achieved by post-movement testing in the LRA, where 4-yearly testing makes the post movement testing more valuable, would be smaller in the HRA where annual whole herd testing is carried out.

- **Interferon gamma assay testing, or severe interpretation to tuberculin skin testing for routine herd testing, pre- and post-movement testing**

  This is not a preferred option for the legal and practical reasons given in the LRA.

- **Interferon gamma assay in all OTFW herds in the HRA**

  Defra's independent Diagnostic Programme Advisory Group (DPAG) has considered options for increasing the use of interferon gamma assay in the HRA. However, blanket interferon gamma assay testing in all OTFW herds in the HRA would cost the government in the region of £6.5 million per annum with a potential additional compensation bill of around twice that (not including the additional costs of increasing staffing and laboratory capacity for conducting the additional tests). Blanket use of interferon gamma assay and the increased number of removals that this would result in, would also be less effective as a disease control tool in the HRA where the re-infection risk from local badgers is so high for replacement animals. While this blunt approach is neither logistically feasible nor cost-effective, particularly in the current financial climate, there are good disease control arguments for the continued targeted use of interferon gamma assay in the HRA.

- **Depopulation of all breakdown herds and a prohibition on restocking**

This is not a preferred option for similar reasons to those given in respect of the LRA. It is normally deployed as an additional means of clearing infection from a herd. In the HRA the costs could be high. Using the estimates used in the LRA, the total cost of depopulating over 3,000 new breakdowns in the HRA in 2012 would have cost the taxpayer in excess of £290 million. If subsequent re-stocking was prohibited, the cattle industry would quickly disappear from large parts of the South West and West Midlands.

- **Prohibit restocking until clear herd test**

  This is not a preferred option for similar reasons to those given in respect of the LRA and Edge Area. The risk of closing down businesses will be highest in the HRA businesses where the risk of long-running breakdowns is highest.

- **No restocking permitted if under restrictions for a defined period**

  Within England more than 400 herds have had ongoing TB breakdowns for over a year. The Government agrees with the European Commission's view that current restocking policy (see the "prohibit restocking until clear herd test" option in the "most rigorous options" in the LRA) is unhelpful from a disease control and financial perspective i.e. bringing infection-free cattle into infected herds fuels the problem. This option would certainly produce disease control benefits though the cost for industry would be high – the affected businesses that have to re-stock if they are to survive would slowly be closed down.

- **Ban movements of cattle from 'higher risk' herds to 'lower risk' herds**

  As for the LRA, options such as risk-based trading would be more proportionate and offer a risk-based approach for herd-owners without recourse to an outright ban on movements.

- **Six-monthly routine testing in all or parts of HRA**

  Projections derived from mathematical models of bovine TB surveillance developed at AHVLA have shown that six-monthly TB testing of cattle herds in the HRA, on its own, would have little impact on the shape of the bTB epidemic curve and on reducing the number of OTFW breakdowns in the long term. The evidence from New Zealand also supports this view. In that country, despite intense testing (four whole herd tests per year) for two years, the incidence of infection in cattle herds remained constant at about 4%. It was not until TB was discovered in possums and their population controlled that incidence rates in cattle and farmed deer herds dropped.

- **Remove inconclusive reactors as reactors**

  Whilst the higher prevalence of bTB within the HRA makes this a more appealing option than its potential deployment in the LRA, it is not a preferred option for similar

reasons to those given in respect of the LRA. The preferred approach is to advise farmers to remove IRs immediately where there is particular risk of infection.

- **Treat all herds in which reactor animals are found as OTFW in terms of breakdown management**

  This option is considered under the “Treat all OTFS2 breakdowns as OTFW in terms of breakdown management” option in the preferred package for the HRA.

- **Deploy badger vaccination across HRA**

  This is not a preferred option for the reasons set out for the Edge Area.

Preferred Package for the High Risk Area

The preferred package of options would entail continuing with existing measures and potentially to introduce the measures outlined below.

- **Voluntary risk-based trading**

  The Government has decided to deploy this option, which is covered in more detail elsewhere.

- **Link top-up compensation to biosecurity, which includes for example risk-based trading**

  The option is covered in more detail elsewhere.

- **Enable cattle keepers to deal with identified bio-security weaknesses**

  The proposed approach to providing advice to farmers to reduce bTB transmission risks is covered in more detail elsewhere.

