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The Strategy for achieving Officially Bovine Tuberculosis Free status for England

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Contents

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. It is a devastating zoonosis that 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 1979 only 0.01 percent of British cattle tested as infected. It has now spread extensively northwards and eastwards from infected pockets in the south west of England and Wales. The number of new herd breakdowns has doubled every nine years and in the last decade we have slaughtered 314,000 otherwise healthy cattle across Great Britain in our attempt to control this disease. In 2013 over 6.2 million bTB tests were performed in England leading to the slaughter of over 26,000 cattle. One quarter of herds in the South West and West Midlands were placed under movement restrictions at some point; bTB causes misery for affected farmers. In the last decade it has cost the taxpayer £500 million. In 2014 it will cost the taxpayer nearly £100 million with costs to farmers estimated to run to tens of millions of pounds.

If we do not get on top of the disease we will see a continued increase in the number of herds affected, further geographical spread and a taxpayer bill over the next decade exceeding £1 billion. It is therefore vital that farmers, vets, non-government organisations and politicians work together to free England of bTB. We want to build a thriving cattle sector which maintains our countryside, trades internationally and delivers economic growth.

The current surveillance and control scheme is based on the traditional approach applied across Europe: 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, areas we believe do not yet have a significant reservoir of infection in wildlife. The same approach has reduced the spread of the disease in the areas where bTB is established but on its own it is not enough.

Where there is a reservoir of disease in wildlife, tackling this disease will require long-term solutions and considerable national resolve. Half measures are simply not enough. I intend to pursue policies which will 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 the country of bTB. So we need a control and eradication strategy with these

clear aims at its heart. It must be dynamic, tailored to the sources of disease and the potential for eliminating it. It must adapt as new tools become available.

In achieving these aims, we must learn the lessons from those countries that have succeeded in tackling bTB where there has been a reservoir of the disease in wildlife. I have visited Australia, New Zealand, the Republic of Ireland and the USA. I have talked to the Ministers, farmers and officials involved and I intend to apply the lessons of their success here in England:

- Australia achieved official freedom from bTB in 1997 after a sustained campaign over nearly three decades.
- Michigan has reduced the prevalence of TB in white-tailed deer by 60 per cent since the mid-1990s and 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 66 in 2011/12.
- The Republic of Ireland reduced the proportion of herds affected from 9.6 percent in 1995 to 7.4 percent in 2010. In the same period it increased from 0.8 percent to 9 percent in England and from 5.5 to 7.9 percent in Northern Ireland. The number of bTB reactors in the Republic of Ireland fell by over 65 percent between 1999 and 2013, from 44,903 to 15,612, the lowest level since the eradication programme started in the 1950s.

The vital lesson I have 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.

No two countries are the same, so we will need to be smart in how we adapt and apply the key elements of others' eradication strategies to our countryside. However, the common thread is undoubtedly the sustained and adaptive application of a control programme that addresses significant reservoirs of infection in cattle and wildlife as well as pockets of infection in other species such as camelids, deer and goats, through a partnership approach.

I am delighted to publish the Government's bTB Strategy for England following a public consultation and extensive dialogue in 2013. For the first time it:

- brings together all the tools we need to address the disease including those currently available and those under development such as cattle vaccine,
- explicitly rejects the one size fits all approach, recognising the need to apply different tools in different herds depending on local circumstances and disease risk,

- sets targets by which we can measure progress towards achieving OTF status for England.

The Strategy is comprehensive using all available tools to:

- contain bTB in the high risk area and progressively reduce its spread, thereby increasing the number of bTB-free herds,
- maintain the commercial viability of herds in the high risk area,
- maintain consumer confidence and exports without undermining the detection and control of bTB,
- reduce the risk of spread of the bTB to currently free areas,
- rapidly find and eliminate bTB wherever it occurs,
- reduce and eliminate the spread of TB from badgers,
- identify and apply management practices that minimise transmission risk within herds,
- deploy market measures, regulation, incentives and deterrents to reduce the risk of disease spread due to movements.

The Strategy will simply not work without addressing the reservoir of TB infection in badgers. The option of using injectable badger vaccine has been available since 2010. However, we estimate that a third of badgers in endemic areas are infected with TB; we know that the vaccine does not cure them and that they remain free to spread TB. Despite the fact that injectable badger vaccination does not entail all the licensing criteria landowners must meet to carry out culling, there has been no widespread deployment either by farmers or NGOs. Based on first veterinary principles and supported by modelling, one would expect culling to be more effective than a badger vaccination programme; that is why I have decided to continue the policy of badger culling in endemic areas learning lessons from the pilots in 2013.

As well as using available tools, I am determined to develop new ones to support the Strategy. Over this Parliament, we are investing £24.6 million in the development of effective TB vaccines for both cattle and badgers. Our scientists are leading the world in the development of a deployable cattle vaccine. I secured a clear programme from Commissioner Tonio Borg (DG-SANCO) on the work necessary to bring a cattle vaccine to the market. We are making progress in designing the large scale field trials necessary to take this forward. Subject to an assessment of costs and benefits, I am committed to meeting the earliest deadline for its implementation, but the need for the field trials and changes in the law mean that a usable cattle vaccine is still many years away. In the future, an oral badger vaccine might address some of the deployment issues with injectable vaccine deployment and serve as a targeted control measure. Although some progress has been made, we have not yet identified a candidate vaccine to take forward for authorisation. We will also continue to invest in the development of improved diagnostic tests for both cattle and badgers such as DNA-based technologies. My goal is to move to a position whereby we have the tools to enable us to deploy a targeted approach, identifying and removing only TB-infected badgers either at individual or sett level. In the meantime we will not sit on our hands and let the problem get worse.

A key point drawn from other countries is the need for a partnership approach to governance, delivery, and funding of eradication programmes with farmers making the key implementation decisions and significantly contributing to the costs. The New Zealand government has commissioned an independent, farmer-led body, jointly funded by industry and government with responsibility for oversight and implementation of the eradication strategy. It has been a great success. I am absolutely clear that if we are to tackle this disease successfully, we need a different way of working together in England, which acknowledges the respective responsibilities for government and industry both in terms of what we do and how we pay for it. I intend to continue discussions with the industry as to how we might achieve this new way of working.

I accept that the right approach is not always the popular approach. The House of Commons gave its view in June 2013, when it endorsed by a majority of 61 votes a motion reflecting our strategic approach. This includes drawing on international experience which demonstrates the importance of bearing down on bTB in cattle and wildlife. It also stresses the need to employ every available tool to deal effectively with the disease, researching and investing in the development and deployment of new technologies.

I am extremely grateful for the work of the Animal Health and Welfare Board for England, the Bovine TB Eradication Advisory Group for England and to all those who responded to our public consultation or took part in stakeholder and public dialogue events. The Strategy, which they have all played a part in developing, recognises that achieving OTF status for England will be a long haul. I am however confident that it is not beyond industry and government to achieve it for England within the timescales we envisage. My aim is for England to be free of bTB by 2038 with healthy livestock living alongside healthy badgers. Our livestock industry, our badgers and our countryside deserve no less.

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

I. The Strategy for achieving Officially Bovine Tuberculosis Free status for England

Objective

The objective of the Government is to achieve Officially Bovine Tuberculosis Free (OTF) status for England by 2038. It also has an interim objective of achieving OTF status for large parts of the north and east of England as soon as possible but most likely by 2025.

This will be achieved by three key actions:

a) establishing three bovine tuberculosis (bTB) management regions or zones (a High Risk Area, a Low Risk Area and a buffer zone (Edge Area) in between);

b) applying a range of measures to control the disease within these zones that is practical and proportionate to the disease risk while maintaining an economically sustainable livestock industry;

c) ensuring that there is shared governance of the delivery process between the main beneficiaries including the food and farming industry and the taxpayer.

This activity will be led increasingly by the farming industry and other stakeholders, and their responsibilities will include the effective application of disease control measures in cattle, securing best practice in livestock farming including on-farm methods for preventing the spread of disease, and addressing the reservoir of bTB in wildlife[1] whilst maintaining biodiversity. We explicitly recognise the need to adapt our approach as the epidemic evolves and new evidence and technology becomes available and to embrace partnership working with a range of stakeholders, as well as working effectively in the European Union (EU).

Rationale for intervention

Bovine tuberculosis (bTB) is an increasing social and economic problem in England. There is a strong social and economic case for controlling the disease in order to support a thriving and sustainable livestock sector and the United Kingdom (UK)'s statutory bTB eradication programme is designed to comply with international standards for trade. The fact that the bTB situation in the UK (excluding Scotland) is the worst by far in the EU and

[1] While *Mycobacterium bovis* has been found in wildlife other than badgers, evidence from surveillance and modelling indicates that the badger remains the principal and possibly the only wildlife maintenance host in England. However, we will continue to review the potential role of other wildlife species in the epidemiology of bTB.

probably the worst in the developed world, poses an increasing risk to intra-EU and international trade. Additionally, bTB can pose a risk to human health.

The problem of bTB

Over the past three decades, the incidence of bTB in England has continued to increase and the disease has spread from parts of the South West. Although most of the north and east of England has had a very low incidence of bTB herd incidents ('breakdowns') there has been a much higher disease incidence in the West and South West. Parts of Wales have had a similar problem but Scotland achieved OTF status in 2009.

The epidemiology of bTB is complex and, despite considerable investment in the evidence base over the last 20 years, much remains highly uncertain. While the evidence that is available needs to be used and weighted appropriately according to its relevance and reliability, there is a need to pursue an adaptive approach to policy development, particularly as the evidence base grows and new interventions are tried and tested.

We will deploy a package of interventions, flexibly informed by scientific and veterinary advice, to address all likely routes of disease transmission. Due to the biology of bTB and its complex epidemiology, most effects of interventions will only be seen several years after their introduction and, even then, it will be difficult to assign cause and effect to any particular intervention. As a result, each of these interventions is open to challenge by those with different perceptions of where the real problem lies. Consequently, success is measured through the combined impacts of a national system of intervention, rather than looking at individual control measures in isolation.

Defining the solution

There is no single intervention that will on its own achieve control of the bTB epidemic. Disease control needs to be constructed around controlling all routes of transmission of the disease. These are principally cattle-cattle, but will also include cattle-badger, badger-badger and badger-cattle as well as spillover into other susceptible species. The different contribution made by these routes will vary with circumstances.

This approach means using all the available interventions in proportion to their likely contributions to the aim of achieving reduced disease incidence in cattle, and as part of the national framework. Therefore we need to:

- bear down on the highest impact risks using the latest and most relevant evidence;
- ensure that future interventions are designed to minimise these risks and that they are applied proportionately to the circumstances; and

- ensure that those who are responsible for managing the behaviours that change the risks are aware of their responsibilities and are incentivised to deliver effective disease control.

Improved application of epidemiological techniques has the capacity to refine our understanding of the risk factors determining the probability of infection with bTB and to design interventions in ways that are increasingly effective. This is a key priority and we are committed to developing this by strengthening our application of epidemiology at local, regional and national scales. Additional data collection and epidemiological analysis conducted alongside implementation of integrated controls will lead to improvement in modelling and risk assessments and in turn to improvement in the design of cost-effective interventions to reduce disease.

This approach to risk assessment, enabling interventions to be tailored to specific circumstances, has the greatest probability of success if it is shared with the farming community and implemented in a partnership between farmers, veterinarians and regulators. We intend to adapt compulsory surveillance and control measures, and the way in which compensation funding is used, both to improve the implementation of control measures and incentivise risk reduction actions at the scale of individual farms.

It is widely accepted that no single intervention has the capacity to control the disease. Each intervention has strengths and weaknesses, which will vary depending upon local circumstances. Therefore an integrated approach to controlling bTB will require the use of a range of disease surveillance and control interventions, including statutory and non-statutory controls.

Current statutory controls include continued surveillance for disease within cattle herds and at slaughter, pre-movement testing, removal of bTB test reactors and other cattle suspected of being infected with bTB from the national herd, and additional measures in bTB breakdown herds such as movement restrictions, disinfection, and more sensitive tests to increase the chances of removing infection from affected herds and to reduce the probability of spread between herds.

Non-statutory controls include a range of measures that are expected to reduce the likelihood of introducing infection into cattle herds. These include: the risk-based trading scheme introduced in 2013 in response to the recommendations of an industry-led Risk-Based Trading Group to enable farmers to better understand and act on the risk of introducing disease when buying cattle; post-movement testing; biosecurity measures on farms against both cattle-cattle and badger-cattle transmission; reduction in badger populations; and BCG vaccination of badgers against bTB by injection. BCG is not a very effective vaccine.

Notable potential interventions that are either not currently available or not deployable on an operational scale are cattle TB vaccination, oral TB vaccination of badgers, the identification and removal of TB-infected badgers and alternative approaches to badger population control ideally focussed on removing from the population only those badgers infected with TB. A combination of scientific and technical challenges means that each of

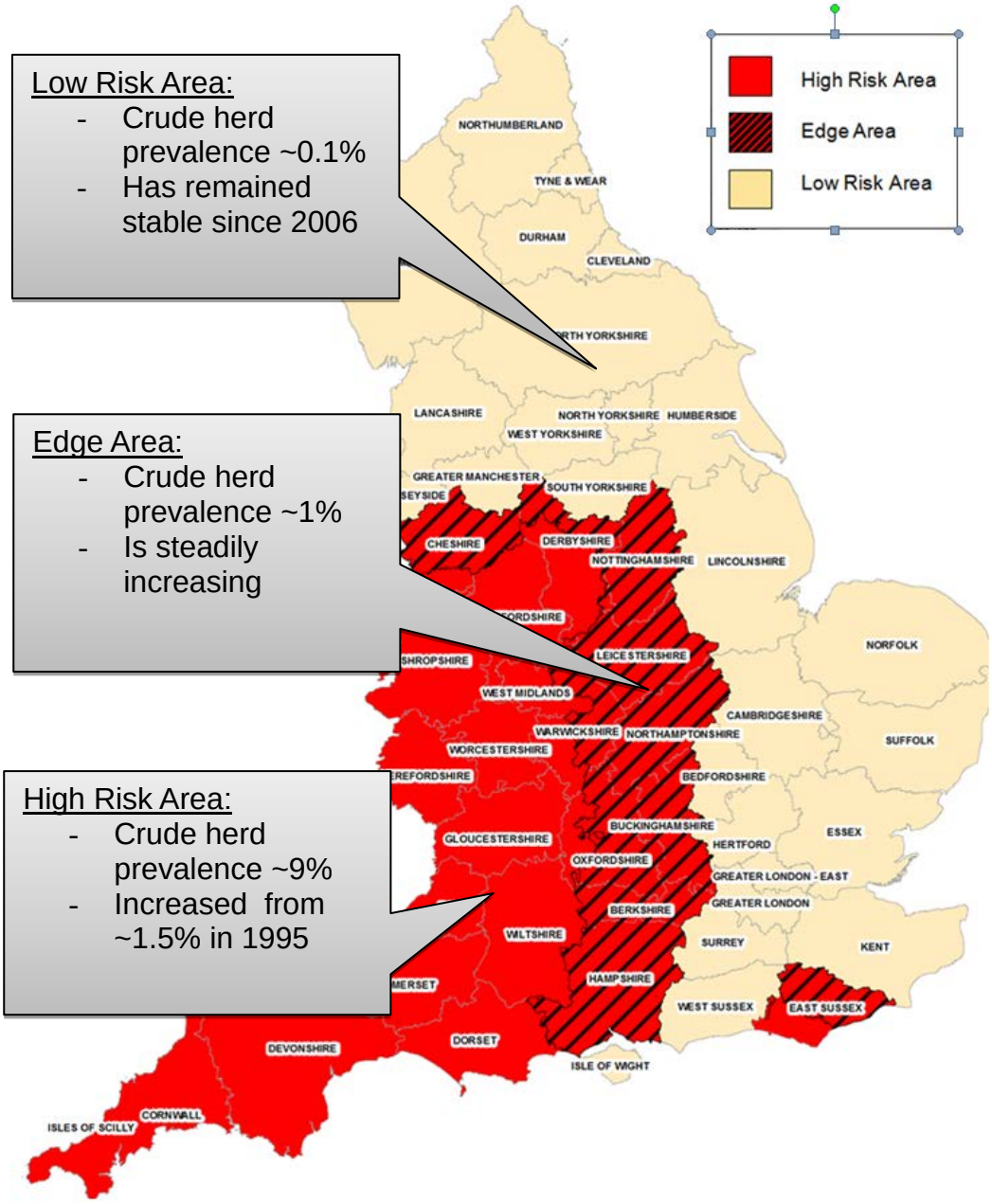
these approaches requires further work before they can be implemented but we will look to deploy them to best effect as they become available. Ongoing research and pilots are examining ways in which some of these interventions can be turned into operational tools.

