Bovine TB Eradication Programme for England

July 2011



© Crown copyright 2011

You may re-use this information (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/ or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or e-mail: psi@nationalarchives.gsi.gov.uk

This document/publication is also available on our website at: www.defra.gov.uk

Any enquiries regarding this document/publication should be sent to us at: TB.Webmaster@defra.gsi.gov.uk or

TB Communications
Defra
17 Smith Square
London
SW1P 3JR

PB 13601

Contents

Ministerial Foreword	4
Executive Summary	6
1. Introduction	11
1.1 What is the scale of the problem?	12
1.2 History and epidemiology of TB in cattle	13
1.3 Costs of TB	15
2. The Government's Approach	17
2.1 A comprehensive programme	18
2.2 A risk-based approach	21
2.3 A staged approach to eradication	24
2.4 Working in partnership	24
2.5 Sharing responsibility and costs	26
2.6 Working effectively in the EU	27
2.7 Support to farmers	28
3. TB in Cattle	29
3.1 Cattle measures	29
3.1.1 Cattle surveillance measures	31
3.1.2 Cattle control measures	33
3.1.3 Compliance and Enforcement	36
3.1.4 Other cattle measures	37
3.2 Biosecurity	40
3.3 Badger control	42
3.4 Farmer advice and support	44
4. TB in Non-Bovine Farmed Animals	48
4.1 Surveillance and control measures in non-bovine farmed animals	49
4.2 Compensation and ex-gratia payments for non-bovine farmed animals	51
4.3 TB in pets and wildlife	51

5. Research and Evidence	53
5.1 Vaccines	54
5.2 Diagnostics	54
5.3 Economic and social science	54
5.4 Epidemiology and wildlife risks	55
5.5 Future priorities	55
5.6 TB statistics	56
6. Governance, Monitoring and Reporting	58
6.1 Governance	58
6.2 Monitoring and reporting	59
Annex A: TB surveillance and control requirements under EU law	61
Annex B: The Bovine TB Eradication Group for England	63

List of figures

- **Figure 1:** Geographical distribution (point location) of herds sustaining new breakdowns of bovine TB in 1986 and 2009.
- **Figure 2:** Maps showing spread of TB between 1986 and 2010, as measured by number of reactors found in Officially Tuberculosis Free status withdrawn (OTFW; culture confirmed) TB breakdowns per km.
- Figure 3: Number of new TB herd breakdowns disclosed annually in England (1994-2010)
- **Figure 4:** Quarterly numbers of total and OTFW herd incidents between January 1986 and June 2010.
- Figure 5: Overview of the Bovine TB Eradication Programme for England.
- Figure 6: 2011 routine TB testing map of Great Britain showing geographic areas of TB risk.
- **Figure 7:** Expansion and consolidation of annual routine TB testing areas and the two-yearly testing buffer between 2009 and 2011.
- **Figure 8:** Flow diagram showing the TB surveillance and control regime for cattle herds in England.

List of tables

- **Table 1:** Geographic areas of TB risk.
- **Table 2:** TB delivery bodies and responsibilities.
- **Table 3:** Cattle compensation paid for TB in England from 2005-09.
- **Table 4:** Incidents of confirmed *M. bovis* infection in non-bovine farmed animals in Great Britain since 2000.

Bovine TB Eradication Programme for England

Ministerial Foreword

TB is a serious animal health problem. Tens of thousands of cattle are slaughtered every year. It can be devastating for affected farmers. And the cost to the taxpayer is huge – it is set to exceed £1 billion over the next ten years in England alone.

That is why this Government is committed to ensuring we have a comprehensive and balanced package of measures to tackle TB, with eradication as our ultimate long-term goal. This Bovine TB Eradication Programme for England describes our approach in detail and reflects our determination to tackle TB in cattle, badgers and non-bovine farmed animals.

We already have a robust set of measures in place to tackle transmission between cattle – including compulsory testing, slaughter of infected animals and movement restrictions on infected herds. We are committed to maintaining these controls and strengthening them where it makes sense to do so, taking a risk-based approach.

But it's clear that these cattle controls alone are not working in the west and south-west of England where we know the disease in cattle is perpetuated through spread from an infected badger population. And it is also spreading into previously unaffected areas.

We cannot go on like this. Many farmers are desperate and feel unable to control the disease in their herds. We know that unless we tackle the disease in badgers we will never be able to eradicate it in cattle. No other country has successfully controlled the disease in cattle without tackling its presence in the native wildlife population.

This Government therefore gave a commitment to introduce, as part of a package of measures, a carefully-managed and science-led policy of badger control in areas with high incidence of TB in cattle. Having carefully considered all the evidence and the responses to the public consultation we held last autumn, we are of the view that badger culling could make an important contribution to our fight against TB as part of a comprehensive package of measures. But we have made some changes to the proposed policy in an effort to address the concerns that have been raised, and we want to give key stakeholders an opportunity to comment on detailed Guidance to Natural England before making a final decision to proceed with a policy of badger control. If the decision is to proceed, controlled shooting as a method of badger control would then be piloted in the first year and if this is found to be humane and effective by an independent scientific panel of experts, only then would this policy be rolled out more widely.

We are continuing to invest heavily in research, in particular to develop a cattle vaccine and an oral badger vaccine. However, these are still many years away and we cannot predict with any certainty when they might be ready to deploy.

Underpinning the successful delivery of this Eradication Programme is the role of the farming industry and individual farmers, working in partnership with vets, Government and others. We would particularly like to thank the Bovine TB Eradication Group for England for their advice.





Carolin Alpelran.

The Rt Hon Caroline Spelman MP

Secretary of State for Environment, Food and Rural Affairs

Jim Paice MP

Minister of State for Agriculture and Food

Jui Pouri

Executive Summary

- 1. TB is a serious animal health problem. Nearly 25,000 cattle were slaughtered in England alone in 2010/11, at a cost to the taxpayer of £91 million. The problem has been getting worse over the last few years. During 2010, 10.8 % of herds in England were under restrictions, whilst in the West and South West this figure was 22.8 %. The number of new TB incidents in England rose in 2010, compared to 2009, and although still lower than seen in 2008 suggests the disease situation is not improving.
- 2. We already have a comprehensive programme of cattle controls in place but it is apparent that in some parts of the country these controls are not working. It is therefore clear that more needs to be done. Unless we tackle each and every transmission route the disease situation is likely to continue to worsen.
- 3. The disease is having a devastating impact on livestock farmers and their businesses, costing them and the taxpayer significant amounts of money. Fortunately, the risk to public health is very low these days, largely thanks to milk pasteurisation and the TB surveillance and control programme in cattle. However, we still need to tackle TB in order to support high standards of animal health and welfare, to promote sustainable beef and dairy sectors, to meet EU legal and trade requirements, and to reduce the cost and burden on farmers and taxpayers. It is therefore essential that we step up our efforts and finally start to get on top of this disease.
- 4. The Government is committed to taking a comprehensive and balanced approach to tackling TB, with eradication as the long-term goal. We must find the disease where it is present, stamp it out when it is found, stop it recurring and prevent it from spreading. Our approach needs to be:
 - Comprehensive:
 - Tackling TB in cattle, non-bovine farmed animals, and wildlife.
 - Addressing all transmission routes to tackle TB in cattle (cattle to cattle and between badgers and cattle).
 - Making best use of all available tools.
 - Risk-based: targeting controls on disease risk, based on veterinary advice and discretion, and making the best possible use of resources.
 - Staged: seeking to stop the disease spreading in the short-term, bringing it under control, and ultimately eradicating it.

- 5. We are also committed to a number of key principles which will shape our delivery and ways of working:
 - Partnership working: recognising the progress that has been made in Government, industry and the veterinary profession working together effectively and the need to continue to build on and strengthen this relationship if we are to succeed. This Eradication Programme has been shaped by the advice and recommendations of the Bovine TB Eradication Group for England (TBEG).
 - Responsibility and cost-sharing: giving farmers more control and choice, empowering the
 industry to take greater responsibility for tackling TB, because farmers are best placed to
 manage disease risks in their own herds; ensuring farmers have the right incentives; and
 reducing the cost to the taxpayer. The reduction in Defra's budget and increasing costs
 of TB control mean we will need to make progress on cost-sharing during the Spending
 Review period (2011-15).
 - Working effectively in the EU: ensuring we comply with EU legislation, while pushing for a more flexible, risk-based EU legal framework.
 - Supporting farmers: reducing unnecessary burdens and restrictions on farmers where
 possible and without compromising disease controls. Also, working with the industry and
 veterinary profession to provide targeted advice and support to farmers.
- 6. The Eradication Programme set out in this document includes the following key measures:
 - Cattle surveillance and control measures to address cattle to cattle transmission.
 - Promoting good biosecurity, to address transmission between cattle, and between badgers and cattle.
 - Control of TB in badgers, to reduce transmission from badgers to cattle in TB endemic areas.
 - Measures to tackle TB in non-bovine farmed species (including pigs, goats, deer, sheep, alpacas and llamas).
 - Advice and support for farmers.
 - A targeted research and development programme.
 - Robust governance, monitoring and reporting arrangements.

- 7. We already have a comprehensive range of **cattle measures** in place to address cattle to cattle transmission, including routine testing and surveillance, pre-movement testing, movement restrictions and rapid slaughter of infected animals. These cattle measures will remain the foundation of our TB Eradication Programme. We can do more to maximise their effectiveness, but it is clear that on their own they will not enable us to eradicate TB in England.
- 8. We will continue to look for opportunities to tighten these controls where this would be sensible, proportionate and cost-effective. We have already made a number of changes to strengthen cattle measures, including:
 - A significant expansion in 2010 and 2011 of the areas and number of herds on annual and two-yearly routine testing, and therefore also an expansion in the number of herds required to pre-movement test cattle.
 - We have reviewed the pre-movement testing policy and confirmed this will remain in place.
 - Enhanced controls on some high risk herds.
 - We have extended the use of gamma interferon blood testing to infected herds in twoyearly routine testing areas to reduce the risk of TB becoming established in these medium risk areas.
 - Adopting new, clearer terminology using Officially Tuberculosis Free (OTF), OTF Suspended (OTFS) or OTF Withdrawn (OTFW) to describe the herd TB status and breakdowns, to help farmers better understand the disease risks.
 - Enhanced slaughterhouse surveillance.
 - Applying DNA tags to TB reactor animals.
- 9. We are now planning or considering a number of further measures:
 - We plan to revise the existing exemption for shows and remove the 30-day rule exemption from pre-movement testing. We will also consider how best to deal with disease risks posed by the existing Single Occupancy Authority (SOA) exemption in light of the Farming Regulation Task Force's recommendation that SOAs should be abolished.
 - We will reduce compensation payments for reactor animals from herds where TB tests become significantly overdue from April 2012.
 - We will review the options for moving to a risk-based approach to routine TB surveillance with a view to implementing this in 2012.

- We will review the rules and procedures for TB infected herds regaining officially TB-free (OTF) status by the end of 2011.
- We will look at the feasibility of options for a TB risk-based trading system for cattle by the end of 2011.
- We will develop and implement an enhanced TB compliance and enforcement strategy by the end of 2011.
- 10. Improving **biosecurity** can also help to prevent the spread of disease and is an essential part of farmers managing their own risks. By taking steps to prevent cattle to cattle transmission and reduce some of the risk of transmission from wildlife, farmers could reduce the risk of experiencing a breakdown. We will work with the industry and the veterinary profession to provide targeted advice and support to help farmers do this.
- 11. However, cattle measures and good biosecurity alone will not be enough. Unless we reduce the transmission of TB from badgers to cattle we will never eradicate TB in cattle. We are therefore committed to introducing a carefully managed and science led policy of **badger control**. The scientific evidence is clear: we know from the Randomised Badger Culling Trial that culling badgers can reduce the incidence of TB in cattle. However we also know that if not done properly culling can make matters worse.
- 12. In September 2010 we consulted on a proposal to enable farmers and landowners to apply for licences to cull and/or vaccinate badgers in areas with high incidence of TB in cattle (see http://archive.defra.gov.uk/corporate/consult/tb-control-measures/index.htm). Applicants would need to demonstrate that they meet strict criteria in order to obtain a licence to cull, or cull and vaccinate badgers in combination. The Government would take responsibility for monitoring the effectiveness, humaneness and impact of the policy. Having considered the large number of consultation responses, we remain strongly minded to proceed with this proposal, subject to some amendments designed to take account of the issues raised in the consultation, and further consultation on those changes. Therefore we are now consulting key stakeholders on the detailed proposals for implementation articulated in draft statutory guidance to Natural England. We will consider the responses to this consultation, alongside responses to the public consultation before taking a final decision on whether to proceed with a policy of badger control in the autumn. If the decision is to proceed, we will initially issue licenses to two areas, which will be closely monitored to ensure that this method is both effective and humane. The results of this monitoring will be examined by a panel of independent experts who will advise the Secretary of State over whether further licenses should be issued.
- 13. We have carefully considered the case for badger vaccination, given that we now have the injectable Badger BCG vaccine available. The veterinary advice is that currently badger culling will be more effective than the injectable vaccine in quickly reducing the weight of infection in the badger population. Although the available evidence on the effects of vaccination on bovine TB in cattle is currently very limited, vaccination does still have value, as it reduces

the prevalence and severity of disease in the badger population and has greater disease control benefits than taking no action at all to tackle the disease in badgers. For some farmers and landowners, using vaccination may be the preferred option for tackling bovine TB in badgers and licences to trap and vaccinate badgers will continue to be available. Vaccination may also have a role in helping to reduce the risks from perturbation caused by culling, when no other buffers are available. To support its use in these circumstances, we propose to make available up to £250,000 a year in grant funding to help meet the costs of vaccination. Further details about how to apply for funding will be published shortly.