- **Wider roll out of badger culling subject to successful pilot culls**

  Culling of the wildlife reservoir will reduce the spread of *M. bovis* from badgers to cattle. Using the results of the RBCT, culling over an area of 150km^2 is estimated to lead to an overall net reduction in cattle herd bTB breakdowns of 16% (confidence interval: 7.9% to 24% reduction) over a nine-year period, relative to a similar unculled area. This estimate does not take into account the impact of additional measures to reduce the likelihood of increased bTB in cattle at the edge of the culled area. Two licensed pilot culls will start in summer 2013 to assess the humaneness, effectiveness (in terms of badger removal) and safety of controlled shooting of free-ranging badgers. A decision on wider roll out (up to ten new licences per year) is expected in early 2014.

- **Enhanced use of depopulation and controlled restocking of herds with on-going and recurring breakdowns**

In the HRA depopulation is currently used in situations where testing does not appear to clear the herd of infection and re-infection by badgers is not the likely cause to this. Annual number of depopulations varies greatly but has remained below ten depopulations per year in the past six years.

In order to avoid a situation where depopulation is followed by a re-introduction of TB infection by cattle movement or by badgers, depopulation would have to be accompanied with additional measures that would prevent this from happening. This would potentially require restocking under specific licensing conditions; e.g. type of stock that can be introduced, testing that is required, badger biosecurity that needs to be introduced, etc. This could be done under the current legislation and be introduced immediately.

- **Improved epidemiological investigations to establish approaches that address local and herd level risk factors more appropriately**

  The local epidemiology of bTB can also be characterised by using genotyping of different strains of *M. bovis*, and there is strong evidence to show that local strains are clustered in expanding areas, called 'home ranges'. In the HRA, breakdowns are usually caused by genotypes that are prevalent in the home range but can also be caused by genotypes that have a home range elsewhere in the HRA. The genotypes can be used to investigate the origin of breakdowns and are a powerful epidemiological tool in all risk areas.

  It is proposed that more use of the new data management and central data mining capabilities are utilised in order to develop a consistent approach to epidemiological breakdown assessment, creating an accessible dataset of all approximately 2,500 annual herd breakdowns in the HRA. This dataset will provide information for both analytical and descriptive data analysis and will form the basis of regional epidemiology reporting that will be established as part of the strategy.

  While improved epidemiological assessment and reporting on its own will not have an impact on disease control, it is proposed that the enhanced epidemiological assessment of each breakdown will form the basis for the proposed improved breakdown management (see below) which will have an impact on disease.

  Enhanced epidemiological assessment and reporting of breakdown causes and risk factors can be rolled out using the current data systems and following a feasibility and deliverability assessment by AHVLA. This would from part of the current AHVLA project to integrated field epidemiology function with bTB control function.

- **Local eradication strategies**

  As is true of England as a whole, the HRA is not an epidemiologically homogenous area with regard to bTB. The HRA can be characterised by different county prevalence figures (proportion of herd with an OTFW breakdown within a year), ranging from 15.7% in Gloucestershire to 4.8% in Warwickshire. There are clear, geographically

defined clusters of different *M. bovis*-strains (genotypes) within the area, and there are advancing disease fronts within, not just on the edges of the area.

It is, therefore important that the strategy addresses the differing disease situations locally and identifies areas and situations where disease control measures could be tailored to address local issues of spread and risk.

It is proposed that AHVLA field epidemiology teams are integrated into local bTB teams and take responsibility for local epidemiology assessment, developing operational approaches to local situation.

It is also proposed that specific areas or disease clusters are identified to tailor target-based control strategies. This could apply to specific geographic areas, such as the East Sussex enclave of bTB that is related to specific and unique genotypes or to specific genotype clusters in the South West of West Midlands.

The tools to develop local eradication strategies exist but the feasibility and cost of targeting resource to this work and the acceptability of the approach with the farming community would have to be assessed.

- **Improved breakdown management measures to identify and address the most likely causes of recurrent or persistent breakdowns**

  The Government will introduce a more structured and rigorous approach to dealing with recurrent and persistent breakdowns. AHVLA will work closely with herd-owners and their private veterinary surgeons to assess likely causes and agree/deliver actions and tools (for example, greater use of the gamma interferon test) to reduce disease risks thereby minimising impacts on the farm business and the general taxpayer.

- **More sensitive breakdown control regimes in areas where badger infection is controlled; e.g. introduce parallel interferon gamma assay in all OTFW breakdowns**

  The interferon gamma assay test is available for use in OTFW breakdowns in the HRA that meet certain criteria including biosecurity measures (the most common reason cited for the non-application of interferon gamma assay is the lack of effective biosecurity controls). Those herds taking part in the badger cull are required to ensure effective biosecurity measures are in place as part of their licensing agreement. They therefore already qualify for interferon gamma assay testing if they are declared OTFW.