Implementing the solution

The approach to controlling bTB ultimately aims to tackle the disease nationally. However, achieving this will require us to apply different sets of interventions according to circumstances because the problem is different in different parts of the country. In practice, interventions take place mainly at the scale of individual farms but it is important to see a coherent link between the application of these interventions and the wider national objective of achieving OTF status by 2038.

Regional variation will be addressed by different generic control policies in three management regions or zones. These zones are defined as the High Risk (HRA) the Edge, and the Low Risk (LRA) Areas (**Figure 1**).

Figure 1 – Geographical location of the three risk areas in 2013



Local variation in disease characteristics can be addressed, for example, by more frequent surveillance testing of local herds in response to emerging problems and where the epidemiological evidence shows that bTB herd breakdowns detected by testing or by slaughterhouse surveillance are in some way geographically and temporally associated. This kind of intervention is already a standard approach within the LRA and Edge Area. As our epidemiological knowledge improves, it may signal new ways of controlling the disease at these local levels and we will introduce new measures to achieve this whenever feasible and cost-effective.

The strategic disease control principles used in implementation are set out in **Table 1**. This builds upon the interventions that we know from past experience are effective. Applying

these in proportion to the risk will improve their effectiveness. It also uses the information we have from surveillance, epidemiology and local knowledge to greatest effect. It will lead to a step change in the effectiveness of our approach to control bTB because it will focus the resources in those places and situations where the problem is most profound.

Table 1 – Strategic disease control principles

- Define areas of the country on the basis of risk (**Figure 1**).
- Focus disease control measures on those risks, to contain the disease in the HRA and progressively reduce its size.
- Establish a risk rating system for herds and incentivise actions by farmers to reduce their risk.
- Reduce the risk of spread of the disease to currently free geographic areas and to unaffected cattle herds in affected areas.
- Rapidly find and eliminate disease in cattle when it occurs in areas previously free of disease.
- Reduce the spread of TB between cattle both within and between herds.
- Minimise the exposure of cattle to infected badgers (a key risk factor for its introduction to cattle) and other possible wildlife vectors.
- Deal promptly with any other epidemiologically significant reservoirs of TB infection that are discovered.
- Move towards an increasingly farmer-led control and eradication process, with farmers significantly contributing to the costs of implementing the practical decisions they are taking to eradicate the disease.

Improving bio-security is a priority. This focuses attention on the processes involved in disease transmission. Early interventions to improve bio-security include developing the voluntary risk-based trading scheme introduced in 2013, deploying measures at the farm level to reduce cattle-cattle and wildlife-cattle transmission, providing the necessary incentives to farmers to achieve risk-reduction, improving advice for farmers, improving compliance and enforcement, and tackling TB in non-bovine species such as South American camelids.

The intention is to progress region-by-region towards OTF status. Consequently a key development to achieve this is the introduction of a risk-based approach to disease control applied to three management regions or zones. The differing approaches being adopted in these zones are set out in **Table 2**. Zoning will allow the system of disease management to be proportionate to the impact upon the industry and be flexible to the different circumstances of evolving disease risk in each zone.

Low Risk Area (LRA)

The LRA covers large parts of the north and east of England (**Figure 1**). It has a low incidence of bTB and no recognised significant reservoir of the disease in wildlife. Consequently, the objective in the LRA is to continue to protect it from the ingress of disease through the movement of cattle and the possible resulting infection of wildlife vectors. This will continue to involve testing of cattle before being introduced from other

areas, as well as improving risk-based surveillance and incentivising risk-based approaches such as risk-based trading and the testing of cattle after being introduced as happens in Scotland. Isolated outbreaks will be controlled using the most sensitive tests to remove infected cattle and by testing neighbouring herds for disease. This approach is designed to achieve early OTF status for this geographical area.

Edge Area

The Edge Area is the buffer zone between the HRA and the LRA (**Figure 1**) which contains local disease fronts advancing from the HRA towards the LRA. The incidence of bTB in the Edge Area is much lower than that in the HRA, but higher than that in the LRA. Additional evidence is needed to determine the respective role of cattle and wildlife in the spread of the disease in the Edge Area. The Edge Area will be managed to contain and reverse the spread of bTB from the HRA to the LRA, with the aim of obtaining OTF status for this geographical area as soon as possible. This will incorporate strict cattle measures similar to those applied to the LRA with the additional focus on surveillance to identify the role of wildlife vectors. Management of these wildlife vectors will include vaccination and possibly culling where the evidence supports its deployment.

High Risk Area (HRA)

This zone covers the South West, West Midlands and East Sussex (**Figure 1**) and it is where a relatively high proportion of herds are infected by bTB. It is also where there is a high proportion of repeat cases among herds, and there is a recognised reservoir of infection in badgers. Even against this background, some herds and areas remain bTB-free, and we want to do all we can to maintain this position. This will include applying the methodology currently used in the LRA and Edge Area where it is cost-effective to do so. The objective is to halt and then reverse the increasing prevalence of bTB and ultimately to achieve OTF status for this geographical area. Because of the greater challenge in this area, and recognising the need for proportionality of the impact of disease control on the capacity of the industry to operate, we need to develop a more complex set of interventions that address the specific local needs. This includes incentivising risk-based approaches, such as risk-based trading and farm management measures, to reduce the likelihood of both cattle-cattle and badger-cattle infection. Management of the latter will include vaccination and culling.

Research

Research into the development of new interventions to control the disease is an essential part of the Government's strategy. This includes continuation of our search for affordable and effective vaccines for both cattle and badgers, more effective diagnostic tests and the development of the capacity to provide near-real-time epidemiological intelligence to inform how disease can be controlled in specific circumstances. It also includes new research into more effective ways of controlling the routes of transmission of disease between wildlife and cattle. An essential component of future research capacity will continue to be the collection of information about the nature of bTB risk, including

effectiveness of different sets of interventions and the ways in which these provide benefits for farm businesses. This will contribute to an approach involving adaptive learning; as we implement new ideas we will learn from them and make them incrementally better.

Governance

Experience in other countries has shown that governance is key to addressing successfully the control and elimination of bTB. For example, in New Zealand delegating responsibility for the control of bTB to an independent organisation with strong representation from the farming industry has been an important feature of their strategy. The Government will work with stakeholders to develop an enhanced partnership approach to the delivery of OTF status.

Within the context of such an approach the role of government will be to review delivery and provide the necessary support to ensure that delivery is efficient and effective and that operational decisions are taken at the most appropriate level. This recognises that tackling bTB carries significant costs to farmers and other taxpayers and that these costs are not sustainable, but also that additional investment will be required over the short term to bring the disease under control and reduce the costs in the long term.

We will develop proposals for a sustainable funding model for this governance structure in partnership with stakeholders. The experiences of both New Zealand and the Republic of Ireland provide evidence of the success of innovative delivery and co-financed bTB disease control.

Table 2 – Summary of current measures and additional future measures or options

Risk area	Type of measure	Current measures	Additional future measures or options[2]
All Risk Areas	Surveillance	-Slaughterhouse surveillance -TB surveillance in non-bovines	-Enhance the sensitivity of slaughterhouse surveillance -Enhance the sensitivity of TB surveillance in non-bovines
	Breakdown management	-Movement restrictions -Isolation and rapid removal of suspected infected animals/contacts -Increased testing in	-Phase out the practice of lifting restrictions on different parts of bTB holdings at different times -Introduce more sensitive testing of cattle traced

[2] Subject to change in the light of new evidence and experience

Risk area	Type of measure	Current measures	Additional future measures or options[2]
		infected and surrounding herds -Epidemiological investigations/reports	from breakdown herds -Introduce stricter measures for bTB breakdown herds on a risk basis -Extend the time between short-interval herd tests to reduce the risk of test de-sensitisation and increase detection of residual infection -Improve epidemiological investigation/ reporting -Introduce stricter measures for TB breakdowns non-bovine -Enhance the management of persistent and recurrent breakdowns
	Other disease prevention	-Voluntary risk-based trading -Advice and guidance -Sanctions -Public health protection measures	-Improve advice and guidance -Improve local information on bTB -Review pre-movement testing exemptions -Review compensation to encourage risk-reduction -Improve biosecurity on and off farm -Encourage voluntary local eradication boards -Work with industry to support risk-based trading -Consider interferon-gamma assay for private pre- and post- movement testing -Pilot bTB enforcement

Risk area	Type of measure	Current measures	Additional future measures or options[2]
			team - Support the introduction of bTB risk accreditation standards
Low Risk Area	Surveillance	Four-yearly herd testing (except higher risk herds on annual testing)	-Improve risk-based testing by reviewing current approach to identifying higher risk herds and based on recommendations from research
	Breakdown management	- Interferon-gamma assay of higher risk breakdown herds -Surveillance skin testing of herds within 3km radius	
	Other disease prevention	-Biosecure (non-grazing) Approved Finishing Units -Regional epidemiology reporting	-Introduce compulsory post-movement testing into LRA -Encourage improved biosecurity in other finishing units receiving cattle into the LRA
Edge of High Risk Area	Surveillance	-Annual herd testing	
	Breakdown management	- Interferon-gamma assay of higher risk breakdown herds -Skin testing of contiguous herds -Surveillance skin testing of herds within 3km radius (some counties)	
	Reduce risk of TB from badgers	-Biosecurity -Injectable badger vaccination	-Increase surveillance for TB in badgers -Deploy oral badger vaccination (R&D)

Risk area	Type of measure	Current measures	Additional future measures or options[2]
	Other disease prevention	-Compulsory pre-movement testing -Biosecure Approved Finishing Units -Regional epidemiology reporting	-Deploy cattle vaccination (R&D)
High Risk Area	Surveillance	-Annual herd testing	
	Breakdown management	-Skin testing of contiguous herds	-Additional use of interferon-gamma assay in some herds e.g. where the risk of TB infection from badgers is under control -Improve field epidemiological investigation of breakdowns (including use of genetic sequencing)
	Reduce risk of TB from badgers	-Biosecurity -Injectable badger vaccination -Badger culling pilots	-Badger culling -Deploy oral badger vaccination (R&D)
	Other disease prevention	-Compulsory pre-movement testing -Biosecure Approved Finishing Units	-Deploy cattle vaccination (R&D) -Regional and cluster based epidemiological reporting

Notes:

1. Measures in all areas are deployed in addition to measures in specific risk areas.
2. R&D indicates areas in which the Government is funding multi-million pound research projects to develop operational tools.

II. 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. bTB is primarily a respiratory disease. Infection most often happens when moisture droplets containing *M. bovis* are inhaled but there are other routes of infection e.g. eating or drinking contaminated material.

The 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.

The vast majority of cases of TB in humans in the United Kingdom (UK) are caused by human-to-human transmission of *M. tuberculosis*.

History of bovine tuberculosis in England

Efforts to eradicate bTB from Great Britain (GB) 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 skin testing with immediate slaughter of any reactors.

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[3] EFSA (European Food Safety Authority) and ECDC (European Centre for Disease Prevention and Control), 2014. The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2012. EFSA Journal 2014;12(2):3547, 312 pp. doi:10.2903/j.efsa.2014.3547 http://www.efsa.europa.eu/en/efsajournal/pub/3547.htm

[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/pub/3266.htm

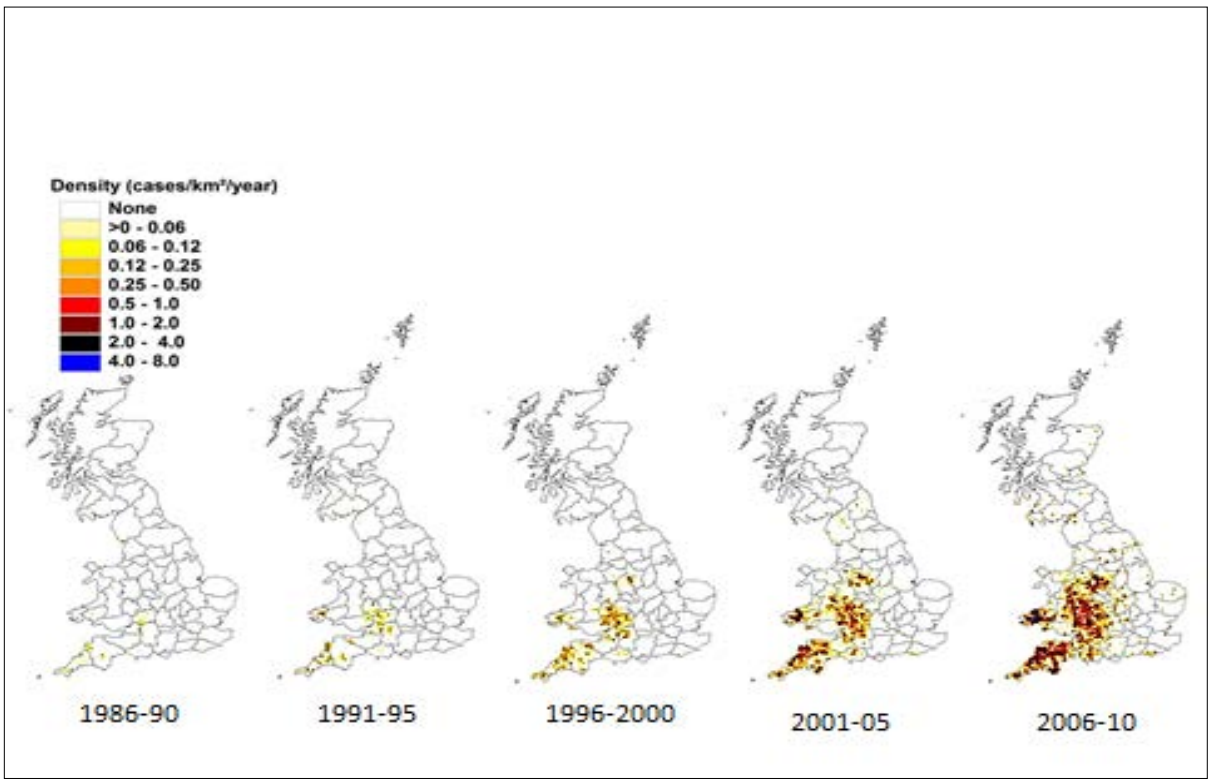
For the next two decades there was a steady decline in the incidence of reactor cattle, clinical cases and infected herds detected and every year new counties would be designated bTB-free areas in which the herd testing frequency could be gradually relaxed to reflect the improved situation. In 1979 the lowest bTB prevalence was recorded in GB, with 0.49 percent of all herds tested having a reactor, which equated to 0.018 percent of all cattle tested.

While the frequent testing of cattle herds and the removal of reactors to limit cattle-to-cattle spread of *M. bovis* remained the cornerstone of bTB control, a high prevalence of bTB persisted in parts of south west England despite enhanced herd control measures. In the early 1970s the badger was first identified as a possible wildlife reservoir of infection for cattle in this area. A series of different strategies were developed throughout the 1970s, 1980s and 1990s to tackle this wildlife source of bTB alongside further cattle-based measures in the area. 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 and subsequently the incidence progressively increased with new breakdowns extending eastwards and northwards (**Figure 2**). Prior to this, bTB herd incidence in south west England had remained about three times higher than in the rest of GB despite the retention of an annual (and occasionally more frequent) tuberculin skin testing regime for herds in this area.