- 14. We recognise the importance of providing farm businesses affected by TB with practical support. In November 2009 we launched a new TB farmer advice and support service making advice available to TB affected farmers to help them reduce the risk of repeat TB breakdowns and minimise the business impacts of the disease. We have reviewed the controls imposed on TB breakdown herds and made a number of policy changes to increase trade opportunities for restricted herds, without undermining disease controls; for example, TB restricted sales, where clear tested cattle from TB affected herds are bought by owners of other TB restricted herds.
- 15. TB is also occasionally found in **non-bovine farmed animals** (such as alpacas, llamas, deer, goats, pigs and sheep) although the number of cases has historically been very small. Monitoring and surveillance arrangements have therefore been proportionately lighter than for cattle. We will continue to provide advice and support and work with private veterinary surgeons to heighten awareness of TB in these species. We intend to work with the relevant sectors and the insurance industry to explore opportunities for insuring higher value animals, as well as reviewing the current policy on movement restrictions and how these might be adjusted to help farmers better manage disease outbreaks. By encouraging a more consistent risk based approach we are looking to the non-bovine sectors to become more self-regulating without interference from government.
- 16. We remain committed to a substantial **research programme** to support policy development and delivery, and are protecting the TB research budget from significant cuts. The budget for 2011/12 is £7.9 million. One of our top priorities will be to continue to develop a **cattle vaccine** and an **oral badger vaccine**. However, on even the most optimistic scenarios it is likely to be many years before either of these is ready for widespread deployment in the field.
- 17. TB is a chronic, slow-moving and complex disease and it is likely to be some time before we see a significant improvement in the disease situation. We will continue to **monitor and report** on the TB situation in cattle and non-bovine species, and will publish progress reports. We will continue to look for ways to develop and enhance this eradication programme through cost-effective and affordable measures, in close consultation with the Bovine TB Eradication Group for England (TBEG).

1. Introduction

Summary

- TB is a serious animal health problem, with nearly 25,000 cattle slaughtered in England alone in 2010/11, at a cost to the taxpayer of over £91 million¹.
- The problem has been getting worse over the last few years. During 2010 10.8% of herds in England were under restrictions at some point due to a TB incident, and the situation is worse in the West and South West.
- The number of new TB incidents in England rose in 2010, compared to 2009, and although still lower than seen in 2008 suggests the disease situation is not improving.
- TB is transmitted between cattle, between badgers, and between the two species. It is also found in other, non-bovine animals. It is clear that the worsening TB situation in the West and South-West of England is in large part being driven by the transmission of TB from badgers to cattle.
- The risk to public health is very low these days, largely thanks to milk pasteurisation and the TB surveillance and control programme in cattle, but we still need to tackle TB in order to support high standards of animal health and welfare, to promote sustainable beef and dairy sectors, to meet EU legal and trade requirements and to reduce the cost and burden on farmers and taxpayers.
- It is therefore important that we step up our efforts to finally get on top of this disease.
- 1. Bovine Tuberculosis (TB) is one of the most pressing animal health problems faced by the cattle industry in England. Large numbers of animals are slaughtered due to TB each year, nearly 25,000 in 2010, which, combined with the comprehensive testing programme and movement restrictions, results in significant financial and emotional pressures on farmers and rural communities. It also results in large costs to the taxpayer, over £91 million in England alone in 2010/11.
- 2. TB is a serious infectious disease of cattle, caused by the bacterium *Mycobacterium bovis (M. bovis)*. It can also affect a range of other mammalian species, most significant of which is the reservoir of infection in badgers. The disease is transmitted between cattle, between badgers, and between the two species. It can also occasionally affect a range of other farmed, pet and wild animal species including sheep, pigs, goats and camelids (Ilamas and alpacas); dogs and cats; and other wild animals such as deer. It can be transmitted to humans, although for the overwhelming majority of people in the UK the risk of contracting *M. bovis* infection from animals is very low largely thanks to milk pasteurisation, and the other controls in place.

_

¹ This includes research costs and Animal Health Veterinary Laboratories Agency's central costs

- 3. There are a number of reasons why it is important that we tackle TB, including to:
 - Protect the health of the public and maintain public confidence in the safety of products entering the food chain.
 - Protect and promote the health and welfare of animals.
 - Meet our international (in particular EU) and domestic legal commitments and maintain the UK's reputation for safe and high quality food.
 - Maintain productive and sustainable beef and dairy sectors in England, securing opportunities for international trade and minimising environmental impacts.
 - Reduce the cost of TB to farmers and taxpayers.

1.1 What is the scale of the problem?

4. The trend of cattle TB incidence in England has been rising for 25 years. The area affected by TB has spread from isolated pockets in the late 1980s to cover large areas of the West and South-West of England and Wales. Figure 1 shows the extent of the problem in those areas.

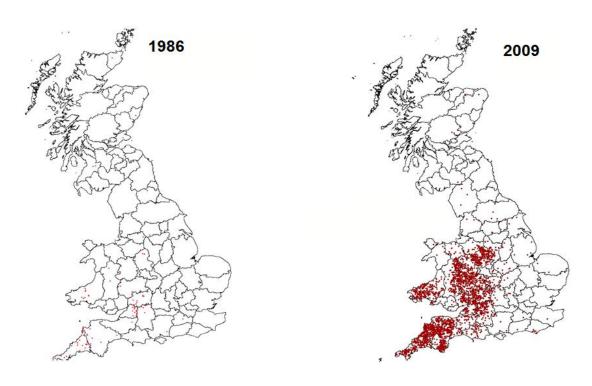


Figure 1: Geographical distribution (point location) of herds sustaining new breakdowns of bovine TB in 1986 and 2009. Only herds with Officially Tuberculosis Free status withdrawn are shown (source: VLA).

5. During 2010, 10.8% of herds in England were under restrictions at some point due to a TB incident. The figure was 22.7% in the South-West. Nearly 25,000 cattle were slaughtered for TB control, identified at over 40,000 herd tests involving more than 5 million individual animal tests.

1.2 History and epidemiology of TB in cattle

6. In Great Britain as a whole, a large proportion of cattle herds were infected with *M. bovis* in the early part of the 20th century. At that time consumption of infected cows' milk was thought to have led to over 2,500 deaths and over 50,000 new cases of TB per year in the human population. The gradual introduction of milk pasteurisation (which destroys any *M. bovis*), meat inspection at slaughterhouses, and the statutory cattle testing and slaughter programme are now effective safeguards for public health. There are now very few cases of human TB caused by native *M. bovis* infection as a result (although certain groups are at higher risk e.g. consumers of unpasteurised milk, those working with cattle or carcases or those exposed to risks abroad).

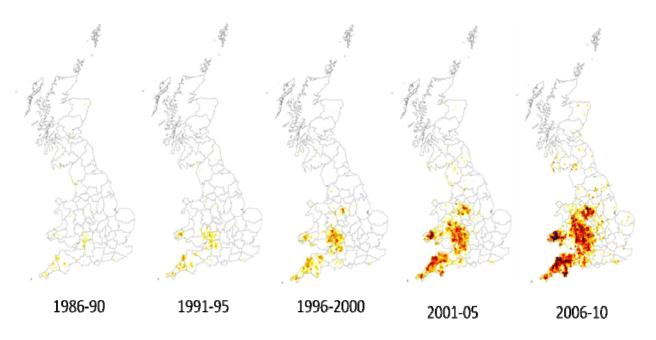


Figure 2: Maps showing spread of TB between 1986 and 2010, as measured by number of reactors found in Officially Tuberculosis Free status withdrawn (OTFW; culture confirmed) TB breakdowns per km (darker colours show greater density of cases) (source: VLA).

7. In 1935 a voluntary GB-wide test and slaughter programme for cattle herds was introduced which became compulsory in 1950. By the end of the 1960s the disease was confined to a few pockets in the South West of England and it was established that persistence of disease in these areas was due to reservoir of infection in badgers. In 1979 there was the lowest recorded level of TB incidence, with only 0.49% of all herds tested having a reactor,

which equated to less than 0.02% of all cattle tested. However, despite continuous compulsory cattle testing and slaughter over 60 years, levels of TB in cattle in England have been rising since the mid-1980s.

- 8. The area affected by TB has spread from isolated pockets in the 1980s to cover large areas of the West and South-West of England and Wales (see figure 2). Other parts of England subject to the same control programme but where there is no transmission risk from infected badgers continue to be effectively disease-free, as is the whole of Scotland, which was recognised as an OTF region of the UK in 2009. The cost to farmers and taxpayers of dealing with the disease, and its emotional impact on famers and their families, are rising and are becoming increasingly unsustainable.
- 9. In 2010 there was an increase in the number of new TB breakdowns in England, compared with 2009 (see figure 3). Although this is still fewer than seen in 2008 it suggests that the disease situation may be starting to worsen again. We have observed this pattern of decline followed by a rise to a new peak over the last nine years (in 2002 and 2005; see figure 3) and there is evidence of a three-year cycle emerging. Also, the disclosure of TB breakdowns in previously unaffected areas and herds has continued throughout 2010. It is not currently possible to know with any certainty what may have caused the reductions in 2009 or increases in 2010. We will need to await data for future months to see if this upward trend continues, but this does not suggest that the overall improvement in the disease situation that we saw during 2009 and first half of 2010 is set to continue on the basis of current control measures.

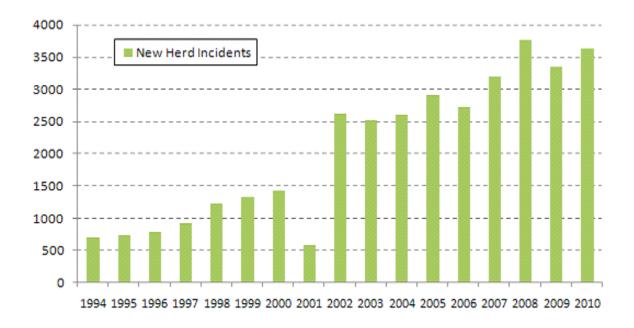


Figure 3: Number of new TB herd breakdowns disclosed annually in England (1994-2010)²

² The dip in 2001 is due to the suspension of the TB control programme during the Foot and Mouth Disease outbreak.

10. Figure 4 shows that since 2003 the total number of new bTB breakdowns identified (every quarter) in GB has been doubling at a rate of every 10 years. Prior to the Foot and Mouth Disease epidemic of 2001, the doubling rate was every 5.2 years. Although the rate of disclosure of new TB breakdowns has been approximately halved it is still an increasing one. This deceleration may be due to the intensification of TB surveillance and control measures in cattle herds over recent years, some form of 'saturation' in the endemic areas (as TB breakdowns last longer and the number of susceptible herds at risk of being newly identified as infected is decreasing over time), or a combination of these and other factors. However this does not detract from the fact that the incidence of TB in England (and the West in particular) is unacceptably high and on a continuing upward trend.

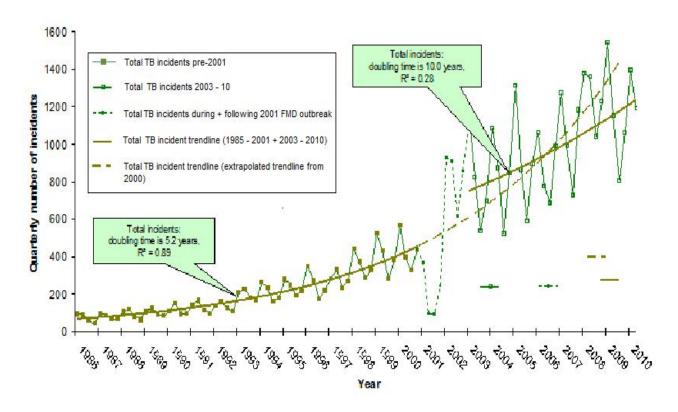


Figure 4: Quarterly numbers of total and OTFW herd incidents between January 1986 and June 2010.

1.3 Costs of TB

- 11. Dealing with TB remains the largest single component of animal health related expenditure for England. The cost to the taxpayer has risen steadily over the last few years and was over £91 million in 2010/11. Around 90 % of this spend is accounted for by Government-funded cattle testing and compensation payments to farmers for slaughtered animals.
- 12. There are also significant costs for farmers including losses incurred as a result of movement restrictions, the need to buy in replacement animals, and supporting the required programme of TB testing (routine, breakdown and pre-movement) in a herd. It is more difficult

to quantify the costs to the industry but we can be sure they run into tens of millions of pounds a year.

- 13. The average cost of a TB breakdown is around £30,000 in a cattle herd in England where officially TB-free (OTF) status has been withdrawn. About £20,000 of this falls to Government, mainly as compensation for animals compulsorily slaughtered and costs of testing. This leaves about £10,000 in costs falling to farmers as a result of their consequential losses, on-farm costs of testing, and disruption to business through movement restrictions. The average cost of a breakdown where OTF status is only suspended (not withdrawn) is estimated at around £9,400.
- 14. The annual costs of dealing with TB have risen by more than 10 % a year over the past decade. Our epidemiological modelling suggests that with no change to present policies, i.e. without an effective intervention to tackle the transmission of TB from badgers to cattle, the TB epidemic will continue to worsen in the long-term, although interventions such as pre-movement testing are slowing its growth rate. If this proves to be the case, the annual cost of dealing with TB in Great Britain is projected to continue to rise, approaching £400 million by 2050 and costing the economy around £9 billion pounds in total over the 40 years up to then. This makes a powerful case for taking effective action now to save control costs in future.
- 15. The 2010 Spending Review settlement requires Defra to reduce its overall expenditure by 29% over the period 2011-15. This will have an impact on the level of Government funding available for TB controls and we will need to make sure that we maximise the benefits from the available funding.