- **Extend time between short interval tests and/or do not allow the short interval test to be used as a pre-movement test**

Around 38% of herds with TB breakdowns experience a new breakdown within 24 months of gaining OTF status.[66] In the worst-case scenario up to 21% of cattle herds may be harbouring infected animals when movement restrictions are lifted.[67] Furthermore, depending on the modelling assumptions, 50% or 24% of the recurrent bTB breakdowns could be due to infection missed by the SIT regime[68]. In light of this evidence, it could be argued that a minimum period of four months (two SITs) is too short to lift restrictions in an OTFW herd.

AHVLA research has also shown that infected cattle can exhibit significantly reduced skin test responses (desensitisation) after repeated 60-day testing.[69]

Therefore, the current protocol for restoring OTF status for breakdowns in the HRA could be strengthened to reduce the risk of residual infection and de-sensitisation. One way to do this would be to require a longer period between two qualifying SITs. This could be achieved by extending the minimum testing interval from 60 to 90 or 120 days, by requiring additional tests, or by a combination of the two approaches.

The above mentioned model has been used to look at the effect of increasing the interval between tests: overall, the evidence suggests that any benefits of extending the SIT interval for OTFW breakdowns in the HRA may be negated (at least in part) by the external infection pressure (from badgers and cattle movements) and the risk of cattle-to-cattle spread within infected herds (if we delay tests too much). However, by keeping herds under restriction for a longer period, the risk of infection to other herds linked to movements of cattle (including exports) off herds that get de-restricted while still containing infected animals would be reduced. This would be strengthened by amending the pre-movement testing rules so that in recently de-restricted herds the last SIT herd test could not be used as a qualifying test for cattle moved to other holdings

- **Treat all OTFS2 breakdowns as OTFW in terms of breakdown management**

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[66] Karolemeas, K. *et al*. (2011). Recurrence of bovine tuberculosis breakdowns in Great Britain: Risk factors and prediction. Prev Vet Med 102: 22–29.

[67] Conlan *et al*. (2013). Estimating the Hidden Burden of bovine tuberculosis in Great Britain. PLoS Comput Biol 8(10): e1002730. doi:10.1371/journal.pcbi.1002730.

[68] However, this model also showed that, in the high-risk area, eliminating this residue of infection through highly sensitive testing or depopulation of holdings would of course shorten the duration of TB breakdowns, but it would be unlikely on its own to reduce the rate of recurrence of breakdowns due to the high risk of re-infection from external sources (i.e. badgers and cattle movements).

[69] Coad *et al*. (2010) Veterinary Research 2010, 41:14. In this experiment 23 field TB reactor cattle from nine UK farms with a history of confirmed TB were kept in a research facility for up to four further tests at 60-day intervals. This was to evaluate the impact of repeat skin testing on the magnitude of the skin responses to tuberculin (and interferon-gamma blood test). This was obviously an artificial set-up which would not occur in a real-life situation on a farm because all TB reactors would be removed straight away and any inconclusive reactors would be re-tested only once after 60 days (and removed if they fail to give a negative result at that test). Furthermore, in this experiment it was not until the third retest of the TB field reactors that the differences between the responses of the repeat and original tests became statistically significant.

Tuberculin test sensitivity in the HRA could be increased through the compulsory use of stricter control measures for all OTFS breakdowns (see further evidence in the LRA section under the same heading) thereby treating them like OTFW breakdowns (except that OTF status would not be withdrawn unless post-mortem evidence of infection could be found). Herds suffering OTFS breakdowns in the HRA would need two successive short interval tests at the severe interpretation. All herds that had suffered OTFS breakdowns in the HRA would then have a check test six and twelve months after restrictions had been lifted.

In principle, from a disease control point of view these measures would also help to reduce the probability of residual *M. bovis* infection when herd restrictions are lifted and would contribute to mitigate the risk of spreading bTB. With for example some 900 new OTFS breakdowns in the HRA in 2012, the cost-effectiveness of these additional measures depends on two factors:

- The probability of an OTFS reactor herd representing a true *M. bovis* infection (this is much reduced in areas of low TB prevalence); and
- The likelihood of infection being reintroduced into the herd following de-restriction (i.e. through cattle movements or from infected badgers in the locality).