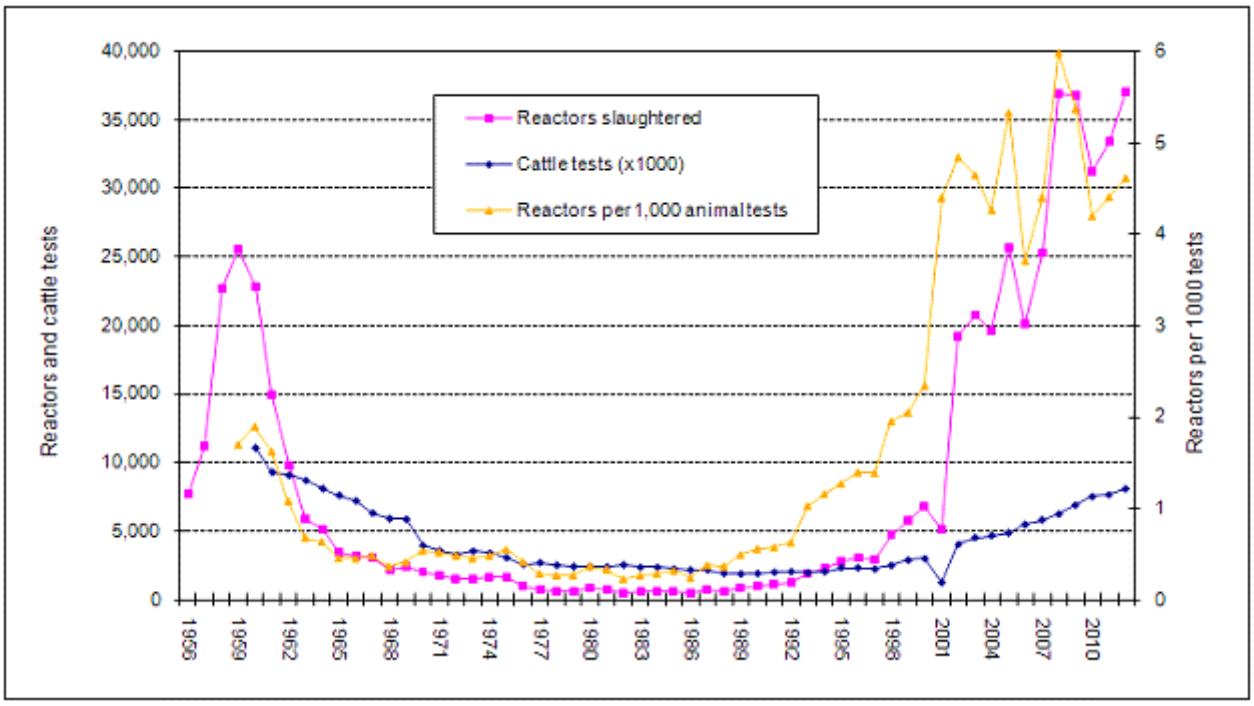
The Krebs report published in 1997 concluded that "*the sum of evidence strongly supports the view that, in Britain, badgers are a significant source of infection in cattle*". The main recommendation was to set up a controlled field experiment (the Randomised Badger Culling Trial (RBCT)) overseen by the Independent Scientific Group on cattle TB (ISG) to quantify the impact of culling badgers on bTB incidence in cattle. Immediately after the publication of the Krebs report, the Government suspended all badger removal operations outside the RBCT pending its outcome. Statutory compensation for bTB reactor cattle was increased from 75 percent to 100 percent of the individual market value of a normal animal from 1998.

Figure 2 – Number of skin and interferon-gamma test reactors and slaughterhouse cases found between 1986 and 2010 in cattle holdings experiencing bovine TB breakdowns with officially TB-free status withdrawn per km^2 per year



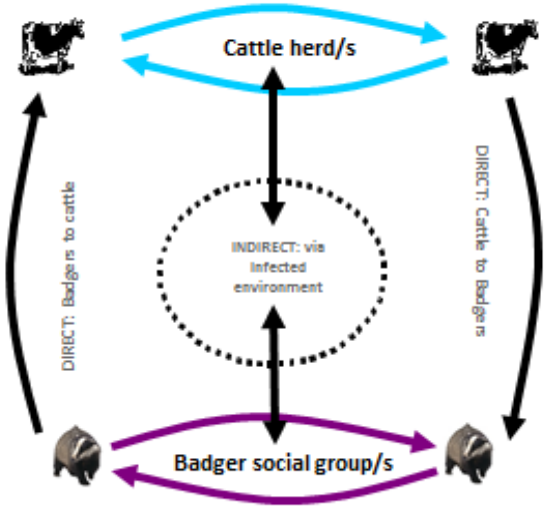
In 2001 the national bTB testing programme was severely disrupted due to a major outbreak of Foot and Mouth Disease, which led to anomalous bTB statistics from 2001 to early 2003. This led to a marked fall in the number of bTB breakdowns and reactors detected in 2001, followed by a sharp increase in 2002 as tuberculin skin testing of herds resumed (**Figure 3**). Another consequence of the outbreak was the geographical spread of bTB to new areas of England through the restocking of depopulated herds.

Figure 3 – 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). Using data from the start of the RBCT, it has been estimated that badgers contributed to some 50 percent of cattle herd bTB breakdowns in high incidence areas, either directly (badger-to-cattle spread of *M.bovis*) or indirectly (badger-to-cattle, followed by cattle-to-cattle spread of *M.bovis*). This is why any successful bTB control and eradication strategy must use all available tools to address effectively all the different routes of spread of *M. bovis* (**Figure 4**).

Figure 4 – Different routes of spread of *M. bovis* between cattle and badgers



From 2006 a range of additional cattle surveillance testing and movement controls were introduced in England, including 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 e.g. in culture and/or lesion positive breakdowns in non-endemic areas. In 2006 a new statutory compensation system for bTB reactor cattle was introduced, using monthly tables of values that reflect the average sales price of different categories of cattle.

By 2008 England reached a historical peak of 6.4 percent of herds experiencing new culture and/or lesion positive (formerly known as Officially bTB Free status withdrawn or OTFW) bTB breakdowns. There was no clear trend in the number of cattle movements in GB between 2002 and 2009[5]. Between 2009 and 2012, the herd incidence remained below 6.4 percent but the geographical spread of the endemic area continued.

In 2010 an injectable TB vaccine for badgers was authorised and this has been deployed in local projects funded by government and by non-government organisations. Multi-million pound government-funded research to develop a deployable cattle bTB vaccine and an oral TB vaccine for badgers is ongoing.

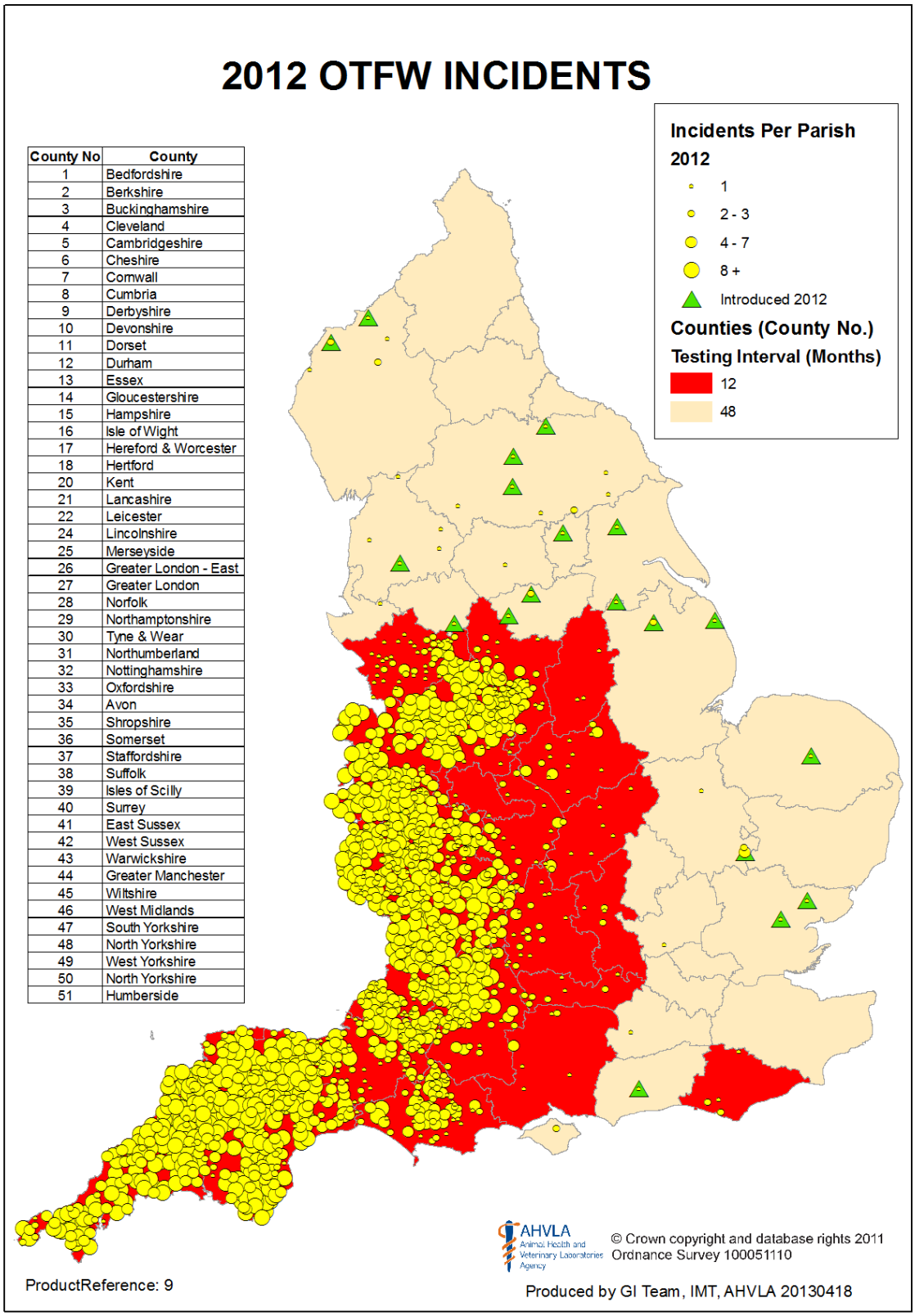
In 2011 the Government published a comprehensive Bovine Tuberculosis Eradication Programme for England[6].

In 2012 most bTB breakdowns in England were in the South West and West Midlands (**Figure 5**). By contrast the north and east of England had a very low and sporadic incidence of breakdowns. Less than 1.5 percent of bTB breakdowns in previously unaffected herds occurred in the areas of the country at low risk of the infection (Low Risk Area). Of these, at least half could be traced directly to the movement of infected cattle from the area at high risk of the infection (High Risk Area) 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.

[5] Vernon, M.C. (2011) Demographics of cattle movements in the UK. BMC Veterinary Research 2011, 7:31

[6] Defra (2011) Bovine Tuberculosis Eradication Programme for England, July 2011 (PB 13601)

Figure 5 – Map showing the uneven geographic distribution of bTB in England. New bTB herd breakdowns, or clusters of breakdowns, with 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)



Additional packages of cattle measures came into effect between 2012 and 2014 (**Annex B**). These included changes to cattle bTB compensation, the removal of some pre-movement bTB testing exemptions, the removal of higher risk links between holdings on the Cattle Tracing System (CTS) and a ban on new or enlarged Sole Occupancy Authorities (SOAs) from 2012. This was followed in 2013 by a tightening of cattle movement controls and a move from parish to county-based bTB testing intervals, further expanding the area in which cattle herds are tested annually.

In October 2013 the Government began deploying a package of measures as part of a new strategy for the Edge Area – a defined area on the eastern and northern border of the High Risk Area (see later). This package included advice to farmers, improved information management, stricter bTB breakdown management and prevention measures, and extension of access to government financial support for vaccination projects in the Edge Area. Additionally research projects were set up to estimate likely locations of badger populations in the Edge Area and to assess how useful post mortem examinations of badgers killed in road traffic accidents would be in estimating TB levels in local badgers.

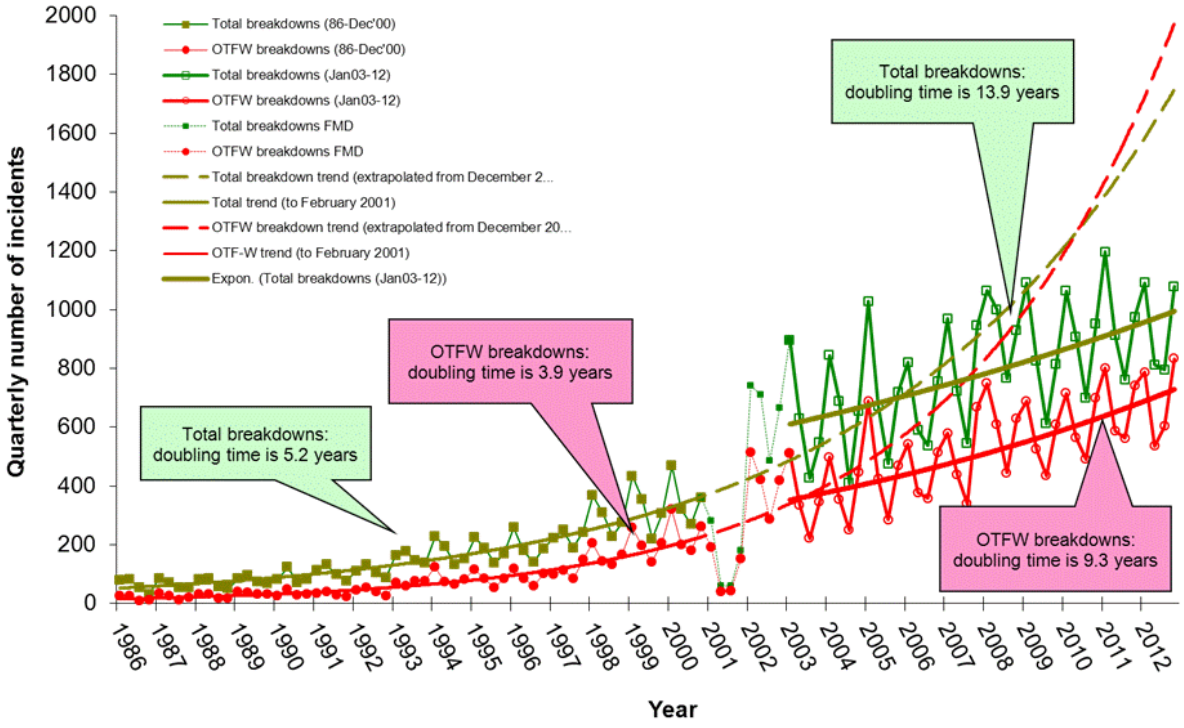
In November 2013 the Government launched a voluntary risk-based trading scheme to encourage farmers to share details of the bTB disease history of cattle they sell and buyers to act on this information. Since January 2014 farmers with overdue bTB surveillance or 'check' tests have faced a reduction of their Common Agricultural Policy Scheme payments. In February 2014 AHVLA announced an enhanced approach to managing long-term bTB breakdown herds in partnership with the farmers' private veterinary surgeons. In March 2014 Defra announced new powers to cull cattle unable to be tested for bTB and the removal of further pre-movement bTB testing exemptions.

In 2012 Natural England issued badger control licences in the HRA in Somerset and Gloucestershire. Each licence has a four-year term authorising control operations to be conducted each year with no control operations permitted during specified close seasons. Two pilot culls were completed in 2013 and an Independent Expert Panel assessed the humaneness, effectiveness (in terms of badger removal) and safety of controlled shooting of free-ranging badgers to inform decisions on a wider roll out of the policy.

Analysis of the bTB epidemic to 2012 showed that since the beginning of 2003, the relative rate of increase of new culture and/or lesion positive (formerly known as OTF status withdrawn or OTFW) bTB breakdowns in England fell by more than half compared with 1986-2000 (**Figure 6**). This was despite a year-on-year increase in the annual number of herd and animal tests carried out. However, the rolling average proportion of live cattle herds under restriction as a result of culture and/or lesion confirmed positive bTB breakdowns rose from just under one percent in 2000 to just over five percent in 2012. Further information is available in AHVLA's bTB surveillance reports[7].

[7] Bovine TB surveillance reports are available at http://www.defra.gov.uk/ahvla-en/publication/pub-survreport-tb/

Figure 6 –Quarterly numbers of total and OTFW new bovine TB breakdowns detected in England between January 1986 and December 2012



Evidence

The Government will develop approaches to deliver the Strategy based on the best available evidence, scientific advice and veterinary advice. The term ‘evidence’ encompasses material from multi-disciplinary science research, statistics, economics, social or operational research and geographical information.

Annex C includes links to components of the bTB evidence base, which is constantly evolving. This includes independent Natural Science and Socio-Economic Evidence Statements, and bTB surveillance reports and statistical reports compiled by Government. In some areas, the Government recognises that further research is required to strengthen the evidence base. Further information on Defra’s Evidence and Investment Strategy and the Bovine Tuberculosis Evidence Plan to strengthen the evidence base is provided in the section on ‘Developing New Tools’.

