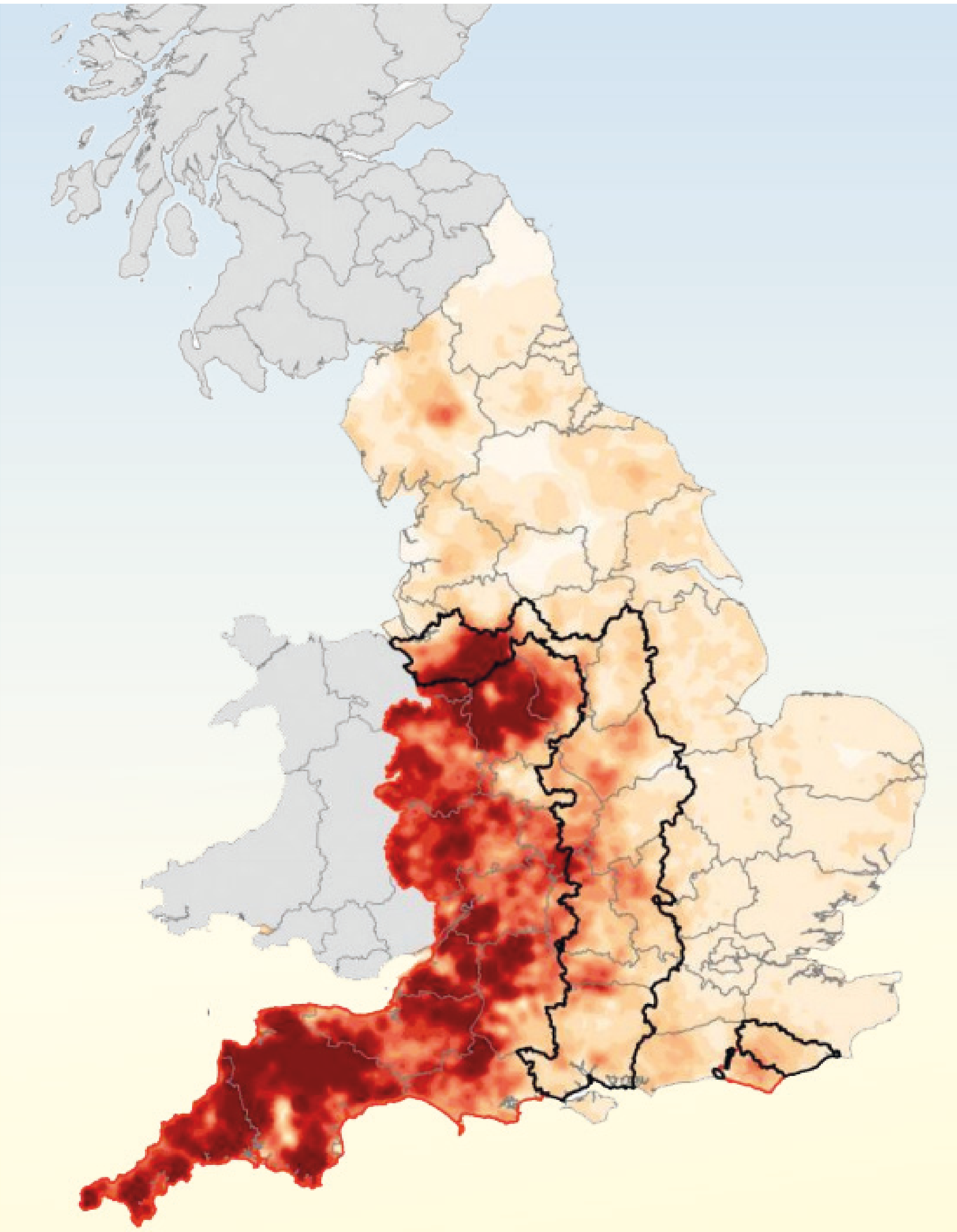
Bovine TB Strategy Review

October 2018



Bovine TB: herd level incidence, England 2017

Department for Environment, Food and Rural Affairs

Bovine TB strategy review

Report to Rt Hon Michael Gove MP, Secretary of State, Defra

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October 2018

Summary and conclusions

Introduction

1. Bovine TB is an infectious disease that spreads between cattle that is unlike any other endemic disease afflicting the livestock industry in England. The prevalence of the disease in parts of the country, coupled with the test and slaughter strategy that is the basis of disease control, makes the risk and consequences of infection one of the greatest factors affecting the livelihoods of numerous farmers. In writing this report we are acutely aware of the burden this disease places on the welfare and well-being of farmers and their families. We do think more can be done to control this disease, and hopefully eventually eliminate it, but we would be offering false hope if we pretended this will be other than a protracted campaign.

2. The disease is also unusual in that it infects an iconic wild animal, the badger, and there is transmission to and from badgers and cattle. Culling of badgers to reduce infection in cattle is seen as unconscionable by some sections of society and currently the Labour Party has pledged that culling will not be part of its bovine TB control strategy (and Wales also currently has a no-cull policy). The deeply held beliefs of people who cannot countenance culling badgers deserve respect, as do the beliefs of people who argue that sacrificing badgers is justified to reduce the burden of this disease on livestock and farmers. The decision whether or not to cull badgers must be informed by evidence which provides important information on likely outcomes. However, final decisions have to take into account the irreconcilable views of different stakeholders and so inevitably require judgements to be made by ministers.