2. The Government's Approach

Summary

- The Government is committed to a comprehensive and balanced approach to tackling TB, with eradication as the long-term goal. We must find the disease where it is present, stamp it out when it is found, to reduce its recurrence and prevent it from spreading.
- Our approach needs to be:
- Comprehensive: Tackling TB in cattle, non-bovine farmed animals and wildlife; addressing all transmission routes to tackle TB in cattle; and making best use of all available tools.
- Risk-based: targeting controls on disease risk, based on veterinary advice and discretion, making the best possible use of resources.
- Staged: seeking to stop the disease spreading in the short-term, bringing it under control, to ultimately eradicate it.
- We are also committed to a number of key principles which will shape our delivery and ways of working:
- Partnership working: recognising that Government, industry and the veterinary profession will need to work together if we are to succeed.
- Responsibility and cost-sharing: giving farmers more control and choice; empowering the industry to take greater responsibility for tackling TB; sharing and reducing the cost of TB and ensuring farmers have the right incentives.
- Working effectively in the EU; ensuring we comply with EU legislation, while pushing for a more flexible, risk-based EU legal framework.
- Supporting farmers: reducing burdens and unnecessary restrictions on farm businesses without compromising disease control; working with the industry and veterinary profession to provide targeted advice and support.
- 16. The TB situation is now so serious that it is likely to take decades to eradicate the disease. The Government is committed to a comprehensive and balanced approach to tackling TB, with eradication as the long-term goal. We must:
 - Find the disease where it is present.
 - Stamp out the disease when it is found.
 - Prevent the disease from spreading.
- 17. Our approach needs to be **comprehensive**, tackling TB in cattle and other farmed animals, addressing all TB transmission routes to cattle and making the best use of all the available tools. This includes fulfilling the Coalition Government's commitment to a carefully managed and science led policy of badger control in areas of high and persistent levels of TB. It should also be **risk-based**, making use of veterinary advice and discretion to target controls

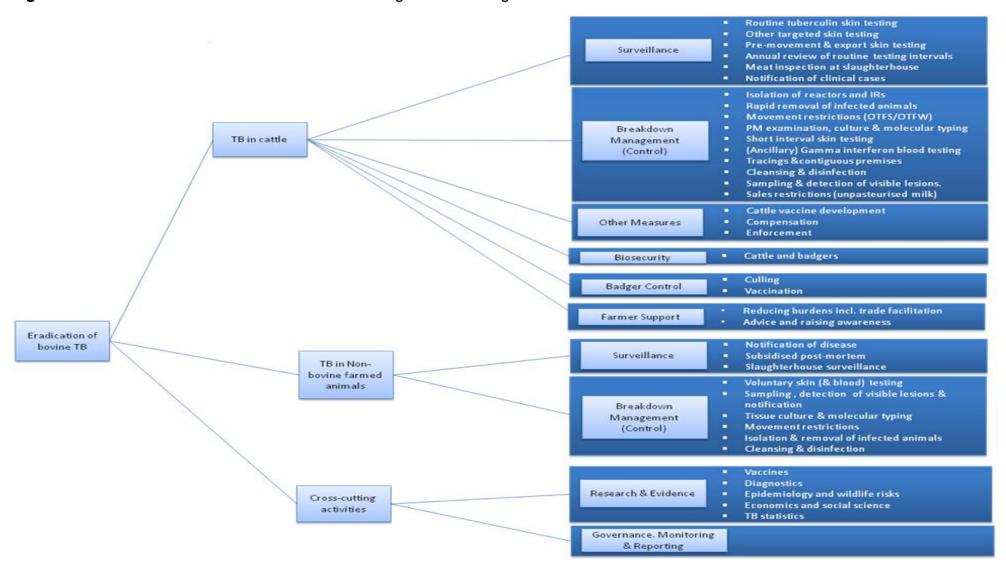
on the basis of disease risk and make the best possible use of resources. The long timescale for tackling TB means we need to take a **staged approach**, initially seeking to stop the disease spreading in the short-term, then bringing it under control, and ultimately eradicating it. We already have a comprehensive and progressively strengthened programme of cattle controls in place and we need to focus on making use of the available tools to control the risks posed by transmission from badgers to cattle, which has not been meaningfully addressed for over 10 years.

- 18. In delivering the programme we are also committed to following a number of key principles which will shape our delivery and ways of working:
 - Government, industry and the veterinary profession need to continue to build on the current relationships, working together if we are to succeed, so there needs to partnership working at national and local level.
 - Farmers are best placed to manage disease risks in their own herds, so a new approach
 to sharing responsibility and costs will give them more control and choice, empowering
 and incentivising them to take greater responsibility for tackling TB, and help reduce the
 cost of TB to the industry and taxpayers.
 - We need to **work effectively in the EU**, ensuring that we comply with EU legislation, while pushing for a more flexible and risk-based EU legal framework.
 - Supporting farmers, reducing burdens and unnecessary restrictions where possible, without compromising disease control and working with the industry and veterinary profession to provide targeted advice and support.

2.1 A comprehensive programme

- 19. Figure 5 presents an overview of the TB programme. The programme needs to be comprehensive:
 - Tackling TB in cattle, non-bovine farmed animals and wildlife.
 - Addressing all transmission routes to tackle TB in cattle; from cattle to cattle and between badgers and cattle.
 - Making best use of all the available tools for TB surveillance and control.
- 20. We already have a comprehensive programme of **cattle measures** in place and these will remain the foundation of our efforts to bring TB under control (see section 3.1). Addressing cattle to cattle transmission risks is the most vital part of any control programme and has been the focus of our TB control programme for over 60 years. Continuing to improve our ability to

Figure 5 – Overview of the Bovine TB Eradication Programme for England



identify infected animals early through enhanced surveillance and controls will still be a priority. It is also essential to prevent the disease spreading to and becoming established in new areas of the country. We will therefore ensure a rigorous and consistent approach to movement restrictions is maintained. Where disease is identified, action must be swift and effective to stamp it out within a herd and to reduce the risk of residual and external re-infection, so we need effective breakdown controls. Because of the seriousness of this disease and the risks to other farmers, non-compliance with control measures cannot be tolerated and will be dealt with robustly.

- 21. **Improved biosecurity** helps to reduce the risk of disease spread and is an essential part of farmers managing risks to their herds (see section 3.2). By taking steps to prevent cattle to cattle transmission and reduce the risk of transmission from wildlife, farmers can reduce the risk of a TB breakdown in their herd. The new focus for disease investigation visits, introduced in 2010 by Animal Health (now AHVLA), includes tailored advice on improving biosecurity and supplements the information leaflets already available.
- 22. However, it is clear that just tightening cattle measures and biosecurity will not be sufficient to eradicate TB while the risk of re-infection from badgers is not fully addressed. We are strongly minded to allow badger culling under licence as part of a carefully managed and science-led policy of badger control (see section 3.3), which aims to reduce the risk of TB transmission from badgers to cattle. Our proposed approach is to enable farmers and landowners to apply for licences to cull and/or vaccinate badgers. Licences would be subject to strict criteria to ensure that the badger control measures are carried out effectively, and with high regard to animal welfare. Culling would only be permitted by cage-trapping and controlled shooting of badgers in the field, carried out by competent operators with the appropriate licences. Government would monitor actions taken under the licence, the impact on cattle herd breakdowns within the areas culled or vaccinated, humaneness of the culling methods, and the remaining badger population. We propose to take a precautionary approach through a pilot of the policy; initially issuing licences in two areas in the first year, which will be closely monitored to ensure that this method is both effective and humane. The results of this monitoring will be examined by a panel of independent scientific experts who will advise the Secretary of State over whether further licences should be issued. Monitoring would continue throughout the culling period in all licensed areas to ensure standards are maintained. We are now consulting key stakeholders on a detailed proposal before taking a final decision on whether to proceed with the policy of badger control. The consultation document and draft guidance are available on the Defra website.
- 23. We will continue to invest in the development of a **cattle vaccine** (see section 3.1.4) and an **oral badger vaccine** (see section 3.3). Our overall objective is to have licensed vaccines for both cattle and badgers available and widely used in the field, making a significant contribution to reducing the prevalence and spread of TB in cattle and contributing towards its eventual eradication. However, while we remain committed to the development of these vaccines, we should not underestimate the significant technical and regulatory challenges that

still need to be overcome before vaccines could be used. Even if these challenges can be addressed, cattle and badger vaccines will not be available for use in the field for many years.

24. The number of reported cases of TB in non-bovine farmed animals (see chapter 4) such as sheep, pigs, goats and camelids have been increasing in the last three years though still remain very low overall. A proportionate surveillance and breakdown management regime is being developed in partnership with representatives from the different industries to address the disease in each of the livestock sectors.

2.2 A risk-based approach

Geographic area of risk	Description
High risk areas	Established endemic areas: the South-West, West and Midlands and parts of East Sussex which are on annual testing and where there is a recognised, established wildlife reservoir.
Edge of high risk areas	Areas at increased risk at the edge of high risk areas in the South-West, Midlands and East Sussex, predominantly on two-year routine testing.
Medium risk areas	Areas in England under restriction but not in the high risk and to the North and East of the edge of high risk areas where breakdowns are considered due to the translocation of infection through cattle movements and there is no evidence of transmission from wildlife. Areas where this would currently apply include, for example, Nottinghamshire, Northamptonshire and the east of Hampshire.
Declining risk areas	Areas where, from an epidemiological point of view, the situation is improving and this is reflected by local areas coming off of annual testing and the increasing intervals between routine tests. One of the areas where this would currently apply is Cumbria, where infection was introduced widely through cattle movements restocking herds after the Foot and Mouth Disease outbreak of 2001. In Northumberland, the sustained reduction in numbers of TB breakdowns has allowed a return to four-yearly TB herd testing across the county in 2011.
Low risk areas	The remaining areas that would not fall within the categories above, which will be on four yearly testing and where only the occasional herd is currently under restriction. Areas where this would currently apply include, for example, Kent, Humberside and Norfolk.

Table 1: Geographic areas of TB risk.

- 25. In recent years we have increasingly taken a more risk-based approach to TB surveillance and control. The Bovine TB Eradication Group for England (TBEG; see section 2.4) has helped take this further by setting out, in their progress report of October 2009, a regional framework for developing this risk-based approach to TB control. They identified five geographic areas of TB risk, set out in table 1.
- 26. These risk areas are not static and whilst their current geographic distribution can be broadly represented using the 2011 map of routine TB testing intervals (see figure 6) they will change as local TB risks vary over time. This is illustrated by the expansion of the area under more frequent routine TB testing (see figure 7). There was a step change in our approach to routine testing in 2010 with all herds in the South West and West of England placed on annual

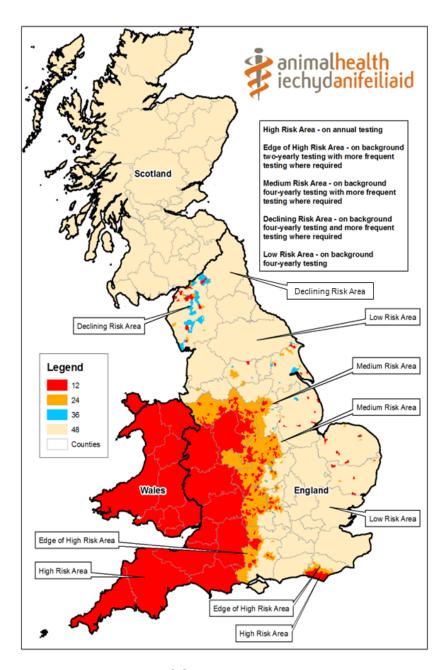


Figure 6: 2011 routine TB testing map of Great Britain showing geographic areas of TB risk.

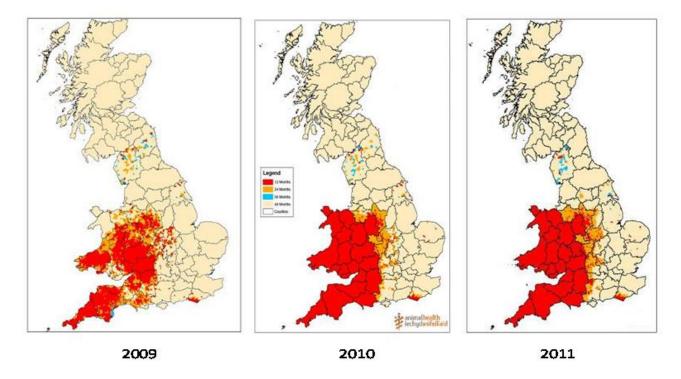


Figure 7: Expansion and consolidation of annual routine TB testing areas and the two-yearly testing buffer between 2009 and 2011.

testing, and herds in an area to the North and East on two-yearly testing. This created a buffer, separating the high TB risk areas from the low TB risk four-yearly testing areas. There is a further expansion of the annual testing area and widening of the two-yearly testing buffer for 2011. Epidemiological evidence and understanding points to the presence of a badger reservoir as the main factor in determining risk on a geographical basis (i.e. in the expanding high risk areas) and tackling this must be the priority in those areas. For example, in the North and East of England (as in Scotland), where there is not a risk of infection from a badger population, the cattle test and slaughter regime works well and the occasional breakdown due to the introduction of infected cattle is stamped out.

27. At the individual herd level, in addition to the regional situation, the risk of TB infection is also affected by farmer behaviour in particular cattle trading patterns and also on-farm husbandry and biosecurity practices. We are looking at options for measures targeted at local and herd level risks, such as how we set routine testing intervals and herd descriptors to facilitate risk-based trading (see section 3.1.4).

2.3 A staged approach to eradication

- 28. EU legislation allows for a country or region to be designated as officially TB-free when the percentage of herds confirmed as infected with TB has not exceeded 0.1 % per year of all herds for six consecutive years. Many European countries are considered officially TB-free by the European Commission. Scotland achieved this status in October 2009. It is likely to be a matter of decades before England as a whole achieves officially TB-free status. TBEG has identified a number of stages on the path to eradication:
 - Immediate (where we are now): strengthening controls for TB and in particular addressing badger to cattle transmission, whilst ensuring the risk to public health remains very low. Measures are in place to reduce the impact of TB restrictions on farm businesses.
 - **Short term:** strengthened controls beginning to have an impact on disease control in areas where disease is newly introduced and areas at the edge of high risk areas through reflecting the risk in testing intervals and by identifying infection early so the full range of existing measures can be used to prevent disease becoming established.
 - Medium term: measures starting to have a real impact in newly affected areas and are
 reducing the risk of expansion of high risk areas by reducing the scope for infection to be
 moved out of herds; reducing the risk of TB spreading in wildlife; and protecting as many
 uninfected areas and herds as possible from infection. The introduction of further
 measures to reduce TB in high risk areas will have begun.
 - Long term: increasing activity to reduce TB incidence and reduce the disease risk
 presented by all routes of transmission. Followed by a continuing reduction in TB and
 beginning to reduce the overall cost of TB to the economy and ultimately England
 achieving officially TB-free status.

2.4 Working in partnership

Bovine TB Eradication Group for England (TBEG)

- 29. This Eradication Programme has been drawn up in partnership with the industry and veterinary profession, through the Bovine TB Eradication Group for England (TBEG). TBEG was established in November 2008, made up of representatives from Defra (including the Government's Chief Veterinary Officer), AHVLA, the farming industry, and the private veterinary profession. Its remit is to give advice and make recommendations to Ministers on TB and its eradication.
- 30. The Group has reviewed the existing TB control programme and looked at both the overall strategy and specific measures for tackling the disease. Their initial recommendations,

set out in a progress report in October 2009 (see full report at http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/tb-erad091008.pdf), have all been implemented including a more coherent, risk-based approach to routine TB testing, enhanced controls applied to some higher risk breakdowns and developing options to support farmers under TB restrictions. Their recommendations have also been instrumental in securing European Commission approval of the UK TB Eradication Plans for 2010 and 2011. TBEG has driven the development of the more comprehensive and risk-based approach to tackling TB and their work and advice to Ministers underpins all aspects of the Eradication Programme, including the development of the badger control regime. Further details on the work of the Group can be found at annex B.