As well as developing new tools for controlling bTB, the Government will also address the continuing need to improve the understanding of the epidemiology of bTB. This includes strengthening field epidemiology to improve incorporation of local information into the national picture of the epidemic. It also includes the development and use of mathematical

models to inform the development, application, assessment, monitoring and evaluation of bTB control tools and policy options.

Strategy aim

The aim of the Strategy is to eradicate bTB, achieving Officially bTB Free (OTF) Status[8] for England incrementally, whilst maintaining an economically sustainable livestock industry[9].

The Strategy sets out how the aim will be achieved through greater partnership working, increasingly non-government-led implementation and a fair sharing of the associated costs. It draws upon the demonstratively successful approaches taken elsewhere in 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 successfully applied a package of conventional cattle measures in the absence of a significant reservoir of TB in wildlife, 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 percent 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;

- New Zealand, where a farmer-led management agency has delivered an effective national bTB eradication plan comprising cattle and wildlife controls co-financed by government and industry. The primary wildlife reservoir of *M. bovis* is in brush-tailed possums, introduced into New Zealand in the nineteenth century. Wildlife control

[8] For a Member State or region to achieve OTF status as defined in Council Directive 64/432/EEC, at least 99.9 percent 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 percent of herds experience the infection annually in a region defined as OTF, whilst eradication would represent elimination of the infection

[9] 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.

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 less than 100 (0.13 percent of herds) in 2012/13;

- The Republic of Ireland, where there has been a comprehensive bTB eradication programme including cattle controls and since 2000[10] an increasingly coordinated reactive cull of badgers in response to epidemiologically linked bTB breakdowns in cattle. The current badger culling strategy involving up to 30 percent of agricultural land has been in place since 2004[11]. The Irish programme has seen the proportion of bTB herd breakdowns fall from 9.6 percent (i.e. percentage of annual active herds with at least one TB reactor or slaughterhouse case) in 1995 to 7.4 percent in 2010, compared to increases from 0.8 percent to 9.0 percent in England and from 5.5 percent to 7.9 percent in Northern Ireland over the same period.[12] Cattle bTB testing and compensation in the Republic of Ireland are co-funded by government and industry;

- France, which achieved OTF status in 2000 and is working to eradicate bTB through a comprehensive eradication programme which includes cattle controls and culling of infected wildlife species (badgers, wild boar and deer). One of the most heavily infected *départements* used local trappers to catch and kill some 10,000 badgers over a large area between 2010 and 2013. Cattle bTB testing is co-funded by government and industry.

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, evidence-based use of rewards and penalties;

- Addressing the reservoir of *M. bovis* in wildlife whilst maintaining biodiversity 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 in the Edge Area, and radically reducing the prevalence of bTB in the High Risk Area, progressively achieving OTF status for England.

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[10] Good, M. *et al* (2011) Impact of the full herd depopulation policy on the recurrence of bovine tuberculosis in Irish herds, 2003 to 2005. Veterinary Record (2011) doi: 10.1136/vr.d4571

[11] Sheridan, M. (2011) Progress in tuberculosis eradication in Ireland. Veterinary Microbiology 151 (2011) 160-169

[12] 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

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.

In 2012, 481 thousand people worked on UK farms. The value of UK production was £3.8 billion for dairy products and £2.8 billion for beef. The value of UK exports was £1.2 billion for dairy products and £389 million for beef[13].

In 2013, the total number of cattle and calves in England was just under 5.4 million. The female breeding herd, which steadily decreased from just over 2.0 million in 2005 to 1.8 million in 2013, accounted for just over a third of this total; the dairy herd accounted for 61 percent of the breeding herd and remained at 1.1 million animals between 2010 and 2013; the beef herd decreased from 742 thousand in 2012 to 720 thousand in 2013[14].

bTB is one of the most pressing challenges facing the industry today; it has social and economic impacts. In 2012 the estimated average cost of a bTB breakdown in the High Risk Area was £14,000 to farmers and £20,000 to taxpayers; in 2011/12 the average cost of a routine bTB test was £350 to farmers and £770 to taxpayers. Based on current expenditure, the forecast cost to taxpayers 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 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 reduce the financial strain on public finances and industry through increased partnership working, industry-led

[13] Source: Agriculture in the United Kingdom 2012, UK Rural Affairs Departments https://www.gov.uk/government/publications/agriculture-in-the-united-kingdom-2012

[14] Source: Farming Statistics, Final Crop Areas and Cattle, Sheep and Pig Populations at 1 June 2013 - England, Defra https://www.gov.uk/government/publications/farming-statistics-final-crop-areas-yields-livestock-populations-and-agricultural-workforce-at-1-june-2013-uk

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.

The UK programme for accelerating the eradication of bTB[15] is designed on the basis of Council Directives 64/432/EEC, 77/391/EEC and 78/52/EEC with a view to enabling the UK to benefit from an EU financial contribution for the programme and mitigating the risk of infraction proceedings, financial penalties and trade sanctions.

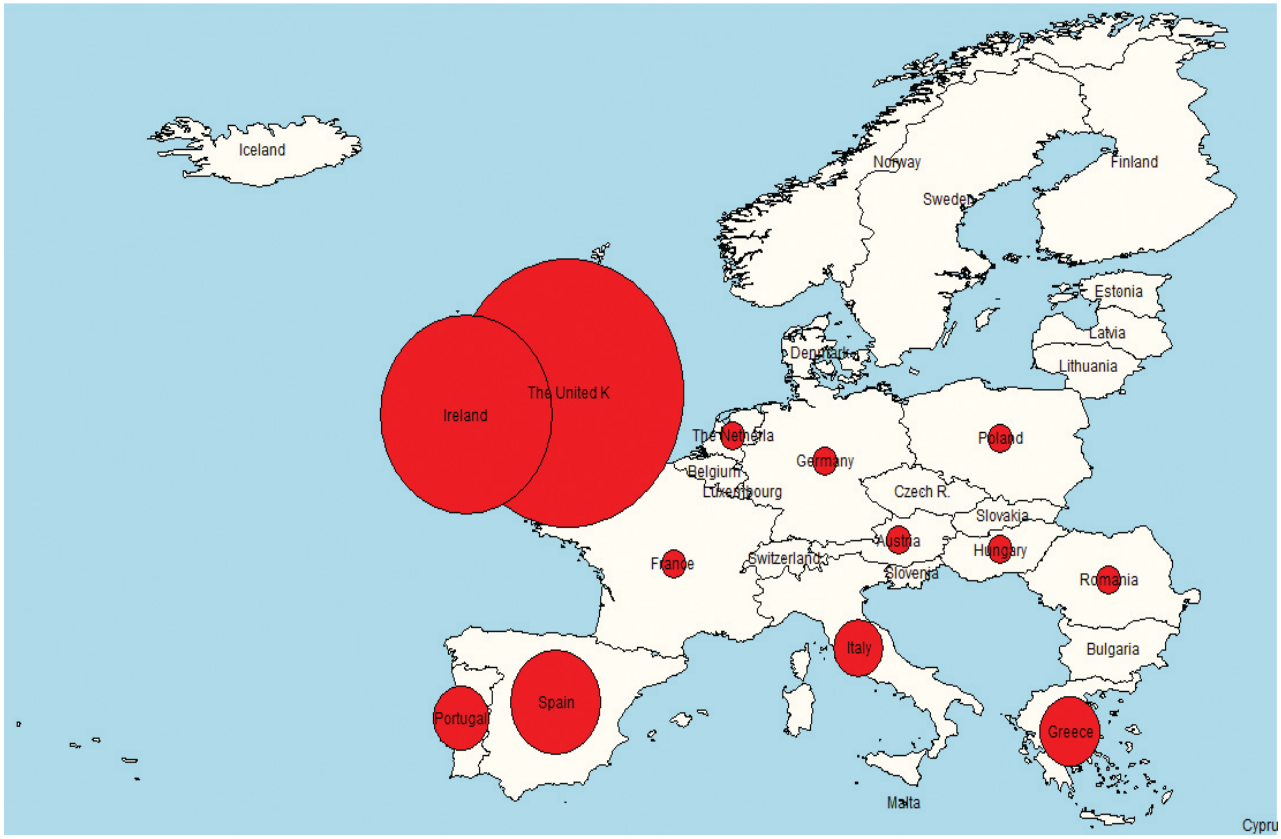
Achieving OTF status for England will provide tangible benefits for the cattle industry, rural communities and Government. These include significant savings in combating the disease both to Government and to industry, increasing the ability to trade within the EU and internationally[16] and alleviating 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 7)**. Many other EU Member States are already OTF. A map showing the OTF status of EU Member States can be found at **Annex D**.

[15] 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

[16] 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/

Figure 7: National herd prevalence[17] for bovine TB in EU member states[18]



The Government does not envisage disadvantages arising from the achievement of OTF status for England in a staged manner. Nevertheless, it proposes working with the Agricultural and Horticultural Development Board to assess any regional market impacts which might arise as a 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 and adaptive**: 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 evidence and tools whilst funding research to address evidence gaps and develop new tools;

[17] 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

[18] 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

- **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:

- **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 industries, the veterinary profession, local authorities, wildlife interest groups and other stakeholders will need to collaborate effectively to deliver the Strategy's aim. 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 programme.

- **Fair balance of costs and supported responsibility**: 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. 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 Regulation[19]. Government will work closely with the European Commission in the context of the evolution of the UK's bTB eradication programme and in presenting evidence for OTF status for regions of England. Government will also 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 are set out in **Table 3,** below. The targets will be used to monitor and evaluate the Strategy (see Monitoring and Evaluation of the Strategy) and further targets may be developed.

[19] 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

Table 3 – Initial targets

Basic measures of performance	Targets	Delivery scale	Indicators of success
Annual proportion of Officially bTB-Free (OTF) herds	Progressive attainment of OTF status for **individual counties** (or groups of counties) within the current **low risk area**[20]	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**[21]	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	
	The Government will set targets for individual counties within the **high risk area**		
	Achieve OTF status for **England**	By 2038	

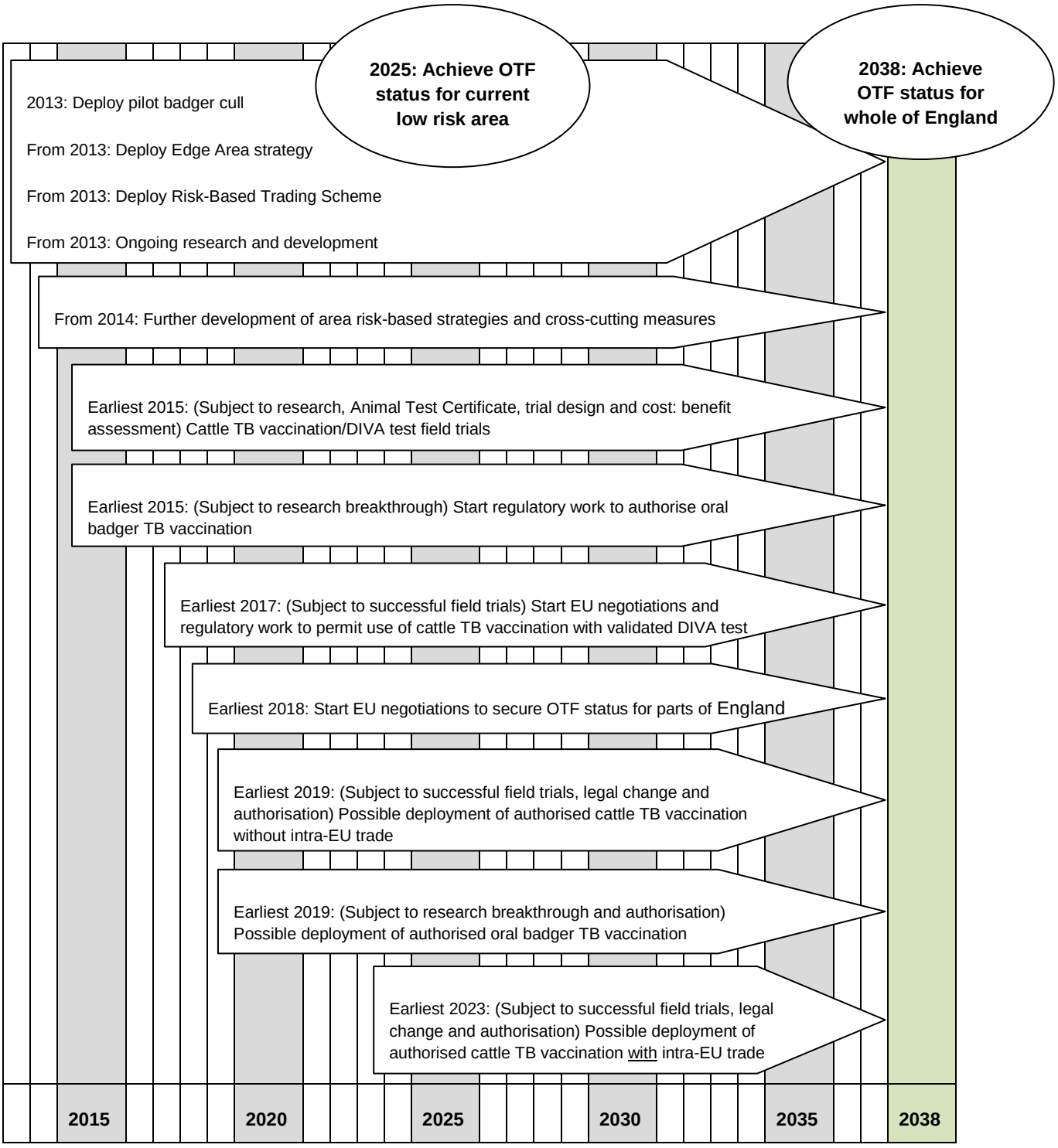
Timeline

Figure 8 illustrates the tentative timeline for potential deployment of measures to achieve the targets in the preceding section.

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

[21] As defined in 2013

Figure 8 – Tentative timeline of activity



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

Key elements

Developing our risk-based approach

Introduction

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. 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 9** shows the trend in bTB and the relative risk in each of the three risk areas. **Figure 1** illustrates the coverage of each risk area in England in 2013 with crude herd prevalence (bTB incidents as a proportion of live herds) in each area. The herd prevalence varies across each area, particularly in the HRA and the Edge Area and specific county prevalence figures are shown in **Figure 10**. **Table 4** provides details of the land coverage and the number of herds in each risk area in 2012.