Whilst the breakdowns in the HRA will fulfil the second criteria, they would be at high risk of being re-infected by badgers, and this would reduce the cost effectiveness of stricter breakdown measures. It is proposed that, in the HRA, the current policy of categorising breakdowns as OTFS2 on the basis of either disease risk through management practices, proximity to disease in other cattle herds or risk of infection from badgers would be preferable As the disease risk is not the same across the HRA, the possibility of early return to OTF herd status would be maintained with this approach for those herds that can be shown to be at low risk of infection and to present a low risk of spread to other herds.

- **Deploy cattle vaccination as soon as vaccine available**

  This option is not yet available.

- **Deploy oral badger vaccination as soon as vaccine available**

  This option is not yet available.

ANNEX I – DEFRA'S BOVINE TUBERCULOSIS RESEARCH PROGRAMME

Background

Defra has funded a wide-ranging bTB research and development programme including:

- The development of a vaccine for bTB (for potential use either in cattle or badgers);
- Developing improved diagnostic techniques (both for bTB in cattle and badgers);
- Epidemiological studies on factors influencing the prevalence and persistence of the disease in cattle and wildlife;
- Analysis of data from the Randomised Badger Culling Trial & associated research;
- Investigating transmission routes between and within species;
- Investigating risk factors contributing to the development of the disease in cattle; and
- Economic, epidemiological and social scientific analyses of bTB control strategies and impact of the disease.

Between 1991/92 and 2012/13 Defra and its predecessor MAFF, funded over 110 individual research projects and invested approx £108 million in its bTB R&D programme plus a further £49 million on the Randomised Badger Culling Trial (RBCT). Defra's Animal Health and Welfare research budget covers England, Wales and Scotland.

Research Spend by Scientific Area

Figure 1 shows the research expenditure in the following scientific areas (excluding the RBCT) since 1991.

- Ecology and Husbandry
- Epidemiology, Economics and Modelling
- Pathogenesis/Genomics/Immunology
- Cattle Vaccines
- Badger Vaccines
- Cattle Diagnostics
- Badger Diagnostics
- General Diagnostics (those projects which cover badgers and cattle and/or other species)