Our delivery partners

- 31. There are a range of delivery bodies working closely with farmers, private veterinary surgeons and others, to administer and deliver the TB programme in England (see table 2). The Animal Health and Veterinary Laboratories Agency (AHVLA) is an executive agency working on behalf of Defra, Scottish Government and Welsh Assembly Government. The agency was formed on 1 April 2011, following the merger of Animal Health and the Veterinary Laboratories Agency. The new agency's role is to help safeguard animal health and welfare and public health, protect the economy and enhance food security through research, surveillance and inspection. AHVLA has the authority to deal with local issues and leads on individual case management, applying local veterinary knowledge and discretion to the management of TB breakdowns in individual herds. In 2009-10 over £61 million of the Animal Health budget (45% of the total £137 million for GB as a whole) was spent on TB controls in England. There is close liaison between AHVLA and the other delivery bodies, including Local Authorities.
- 32. TB testing is predominantly carried out by vets, mostly private practitioners contracted by Government as Official Veterinarians (OVs). AHVLA has recently reviewed and updated the programme in place to audit and oversee the quality of TB testing. AHVLA is also running a procurement project for the supply of veterinary services, which aims to place the arrangements with private sector suppliers, such as veterinary practices, onto a normal commercial footing. As part of this process, it is planned to let a tender for supply of a tuberculin skin testing service. A move to more formal contractual arrangements will help ensure an agreed standard of testing and demonstrate that it is being purchased at a fair price. The formal procurement process (in England and Wales) is unlikely to begin before late 2011, and will take a further 9 to 12 months to complete. Detailed information about the procurement will not be available until this formal process begins. We will work to mitigate any risks these changes pose to the delivery of the TB testing programme.
- 33. TB policy is a devolved issue. Defra works closely with the Devolved Administrations in Wales, Scotland and Northern Ireland to ensure coherent and joined-up policies for the UK. The Chief Veterinary Officers and lead TB policy officials from each country meet on a monthly basis to discuss TB issues through the UK TB Liaison Group. The Group shares information on

latest developments and policy changes in each country and coordinates the UK's approach on TB within the EU.

Organisation	Responsibilities
Animal Health and Veterinary Laboratories Agency	Primarily responsible for ensuring that farmed animals in Great Britain are healthy, disease free and well looked after. The lead delivery body on TB issues, carrying out or managing TB surveillance and auditing, removal of reactors and controls around TB (e.g. movement restrictions); approval of special types of units; field epidemiology to inform management and control measures. Also responsible for laboratory support to Defra's animal disease surveillance and control programmes, including diagnostic services and culture analysis, and other TB research and development.
Rural Payments Agency	The RPA is the competent authority for livestock movements, identification, imports, deaths and tracing for all cattle to be used for animal health (surveillance, planning and control) and subsidy control purposes.
Food Standards Agency	The functions of the former Meat Hygiene Service have been assumed by the FSA. This covers post mortem inspection of carcases of all animals slaughtered for food consumption in licensed red meat abattoirs.
Local Authorities	Monitoring and enforcement of animal health aspects of TB legislation will be borne by the Trading Standards Departments of Local Authorities throughout England. Environmental Health departments of Local Authorities enforce EU feed and food (e.g. dairy) legislation. Local Authorities liaise at a local level with AHVLA in relation to enforcement and with the British Cattle Movement Service (BCMS) on cattle identification issues.
Environment Agency	The Environment Agency is responsible for enforcement of the requirement for disposal of waste including by-products from reactors and milk from reactor cows.
Food and Environment Research Agency	Fera provides advice and conducts research on wildlife and husbandry issues relating to TB and runs the delivery of the Badger Vaccine Deployment Project.
Natural England	Natural England is the licensing authority for the Protection of Badgers Act 1992 and other wildlife legislation in England.

Table 2: TB delivery bodies and responsibilities.

2.5 Sharing responsibility and costs

34. Historically, a great deal of emphasis has been placed on the role of Government in TB control. However, it is apparent that farmers, with the support of the veterinary profession, are

best placed to manage the TB risks to their herd. This is already happening to a large extent with farmers, private vets and AHVLA working together to deliver the TB control programme on the ground. Farmers need to be further empowered to take decisions which are in the best interests of their businesses.

35. Future responsibility for managing TB risks will therefore need to be consistent with the Government's commitment to greater responsibility and cost sharing with industry on animal health and welfare. The final report of the England Advisory Group on Responsibility and Cost Sharing recommended that a new board, made up of officials, industry experts and specialists, should be established to share responsibility for strategic policy making on animal health and welfare in England. This is consistent with the successful partnership working on TB within TBEG. It also proposes that a staged approach to cost sharing be developed by the new Board. In April we announced our intention to establish a new Animal Health and Welfare Board for England which is expected to be in place by the end of 2011. The Board will be responsible for making recommendations on cost sharing after it is established. However, given the overall reduction in Defra's budget and the increasing costs of controlling TB, it is already clear that we will need to make progress on cost-sharing before the end of the current Spending Review period (2011-15), working in close consultation with the industry to look at possible options, including sharing more of the costs of TB testing and/or reducing compensation payments.

2.6 Working effectively in the EU

- 36. Our TB Eradication Programme must meet the requirements laid down in EU legislation, notably *Council Directive 64/432/EEC* on animal health problems affecting intra-Community trade in bovine animals and swine (see annex A for details). This Directive sets out the animal health status and disease control requirements for cattle trade within the EU, including TB testing for certification of animals for export, general rules on TB testing and conditions for designating the official TB freedom of herds. Our TB control programme is already consistent with and goes beyond these requirements which are designed to eradicate TB and which have been successful in most countries without a wildlife reservoir. However, we need to further strengthen our approach in the face of a worsening disease situation.
- 37. The existing EU legislation is very prescriptive and input-based rather than outcome-focused, thus limiting the flexibility to change our surveillance and control regime. The European Commission is developing a new EU Animal Health Law, with a formal proposal expected in 2012. The new Law is intended to set out a framework of principles for animal health and welfare in the EU, bringing together and where necessary updating the diverse range of existing health and trade legislation. We will take this opportunity to push for a more flexible, responsive and risk-based framework at the European level.

2.7 Support to farmers

Advice

38. A new **TB support and advice** service for farmers (see section 3.4) was launched in November 2010. This free advisory service aims to provide farmers with information which they can use to reduce their TB risks and minimise the business impacts of the disease. As well as biosecurity advice events, being delivered in partnership with industry, farmers can access free business support through the Farm Crisis Network. We are also enhancing the quality of support provided by private vets to TB affected farm businesses. There are also a number of industry led initiatives; for example in the South-West, any farmer can access an industry led, RDPE³ funded TB advisory service.

Reducing burdens

- 39. The Government is committed to a more risk-based and proportionate system of regulation and enforcement. Controls must find a balance between ensuring robust disease control and maintaining a viable cattle farming industry. Better targeting of controls will help to reduce burdens on the industry without compromising disease control. However, in a worsening disease situation, some controls may need to become tighter to reflect the increased disease risk.
- 40. The Task Force on Farming Regulation was set up by the Minister of State for Food and Farming in July 2010 to look at how to reduce regulatory burdens on the farming and food industry. The Task Force worked closely with TBEG, agreeing that the two groups should not duplicate their efforts and that TB related issues raised with the Task Force would be passed to TBEG for consideration; these included testing, movement, enforcement, tracing, markets and compensation. The Task Force reported on 17 May 2011. For further information and their report see www.defra.gov.uk/food-farm/farm-manage/farm-regulation/. The Task Force made two recommendations to TBEG in respect of TB controls:
- To consider options for a system of communicating the test history and status of cattle to farmers purchasing cattle with the aim of developing a joint industry and Government solution.
- That non-bovine species should be part of the national TB Eradication Programme and, to reflect the relatively lower risk presented by these animals, that a risk-based approach should be developed.
- 41. These recommendations are being considered within this Programme: at paragraphs 80-82 on risk-based trading and chapter 4 on non-bovines. The Task Force also made recommendations about animal movements and identification, but making clear that precedence must be given to disease control regimes such as those for TB.

_

³ Rural Development Programme for England

3. TB in Cattle

Summary

- We already have a comprehensive set of surveillance and control measures to address cattle to cattle transmission. These will continue to form the foundation of our TB Eradication Programme in England.
- However, without tackling the transmission of TB from badgers to cattle the disease situation
 will continue to worsen. To tackle this risk of transmission from badgers to cattle we remain
 strongly minded to proceed with a policy of issuing licences to cull and/or vaccinate badgers,
 subject to further consultation on the detail of the policy.
- We have recently made a number of changes to strengthen cattle measures:
- A significant expansion of the areas on annual and two-yearly routine testing.
- Enhanced controls on some high risk herds.
- Clarifying TB breakdown terminology so farmers better understand disease risk.
- Enhanced surveillance for TB at abattoirs.
- Extended the use of gamma interferon blood testing to infected herds in two-year routine testing areas.
- Reviewed and confirmed the effectiveness of the pre-movement testing policy.
- DNA tagging of TB positive cattle from April 2011.
- Over the next year we are planning a number of further measures including:
- Revising some of the existing pre-movement testing exemptions.
- Reducing compensation payments for reactor animals from herds where TB tests are significantly overdue.
- Reviewing options for an enhanced risk-based approach to routine TB surveillance.
- Reviewing the procedures for TB infected herds regaining OTF status.
- Assessing the feasibility of options for a risk-based trading system.
- Developing a more rigorous, risk-based TB compliance and enforcement strategy.
- We will continue to invest in the development of a cattle vaccine and seek to persuade the EU to lift the current ban on TB vaccination of cattle.
- We have introduced a free advice service for TB affected farm businesses to help farmers to reduce their TB risks and minimise the business impacts of the disease and will continue to provide advice to farmers on what they can do to improve their biosecurity.

3.1 Cattle measures

42. We already have a wide range of cattle measures in place to address cattle to cattle transmission, including routine testing and surveillance, pre-movement testing, movement restrictions on infected herds and removal and slaughter of infected animals. These cattle

measures will remain the foundation of our TB Eradication Programme, but we will continue to look for opportunities to tighten these controls where this would be sensible and cost-effective.

- 43. Bovine TB is a **notifiable disease**. Compulsory TB controls in cattle have been in place in England since 1950. In line with the approach taken in other developed countries and in compliance with EU legislation, surveillance and control of TB in cattle form the basis of our eradication programme.
- 44. The main measures used to tackle TB can be brigaded into:
 - **Surveillance measures** which are designed to identify infected animals within herds currently designated as officially TB-free (OTF) herds; and
 - **Control measures**, which are designed to eradicate infection and prevent its further spread once it has been found; i.e. in herds where the officially TB-free status has been suspended and withdrawn due to a TB breakdown.
 - A simple flowchart explaining how these measures work is set out in figure 8.

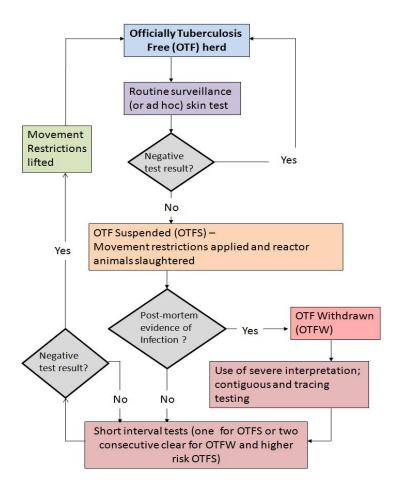


Figure 8: Flow diagram showing the TB surveillance and control regime for cattle herds in England.

3.1.1 Cattle surveillance measures

Routine surveillance testing

- 45. In general, cattle herds can trade freely if they have qualified for and maintain officially TB-free (OTF) status through a programme of periodic routine herd testing supplemented by abattoir surveillance of any slaughtered animals. However, owners of OTF herds that are subject to routine annual or two-yearly testing (i.e. those in the higher incidence regions of England) must skin test at their expense any animals over 42 days of age before they are moved to other holdings in GB (pre-movement testing see paragraph 49).
- On-farm surveillance for TB is carried out primarily through a programme of risk-based 46. routine testing, with all eligible cattle herds skin tested every one, two, three or four years depending on the level of risk of infection with M. bovis and historic incidence of infection in the local area. The incidence and risk of M. bovis infection are reviewed annually to confirm or change the frequency of routine testing. This annual review has resulted in steady increases in the proportion of herds tested at annual intervals and in the total number of herds and animals tests carried out. In 2010 we introduced changes to how routine TB testing intervals were set, resulting in a significant expansion of the number of herds on more frequent testing, resulting in all herds in the South West and West of England placed on annual testing and herds in an area to the North and East on two-yearly testing. This created a buffer, separating the high TB risk areas from the low TB risk four-year testing areas to the North and East (see figures 6 and 7). The intention was to ensure all herds in high risk TB areas are tested annually and to ensure that routine surveillance does not lag behind the spread of the disease which had been a concern until then. This approach has been further strengthened for 2011, with an expansion of the annual and two-year testing buffer areas (see figure 6) in an effort to stop the geographical spread of TB.
- 47. Even with these changes we are still not making the best use of our epidemiological knowledge and data, and still largely rely on information at county and parish level, which may present some inconsistencies. We are therefore initiating a **review of the options for setting routine TB testing intervals** based on an improved understanding of epidemiology and risks at national and local level, more in line with the approach taken to managing other animal disease epidemics.
- 48. TB surveillance (and breakdown) testing in cattle is by the **single intradermal comparative cervical tuberculin (SICCT) test** (also known as the tuberculin skin test)⁴. The tuberculin skin test generally results in a very low proportion of false positive results (a feature of high test specificity). However, the sensitivity of this test is not as high as its specificity and a greater percentage of false negative results may be expected in truly infected animals. We will continue to look at ways to improve the sensitivity of the SICCT test on its own or in

_

⁴ Internationally recognised test for TB surveillance

combination with other types of diagnostics and how those tests can be better deployed in the field.