Figure 9 - Variation in the number of culture and/or lesion positive new bovine TB breakdowns per 100 herd years at risk between 2003 and 2012, in the High Risk Area, Edge Area, Low Risk Area and whole of England (based on identical geographical areas throughout)

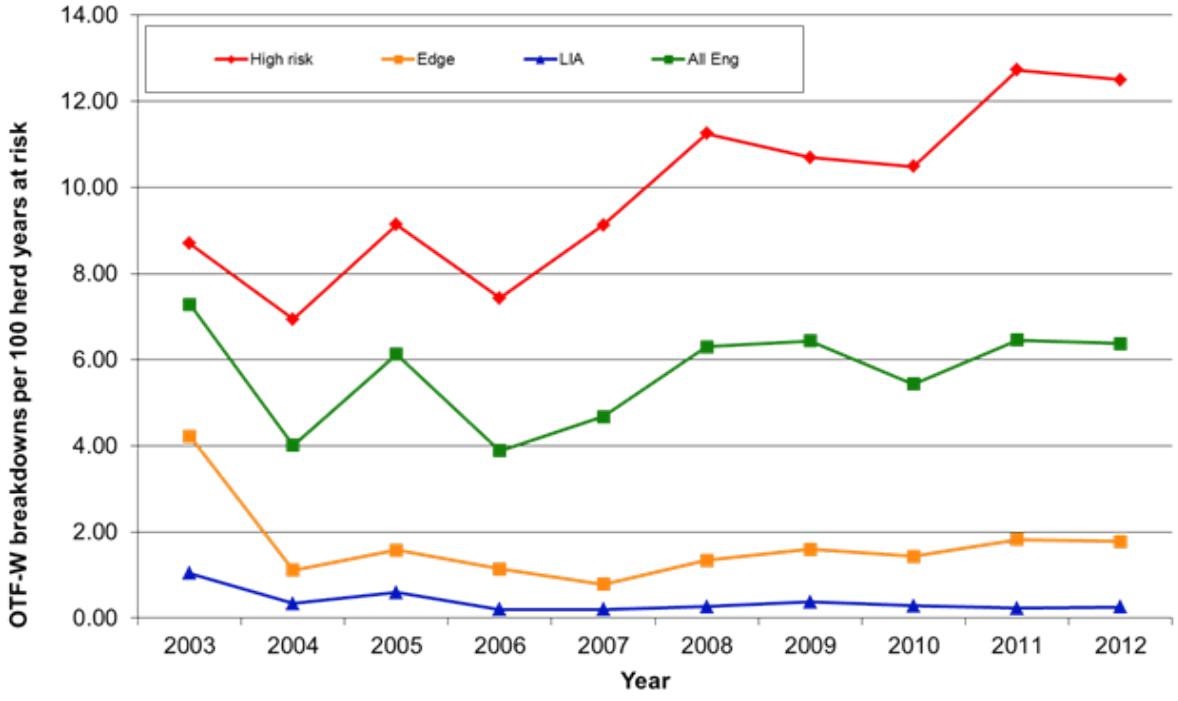


Figure 10 – Proportion of live herds with Officially bTB Free status withdrawn by county between January and December 2012: number of OTFW new bTB breakdowns per 100 live herds

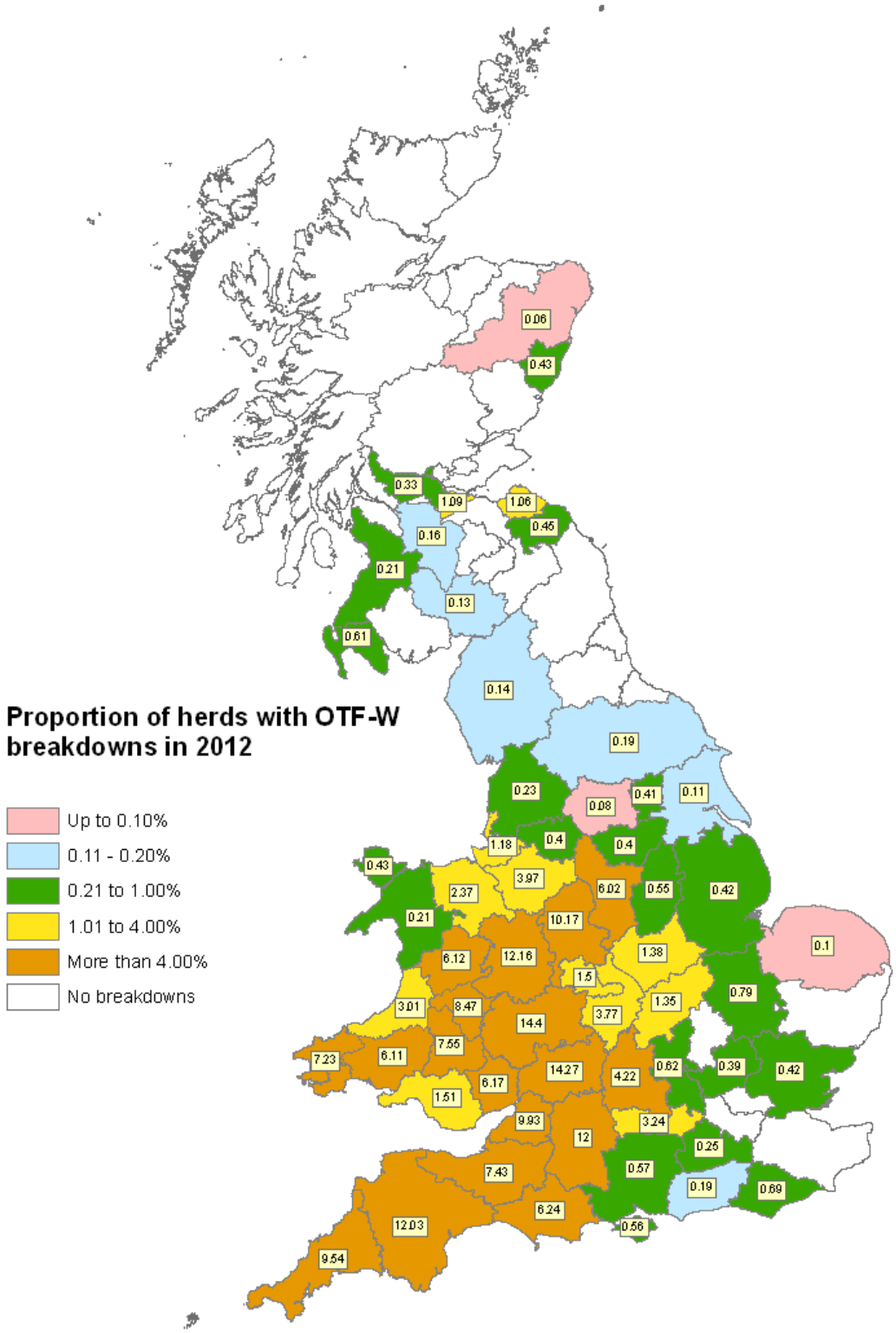


Table 4 – Land coverage and number of herds (*and percentage of total*) in each risk area in 2012

	High Risk Area	Edge Area	Low Risk Area
Land area (km^2)	38,570 *(29%)*	21,574 *(16%)*	72,621 *(55%)*
Number of cattle herds in 2012	~24,800 *(46%)*	~7,800 *(15%)*	~21,000 *(39%)*

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 includes sub-strategies for each risk area. Cross-cutting tools such as biosecurity, advice, compliance and enforcement underpin the approaches. The Government also needs to ensure that proportionate measures are in place to address the risk posed by TB in 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 apply across all risk areas, others are 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. **Table 5** summarises the objectives for each of the area risk-based strategies.

Table 5 - Summary of objectives of area risk-based strategies

For ALL areas of England		
Aim – to eradicate bTB, achieving Officially bTB Free (OTF) status for England incrementally, whilst maintaining an economically sustainable livestock industry		
For the LOW RISK AREA	**For the EDGE AREA**	**For the HIGH RISK AREA**
General characteristics • Low level of bTB • Breakdowns linked to cattle movements relatively short duration; low recurrence • No significant reservoir of TB in wildlife North and East of England	**General characteristics** • Levels of bTB variable; higher than Low Risk Area but lower than High Risk Area • Infection spreading north and east • Role of cattle and badgers uncertain Buffer zone east and north of High Risk Area	**General characteristics** • High level of bTB • Breakdowns relatively long duration; high recurrence • Significant reservoir of TB in wildlife (badgers) South West and West of England and East Sussex
Objectives To expand current area **Short to Medium Term** • Maintain or further reduce very low level of bTB • Achieve OTF status for area	**Objectives** To move current area west and south **Short to Medium Term** • Stop geographical spread of bTB • Begin to reduce level of bTB **Longer Term** • Reduce level of bTB and secure OTF status for area	**Objectives** To contract current area **Short Term** • Stabilise level of bTB **Medium Term** • Begin to reduce level of bTB **Longer Term** • Reduce level of bTB and secure OTF status for area

The level of bTB risk and incidence within each risk area is not uniform and stable. For example, forty percent of herds in the HRA in the ten years to 2012 did not have a bTB breakdown in this period; in the LRA, some individual herds may pose greater risks of infection than others because of their size, bTB history, cattle husbandry and trading practices. To reflect this, the Government wants to move towards a better definition of bTB risk on an individual herd basis rather than defining risk simply by geography. AHVLA has completed work that can generate a bTB risk rating for every herd in the country, which could be used to support risk-based trading decisions and potentially to enable the application of the principle of 'earned recognition' whereby best practice is rewarded with fewer burdens. Alternatively, there is scope for industry to develop an accreditation scheme to support risk-based trading decisions.

The remainder of this section explains:

- Existing bTB control measures applied in England
- Developing bTB control measures applicable in all risk areas
- Developing the LRA strategy
- Developing the Edge Area strategy
- Developing the HRA strategy

Existing bTB control measures applied in England

The existing bTB control measures in England are directed primarily to controlling *M. bovis* infection in cattle[22]. Some measures address the disease in other animals, such as badgers, deer and South American camelids (SAC) in order to reduce the risk of TB transmission to cattle. The measures include 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;

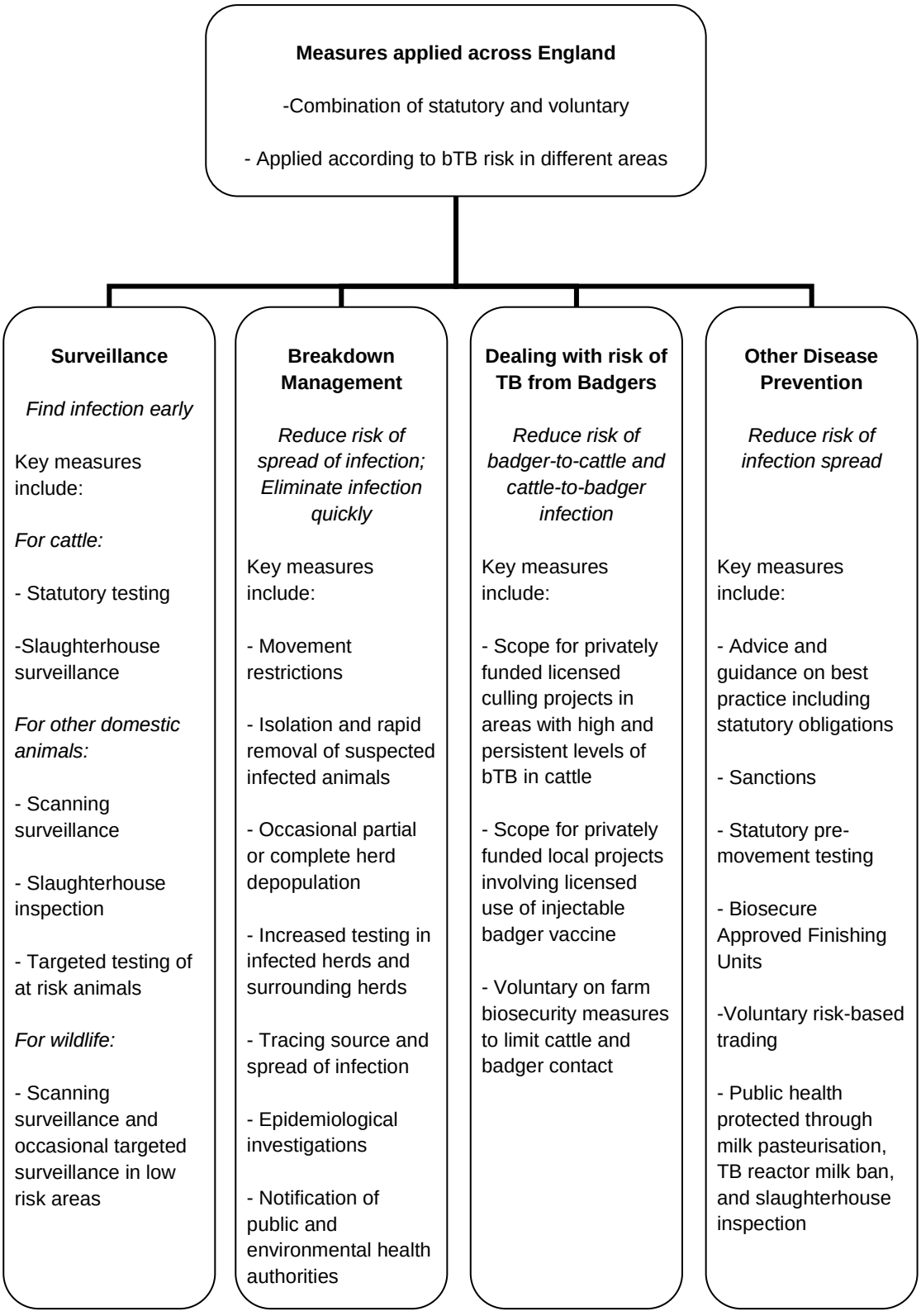
- measures that are statutory (in domestic legislation) but are only applied on a discretionary basis, depending on a particular situation; and

- voluntary measures such as private deployment of badger vaccines.

They can be categorised under the following headings: surveillance; breakdown management, dealing with the risk of TB from badgers; and other disease prevention (**Figure 11**). The measures, both statutory and non-statutory, are applied in a tailored manner across the different disease risk zones reflecting the value of each measure in a particular disease situation.

[22] 'Cattle' includes farmed buffalo and bison

Figure 11 – Summary of existing bTB control measures applied in England



The existing measures which may be applied 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)) and slaughterhouse

surveillance. In areas that have endemic bTB or are otherwise considered to be at high risk of bTB spread, there is annual whole herd tuberculin skin testing of cattle. In the low risk area (LRA) of the country, four-yearly testing of breeding stock (routine herd testing) is carried out by default. This herd-based surveillance is statutory, EU law sets out 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. In the LRA, individual herds may be subject to annual whole herd testing (a discretionary statutory measure) for public (e.g. producer-retailers of raw milk, or open farms) or animal health (e.g. herds regularly purchasing cattle from higher risk areas) reasons. Zero-tolerance is applied to the timing of statutory tuberculin skin testing in cattle: overdue tests trigger movement restrictions and, since 2014, a reduction in Common Agricultural Policy Scheme payments for overdue bTB surveillance or 'check' tests.

- 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, where more than 50 percent of all bTB incidents are disclosed at slaughterhouse.

- Statutory scanning surveillance via compulsory notification and investigation of suspect clinical cases applies to cattle but such cases are very rare now as active surveillance tends to remove infected animals before clinical signs appear;

- Surveillance in other livestock and in captive deer is carried out by statutory slaughterhouse and non-statutory scanning surveillance and with occasional targeted surveillance of at risk herds/flocks (e.g. contiguous or co-located animals);

- Surveillance in South American camelids (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). However, if there is a strong suspicion of wildlife spread in an area of low cattle incidence, enhanced wildlife surveillance is initiated.

(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 movements to slaughter or to other herds in some specific circumstances subject to AHVLA licence; (ii) restrictions on movements into the herd subject to AHVLA veterinary risk assessment and licence (statutory; EU)

(iii) short interval testing with the SICCT (at not less than 60-day intervals) until one or two clear tests dependent on the risk status of the herd (statutory; EU) and (iv) 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 has been applied to all breakdowns where OTF status has been withdrawn in the LRA and to some breakdowns in the Edge Area. Since 2014, use of gamma-interferon testing has been extended throughout the Edge Area where it is compulsory for TB culture and/or lesion positive breakdowns and discretionary for lower risk breakdowns based on AHVLA veterinary risk assessment;

- Cattle suspected of being infected with bTB, on the basis of the results of the tuberculin test or the gamma-interferon test must be removed from the herd and slaughtered within 30 days (EU). Farmers have the option of arranging the removal and sale of the animal to the slaughterhouse themselves. However, most farmers opt for AHVLA to arrange the removal and sale of the animal to the slaughterhouse with statutory compensation payable to the farmer. Statutory compensation is determined primarily using monthly table values, which reflect 100 percent 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 (e.g. buffalo or bison). Statutory compensation is reduced on a sliding scale if bTB reactors are detected in overdue tests. The Government retains the revenue generated from selling the animal to the slaughterhouse (the ‘salvage’ value) which takes account of transport, handling and disposal costs.

- Following the removal of animals suspected of being infected with bTB, the farmer is responsible for any statutory cleansing and disinfection of the premises that is required by AHVLA.

- 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 on a whole herd basis; partial depopulation is more commonly used.

- Contiguous risk in breakdown situations is addressed: in the HRA and parts of the Edge Area, by testing of contiguous herds on a discretionary basis; in the LRA and the remainder of the Edge Area, by surveillance testing of 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, 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 3 km 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 or camelids and the need for additional surveillance.

(3) Dealing with the risk of TB from badgers

- Badgers are not an endangered species in the UK (see **Annex A**) but they are protected by UK legislation. The Protection of Badgers Act 1992 and the Wildlife and Countryside Act 1981 protect badgers and their setts, but make provision for licences to be granted to kill or trap badgers or to interfere with their setts for the purpose of preventing the spread of disease, provided the methods of capture and dispatch are humane. Unlicensed taking, possession, selling, or killing of badgers, or interference with their setts, is illegal. Badgers are also a protected species under the Convention of European Wildlife and Natural Habitats (1979) (known as the Bern Convention). The Convention requires contracting parties, including the UK, to take appropriate legislative and administrative measures to ensure the protection of badgers. Article 9 of the Convention allows parties to make exceptions to this for various purposes, but only provided that the exception will not be detrimental to the survival of the population concerned.