Figure 1: Defra bTB research spend by scientific area

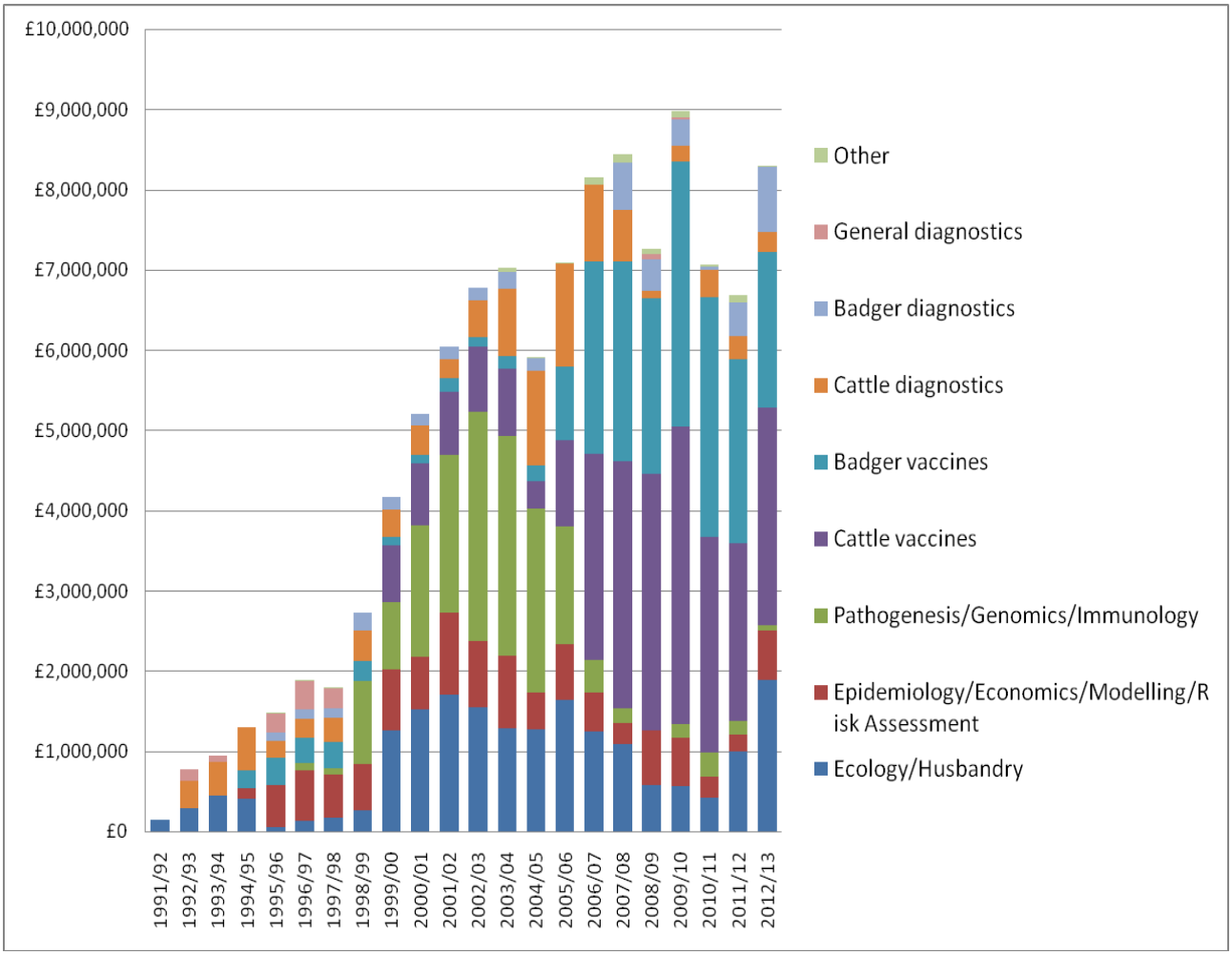

Table 1 provides a list of ongoing bTB research projects funded by Defra as of April 2013. Further information on Defra-funded research projects is available at http://randd.defra.gov.uk/

Table 1. List of ongoing bTB research projects funded by Defra as of April 2013

Project code	Title	Start date	End-date	Research Institution
SE3045	An exploration of factors that influence the expansion of the area affected by endemic TB	16/01/2012	31/07/2013	AHVLA
SE3046	A study to examine the interactions between cattle and badgers	01/04/2012	30/03/2015	Institute of Zoology
SE3121	Social Science study to accompany the Badger Vaccine Deployment Project	11/01/2010	10/01/2017	University of the West of England
SE3126	Development of a farm assessment tool for targeting badger biosecurity measures	01/04/2011	31/03/2013	Fera

SE3127	Cattle vaccination for the control of bovine Tuberculosis (bTB)	01/11/2011	01/11/2013	Cambridge
SE3129	Badger survey of England and Wales	2011	2013	Fera
SE3130	Transmission modelling and cost-effectiveness analysis of cattle vaccination at a herd level	01/11/2011	30/04/2014	Imperial College
SE3132	Estimating Badger Group Sizes in Different Landscapes in England and Wales	01/09/2012	01/07/2013	Fera
SE3247	Development of an oral BCG vaccine for badgers - REGULATORY	01/04/2010	31/03/2016	AHVLA
SE3265	Field approaches to identifying Mycobacterium bovis infection in badger populations	01/01/2011	31/03/2016	Fera
SE3266	Continued vaccine development: Improving BCG and developing non-sensitising vaccines for cattle	01/01/2012	31/03/2016	AHVLA
SE3268	Antigen mining, DIVA assays and other diagnostic approaches	01/01/2012	31/03/2016	AHVLA
SE3270	Development of novel diagnostic strategies for the ante-mortem immunodiagnosis of bovine tuberculosis and Johne's Disease	01/04/2012	31/03/2015	AHVLA / MRI / AFBI
SE3271	Development and field validation of a rapid immunomagnetic separation - lateral flow (IMS-LF) test for detecting Mycobacterium bovis infection in badgers and/or badger setts.	01/01/2012	30/06/2013	QUB
SE3272	Ecological and epidemiological effects of small-scale badger culling	01/12/2011	31/03/2013	Institute of Zoology
SE3273	Systems for sample collection (blood and urine) from unanaesthetised badgers for diagnostic purposes	01/10/2011	03/01/2014	AHVLA
SE3277	Fertility control in badgers	01/09/2011	31/03/2014	Fera
SE3280	Optimisation of sampling strategies for improving sensitivity of M. bovis detection by PCR	09/01/2012	08/07/2013	Warwick University
SE3281	R&D towards novel field-based approaches to the diagnosis of bovine tuberculosis in badgers	02/04/2012	31/03/2015	AHVLA
SE3283	A study to evaluate risk informed bTB trading schemes	01/04/2012	30/09/2013	AHVLA
SE3284	A study to design risk based bTB surveillance regimes in England and	01/04/2012	31/03/2014	Warwick University

	Wales			
SE3285	The development of quantitative risk-based surveillance strategies for bTB in England & Wales	01/07/2012	30/06/2014	Glasgow University