- 49. Since 2006 most cattle moved from herds in annual or two-yearly routine TB testing areas must have been skin-tested with a negative test result within the 60 days preceding the movement date. The primary objective of this **pre-movement testing** policy is to reduce the risk of disease spread through the movement of cattle from herds in high TB risk areas and also to augment TB surveillance in high risk herds between their routine tests. Herd owners are required to pay for their own pre-movement tests, although they can time their routine (Government funded) herd test so that it takes place in the 60 days before the intended date of sale, thus also qualifying as a pre-movement TB test. Detailed statistics on pre-movement testing are published on the Defra website (see http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/premovement/monitoring-data.htm). Between March 2006 and March 2011 there were 1.7 million farmer paid premovement tests. In addition to this level of control on domestic movements, all cattle over 42 days of age intended for export must have had a clear single intradermal tuberculin skin test before being moved. The costs of these tests are also met by the herd owner.
- 50. In September 2010 Defra published the report of a review of the impacts of this premovement testing policy. The report is available on the Defra website (see http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/pre-movement-testing-review.pdf). The review's main conclusion was that pre-movement testing has had a positive effect: it has reduced the level of TB spread, delivering benefits for industry and Government. The review also recognised that some of the permitted exemptions to pre-movement testing might present risks to disease control. In the light of this, we are currently considering possible enhancements to the policy, notably whether there is a case for removing any of the current exemptions.
- 51. In considering enhancements to the pre-movement testing policy we plan to revise the existing exemption for shows and remove the 30-day rule exemption. We will also consider how best to deal with disease risks posed by the existing Single Occupancy Authority (SOA) exemption in light of the Farming Regulation Task Force's recommendation that SOAs should be abolished.
- 52. In certain circumstances the use of **post movement testing** is encouraged as best practice, in particular for herds in low TB incidence and risk areas that source cattle from higher risk areas. We will look at how to encourage post-movement testing in England to help better protect TB-free herds in low incidence areas.

⁵ For export the single intradermal test (SIT) is required so only the bovine tuberculin reaction is measured, i.e. it is not read as a comparative test against avian tuberculin.

Slaughterhouse surveillance

- 53. The on-farm surveillance regime for TB is supplemented by post mortem inspection of all cattle entering the human food chain by FSA Official Veterinarians and Meat Hygiene Inspectors. Slaughterhouse cases of TB detected in herds that are not already under restrictions will trigger a new TB breakdown (OTF status Withdrawn) if subsequently confirmed by laboratory tests.
- 54. There has been an increasing trend in the number of cases of suspect TB in cattle reported by FSA inspectors at routine slaughter since 2004, broadly in line with the annual incidence rates of TB test reactors. Over the last three years, between 1000 and 1300 such cases have been reported annually. About 80% of these cases originate from English herds and approximately two thirds of the cattle identified with suspect tuberculous lesions by slaughterhouse surveillance are subsequently confirmed as *M. bovis* infections by laboratory culture.
- 55. The proportion of new cattle TB breakdowns initiated by culture-positive slaughterhouse cases has increased slowly but steadily over time since the mid-1990s. Culture-confirmed slaughterhouse cases now account, on average, for approximately 17% of all new OTF status withdrawn incidents detected in cattle herds in GB every year (ranging from 16% in endemic TB areas to 31% in the four-yearly testing areas). Even so, the rate of suspect slaughterhouse cases detected per 1,000 cattle slaughtered is lower than what might be expected from the prevalence of *M. bovis* in the national herd. Furthermore, compared with Northern Ireland and the Republic of Ireland, meat inspection in GB makes a smaller contribution to the overall detection of new TB breakdowns.
- 56. The FSA has committed to improving TB detection rates at all slaughterhouses by increasing the accuracy of diagnosis when TB is suspected and the level of submission of suspect cases. The FSA have recently extended enhanced TB sampling and awareness training for all their inspection staff, not only on cattle slaughtering premises, but more widely to include all non-cattle red meat abattoirs. They also plan to improve monitoring of sample submission and confirmation rates to inform the need for future intervention.

3.1.2 Cattle control measures

57. When TB is suspected in a cattle herd, either through disclosure of test reactors or suspect lesions in carcases at slaughterhouses, the OTF status of the herd is suspended (OTFS) and **movement restrictions** imposed. The same applies to all herds with overdue TB tests. If evidence of *M. bovis* infection is found in at least one reactor animal during postmortem examination or laboratory investigation of tissue samples, the OTF status of the herd is withdrawn (OTFW). Otherwise the OTF status of the herd remains suspended (see figure 8). OTFS and OTFW herds must then undergo a series of short interval tests with negative results to regain OTF status. Cattle movements from TB restricted herds are only allowed to a limited

number of destinations (e.g. direct to slaughterhouses) under an AHVLA issued licence, subject to certain conditions and a satisfactory veterinary risk assessment being completed.

- 58. Skin or gamma interferon blood test reactors (see paragraph 60) and test negative animals identified as exposed (direct contacts) to known infected cattle have to be isolated from the rest of the herd and then **removed to slaughter**. Test positive and high risk contact animals are removed quickly (within 10 days of their identification test) to reduce the risk of infection to other animals in the herd. Owners of these animals receive **compensation** for these animals from Defra (see paragraph 75). Owners of OTFW herds are required under statutory notice to thoroughly **cleanse and disinfect** all buildings where reactor cattle have been kept using a disinfectant approved for use against TB.
- 59. If an OTF herd has animals with an inconclusive result to the skin test (**inconclusive reactors** or IRs) and there are no reactors at that test, the IR animals alone are placed under restriction. However, in herds where the OTF status has been withdrawn within the past three years, herd restrictions are applied to the whole herd and its OTF status suspended pending resolution of all the IRs. The IRs are re-tested after 60 days, and if all test results are negative all restrictions are lifted. Where any IR animals give a second inconclusive or a positive result on this re-test, they are removed as reactors triggering a new breakdown and whole herd movement restrictions (if not already in place).
- 60. In England, the **gamma interferon blood test** has been used since October 2006 in every new OTFW breakdown herd in low TB risk, three- and four-yearly testing areas. It is also used in some OTFW herds with persistent and severe TB breakdowns in high TB risk areas of the country. Using the gamma interferon test alongside the skin test improves the sensitivity of the TB testing regime, enabling us to identify more infected animals more quickly. By focusing use of the gamma interferon test in low TB risk areas we aim to reduce the risk of TB gaining a firm foothold in those areas.
- 61. We have started to make increased use of the gamma interferon test in the two-yearly tested TB areas to improve the sensitivity of the short interval testing regime in this advancing front and so provide better protection for cattle herds in neighbouring low-incidence areas.
- 62. TB breakdown herds are tested more frequently, at minimum intervals of 60 days (**short interval testing**). If evidence of *M. bovis* infection is detected post mortem and/or by laboratory culture the OTF status of the herd is withdrawn, and such herds must then pass two consecutive short interval tests with negative results to regain OTF status. An OTFW herd is also subject to a range of additional control measures (severe interpretation⁶ of the short interval tests, tracing and testing of epidemiologically linked herds, supplementary blood testing etc.).

34

⁶ Stricter than standard interpretation of the SICTT test so that animals with a relatively small positive comparative result are identified as being infected TB and when some inconclusive reactors are classed as reactors and removed without further testing.

- 63. If TB is found to be widespread within a herd, total or partial **depopulation**⁷ may be carried out. In practice this happens rarely. The decision to depopulate herds is taken by AHVLA on a case by case basis, following a risk assessment and usually informed by the results of parallel gamma interferon testing. In low TB incidence areas depopulation of heavily infected herds is designed to prevent the development of a potential new TB hotspot. In endemic areas, depopulation is contemplated in very severe TB incidents due to the ongoing risks from infected badgers to any newly established herd.
- 64. From 1st January 2011 we introduced two further changes to improve the effectiveness of our cattle controls:
 - The terminology used to describe and manage TB breakdowns has been changed from unconfirmed and confirmed to herd OTF status 'suspended' (OTFS) and 'withdrawn' (OTFW) respectively. This is to address the common misconception that failure to detect visible M. bovis lesions at post-mortem examination or in laboratory culture means that disease is not present. The terminology change more accurately communicates the TB status of the herd and has the added advantage of aligning us with the language used in EU legislation.
 - Higher risk OTF status suspended (OTFS) herds with a recent history of TB infection or
 adjoining an OTF status withdrawn (OTFW) herd must now complete **two** consecutive
 short interval tests with negative results before regaining OTF status. These enhanced
 controls better reflect the true disease status of the herd and give us greater confidence
 that the herd is clear of TB when the herd's OTF status is regained.
- 65. Further to these changes to controls and terminology, we are planning to work with TBEG during 2011 on a more detailed **review of procedures for TB infected herds to regain OTF status** to explore whether the current OTF re-qualifying rules are still appropriate. Two aspects of this are: how long it takes a herd to regain OTF status following a TB breakdown (which can be as little as two months after removal of the last reactor); and the most appropriate minimum interval for short interval tests to take place in order to give the best assurance that there is no residual infection in a herd when its OTF status is restored.
- 66. For every new TB breakdown herd, AHVLA completes an **epidemiological inquiry**. In the case of OTFW herds this includes back-tracings to cattle herds that supplied infected animals (to check for possible sources of infection) and forward tracings of potentially infected animals moved to other herds (to check for potential spread of infection). These field investigations are supported by **DNA strain typing** of *M. bovis* isolates obtained from positive tissue cultures, which gives information on possible origins for the infection.

⁷ Slaughter of all animals in a heavily or chronically infected herd or group of cattle conducted at the outset or in explosive breakdowns or where repeated testing has failed to resolve a TB breakdown.

- 67. AHVLA will assess the risk of spread of *M. bovis* infection to or from herds adjoining an OTFW herd, as well as the potential for exposure of neighbouring herds to a common source of (wildlife) infection. Where necessary, such at-risk herds are tested in what is known as **contiguous check testing**.
- 68. After regaining OTF status following a breakdown a herd undergoes a programme of **more frequent (check) testing** before reverting to the background routine TB testing interval for that herd.

3.1.3 Compliance and Enforcement

- 69. Most cattle owners comply with the TB surveillance and control regime and recognise the importance of adhering to the rules to reduce disease risks. However, a minority of farmers deliberately avoid the rules and not only jeopardise their own businesses but also pose unacceptable levels of financial and disease risks to other farmers and the taxpayer, as well as potentially seeding TB into the local wildlife populations.
- 70. Local Authorities are responsible for enforcing the TB cattle controls detailed in the TB (England) Order 2007⁸. Their work ranges from checking the movements of cattle from restricted premises (to ensure all movements have been authorised) to identifying and dealing with cases of fraud. AHVLA provides crucial support to Local Authorities, for example by monitoring compliance with movement restrictions and confirming animals have been premovement tested where required. A number of enforcement sanctions are used when lapses are identified. These range from providing timely advice to cattle owners and sending warning letters for minor offences, through to taking court action for more serious offences and against repeat offenders.
- 71. It is also worth noting that some TB policies support the broad objective of 'enforcing' compliance with TB controls, a good example being the immediate application of movement restrictions on cattle herds with overdue TB tests. AHVLA closely monitors TB test dates to ensure that any herds not tested by their individual due date are placed under movement restriction and, if the herd owner continues to ignore the requirement to test, the case is referred to the Local Authority to be considered for prosecution. Furthermore, any herd owner in receipt of single farm payment is referred to the Rural Payments Agency for imposition of a penalty for breaching their cross compliance requirements. These sanctions have helped to significantly reduce the number of overdue TB tests.
- 72. The FSA (along with Chief Environmental Health Officers) are responsible for enforcing controls on milk from TB reactors and herds.
- 73. In early 2011 Defra received evidence suggesting that a small minority of farmers may have been illegally swapping cattle eartags so that they could retain TB test positive animals in

_

⁸ <u>www.legislation.gov.uk/uksi/2007/740/contents/made</u>

their herds and send other less productive animals to slaughter in their place. To protect the interests of all cattle farmers we took immediate action to prevent further instances of this type of fraudulent behaviour. TB reactors are now tagged when the skin test is read, in such a way that enables us to cross-check the DNA of reactors with the DNA of cattle sent to slaughter, either on a random sample basis or where fraud is suspected.

- 74. More generally we are reviewing the current approach to enforcing TB controls with a view to rolling out, later this year, a more rigorous and risk-based TB compliance and enforcement strategy. In line with our broad objective for more risk-based TB controls, we are developing proposals to better target enforcement activities by identifying high risk herds and to optimise co-ordination between the different enforcement agencies. This will facilitate more effective targeting of limited resources towards identifying and dealing with higher risk contraventions and herds. We are also looking at how we can more effectively incentivise compliance with TB controls, which we will outline further during 2011. These include:
 - Linking compensation to behaviour (also see paragraph 79).
 - Recouping more of the cost of some enforcement actions.
 - Further action on overdue routine and other tests.
 - Detecting and preventing fraudulent activity and applying appropriate penalties.
 - Placing greater onus on sellers to provide information about herds (linked to risk-based trading, see paragraphs 80-82 below).

3.1.4 Other cattle measures

Compensation

- 75. Government compensation is paid to owners of TB-affected cattle compulsorily slaughtered for TB control purposes.
- 76. Before February 2006, TB compensation was determined through individual valuations, but evidence indicated that this system led to significant and widespread over-compensation and delayed the removal of reactors from breakdown farms. Since February 2006, compensation for cattle in England has been determined primarily through table values based on the average open market sale prices in the preceding month (or 6 months for pedigree stock) in 47 different cattle categories. The categories are based on the age, gender, type (dairy or beef) and status (pedigree or non-pedigree) of an animal. Our default position is to use a table valuation, but where inadequate sales data has been collected for a particular category, the most recently determined table value is used or, if that is not possible, compensation is

determined through individual valuation. Individual valuations are used in less than 1% of cases.

- 77. Our table valuation system has been the subject of a Judicial Review. The Court of Appeal ruled in April 2009 that the Cattle Compensation (England) Order 2006 is not discriminatory against owners of high-value animals and concluded that the true value of a TB infected animal is its meat salvage value. Defra is operating a system that meets the requirements of European legislation which stipulates that "compensation for animals slaughtered on the instructions of the official veterinarian must be adjusted so that breeders are appropriately compensated".
- 78. The provision of compensation for TB affected cattle farmers is a significant cost for Government. The total amount of compensation paid to farmers for animals slaughtered in England under statutory tuberculosis compensation schemes between 2005 and 2009 is shown in table 3. Compensation levels were lower in 2006 and 2007 as a result of a decrease in reactor numbers and a reduction in compensation paid per animal following the introduction of the table-based system. However the compensation bill is rising again due to the increased number of TB cases and the general increase in cattle values.

Year	Reactor	Compensation	Average			
	numbers	paid	compensation value			
		(£ million)	per animal			
2005	22,730	£31.4	£1,381			
2006	15,653	£16.3	£1,042			
2007	19,432	£13.6	£701			
2008	27,056	£28.6	£1,056			
2009	25,208	£30.6	£1,214			

Table 3: Cattle compensation paid for TB in England from 2005-09.

79. Later this year we will consult on proposals to make certain changes to the Compensation Order, including introducing a new category for male pedigree beef animals aged 0 to 6 months, and reducing compensation to herd owners that have had a TB breakdown following significantly delayed TB tests. This policy has already been introduced in Wales.