- Licensed methods of culling badgers may be cage trapping and shooting and controlled shooting of free ranging badgers. Determining the size of badger populations is challenging and the efficiency of cage trapping and of controlled shooting is variable. Culling can be deployed subject to land access and a licence from Natural England. Evidence shows that carefully managed badger culling to achieve a substantial reduction of the badger population over a sufficiently large geographic area leads to an overall net reduction in cattle herd bTB breakdowns over a defined period relative to a similar un-culled area. Small-scale or short term culling may exacerbate the disease situation through perturbation (see Glossary). The Government considers that licensed badger culling, delivered effectively, is an important bTB control measure in areas with high and persistent levels of bTB in cattle epidemiologically linked to endemic TB infection in badgers. On the basis of historical evidence an estimated one third of the badger population in endemic areas is infected with *M. bovis*.

- The Government believes that any licensed badger culling projects should be coordinated, delivered and funded privately. Culling projects should be deployed strategically to help deliver the aim of staged achievement of OTF status for England. Two licensed four-year badger culls started in Somerset and Gloucestershire in 2013. The Government will consult Natural England on revised criteria for licensing culling. Subject to available resources, the Government will also consider transitional financial support for private sector-led deployment of the policy.

- An injectable TB vaccine for badgers (BadgerBCG) has been available on veterinary prescription since 2010. Injectable vaccine can be deployed subject to land access, a licence from Natural England, and the vaccine being administered by a veterinary surgeon or by a trained and competent lay person[23]. Trapping and injecting badgers is not believed to cause perturbation. BCG is not a very effective vaccine. Evidence shows that while BCG vaccination of adult badgers can reduce the risk of infection in unvaccinated cubs in a social group, the vaccine is not totally effective; a spectrum of protective immunity is seen in uninfected vaccinated badgers with no known benefit in animals infected with *M. bovis* (estimated at around one third of the badger population in endemic areas). Annual cage trapping programmes are required to target newly emerged badger cubs and maximise immunity in a social group; the annual turnover of the British badger population is estimated to be 30 percent. Determining the size of badger populations is challenging and the efficiency of cage-trapping is variable. A Food and Environment Research Agency (Fera) model[24] suggests that it could take over forty years to eradicate TB in badgers using vaccination. The effects of injectable badger vaccine deployment on bTB in cattle are not known. While it is reasonable to expect it to reduce the incidence of bTB in cattle in endemic areas, there has been no trial to assess the magnitude and timing of these effects. However, modelling[25] suggests that culling can reduce bTB levels in cattle more quickly than vaccination alone. In its response to the Environment, Food and Rural Affairs (EFRA) Committee's report on bTB vaccination in 2013, the Government[26] said that '*badger vaccination must form part of any strategy to eradicate bovine TB, though badger vaccines cannot cure diseased badgers. These diseased animals will continue to infect cattle herds*'.

- The Government believes that any licensed badger vaccination projects should be coordinated, delivered and funded privately. Vaccination projects should be deployed strategically to help deliver the aim of staged achievement of OTF status for England. Injectable badger vaccine has been used in a government-funded, five-year Badger Vaccine Deployment Project (BVDP) in Gloucestershire, established to learn practical lessons about vaccinating badgers and to train lay badger vaccinators. The Government has also provided financial support for private vaccination projects through the Badger Vaccination Fund, a competitive grant scheme which has provided match-funded grants of up to fifty percent of the first year costs, although uptake to date has

[23] Veterinary Surgery (Vaccination of Badgers Against Tuberculosis) Order 2010 (SI 2010 No.510)

[24] Final Report of Project SE3294: Further numerical analyses of the badger vaccine study (BVS) http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=16715

[25] Smith GC, McDonald RA, Wilkinson D (2012) Comparing Badger (Meles meles) Management Strategies for Reducing Tuberculosis Incidence in Cattle. PLoS ONE 7(6): e39250. doi:10.1371/journal.pone.0039250

[26] Government Response to Environment, Food and Rural Affairs Committee Report on vaccination against bovine tuberculosis (October 2013) http://www.publications.parliament.uk/pa/cm201314/cmselect/cmenvfru/705/70504.htm

been limited[27]. In 2013, priority access to the Badger Vaccination Fund was extended to vaccination projects in the Edge Area. In its response to the EFRA Committee, the Government acknowledged '*the enthusiasm among voluntary organisations for deploying badger vaccine*' but noted that while it was '*starting to see voluntary groups working in partnership with farmers to vaccinate badgers, the prospect of vaccination being carried out over a significant proportion of the endemic area in England remained remote*' adding that '*social research, carried out as part of the BVDP, suggests that there is little interest from landowners and farmers partly because of the costs involved and partly because of the limited confidence many have in the ability of badger vaccination to reduce the incidence of TB in cattle.*' Nevertheless, the Government said it would *'continue to offer to work with other organisations to ensure that their collective efforts yield maximum benefit'*. Subject to available resources, the Government will consider transitional financial support for private sector-led strategic projects, for example those focussed on maximising the immunity of badgers in locations at greatest risk of advancing infection. The role of badger vaccination in endemic areas could develop further as the number of TB-infected badgers is reduced through culling.

(4) Other disease prevention measures

- AHVLA provides biosecurity advice to keepers supplementing other sources of information (e.g. from farming organisations and private vets). Defra funds various initiatives to provide such advice to keepers and substantial research effort into biosecurity measures, particularly to address spread from badgers to cattle. Whilst some biosecurity measures are statutory, many on-farm biosecurity measures are voluntary;

- All surveillance and breakdown testing (including tracing and contiguous testing) must be carried out within a given time window. Overdue tests trigger movement restrictions and, since 2014, a reduction in Common Agricultural Policy Scheme payments for overdue bTB surveillance or 'check' tests;

- All cattle over 42-days of age, moving from annually tested herds to live on another holding must have a valid pre-movement bTB test (statutory) at the farmer's expense. In order to support farmers, there are exemptions to this requirement for movements to slaughter (including indirect routes approved by AHVLA) veterinary treatment, artificial insemination centres, shows, common land and between holdings in the same Sole Occupancy Authority (SOA) located wholly within the annual testing area. These exemptions are subject to review. As well as potentially detecting bTB breakdowns, the main benefit of pre-movement bTB testing lies in preventing geographic spread and many new herd breakdowns. In the seven years since the Government introduced pre-movement bTB testing in 2006, some 2500 pre-movement bTB test reactors were

[27] In 2013, 58 percent of badger vaccination (834 vaccinations out of a total of 1429) in England was carried out and paid for directly by government. Across England and Wales, this figure rises to 78 per cent (2186 vaccinations out of total of 2781)

removed in England, i.e. potentially preventing up to 2500 new breakdowns and all herds where pre-movement testing disclosed reactors were put under movement restrictions, potentially preventing even further disease spread.

- Keepers are encouraged voluntarily to isolate and post-movement test any new stock they bring into their herd;

- Cattle from restricted herds may be moved under AHVLA licence directly to slaughter. In order to support farmers, cattle from restricted herds may be moved indirectly to slaughter under licence via biosecure Approved Collection Centres or Approved Finishing Units (AFUs). Non-grazing AFUs are permitted in all areas, and stock must be kept in badger-proof buildings. In the HRA, where there is already a reservoir of *M. bovis* in badgers, grazing AFUs are permitted on double-fenced land. Since 2013, the Government has applied a risk-based, proportionate approach to bTB testing in AFUs with no routine or breakdown testing (other than in exceptional circumstances) in non-grazing AFUs;

- Cattle keepers are no longer allowed to establish 'links' between holdings in different risk areas so all movements of cattle between such holdings must be reported to the Cattle Tracing System (CTS). This enables AHVLA to monitor compliance with pre-movement testing;

- Since 2012, new Sole Occupancy Authorities (SOAs) have not been permitted and new holdings can no longer be added to existing SOAs.

Developing cross-cutting bTB control measures in all risk areas

Cross-cutting measures which may be applicable to all risk areas are explained below.

(1) Biosecurity

- **Risk-based trading**

The way in which livestock are 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 can sometimes 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 industry-led Risk-Based Trading Group[28] recommended 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 (or interface) 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 an animal's bTB history available at the point of sale; the production of buyer and seller best-practice guidance; and the development of an accreditation scheme for assigning a risk status to cattle herds. Since the publication of the Group's report in May 2013, the Government has been working with the industry to act on all of its recommendations.

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 and off-farm biosecurity**

Biosecurity measures aim to prevent cattle-to-cattle, cattle-to-badger and badger-to-cattle spread of bTB[29]. 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 biosecurity measures are aimed at doing everything practical to keep badgers and cattle apart. There may be an opportunity for farmers to apply for Rural Development Programme for England funding towards biosecurity tools such as cattle handling facilities and badger-proof feed troughs. Many biosecurity measures are voluntary, but there is scope to build on the approach introduced in 2012 which reduced statutory compensation for bTB reactors disclosed in significantly overdue herd tests. The Government intends to undertake an evidence-based review of biosecurity measures both on farm and off farm, and will consider measures that would encourage improved uptake.

- **Using compensation to encourage risk-reduction**

[28] Defra (2013) Bovine TB Risk-Based Trading: Empowering Farmers to Manage TB Trading Risks (PB 13911) https://www.gov.uk/government/publications/bovine-tb-risk-based-trading-empowering-farmers-to-manage-tb-trading-risks

[29] Further information on general biosecurity measures is available on the AHVLA website at http://www.defra.gov.uk/ahvla-en/disease-control/bovine-tb/protecting-herd/. Further information on badger exclusion measures is provided in 'Badgers and bovine tuberculosis: on-farm biosecurity and badger exclusion measures (TIN106)' available on the Natural England website at http://publications.naturalengland.org.uk/publication/970479

It is important to consider the extent to which compensation levels influence farmers' approach to managing their bTB risks. For example, in some countries with successful control strategies such as New Zealand and Spain, cattle compensation is paid at 65 percent and 75 percent of market value respectively. The Government plans to review bTB compensation with the objective of encouraging risk-reduction, for example by ensuring that animal (e.g. cattle, South American camelids, farmed deer) keepers observing defined 'best practice' on biosecurity benefit over those who do not.

(2) Improving advice and guidance to farmers

The Government is committed to exploring ways to provide evidence-based, 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. 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 has provided funding for and worked with the Farming Community 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 funding towards training and information exchange activities.

In November 2013, the Government sought views on proposals compatible with data protection and other legislation, to provide farmers with sufficient information on the bTB status of neighbouring herds to enable them to manage any risks to their own herds.

(3) 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 obtaining a clearer understanding of 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. In January 2014 the Government built 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 Common Agricultural Policy Scheme rules for overdue bTB surveillance or 'check' tests; 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.

(4) 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. Evidence suggests that non-bovine species other than the badger 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 *départements* of France (wild boar and red deer in addition to badgers). However, the existing evidence from wildlife surveys and quantitative risk models carried out by 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, primarily due to differences in behaviour and contact levels with cattle. Additionally, once detected, deer infection is often controlled locally by additional culling.[30] [31] [32]

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

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 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**

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 intends to consult with a view to making TB surveillance mandatory in SACs. In the meantime, it is working with the sector to encourage voluntary pre and post-movement testing and surveillance of SAC herds using skin and blood tests. Sharing of these voluntary surveillance results is essential for disease control purposes.

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 Regulation 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 Regulation 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 be 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*

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[31] 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

[32] 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

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 to carry 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.

Developing area risk-based strategies

The epidemiological rationale for, and the objectives of, sub-strategies tailored to specific risk areas are explained below. These sub-strategies will be deployed geographically to deliver the aim of staged achievement of OTF status for England. For example, we could anticipate a movement in the deployment of Edge strategy westwards and southwards if existing strategies are successful in reversing the geographical distribution of the disease.

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 culture and/or lesion positive bTB breakdowns 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 percent throughout the period. The proportion of OTF herds remained above 99.9 percent throughout the period. These figures demonstrate that the area has great potential to gain OTF status as defined in Council Directive 64/432/EEC. 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;

- 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 percent of LRA breakdowns ending in 2011 lasted more than 240 days; the same figure for GB was 33 percent and for Wales 53 percent); and

- Whilst previous, very limited road traffic accident based surveillance has found occasional badgers infected with *M. bovis* in the LRA in the past, there is little evidence of a significant reservoir of *M. bovis* in badgers in the area. AHVLA has carried out badger surveillance measures around unexplained bTB incidence in the LRA (1-2 surveillance zones established annually). In the seven years to 2013, this surveillance has not yielded any positives results.

- 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 culture and/or lesion positive bTB 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) culture and/or lesion positive bTB breakdowns, which is below the threshold set out in Council Directive 64/432/EEC (0.1 percent 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.

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 focuses 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 in the north west and north of England. It makes good disease control sense and is 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 applies 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. Between 2006 and 2011 there was an increasing number of culture and/or lesion positive bTB breakdowns in the Edge Area and the crude prevalence of herd breakdowns reached just over 1 percent.
- 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.

- We currently know very little about the TB-infection status of badgers in the Edge Area. Further research is needed to determine the respective roles of cattle and wildlife in the spread of bTB in the Edge Area and whether or not the badgers there represent a significant wildlife reservoir of *M. bovis* and/or drive the spread of the edge. This will involve gathering information on the badger population density and prevalence of TB infection in badgers in the Edge Area to inform future control measures.

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.

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 residual infection in breakdown herds, cattle movements and the badger reservoir of *M. bovis* infection play 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 and cannot be explained by cattle movement alone;

- Recurrence of herd breakdowns is a 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 percent of herds with culture and/or lesion positive bTB breakdowns in 2011 had a history of a breakdown in the previous 36 months[33];

- There is evidence to suggest that a substantial proportion of herds have residual infection left in the herd at the end of a breakdown. Data indicate that, in the worst-case scenario, up to 21 percent of cattle herds may be harbouring at least one infected animal when movement restrictions are lifted[34]. Furthermore, depending on the modelling assumptions, the researchers estimated that 50 percent (33–67, 95 percent confidence interval) or 24 percent (11–42, 95 percent confidence interval) 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. Ninety-eight percent of movements of cattle from holdings in the HRA to live on other holdings take place within the HRA. Thus there is a need to apply risk-based trading practices in the HRA, perhaps even more so than between the different risk areas;

- 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 percent of herds affected with culture and/or lesion confirmed breakdowns in 2011). Forty percent of cattle herds in the HRA in the ten years to 2012 did not have a bTB breakdown in this period. It is important that the status of these herds is recognised and protected as part of the strategy, particularly in terms of their potential contribution to 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 percent of breakdown costs arise in 10 percent of breakdowns. Addressing these breakdowns more rigorously is an important part of the strategy. AHVLA will launch a project in 2014 to tackle persistent breakdowns; and

- 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.

[33] 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/publication/pub-survreport-tb/

[34] 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.

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 cattle movement related spread, the residual infection and the wildlife reservoir, strengthening and targeting cattle control measures 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.

Next steps to develop our risk-based approach

Table 2 provides a summary of the current measures applied in each area and the additional future measures or options to develop our risk-based approach.

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[35] 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.

[35] Defra Evidence and Investment Strategy 2010 to 2013 and beyond (PB 13471) https://www.gov.uk/government/publications/defra-s-evidence-investment-strategy-2010-to-2013-and-beyond-2011-update

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.[36] Further information is available in **Annex E**. 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**

Under Council Directive 64/432/EEC, the cervical (i.e. applied to the neck) tuberculin skin test is the only official EU standalone test for bTB in live cattle (i.e. for the purposes of granting and retaining OTF herd status). No diagnostic test for bTB is perfect and the tuberculin skin test is no exception. However, if performed correctly it remains the most practical and cost-effective tool for detecting bTB. In areas (e.g. Scotland) where there is no significant reservoir of *M. bovis* in wildlife, traditional cattle herd test and slaughter strategies using the tuberculin skin test have proven efficacy in achieving OTF status.

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 (over 99.9 percent specific if the test is performed correctly) but the test misses around 1 in 5 bTB-infected cattle (at best, 80 percent sensitive at herd level if the test is performed correctly). Using a severe interpretation of the comparative tuberculin skin test marginally reduces the likelihood of false negatives (i.e. increases the sensitivity) 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

[36] Defra Bovine Tuberculosis Evidence Plan 2013/14 – 2017/18 (PB 13909) https://www.gov.uk/government/publications/evidence-plans

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**

Since 2002, Council Directive 64/432/EEC has allowed the more sensitive interferon-gamma assay (a blood test which also uses tuberculin) to be used in parallel with the tuberculin skin test to detect and remove additional infected cattle. Between 2002 and 2006, the Government used the interferon-gamma assay in the context of a field trial in OTF status withdrawn herds and on an *ad hoc* basis elsewhere.