Risk-based trading

80. A more risk-based trading system would provide farmers with information on the herds they are buying from so they are able to take decisions and action to minimise and mitigate TB risks associated with their purchases. The system would aim to minimise the risk of disease spread into low-risk and edge of high risk areas, and reduce the circulation of disease within the endemic high risk areas. Risk-based trading has made a contribution to TB control in Australia and New Zealand and would help to tackle TB risks in England and we are seeing it emerging in

some low TB risk areas in England as farmer and other stakeholder awareness of disease risks increases.

- 81. TBEG has recommended that we consider options and have set out a set of principles that a risk-based trading system in England should be based on:
 - Farmers have accurate and useful information about their herd's TB status.
 - Buyers ask for information and there is full disclosure by the seller and at markets.
 - The system and provision of information is on a voluntary basis (initially at least), but the provision of false information would be illegal (fraudulent).
 - Farmers (seller and buyer) take responsibility for the TB risk in their herd which includes having accurate and up to date information.
 - The system needs to be simple to operate and easy to understand.
- 82. We will be carrying out a review of options for a risk-based trading system during 2011 and subject to there being a workable and cost-effective approach available will work with the industry to put forward proposals in 2012. This is in line with the recommendations of the Farm Regulation Task Force (see paragraph 40).

Cattle vaccines

- 83. Cattle vaccination could have benefits in reducing the prevalence, incidence and spread of TB in the cattle population and could also reduce the severity of a herd breakdown regardless of whether infection is introduced by wildlife or cattle. However, as with all vaccines, a cattle vaccine will not guarantee that all vaccinated animals are fully protected from infection. Current research suggests that re-vaccination is also likely to be necessary on an annual basis to maintain a sufficient level of protection in individual animals.
- 84. Defra has invested around £18 million in the development of cattle vaccines and associated diagnostic tools. The necessary regulatory studies are nearing completion and we intend to submit an application for a marketing authorisation for a BCG cattle vaccine later this year. While the Veterinary Medicines Directorate (VMD) will be able to confirm whether it is satisfied with the safety, quality and efficacy data provided, it will not be able to grant a marketing authorisation for the product while cattle TB vaccination is prohibited in EU legislation.
- 85. The BCG vaccine can sensitise cattle to the tuberculin skin test for some time after vaccination, and therefore lead to a positive result when an animal is not actually infected with *M. bovis* (a "false positive"). In parallel with developing the vaccine, we are therefore also developing a test to differentiate infected from vaccinated animals (so-called "DIVA" test). This

test, based on gamma interferon blood test technology, could be used alongside the tuberculin skin test, where necessary, to confirm whether a skin test positive result is caused by infection or vaccination.

- 86. The EU ban on vaccinating cattle against *M. bovis* is in place, in part because of this issue of sensitising cattle to the tuberculin skin test. Only cattle from OTF herds which test negative to the skin test can enter intra-Community trade and skin test positive animals are required to be killed. These restrictions also have consequences for trade in cattle products. Hygiene rules for food of animal origin stipulate that raw milk and other products must come from cattle belonging to an OTF herd. Further details on the relevant EU regulations can be found at annex A. Once a licensed cattle vaccine and effective DIVA test are available, the basis for declaring herds and animals tuberculosis-free will need to change before trade in vaccinated skin test positive animals and their products could occur.
- 87. We will be using the scientific and technical evidence on the efficacy and safety of the cattle vaccine and the role of a DIVA test to press the case in Europe for the necessary changes to EU legislation and to lift the requirement for the skin test to be the only test to confer herd OTF status. In parallel with discussions at EU level we will be working with the food industry and regulators to provide the necessary reassurances about the safety of meat and other animal products entering the human food chain where they derive from animals and herds which tested clear of TB but which had been vaccinated.
- 88. Changing EU legislation is a lengthy and uncertain process and preliminary discussions with the EU Commission have indicated that a change to the legal framework on vaccination and DIVA testing cannot be considered until sufficient evidence of their effectiveness is available. This is likely to take some time and as a result we anticipate that a cattle vaccine and DIVA test will not be available for use in the field for many years.

3.2 Biosecurity

- 89. As with all other transmissible livestock diseases, generic good husbandry practices, such as: ensuring cattle have carefully balanced diets; careful sourcing of replacement stock; maintaining correct stocking levels; and keeping livestock sheds clean and well ventilated, will help to reduce TB risks.
- 90. Over and above this, TB specific advice is readily available to cattle farmers, for example, a series of leaflets setting out a range of simple and cost effective on-farm measures to improve biosecurity is given to all owners of TB breakdown herds. This advice is also freely available from the AHVLA website (at www.animalhealth.defra.gov.uk/managing-disease/hotifiable-disease/bovine-tb/index.htm)
- 91. To be most effective, TB biosecurity controls should be considered on a farm specific basis, for example owners of herds in high TB risk areas would need to consider how to reduce

the risk of contact between badgers and cattle on their premises and with their cattle management systems, whereas in other parts of the country this would not be such a pressing issue. One to one tailored advice is given by AHVLA Veterinary Officers, to all owners of TB breakdown herds, during their 'disease investigation' visits.

- 92. The results of research into how risks of TB transmission between badgers and cattle can be reduced has been used to inform advice to cattle farmers. One key conclusion from the research was that many farmers were not aware of the extent of badger visits to their farm buildings, and were failing to adopt simple controls such as keeping feedstores secure. In February 2007, updated husbandry best practice advice was published by the Bovine TB Husbandry Working Group. This focuses on evidence-based and practical risk reduction measures, including:
 - Keeping badgers away from stored cattle feed.
 - Making farmyards less attractive to badgers.
 - Having an awareness of high risk areas at pasture.
- 93. By drawing on new evidence as it becomes available we continue to enhance the quality of advice offered. For example, Defra-funded research carried out by the Food and Environment Research Agency (Fera) investigated the effectiveness of farm measures designed to reduce badger to cattle contact. Useful badger exclusion measures trialled included: solid metal gates, gates with adjustable solid metal panels, solid metal fencing, badger-proofed feed bins and electric fencing. This work concluded that where exclusion measures are consistently employed and adequately maintained they are effective in preventing badger access to buildings.
- 94. In addition, through our TB Advice and Support Service for farmers (see section 3.4), we are supporting the delivery of biosecurity advice and targeted veterinary advice to TB affected cattle farmers to help them identify practical steps they can take to reduce cattle to cattle and wildlife to cattle TB transmission risks. We have worked with National Farmers Union (NFU), AHVLA, Fera and others to deliver a series of on-farm biosecurity training events, during 2011.
- 95. In June 2011 we launched a TB bio-security DVD, also available on the Defra website. This was produced in partnership with the NFU, Fera, and the Welsh Government. The video comprises a short overview of TB, some background on badger ecology and behaviour, and uses real life farm situations, explained by cattle farmers, to demonstrate practical measures for reducing TB transmission risks from wildlife.

3.3 Badger control

- 96. While cattle measures will continue to be central to our bovine TB control programme, we will not succeed in eliminating the disease in cattle unless we also tackle the disease in badgers. Scientific evidence indicates that, in areas with high incidence of bovine TB in cattle, it will not be possible to eliminate the disease in cattle without addressing the transmission of disease from badgers. No other country has successfully controlled the disease in cattle without tackling its presence in the native wildlife population. (See http://archive.defra.gov.uk/corporate/consult/tb-control-measures/index.htm for a detailed explanation of the scientific evidence on badger control in the 2010 consultation document "Bovine Tuberculosis: The Government's approach to tackling the disease and consultation on badger control policy".)
- 97. We therefore remain strongly minded to introducing a carefully managed and science-led policy of badger control.

Culling and overall strategy

- 98. In 2010 we consulted on a proposal to enable the issuing of licences under the Protection of Badgers Act 1992 and the Wildlife and Countryside Act 1981 to farmers and/or landowners to cull and/or vaccinate badgers for the purpose of preventing the spread of bovine TB in cattle. These licences would be subject to strict conditions and close monitoring would take place to ensure that the badger control measures are carried out effectively, and with high regard to animal welfare. Culling would only be permitted by cage-trapping and shooting and by controlled shooting of badgers in the field, carried out by competent operators. Government would monitor actions taken under the licence, the impact on cattle herd breakdowns within the areas culled or vaccinated, humaneness of the culling methods, and the remaining badger population. In the event that culling was not carried out effectively by the licensed farmers/land owners Government would be able to intervene, assume responsibility for completing the culling operation, and recover the costs from the famers and landowners.
- 99. Having carefully considered the large number of responses to the public consultation (see http://archive.defra.gov.uk/corporate/consult/tb-control-measures/index.htm), we remain strongly minded to proceed with a policy of badger control as part of the package of measures to address bovine TB.
- 100. A farmer-led approach remains our preferred option, to empower farmers to take control of the wildlife reservoir at the local level and decide for themselves which control measures to use. The approach will encourage farmers and landowners to fully consider the role of vaccination in support of a cull and increase the chance of successful disease control. It could also lead to greater participation from a wider range of farmers who may have different views on the most appropriate tool to use on their land. This approach also means that farmers, rather than taxpayers, will pay the costs of these additional disease-control measures.

101. However, before a decision is made on whether or not to proceed with the proposed policy, we need to ensure that we can address a number of important issues that were raised during the public consultation. We are therefore consulting with key stakeholders on a detailed proposal, articulated in draft statutory guidance to Natural England. The consultation document and draft guidance are available on the Defra website. We will consider responses to this consultation, alongside the responses to the public consultation, before taking a final decision on the policy of badger control in autumn 2011. If the decision is to proceed, controlled shooting as a method of badger control would then be piloted initially in a maximum of two areas in the first year. The results of the monitoring in these areas will be examined by a panel of independent scientific experts. If controlled shooting is found to be effective and humane by this independent panel, then and only then would the policy be rolled out more widely.

Vaccination

- 102. Vaccination also has a role to play in tackling transmission of disease from badgers to cattle, and since 1999, Defra has invested over £11 million on research into badger vaccines. As a result an injectable BCG badger vaccine is now available for use on prescription, subject to a licence from Natural England. In common with other prescription-only medicines, BadgerBCG must be prescribed for use by a veterinary surgeon. Badger vaccination can be performed by a vet, or by a non-veterinary "lay vaccinator" provided they have completed an approved training course. Under existing arrangements, farmers and landowners, individually or collectively, can apply for a licence to trap and vaccinate badgers.
- 103. Laboratory and field studies have demonstrated that vaccination of badgers by injection with BCG significantly reduces the progression, severity and excretion of TB infection. However, while we would expect vaccination of badger populations to result in reduced transmission of TB to cattle, we currently have no direct experimental evidence on this, other than from computer modelling. Therefore the precise contribution badger vaccination could make to reducing disease in cattle is unknown. Determining this in a scientifically robust way would require large-scale field trials and be very costly.

Badger vaccine deployment project

104. The vaccine is being used in a Defra-funded Badger Vaccine Deployment Project in Gloucestershire. During the first trapping year more than 500 badgers were vaccinated in the 100km² project area. The project involves training operatives to use the vaccine in the field and seeks to increase confidence in the use of injectable badger vaccines, while looking at the practicalities of the vaccination process. The first commercial training course in badger vaccination was run in October 2010 and more courses are taking place this year.

Oral badger vaccine

105. Defra and its research agencies continue to lead internationally in developing new TB vaccines for wildlife, working particularly closely with researchers and governments in the Republic of Ireland, New Zealand, Spain and the USA. A current focus for this work is in

developing an **oral badger vaccine**, which, if it can be done, has the potential to make an important contribution to reducing infection levels in badgers, and as a result, badger to cattle transmission. It may also be a more practical option in terms of wide-scale field deployment than the injectable vaccine.

106. We have already invested nearly £6 million on such research since 2005 which is being carried out in collaboration with researchers in the Republic of Ireland and New Zealand. Nevertheless there are still significant technical issues to overcome and no oral vaccine has yet been found to work consistently with badgers. Compared to an injectable vaccine, an oral vaccine is technically more difficult to formulate and could be prohibitively costly as a higher BCG vaccine dose is likely to be required as well as the need for multiple baits per vaccinated badger. It also requires the selection of bait, which encourages ingestion of the vaccine by badgers but minimises the potential for other species to eat it. Further work to address these issues and progress towards a licensed oral vaccine is planned over the next few years. An oral badger vaccine is therefore highly unlikely to be available for some time.

3.4 Farmer advice and support

107. TB can cause significant financial and other pressures for farmers and their families. If we are to meet our objectives on TB then the eradication programme needs to balance the strengthening of controls with the need to support cattle farming businesses. This includes providing support and opportunities for farmers under restrictions to trade where this does not compromise disease control. Outlined below are some of the steps that Government and industry are taking to assist those affected by TB.

Advice

108. At the recommendation of TBEG we have developed an enhanced (and free) advisory service, to help TB affected or at risk cattle farmers reduce the risk of repeat TB breakdowns and minimize the business impacts of the disease. This advice covers three broad themes:

- Business impacts farmers can access free business support through the Farm Crisis Network (FCN), whose agents will provide practical support and sign-post farmers to sources of other more specialist advice (for more information see www.farmcrisisnetwork.org.uk/tb support). Farmers with significant financial problems can get more in-depth help from FCN's Business Support Group.
- Biosecurity working together, Defra, NFU, AHVLA and Fera are delivering a series of TB biosecurity training events for farmers. These aim to provide practical, cost effective tips, based on the latest scientific evidence, on steps farmers can take to reduce cattle to cattle and wildlife to cattle TB transmission risks.

- Veterinary advice we are working with the veterinary profession to deliver one to one private veterinary support to owners of TB breakdown herds. In a pilot scheme launched in November 2010 in the South-West, farmers under TB restrictions for 12 months or more and those experiencing their first TB breakdown may be eligible for an advisory visit from a private vet who has received in-depth training on TB. The aim is to provide the farmer with continued advice, tailored to their particular circumstances, on how TB spreads and what can de done on their farm to reduce risks. Outside the South-West we have held two pilot events with veterinary practices and their farming clients, the objective being to provide accurate, full and science-based advice on TB and the practical steps that can be taken to reduce risks.
- 109. For 2011 and beyond we will continue to look for opportunities to work with industry and the veterinary profession to enhance the advice provided to TB affected farm businesses both in terms of content and how the advice is delivered.
- 110. In taking this forward we have been conscious of the need to ensure our work supports and complements industry-led initiatives. For example, we worked with the South-West TB Farm Advisory Service, which offers free and independent advice on TB issues to all farmers in the region, to deliver a series of TB biosecurity events in South-West England in spring 2011.
- 111. Defra has worked with NFU, AHVLA and others to develop a series of 'quick guides' for farmers affected by TB, sign-posting them to a range of additional support and providing local contacts for further TB advice. These form part of the 'Dealing with TB in Your Herd' publications (see

http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/tbinyh-0508.pdf) and have also been published on the AHVLA and NFU websites. We have also worked with industry representatives and others to produce a DVD providing farmers with advice, based on the best scientific research, on practical steps that can be taken to reduce wildlife to cattle TB transmission risks. Additionally we have, with the British Bankers Association (BBA), produced a short leaflet which objectively clarifies the business implications of a TB breakdown. A key message in this leaflet (which has been circulated to all BBA members) is that effects will vary from farm to farm but most businesses will continue to operate while under TB restrictions and should be supported by the banking industry.