Since October 2006, the Government has deployed mandatory parallel interferon-gamma assay in OTF status withdrawn herds in four-yearly testing (Low Risk) areas of England to supplement the tuberculin skin test and improve the detection of infected animals.

In 2011, the Government adopted mandatory parallel interferon-gamma assay in OTF status withdrawn herds in two-yearly testing parishes; in 2013 the test continued to be mandatory in OTF status withdrawn herds in these areas after they had been incorporated into the Edge Area as annual testing zones. Since January 2014, the Government has deployed parallel interferon-gamma assay across the Edge Area to supplement the tuberculin skin test and improve the detection of infected animals; interferon-gamma assay is mandatory for culture and/or lesion positive bTB breakdowns and discretionary for lower risk bTB breakdowns, based on an AHVLA veterinary assessment of the herd.

The Government is considering making the interferon-gamma assay available for private pre- and post- movement testing of tuberculin skin test-negative cattle moving between OTF herds.

A European Food Safety Authority (EFSA) scientific opinion[37] 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 for the purpose of granting and retaining OTF herd status, but protocols for use should first be harmonised across the EU. This opinion may result in EU negotiations on the future approval of the

[37] 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/pub/2975.htm

tuberculin-based-interferon-gamma assay as a second official EU standalone 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 *M. bovis* either in individual infected badgers or in their environment. Such tests could have many potential applications including measuring TB prevalence in badgers, monitoring the effect of interventions such as vaccination, and increasing understanding of the epidemiology of the disease and the relative importance of different routes of transmission. Additionally, the availability of suitable tests to identify *M. bovis* infection in badgers will inform the development of new strategies for dealing with the risk of TB in badgers ideally focussed on removing from the population only those badgers infected with TB.

- 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 would need to be killed for this methodology to be used for surveillance and representative meaningful sampling is not straightforward. In live badgers, testing for an immune response associated with exposure to *M. bovis*, such as the BrockTB StatPak[38] or interferon gamma assay testing can be carried out. The former test could be carried out in field conditions allowing animals to be restrained until results are available, but it misses around 1 in 2 infected badgers (around 50 percent sensitive). The latter test misses around 1 in 5 infected badgers (around 80 percent sensitive) 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 has funded a research project which aims to develop methods of taking clinical samples such as blood and urine from badgers without the need for sedation. This would simplify the sampling of trapped badgers and could be used in

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

conjunction with new serological diagnostic[39] methods and methods for testing urine samples that are being developed. In the Republic of Ireland, polymerase chain reaction (PCR) methodology is being tested to assess its sensitivity in detecting infection in faeces samples from individual culled badgers. Results are expected in 2014/15.

- 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 *M. bovis* in latrines, soil or air depends on whether infected badgers have been shedding the bacteria in the sample type collected, in the location being sampled from, and in the sample that is taken. The methods which have been assessed include PCR and immuno-magnetic separation (IMS)[40] coupled with a lateral flow device. Defra started funding the development of a PCR-based test to detect *M. bovis* in environmental samples at Warwick University in 2007. While the test performs well at identifying spiked samples in the laboratory and is reproducible, it has been less sensitive at detecting known infected social groups from faecal samples collected in the field. Warwick University has led on Defra-funded research to optimise the sampling regime with the aim of improving the performance of the PCR test in the field. The IMS technique has the potential to increase the sensitivity of environmental sampling strategies. Defra has funded a project at Queens University in Belfast to develop this method. Defra is planning an inter-laboratory study ('ring-trial') applying different PCR tests and the IMS technique to badger faecal samples to identify which test shows most promise for field use.

Developing deployable bTB vaccines

We have an authorised injectable vaccine for badgers. There are no bTB vaccines authorised 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 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, particularly if there remains an ongoing spread of *M. bovis* from badgers.

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

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

The current best candidate vaccine to protect against TB in cattle is based on BCG. BCG does not offer complete protection from infection with *M. bovis.* Research to date suggests that the proportion of cattle protected or partially protected may be in the order of only 50-70 percent 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[41] 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 'detect infected among vaccinated animals' (DIVA). Development of this DIVA test forms part of the ongoing Defra-funded research programme and candidate diagnostic tests have been developed. The most advanced is a modified version of the currently used interferon-gamma assay.

Following approaches from the Government, the European Commission acknowledged in January 2013 that the UK had invested considerable resources in developing a candidate vaccine and accompanying DIVA test. The European Commission set out a tentative timeline[42] of the steps to be able eventually to deploy a cattle bTB vaccine and associated DIVA; cattle vaccination could only be deployed if it is demonstrably safe. These steps include a field trial of the vaccine and DIVA test under EU conditions. Government scientists are leading the world in developing a deployable cattle vaccine and have been considering the design of a trial that will deliver the European Commission's objectives and deliver the evidence necessary to secure a licensed cattle bTB vaccine and a validated DIVA test. In 2013, EFSA published a scientific opinion[43] providing advice relating to the design of field trials to test the performance of a cattle bTB vaccine along with a DIVA test. Based partly on that advice, the Government has awarded a contract for field trial design and is expecting this work to be completed by August 2014. The trial design work and ongoing research is necessary to provide evidence to support an application for an Animal Test Certificate to permit field trials of an otherwise unauthorised vaccine. Extensive field trials are not expected to start until 2015. The cost of such trials is likely to amount to tens of millions of pounds.

The European Commission estimated that it was unlikely that the EU ban on intra-EU trade in bTB-vaccinated cattle would be lifted within ten years of successful trials starting;

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[41] Chapter 2.4.7, Bovine tuberculosis (version adopted May 2009) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2013 http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/

[42] 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/publications/bovine-tb-eradication-programme-letter-from-the-european-commission-to-owen-paterson

[43] EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare) 2013. Scientific Opinion on field trials for bovine tuberculosis vaccination. EFSA Journal 2013; 11 (12): 3475, 35pp. doi:10.2903/j.efsa.2013.3475 http://www.efsa.europa.eu/en/efsajournal/pub/3475.htm

the European Commission's tentative timeline included the need to amend OIE animal health standards for international trade.

The European Commission indicated that it might be possible to allow the vaccine to be used under controlled conditions in the UK four to five years after successful trials started but that bTB-vaccinated 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 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 issued a marketing authorisation for an injectable BCG-based TB vaccine for badgers (BadgerBCG) in 2010. There is scope to use data from the English Badger Vaccination Deployment Project and the Badger Vaccination Project in the Welsh Intensive Action Area[44] to understand better the long-term costs and benefits of deploying injectable badger vaccination.

The Government has also invested considerable resources in ongoing research to identify an effective and affordable oral badger TB vaccine which could make the vaccine much simpler to deploy than the currently available injectable vaccine. Government scientists have made progress in identifying a candidate edible bait. Further progress is dependent on ensuring a consistent immune response to orally administered vaccine so it is not yet possible to predict with any certainty when there will be a candidate vaccine which can be taken forward for marketing authorisation. However, in the best case scenario an oral badger TB vaccine might be deployable in the field by 2019. The Government's independent vaccines advisory group (comprising vaccines experts from the human and animal fields) has advised that additional investment would not accelerate the development process.

Research into alternative strategies for dealing with risk of TB from badgers

In parallel to research to develop diagnostic tests to detect infected badgers and/or their environment, consideration is being given to how such tests might best be used to support the development, delivery and monitoring of strategies for dealing with the risk of *M. bovis* from badgers, e.g. targeted culling, understanding local epidemiology, and monitoring the effectiveness of badger vaccination at reducing infection. This work will inform where future research and implementation effort should be targeted.

[44] The Intensive Action Area in south west Wales is approximately 288 km^2 primarily located in north Pembrokeshire but also including small parts of Ceredigion and Carmarthenshire. The five-year injectable badger vaccination project is running alongside additional surveillance and controls for cattle and non-bovines, and enhanced biosecurity. The project started in 2012.

Further research into alternative methods for dealing with the risk of *M. bovis* from badgers (e.g. sett-based culling methods and non-lethal methods) has been considered. This includes investigations into the use of gases such as carbon monoxide or anoxic gas-filled foam as a sett-based means of humane culling. Anoxic gases are used humanely to cull farmed animals such as pigs and poultry. The use of hydrogen cyanide gas to cull badgers will not be considered.

The Government has also funded research into the application of fertility control using contraceptives to manage badger populations. Two studies have looked at injectable contraceptive, one in captive badgers and one in free-living urban badgers, and one study has examined the potential to develop an oral contraceptive. This research is at an early stage and it is not yet possible to assess the likely scale on which such an approach might be deployed in future or the likely timescale.

The Government will continue to review evidence emerging from badger control strategies and research in place elsewhere. For example, the Republic of Ireland Government has operated focussed badger culling since 2000. Badgers are captured under licence by trained contractors using specially designed body restraints and then killed, in areas where serious outbreaks of bTB have been detected in cattle herds and an epidemiological investigation has found that badgers are the likely cause of infection. In Northern Ireland, the Department for Agriculture and Rural Development is proposing a five-year 'Test, Vaccinate and Remove' (TVR) research project starting in summer 2014. The research would involve trapping and testing badgers in one or more 100 km^2 areas: badgers testing positive for TB would be killed; badgers testing 'negative' would be vaccinated and released. A further 100 km^2 area would serve as a control. The limitations of tests on live badgers and of the injectable badger vaccine are discussed elsewhere.

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.

Pedigree analysis funded by Defra has shown evidence of genetic variation to bTB susceptibility within Holsteins in the UK. Another study identifying genetic markers linked to susceptibility saw no significant differences in the distribution of these markers across UK breeds. Dairy Co has advised that it expects to be able to select Holstein bulls with resistant genes in 2015 so their daughters would enter the milking herd from 2018. While Dairy Co expects this to improve the resistance of the Holstein herd to bTB over the next decade, it notes that it is unlikely that any animal has full genetic resistance so genetic selection would need to be combined with other measures in order to achieve OTF status.

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[45] and national law and take account of government policies on public bodies[46] and wider impacts on the government's capability to respond to animal

[45] 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

[46] Cabinet Office (2012) The approval process for the creation of non-departmental public bodies https://www.gov.uk/government/publications/public-bodies-information-and-guidance

disease outbreaks. Any changes to funding would need to comply with HM Treasury rules on managing public money[47].

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[48]. The AHWBE is the principal source of Departmental advice to Defra Ministers on all strategic health and welfare matters relating to kept animals in England[49]. 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.

The New Zealand experience shows that alternative governance and delivery models can enhance bTB control. The New Zealand government has delegated management of the National bTB Pest Management Plan, which is defined in law, to an industry-led management agency[50] under the Biosecurity Act 1993. The management agency supports a number of TBfree Committees to maintain effective links with the farming community and stakeholders at a regional level. The TBfree Committees promote the programme in their regions and are a source of feedback and advice to the management agency on policy and operational issues. The National bTB Pest Management Plan budget has been co-

[47] HM Treasury (2013) Managing Public Money (PU 1513)
https://www.gov.uk/government/publications/managing-public-money

[48] Defra (2010) Responsibility and Cost Sharing for Animal Health and Welfare – Final report (PB 13450)

[49] Further information about the Animal Health and Welfare Board for England is available at
https://www.gov.uk/government/policy-advisory-groups/animal-health-and-welfare-board-for-england-ahwbe

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

financed by industry and government with funding from central and local government, statutory beef and dairy sector levies and deer sector grants[51]. The Government will develop proposals for an enhanced partnership approach to the governance of the Strategy in England.

Delivery

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

The Government will continue to review delivery of bTB controls, ensuring a partnership approach with government (i) delivering those services that only it can deliver, building on the efficiency savings delivered to date whilst ensuring quality; and (ii) ensuring that any services provided by the private sector and funded by government are procured in line with legal requirements with robust contracts and effective audit to deliver value for money and ensure quality services.

The veterinary profession is a key delivery partner for bTB controls. The Government will develop a modern commercial relationship with private veterinary businesses delivering bTB testing and controls. The Government will explore ways in which private veterinary businesses can deliver local services currently delivered by government (the so-called 'TB Plus' model) in line with AHVLA's Veterinary and Technical Strategy[52] and mindful of the outcome of the Welsh Government's *Cymorth TB* pilots due for completion in April 2014.

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 6** provides the breakdown of state-funded and privately funded areas in 2013/14.

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

[52] AHVLA (2013) Veterinary and Technical Strategy – Securing a healthy future http://www.defra.gov.uk/ahvla-en/publication/vet-tech-strategy/

Table 6 – Breakdown of state-funded and privately-funded areas in 2013/14

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 bTB reactors • Statutory 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)	• Handling facilities, staff and time away from business for bTB testing • Pre-movement testing and export testing • TB testing of deer • Consequential losses (e.g. from movement restrictions and compulsorily slaughtered cattle) • Biosecurity measures (e.g. badger proofing or double fencing) • Local badger vaccination deployment • Advice and guidance • Deployment of badger culling licensed by Natural England • Costs of slaughter of TB infected non-bovine animals (e.g. goats) without compensation

For the costs which fall to government, the budgetary pressure is expected to increase through a combination of increasing costs and declining budgets; EU financial support at current levels is not guaranteed to continue indefinitely.

Most of the Government's bTB budget is spent on bTB testing, breakdown management and compensation. Almost 80 percent 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 percent of breakdown costs arise in 10 percent 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.

The Government aims to build a framework of modelling tools which could support the production of a reliable estimate of cost of achieving OTF status for England; this will require a credible assessment of the impact of policy options some of which are many years away.

The Government will develop proposals for a sustainable model for funding the Strategy in partnership with stakeholders. 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 percent 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 could include stakeholders paying more for bTB measures such as bTB testing and deployment of cattle and badger vaccination; government reducing its intervention in the market in terms of levels of compensation payable; developing insurance options in partnership with the insurance sector; and the establishment of a mutual bTB control fund co-financed by government and industry. While any new compulsory contribution (i.e. charge) would need to ensure commensurate benefits for those paying, access to additional services could provide an incentive for farmers to contribute to a mutual fund.

The Government will keep bTB compensation and the funding of bTB testing under review; savings to government could be redistributed to fund preventative measures, e.g. transitional financial support for measures to reduce the risk of TB from badgers.

Failure to ensure a sustainable funding model will limit the future development and deployment of full range of new tools.

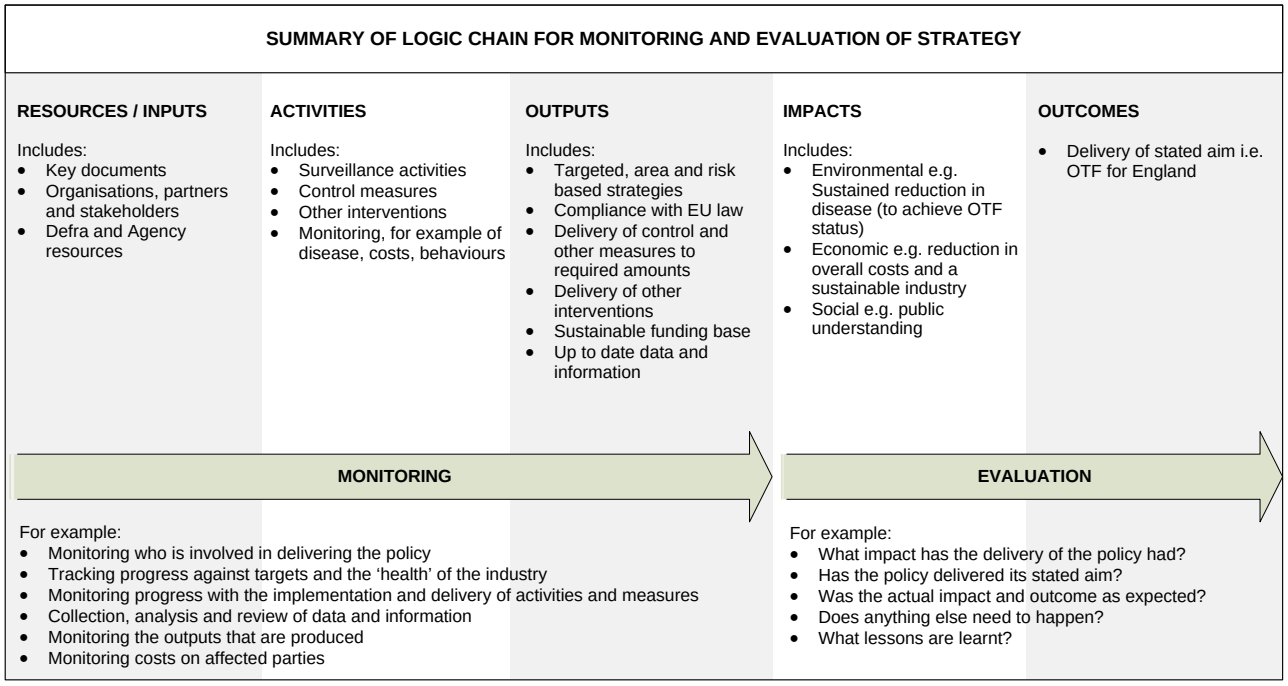
Monitoring and evaluation of the Strategy

Figure 12 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.

The Government will monitor and evaluate the progress of the Strategy in line with best practice[53]. In particular, focus will be placed on progress and delivery of the specified targets and outputs that work toward the overall aim of OTF status for England. 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 inform ongoing decisions on tackling disease appropriately at national, regional and local levels.

[53] HM Treasury (2011) The Magenta Book - Guidance for evaluation (PU 1120) https://www.gov.uk/government/publications/the-magenta-book

Figure 12 – Logic chain



Key tools include using the best available data to review the impact in terms of:

- The health and sustainability of the sector
- Media coverage and social impacts
- Behaviours and attitudes of farmers and the public
- Trade patterns, for example the number of cattle exported
- Monthly laboratory testing result reports
- *M. bovis* 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 Strategy 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. The Strategy will be regularly reviewed and refreshed accordingly.

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

Check tests – cattle herd tuberculin skin tests carried out for a number of reasons, including determining the herd disease status when there is a suspicion of infection, within potential 'hotspot' areas which have previously been free of TB, and for new or re-formed herds.

CTS – Cattle Tracing System, the national cattle identification and movements database

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**etect **i**nfected among **v**accinated **a**nimals

ECDC – European Centre for Disease Prevention and Control

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

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

Lesions – Characteristic tubercles or larger abscess-like structures typically found in lymph nodes and organs such as the lungs, liver and spleen.

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 Protection of Badgers 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 definition has been used for cattle herds where the laboratory culture result is not positive for *M. bovis* but there is an increased likelihood that the animal was infected

OTFW– Officially Bovine Tuberculosis Free status of herd withdrawn as defined in Council Directive 64/432/EEC. This definition has been used for cattle herds where typical lesions of TB are found in a carcase of an animal and/or the laboratory culture result is positive for *M. bovis*

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

SICT – single intradermal cervical test. See tuberculin skin test

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

SOA – Sole Occupancy Authorities approved by AHVLA consist of a group of holdings under the same farm management and control. Movements among holdings within a SOA are not subject to the standstill restrictions that normally apply to livestock movements.

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

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

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

Test Interval – the period of time between tuberculin skin tests

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 and population

Table 7 – 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 in year one. Licences also permit cage trapping and despatch. Each licence has a four-year term. No control operations can take place during specified close seasons.

Changes in the British badger population

Harris *et al* (1992)[54] concluded that there were approximately 250,000 adult badgers in Britain in the 1980s with 172,000 cubs born each year. Annual adult mortality was estimated to be approximately 61,000 animals, annual cub mortality 64,500 pre-emergence and 41,500 post-emergence. The greatest single known cause of badger mortality was road deaths (about 50,000 animals a year) with approximately 10,000 killed illegally and 1,000 killed each year to control bTB. Defra funded a badger sett survey of England and Wales in 2011-2013 (Defra Project SE3129) and a project to generate estimates of typical badger social group size in different landscapes (Defra Project SE3132). The badger sett survey estimated that the number of badger social groups in England had more than doubled (from 31,500 +/- 3,900 to 64,000 +/- 5,000) since the previous comparable survey was carried out in 1985-1988[55]. The social group size survey will report results in summer 2014, allowing updated estimates of the total population of badgers in England and Wales to be made.

Judge *et al* (2014) concluded that the implications of increasing badger populations are numerous as badgers are the largest terrestrial carnivore in the British Isles. They eat mainly soil invertebrates but will also prey upon ground nesting birds, hedgehogs and other vertebrates. Evaluation of the ecological impact of badger culling during the RBCT identified an increase in fox abundance associated with reductions in badger density while reciprocal relationships between hedgehog and badger distributions suggest that increasing badger numbers might have had a negative impact on hedgehogs.

[54] Harris, S., Cresswell, W., Reason, P. and Cresswell, P. (2001) An integrated approach to monitoring badger (*Meles Meles*) population changes in Britain. Wildlife 2001: Populations. Special Session 9. Pages 945-953. DOI: 10.1007/978-94-011-2868-1_72

[55] Judge, J., Wilson, G.J., Macarthur, R., Delahay, R.J. & McDonald, R.A. Density and abundance of badger social groups in England and Wales in 2011–2013. Sci. Rep. 4, 3809; DOI:10.1038/srep03809 (2014).

Annex B – Enhancements of cattle measures since 2011

Table 8 – Enhancements of cattle measures since 2011

2011	Introduced DNA tagging of bTB reactors to ensure they are removed from farms.
2012	Reduced statutory bTB compensation for owners of herds with overdue tests.
	Tightened pre-movement testing rules including amendments to exemption for movements to shows and movements between holdings within the same Sole Occupancy Authority (SOA).
	Banned new SOAs and applications to add new holdings to existing SOAs.
	Phased removal of Cattle Tracing System (CTS) links between holdings in one/two-yearly testing parishes and holdings in three/four-yearly testing parishes.
	Banned new Approved Quarantine Units which sourced calves from TB breakdown herds with existing Units closed by the end of 2013.
2013	Adopted county-based routine bTB surveillance testing with significant extension of annual testing to herds in High Risk/Edge Areas and four-yearly testing of herds in Low Risk Area.
	Introduced radial testing of all herds within 3km of a lesion/culture positive bTB breakdown herd in the Low Risk Area.
	Cattle movements into non-lesion/culture positive bTB breakdown herds only permitted after the first post-breakdown test and subject to a satisfactory veterinary risk assessment (to align with policy for lesion/culture positive bTB breakdown herds).
	Pre-movement testing window for movements from bTB restricted herds reduced from 60 to 30 days.
	Increased auditing of Approved Finishing Units (which send cattle to slaughter) and enhanced sanctions for non-compliance
	Introduced risk-based bTB testing in Approved Finishing Units with higher testing burden remaining in Units with grazing.
	Enhanced the quality assurance programme for Official Vets carrying out bTB testing.
	Phased removal of CTS links between High Risk and Edge Areas.

	Rolled-out a voluntary risk-based trading scheme in livestock markets.
	Introduced requirement for two consecutive clear herd tests (rather than one) at severe interpretation for non-lesion/culture positive bTB breakdown herds in Edge Area before restrictions lifted.
2014	Introduced mandatory parallel interferon-gamma assay for lesion/culture positive bTB breakdown herds in Edge Area; discretionary for non-lesion/culture positive bTB breakdown herds in Edge Area.
	Introduced radial testing of all herds within 3km of a lesion/culture positive bTB breakdown herd in the Cheshire and Derbyshire Edge Area.
	Reduced Common Agricultural Policy Scheme payments for overdue bTB surveillance or ‘check’ tests.
	Enhanced the approach for dealing with persistent bTB breakdowns.
	Introduced powers to remove cattle which are unable to be tested for bTB.
	Tightened pre-movement testing rules by removing exemption for movements to and from common land.

Annex C – Sources of evidence

Natural science

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

Godfray, H.C.J. *et al*. (2013) A restatement of the natural science evidence base relevant to the control of bovine tuberculosis in Great Britain. Proc. R. Soc. B. 2013 280 1768 20131634; doi:10.1098/rspb.2013.1634 (published 7 August 2013) 1471-2954

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

Socio-economic science

The following paper was authored by Professor Richard Bennett and Ian MacFarlane at the University of Reading and Dr Gareth Enticott of Cardiff University.

Bennett, R.M. *et al*. Socio-economic science relevant to the control of bovine tuberculosis in cattle. Report prepared for Defra, July 2013.

Surveillance reports

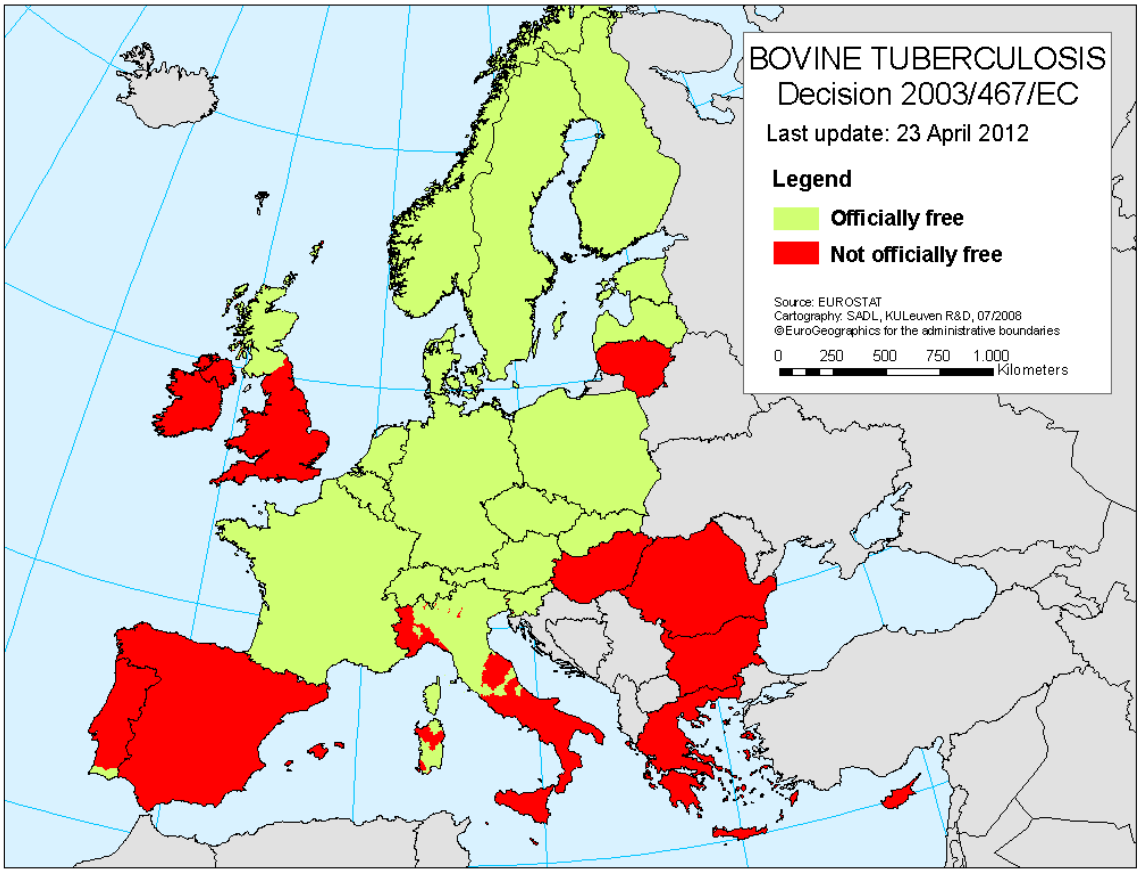
The Government's Bovine TB surveillance reports are available at http://www.defra.gov.uk/ahvla-en/publication/pub-survreport-tb/

Statistical reports

The Government's Bovine TB statistical reports are available at https://www.gov.uk/government/collections/bovine-tb

Annex D – Bovine tuberculosis in Europe

Figure 13: Official bovine tuberculosis status of EU member states in April 2012



(Source: European Commission Annual Report Bovine and Swine Diseases 2012)

Table 9 – EU member states declared officially bovine tuberculosis free in Commission Decision 2003/467 (as amended) in 2014

Belgium	Estonia	Luxembourg	Slovenia
Czech Republic	France	Netherlands	Slovakia
Denmark	Hungary	Austria	Finland
Germany	Latvia	Poland	Sweden

Table 10 – EU member states with specific regions (number) declared officially bovine tuberculosis free in Commission Decision 2003/467 (as amended) in 2014

Italy (12)	Portugal (1)	United Kingdom (1)	

Annex E – 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.

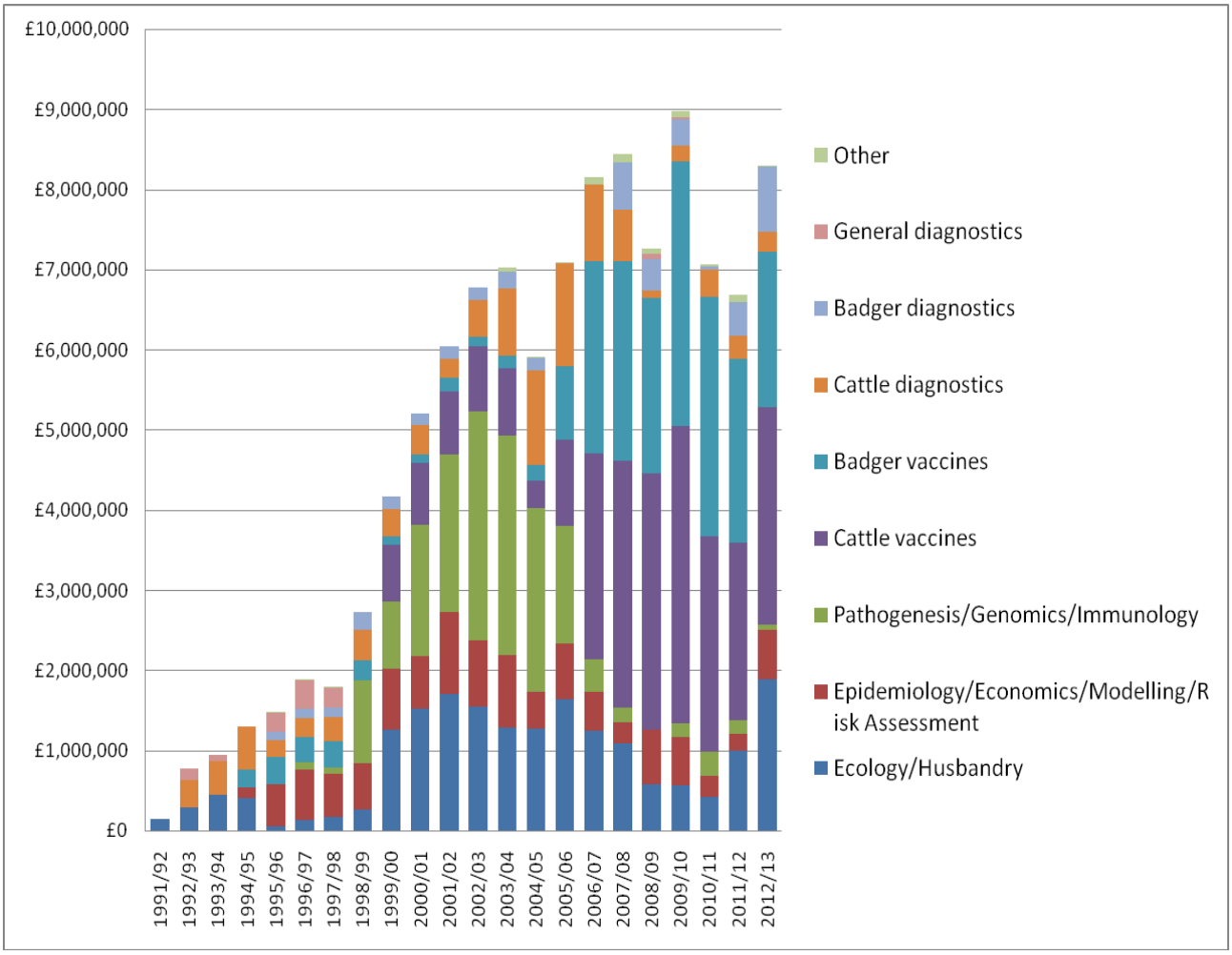
Between 1991/92 and 2012/13 Defra and its predecessor MAFF, funded over 110 individual research projects and invested approx £108 million in its bTB R&D programme plus a further £49 million on the Randomised Badger Culling Trial (RBCT). Defra's Animal Health and Welfare research budget covers England,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

Research spend by scientific area

Figure 14 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 14: Defra bTB research spend by scientific area to 2012/13



Further information on Defra-funded research projects is available at http://randd.defra.gov.uk