Reducing burdens

- 112. In autumn 2009, on the advice of TBEG and other stakeholders, we made some policy changes to help cattle farming businesses under TB restrictions by increasing their options for buying replacement stock and selling surplus animals.
- 113. These new cattle trading options, summarised below, have been carefully developed to help TB affected businesses without compromising disease control. Decisions on whether to approve applications for cattle movements (to and from TB restricted herds) are made on a case by case basis, and are dependent on a satisfactory Veterinary Risk Assessment by

AHVLA. Detailed information on the options introduced in 2009 is available on the AHVLA website (at www.animalhealth.defra.gov.uk/managing-disease/notifiable-disease/bovine-tb/movingcattle/index.htm) or contact your local AHVLA office (which can be found at www.animalhealth.defra.gov.uk/about/contact-us/postcode.asp). In short these options comprise:

- Introduction of a general movement licence to allow movements of unrestricted cattle on to a TB breakdown herd for the duration of a breakdown.
- Allowing restricted farmers to source similar restricted status replacement cattle from anywhere in the country (previously they could only source from herds in the same or neighbouring county).
- Allowing untested restricted calves to move direct to slaughter via approved collection centres.
- Making changes to operating conditions for Approved Finishing Units (AFUs) making them more accessible for owners of TB restricted cattle.
- Introduction of the Approved Quarantine Unit (AQU).
- Introduction of the dedicated sale for TB restricted cattle.
- Facilitating the availability of an option for whole herd sale (i.e. dispersal sale of a restricted herd) for farmers, for example, wanting to retire.
- 114. In 2010, following a review of the effectiveness of these measures, we introduced a new option on-farm post-TB isolation units to help TB restricted farmers obtain competitive prices for their surplus stock when sold through dedicated TB markets. These units mean that TB restricted farmers can now bring their animals back on to their farm if, for example, they are not prepared to accept the prices offered at sales of stock from TB restricted herds.
- 115. In 2010 we also made minor changes to TB testing protocols to reduce burdens for cattle farmers without compromising disease control. These included: reducing testing requirements for newly formed cattle herds and young calves; rationalising post-breakdown testing in low-risk OTF-suspended herds; and rationalising and reducing the amount of contiguous testing through a more risk-based approach.
- 116. We have now introduced a general movement licence allowing TB test negative cattle to go to slaughter via an approved slaughter gathering, subject to a satisfactory risk assessment. This will reduce administrative burdens for farmers and help enhance their chances of getting a good price for their cattle.

117. As part of our move towards a more risk-based TB control framework, and to reduce unnecessary burdens on cattle farming businesses, we will assess our policies for testing cattle traced from TB breakdowns with a view to stopping tests that add no value. For example the necessity to test cattle traced to fattening units, since these animals only move to slaughter and all carcases are inspected for signs of TB post-slaughter.

4. TB in Non-Bovine Farmed Animals

Summary

- TB in non-bovine farmed animals is rare and they do not appear to represent a significant reservoir of disease for other animals. The risks to human health and of spreading disease to cattle are low.
- We are working with the relevant industry sectors to help them to improve the way TB is dealt with in non-bovine farmed animals (camelids, deer, goats, pigs and sheep) and to empower farmers to manage TB risks in their own herds.
- We will improve TB surveillance, improving the identification of disease symptoms in carcases inspected in abattoirs; helping private vets to identify TB at post mortem and publishing improved statistics to better inform farmers about their true risk.
- We will encourage better risk management, including a review of current arrangements for movement restrictions following a TB outbreak to see if these could be liberalised; encouraging the non-bovine sectors to investigate options for insurance; exploring the potential of vaccination and providing targeted information to those managing the highest risks.
- We will work in partnership with each of the sectors' representative bodies to help these
 industries become self regulating without unnecessary interference from Government, in line
 with our objectives on responsibility and cost sharing.
- 118. Evidence of TB detected during post-mortem examination or inspection is notifiable in all non-bovine farmed species: camelids (including alpacas and llamas), farmed deer, goats, pigs and sheep. Generally, these animals are considered to be spill-over hosts for TB and within England do not appear to constitute an ongoing reservoir of disease. They are not currently considered significant in determining the levels of TB in cattle or badgers in England. The risks to human health are also currently considered low. Most of these sectors contain large numbers of animals and yet the number in which here TB infection is detected post mortem is very low (see Table 4).
- 119. A more consistent approach to TB policy for non-bovine farmed species is needed, one where eventually, and through building on partnership working, the various industry groups can become self regulating without unnecessary interference from Government. We want to give livestock owners more responsibility for tackling this disease, giving them a stronger stake in managing risks and empowering them to take action. We want owners to be able to decide for themselves, within a broad framework set by Government and the industry, how to manage their disease risks in the best interest of their businesses.

Species	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Pig	0	0	1	8	1	12	2	5	10	23	29
Camelids	0	0	0	3	1	1	9	20	22	68	43
Sheep	0	0	1	0	3	2	0	0	1	5	13
Goats	0	0	0	0	0	0	0	2	33	0	1
Park Deer	2	0	2	0	2	1	17	4	2	0	6
Farmed Deer	1	0	8	8	0	1	5	1	1	1	1

Table 4: Incidents of confirmed *M. bovis* infection in non-bovine farmed animals in Great Britain since 2000.

120. Some sectors are already well advanced towards that end. For example, the pig industry is financially self supporting and through its industry bodies, and has been successfully raising awareness of the risks of TB by working with individual farmers on improved bio-security measures, particularly to protect outdoor reared animals against transmission risks from badgers. For other sectors, moving towards self-regulation will take time and will only be possible by working in partnership with Government. Our ultimate goal is to enable non-bovine livestock owners to stand on their own without the need for government support or compensation.

4.1 Surveillance and control measures in non-bovine farmed animals

- 121. Detection of TB in non-bovine species either takes place in abattoirs as part of routine meat inspection or during post mortem examinations carried out by private veterinarians. For farmed deer, pigs and sheep, slaughterhouse surveillance is the primary detection method and for pigs and deer this is largely concentrated in a small number of specialist abattoirs. To further improve our ability to identify TB in slaughterhouses, Defra has worked closely with the FSA to provide enhanced TB awareness training to inspectors in all red meat abattoirs. The concentration of slaughterings in a limited number of premises for deer and pigs will assist this process.
- 122. In camelids (alpacas and llamas) and goats disease surveillance mainly relies on private or laboratory veterinarians detecting the presence of infection during post mortem examinations. To continue to raise their awareness of TB in non-bovines and to help ensure disease is identified during post mortem examinations, Defra plans in 2011 to provide specialist veterinary practitioners with additional information on TB and the typical post mortem characteristics in non-bovine species.

Movement restrictions

123. When disease is first identified in a herd or flock, following detection at post mortem surveillance, movement restrictions are imposed to contain any further disease spread. These restrictions last until the herd or flock tests negative (following the voluntary slaughter of any test positive animals) or until the cohort of exposed and potentially infected animals have been

removed as part of normal production. In flocks and herds where animals are being reared for their meat, movement restrictions may not be a particular problem as this group will move direct to slaughter as part of normal business. However, the voluntary slaughter of test positive animals in breeding and rare breed herds or flocks can lead to significant financial losses and a loss of genetic diversity.

124. We plan to review the current policy of the automatic application of movement restrictions to consider whether these are always appropriate, necessary and justified by the risk. This work will take place during 2011 and discussions will be held with the industry sectors.

Testing

- 125. Unlike for cattle, there are no regular testing requirements for non-bovine species. When testing is used, for example to lift movement restrictions the tuberculin skin test is the standard internationally accepted TB test. While the skin test is effective when used in most non-bovine species, our experience of its use in camelids suggests that it is not sufficiently sensitive in these species. This has led to the voluntary deployment of two supplementary blood tests. These are currently undergoing validation at the VLA in a project funded by the main camelid societies. The full validation of blood tests for use in camelids is expected by the end of 2011.
- 126. Currently, TB testing of goats and sheep is only carried out when TB is suspected to be present in the herd or flock following post mortem examination or when linked epidemiologically to a breakdown in cattle. The FSA and Defra are currently working together to develop a proportionate TB control plan to implement the EU hygiene regulations in goat or sheep milk producing units. The FSA is aiming to develop proposals for consultation in 2011. The main focus of the consultation will be on goats but may also seek views on arrangements for other animals. The control plan is likely to require herds to be subject to additional tests for TB and may therefore impact on the present TB testing arrangements.
- 127. At the moment the Government pays for most, but not all, TB testing of non-bovine animals. Over the longer term this may need to be revisited as part of the move to greater responsibility and cost sharing on animal disease control.

Other Measures

- 128. We will be improving the current **statistics** collected for each non-bovine species to provide monthly statistics for the numbers of herds or flocks infected; number of animals' skin or blood tested; number of TB test reactors and cases removed.
- 129. We will continue to work with sector representatives to provide **advice and support** on TB to livestock owners and the veterinary profession, helping to ensure information reflects the latest veterinary understanding and disseminating advice, including hard-to-reach groups such as non-commercial keepers. For example, support work to raise awareness about biosecurity including among small, specialist producers, about the risks from showing animals and other potentially risky management practices.

- 130. We plan to facilitate discussion between the various non-bovine sectors and the insurance industry to see whether there is a greater role for **insurance** in covering the risk of significant losses, in particular from TB in high value breeding herds.
- 131. We will continue to discuss with the various industry sectors what role **vaccination** may play in reducing TB risks in their species. Discussions are at an early stage between the camelid societies, Defra and AHVLA over the possibility of vaccinating camelids and the use of a DIVA test to differentiate vaccinated from infected animals.

4.2 Compensation and ex-gratia payments for non-bovine farmed animals

- 132. For goats, pigs and sheep there is no statutory compensation scheme or ex-gratia payment for the voluntary removal of TB affected or test positive animals. These costs are borne by owners and that is Defra's longer term aim for all non-bovine sectors including deer and camelids. Currently there is a statutory compensation scheme for deer under which keepers receive £600 or 50% of the market value (whichever is less) for any compulsorily slaughtered test positive animal. The call on these funds in recent years has been negligible due to the low level of skin testing of farmed deer that takes place and Defra will discuss phasing it out with the industry during 2011.
- 133. Currently camelid owners who sign a voluntary agreement to allow testing receive an exgratia payment of £750 for each test positive animal voluntarily removed. This arrangement does not satisfy the needs of the industry where high value animals are involved, nor is it sustainable for Government to continue providing even the present level of funding indefinitely. The current arrangements therefore need to be revisited and, together with the camelid industry, we need to develop a solution consistent with a longer term move toward self-regulation. The expected validation of blood tests later this year, which should mean a greater degree of confidence in testing procedures, provides an opportunity to begin that dialogue.

4.3 TB in pets and wildlife

- 134. All mammals are susceptible to TB including pets and wildlife. Pets (e.g. cats) can be spillover hosts for TB as a result of contact with other infected species and their owners are encouraged to be aware of the risks and for example in cases of sudden weight loss or a persistent cough to take the animal to their local veterinarian for a check-up.
- 135. Wild animals may similarly become infected as a result of contact with other infected species. However, apart from badgers, no other wild animal in England is thought to be a significant and widespread maintenance host for disease. In the case of wild deer there is evidence of a particular risk of TB spread where some species are present in high densities

and/or routinely fed. However, wider population control through culling by experienced stalkers should be effective in controlling disease.

5. Research and Evidence

Summary

- Defra funds a wide-ranging TB research programme, focusing on four areas:
- Development of vaccines for use in cattle and badgers.
- Development of improved diagnostic tests for use in cattle and badgers.
- Economic and social research related to the impacts of TB and its control.
- Understanding the epidemiology of TB in cattle and wildlife, and the impact of control measures on disease spread.
- Our priorities for future research include:
- Development of an oral badger vaccine.
- Development of a cattle vaccine with an accompanying DIVA test.
- Work towards a non-sensitising cattle vaccine.
- Development of improved methods to detect infected badgers or setts.
- Understanding the social and economic impacts of TB control policies.
- Understanding the impact of badger ecology and behaviour on TB transmission.
- Alternative methods of badger culling, and non-lethal methods of badger control.
- We plan to make changes to the way the monthly TB statistics are presented so that they
 are more informative and easier to access and interpret.
- 136. Defra funds a wide-ranging TB research and development programme aimed at improving our understanding of the disease and at developing novel tools and refining existing tools and how we apply them to tackle the disease. It covers many branches of science (including immunology, vaccination, diagnostics, epidemiology, ecology and genetics), as well as social science and economics. Between 1991 and 2010 Defra funded over 90 individual research projects, and invested approximately £86 million in TB research and development. In recent years, an increasing proportion of this research budget has been directed towards developing vaccines and associated diagnostic tests. Further details of ongoing research and reports of completed projects can be found at

http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/research/projects.htm and http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/current-research-projects.pdf.
The TB evidence plan also details Defra's current spend and priorities in TB research and surveillance; this can be found at: www.defra.gov.uk/publications/files/pb13471-eis-110427-annex2.pdf. The TB research programme is centred on four areas of research, set out below.

137. The Bovine TB Science Advisory Body (SAB) was set up in January 2008 to provide independent advice to Defra's Chief Scientific Advisor and Chief Veterinary Officer on TB-related research. The SAB has sub-groups focusing on specific areas of Defra's TB research portfolio: epidemiology and wildlife risks; diagnostics; and vaccines.

5.1 Vaccines

- 138. In 1997 an independent group of scientists produced the *Bovine tuberculosis in cattle and badgers* (or "Krebs") report which recommended greater emphasis on the development of TB vaccines for cattle and badgers, and a diagnostic test to differentiate infected from vaccinated cattle.
- 139. A substantial part of our research programme focuses on the development and licensing of efficacious, practical and cost effective badger and cattle vaccines. Total investment in vaccine development since 1998 has reached more than £30 million. An injectable BadgerBCG vaccine was licensed in 2010 and is the first vaccine product available from the vaccines research programme. Research is currently focussed on achieving, licensed vaccines (with DIVA test) for use in cattle and a licensed oral badger vaccine within the shortest timeframe possible. Cattle vaccines that do not sensitise animals to the skin test (and remove the need for a DIVA test) are also a longer-term research goal.

5.2 Diagnostics

- 140. In order to control TB better, more sensitive and specific cattle tests are required, particularly a test that can differentiate infected and vaccinated animals (DIVA test) to accompany the BCG-based cattle vaccine, as described above.
- 141. Practical sensitive and specific badger diagnostics would need to be developed in order to allow us to assess the geographical scale of the wildlife reservoir and also to possibly allow informed judgements in applying control methods. For example diagnostics to support a selective culling policy, which could be targeted at infected badgers or setts rather than the wider population, or inform the effectiveness of a wildlife vaccination programme. This includes both non-invasive tests to identify infected badgers, e.g. non-invasive blood sampling devices, and to identify setts and areas where infected badgers are resident, e.g. development of tests to detect *M. bovis* in environmental (soil, water) samples.

5.3 Economic and social science

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

5.4 Epidemiology and wildlife risks

- 143. There is a continuing need for work to help better understand the epidemiology of the disease and the interaction within and between cattle and badgers, including the development and use of mathematical models, to inform the development, application, assessment and evaluation of TB control tools. Work is also required to identify other methods of monitoring and controlling the epidemic, e.g. improved genetic analysis and molecular typing (known as spoligotyping) of isolates and understanding the genetics of resistance in cattle.
- 144. In addition to this research programme, and in line with the recommendations of the Krebs report, Defra also funded the Randomised Badger Culling Trial (RBCT). This was a large scale project costing £49 million, to examine the effect of badger culling strategies on TB incidence in cattle which, overseen by the Independent Scientific Group on Cattle TB (ISG; see http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/isg/report/final_report.pdf). The trial ran from 1998 to 2007 and involved culling operations in ten areas across England ('triplets', each consisting of two areas where culling took place and one control area where no culling took place). Defra continues to fund analysis of the data collected in this trial, and the ongoing collection of cattle TB data from proactively culled and control areas and this is the principal evidence base to support the badger culling strategy.
- 145. Defra and the Biotechnology and Biological Sciences Research Council (BBSRC) funded research is also looking at the genetic basis for resistance/susceptibility of cattle to infection with *M. bovis*. Pedigree analysis⁹ has demonstrated that there is a low to moderate heritability of resistance or susceptibility to infection in GB Holstein Friesians and further research has been commissioned to investigate this finding. This project is due to finish in 2011 and the findings will be shared with the cattle breeding industry. As the work to date has shown there is a low to moderate heritable variation it may be that genetic selection is likely to play a relatively minor role in bovine TB disease control, as compared to efforts to limit wildlife-to-cattle and cattle-to-cattle transmission.

5.5 Future priorities

146. Following consideration of the Government's priorities, and a range of advice we have identified the following as priorities for our evidence programme:

- Oral badger vaccine.
- Injectable cattle vaccine including non-sensitising vaccines.
- Cattle diagnostics including a DIVA test.
- Epidemiology of the disease and modelling of the effect of different interventions.
- Ecology and behaviour of badgers as relevant to TB transmission.

⁹ Brotherstone et al. (2010) Evidence of genetic resistance of cattle to infection with Mycobacterium bovis J Dairy Sci.;93(3):1234-42

- Understanding changes in badger numbers in recent years and badger ecology, particularly the effect of low level perturbation on disease transmission, to measure the effect of low level culling e.g. selective culling.
- Improved methods for detecting infected badgers or infected setts e.g. PCR-based tests.
- Non-lethal forms of badger control e.g. immunocontraceptives.
- Whole-sett culling methods e.g. gassing.
- Understanding the social and economic aspects of our TB policies on farmers and other stakeholders.
- 147. The budget for the TB research programme in 2011/12 will be £7.9 million.

5.6 TB statistics

- 148. Accurate information on the spread of the disease is vital and we therefore intend to improve the existing published TB statistics to make them easier to understand and provide additional information on the disease situation. We will be replacing the two current sets of monthly statistics published by Defra (the National Statistics at GB level and the detailed provisional TB statistics broken down by region) with a single consolidated notice from autumn 2011.
- 149. The new statistics notice will be accompanied by a detailed explanation of any changes made. Any changes will also be backdated so analysis of TB trends over time will still be possible. Some of the benefits of moving to the new notice will be:
 - To improve comparisons of data over time, we will present data over rolling 12-month periods instead of from January to the current month on a within calendar year basis.
 - The same level of regional breakdown will be published but the new IT system will be able to analyse TB in any defined area.
 - The measure of incidence will be amended to take into account the length of time herds are at risk between tests, as recommended by the Independent Scientific Group on Cattle TB (ISG).
 - The new system will be much easier to adapt when changes are made to testing regimes or administrative boundaries.
- 150. Since the resumption of routine testing following the Foot and Mouth disease outbreak in 2001, although there has been an overall increase in the incidence rate, evidence of a three year cycle has emerged (where the incidence rate peaked in 2005 and 2008 and was then followed by decreases in the following year). This cycle makes it difficult to interpret the long

term trends in incidence and to evaluate the impact of TB policies. We will investigate and attempt to explain the underlying reason for the cycle, to enable a greater understanding of the long term trend in TB incidence.

6. Governance, Monitoring and Reporting

Summary

- If our TB eradication programme is to be effective we will need to rely on a number of partners working together, with farmers at the heart of this network, supported by the veterinary profession and Government.
- The Bovine TB Eradication Group for England (TBEG) will continue to play an important role.
- Farmers need to be empowered to take greater responsibility for managing TB risks in their herds, and will also need to work collectively at the local level.
- We will publish progress reports on this TB Eradication Programme for England in conjunction with TBEG.

6.1 Governance

- 151. The organisation and delivery of TB control involves a number of different partners and stakeholders, with farmers at the heart of this. In the past the control of TB has often been seen as a top-down approach within a rigid control framework. As we continue to move to a more risk-based approach, farmers will need to take increasing responsibility for managing TB risks associated with their farm business. They will continue to need support from their private veterinarian and Government, in particular AHVLA. We want to see farmers working together at local level to tackle the range of challenges TB poses to their businesses.
- 152. It is important that farmers and private vets work in partnership with Government and others to agree the approach at national level, making TBEG's continued advice and recommendations to Ministers central to the further development of the eradication programme. Defra and TBEG will also need to continue to engage with a range of stakeholders as they consider the development of future policies and measures.
- 153. The report of the England Advisory Group on Responsibility and Cost Sharing for animal health and welfare contains a number of recommendations for future joint working arrangements in relation to the governance of policy in this area. Ministers announced on 26th April 2011 that a new Animal Health and Welfare Board would be created for England. The new Defra owned Animal Health and Welfare Board will consist of around 12 members and will be assembled in the second half of 2011. It will bring experts including farmers, veterinarians, welfare experts and others from outside Government together with Nigel Gibbens, Chief Veterinary Officer and civil servants to make direct recommendations on policies affecting the health and welfare of all kept animals, such as farm animals, horses and pets. Final decisions on animal health and welfare policy will remain in the hands of Government Ministers.
- 154. We understand that the NFU plans to take the lead in establishing regional TB committees, involving a range of stakeholders, as a way of facilitating greater understanding of

TB risks, offering advice and support to farmers and groups at local level, and providing a link with national level policy development and decision-making. We welcome this initiative which demonstrates the industry's commitment and determination to tackle the disease.

6.2 Monitoring and reporting

- 155. We will report on progress in delivering this eradication programme in a number of ways. We will report under Defra's **Business Plan.** Defra is required like all Government departments to publish indicators which support transparency and democratic accountability. These indicators are aimed at the public, rather than Defra's internal performance management, enabling the public to hold us to account. A pair of indicators (input and impact) for TB have been developed which are:
 - **Input Indicator**: Total cost to Government of TB controls in animals in England.
 - **Impact indicator**: Cattle herds that are Officially TB Free (OTF) Data on the percentage of herds in England that are OTF (where non-OTF herds are defined as being issued with a TB2 restrictions form) will be presented. This indicator only reports on non-OFT herds because of a TB incident (and not those restricted because of an overdue test or for any other reason).
 - More detail about these indicators can be found on the Defra internet pages at http://archive.defra.gov.uk/corporate/about/what/documents/businessplan-measure-annex-110520.pdf
- 156. In order to track our progress we will continue to monitor a number of key epidemiological indicators of the disease in cattle herds. Many potentially useful descriptive statistics, such as the number and incidence of new total and OTF status withdrawn herd breakdowns, the number of reactors per 1,000 animals tested, the percentage of the national herd that is OTF at any given time, etc. are already being collated and published in Defra's monthly TB statistical notices (see section 5.6), periodic returns (e.g. to the European Commission) and ad hoc reports.
- 157. If we decide to proceed with a policy of badger control (following the current consultation), a comprehensive monitoring programme will be put in place, both to ensure compliance with the licence conditions and to monitor the impact of the policy on incidence of bovine TB and on badger populations. Cattle TB incidence will be monitored and compared both to historical incidence within culled areas and to similar non-culled areas to identify any changes in trends that might be attributable to badger control.
- 158. We will publish a progress report on this TB Eradication Programme for England, in conjunction with TBEG, 12 months after its publication and then report on progress every two

years. This will report progress made on delivering the policies set out in this document and the success achieved in tackling the disease.

159. We are also required to report to the European Commission each year on the implementation of the UK (GB) Bovine TB Eradication Plan.

TB surveillance and control requirements under EU law

The main piece of European legislation that sets out TB surveillance and control requirements is **Council Directive 64/432/EEC (as amended)** on animal health problems affecting intra-Community trade in bovine animals and swine (www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31964L0432:EN:HTML). This directive sets out the rules on trade within the EU for bovine animals (for example on export health certification) as well as the general rules for TB control (for example test type and herd status). In particular:

Article 2: provides definitions. Note in particular those of 'herd', 'animals for breeding and production', 'officially tuberculosis-free bovine herd', 'assembly centre', 'region' and 'dealer'.

Article 3: provides general provisions for bovine animals being exported to other Member States (identity checks, clinical inspection by official vet, proper identification, not from an area in which restrictions apply to bovine animals for health reasons etc.).

Article 5: provides that health certificates must accompany bovine animals during transportation and sets out requirements for the form and issue of such certificates (refers to Annex F for model certificates).

Article 6: outlines the additional provisions for animals intended for breeding or production. As far as TB is concerned, particular requirements include that the animals originate in OTF Member States or regions, or come from an OTF herd and, if more than 42 days old, be skin tested with negative results in the 30 days before departure. For animals intended for slaughter, the only additional requirement is that they originate from OTF herds.

Article 8: This makes TB and other diseases of cattle and pigs listed at Annex E (I) notifiable in Member States and places an obligation to report occurrence of those diseases to the Commission and details of the eradication programme.

Article 11: sets out the minimum approval criteria for assembly centres.

Article 14: provides for the establishment of animal health surveillance networks (to classify the status of holdings and carry out disease monitoring) in Member States, including the appointment of Official Veterinarians.

Annex A: this states the rules for gaining, retaining, suspending and withdrawing the OTF accreditation of a herd based on the skin test, and determining whether a country or region can be considered OTF.

Annex B: this sets out details of the approved primary screening tests for TB in cattle (the skin tests), the ancillary parallel test (gIFN) and the confirmatory diagnostic tests, including the standards for the production of tuberculin and the interpretation of the skin tests.

Other directives relating to the control of TB:

<u>Council Directive 77/391/EEC</u> introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle provides the basic broad principles and generic legal framework for the TB eradication programmes. This Directive sets out a general duty on Member States to submit an eradication plan for TB to the Commission for approval.

Council Directive 78/52/EEC establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle sets out in more detail the specific minimum criteria to be met by national TB, Brucellosis and EBL eradication plans in order to qualify for the EU financial contribution. In particular, Article 13 (b) (ii) specifically prohibits the use of therapeutic treatments or vaccination if an accelerated eradication plan for TB is in place.

Commission Decision 2010/712/EC approving annual and multi-annual programmes and the financial contributions from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2011 and following years contains the approval and allocation of EU funding for the UK's 2011 Bovine TB Eradication Plan.

The Bovine TB Eradication Group for England

In November 2008, the Bovine TB Eradication Group for England (TBEG) was set up to make recommendations to the Secretary of State on TB and its eradication. The membership of the group includes representatives from Defra's Food and Farming Group, AHVLA, the farming industry and the veterinary profession. Details of their meetings can be found at http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/partnership/eradication-group/index.htm.

The remit of the Group is to review the current TB strategy and control measures and develop a plan for reducing the incidence of TB from cattle in England and moving towards eventual eradication. It is also assessing options to help farmers in high incidence areas maintain viable businesses when under disease restrictions.

A first priority output from the work of this group was a series of measures for inclusion in the UK TB Eradication Plan, which was submitted to the European Commission for approval and agreed in November 2009. These measures were outlined in the Group's progress report, *Towards a Bovine TB Eradication Programme for England* (see http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/tb-erad091008.pdf), published on 8 October 2009. The report outlines progress that TBEG made in developing a Bovine TB Eradication Programme for England; the risk-based approach they are taking in identifying and assessing new policies; and changes made following recommendations to the then Secretary of State, which included:

- Testing areas: a decision to change the area basis on which testing frequencies are set to a more risk-based rather than administrative boundaries.
- Establishing an interim approach to setting testing frequencies, which is intended to be a
 move in this direction, by placing whole high TB risk areas onto more frequent annual
 testing, with a buffer of two-yearly tested areas.
- Inconclusive reactor policy: change to allow only one retest.
- Agree in principle to find a new approach to tackling unconfirmed breakdowns and that the terminology around breakdowns will change.
- Providing advice on TB to restricted farms.
- Providing a range of measures for make it easier for those suffering from TB breakdowns
 to be able to trade and manage their businesses (without materially increasing disease
 risk) for example by providing greater flexibility for short interval testing in breakdown
 herds in high risk areas.

The Group continues to look at the options available to address infection in cattle and to reduce the risk of transmission between cattle and between cattle and wildlife (including options for using vaccination in cattle and badgers), and consider costs and benefits in making recommendations for action.

TBEG has been fully engaged in driving forward the development of the proposals and advising on the package of measures and set out in the Eradication Programme.