3. Our interpretation of the evidence is that the presence of infected badgers does pose a threat to local cattle herds. This interpretation reflects the broad consensus amongst epidemiologists who have studied the disease. Reducing this threat, by culling or non-lethal intervention, will thus help lower the incidence of the disease in cattle. If a decision is made not to cull, and if non-lethal interventions prove less effective, then progress towards eliminating the disease will be slower and complete elimination may be even more difficult.

4. A very unfortunate consequence of the controversy around badger culling and the politicisation of the debate has been a deflection of focus from what can be done by the individual farmer and by the livestock industry to help control the disease. In particular, the poor take up of on-farm biosecurity measures and the extent of trading in often high-risk cattle is, we believe, severely hampering disease control measures. All the industry bodies we spoke to recognised this as an issue and saw the need for industry to take more ownership of the problem. Implementing better control measures on the livestock side will mean short- to medium-term costs to the industry to achieve the greater goal of bovine TB elimination. The degree to which the industry as opposed to the state or the consumer bears these costs is a decision for ministers but it is wrong, we believe, to over-emphasise the role of wildlife and so avoid the need for the industry to take measures that have in the short-term negative financial consequences.

5. Bovine TB is a notifiable disease and exactly how it is monitored and controlled affects our ability to trade. The complex statutory underpinning of surveillance and control, involving both national and European legislation, makes agile and adaptive management of the disease very difficult. We believe this legal and administrative viscosity hampers better disease control. We report at a time when the UK is negotiating to leave the EU but when the final settlement of our trading relationship and regulatory alignment with the EU is yet to be agreed. The disadvantage of this timing is that detailed cost-benefit analysis of the consequences of the different control options we discuss is not possible. The advantage is that with the inevitable restructuring of our agricultural governance arrangements there is the opportunity to explore better disease control interventions. We urge that the opportunity to re-fashion the regulation on bovine TB is not missed.

6. The main body of the report, Chapters 3-9, explores a wide range of interventions that we believe should be considered in attempts to control bovine TB in England. We have attempted to broaden the discussion of interventions from a narrow focus on epidemiology, and tried dispassionately to weigh their advantages and disadvantages. In many cases we do not recommend a specific course of actions. This is for a number of reasons including: (i) many decisions require ministerial judgement, for example those involving ethics or costs; (ii) further more detailed cost-benefit analysis and modelling is required than has been possible in this study; (iii) we do not know the final post-EU arrangements. In this chapter we summarise our conclusions and highlight the factors that we believe should be at the front of decision makers' minds when determining future policy.

Governance

7. We believe that there is a strong argument that current governance arrangements poorly serve bovine TB control. They have resulted in too little industry ownership of the disease and a widespread implicit belief that bovine TB is government's problem alone. Within government and its agencies, multiple bodies share responsibility for different aspects of the disease, and the ability of the system to adapt rapidly to new epidemiological evidence or new technologies is inadequate.

8. In New Zealand, bovine TB control efforts are led by the industry and this has produced very good results. There is also a major wildlife reservoir species in New Zealand, but this is the introduced Australian brush-tailed possum; culling possums has agricultural and conservation benefits and is relatively uncontroversial. We do not think adopting this governance model in England would be possible as giving industry as great a control over policy concerning the disease in wildlife would be unacceptable to many, while partial responsibility would be unattractive or unacceptable to industry.

9. We see many advantages of retaining high-level policy making in Defra but devolving much of the disease control operations to a new body that would take over functions currently performed by APHA, Natural England and local authorities. Centralising functions in this way would be more efficient, avoid duplication and allow greater co-ordination and agility. Separation from government would make it easier for the new body to work collaboratively with industry and other stakeholders, encouraging shared ownership of the problem. We have discussed these issues with Dame Glenys Stacey who is currently leading a review for Defra of the broader

issue of farm regulation and inspection and are aware this proposal aligns with some of her likely recommendations.

10. An important part of farmers taking more ownership of the disease is ensuring that they receive the best advice (for example on safe trading practices, on-farm controls and biosecurity) from trusted sources. Existing information available on the web (TB Hub) is very good, though obviously farmers must be motivated to find and make use of it. We believe the role of private veterinarians in providing advice is particularly important and should be supported, taking into account the true costs of its provision for veterinary businesses. Study of best practice in the Devolved Administrations and the Republic of Ireland (RoI) will be very helpful in designing support for farmers in England.

11. Consultation with industry and other stakeholders is an important part of bovine TB control and of achieving shared ownership of the problem. Nevertheless, we believe that the current frequency and granularity of consultation is cumbersome and counter-productive. Concern over ‘consultation fatigue’ was expressed to us by many stakeholders. We see advantages in consulting at a higher level on broad strategy and principles of adaptive management. This will enable operational decisions to be made more swiftly and more flexibly as circumstances change and new evidence emerges. We are aware that changes in the nature of consultation will involve some legislative amendments.

Surveillance and diagnostics

12. If a test is not sensitive enough it will miss too many infected animals, while if it is not specific enough it will produce too many false positives. There is often a trade-off between sensitivity and specificity. The test we use in the United Kingdom (UK) and the RoI (the Single Intradermal Comparative Cervical Test, SICCT) has high specificity but lower sensitivity than that used in continental Europe (the Single Intradermal Cervical Test, SICT). There is some evidence that the sensitivity of the SICCT under operational field conditions is lower than that estimated in formal trials.

13. Policy makers need to balance the disadvantages of low specificity (more cattle sent to slaughter and herds placed under provisional restrictions) and low sensitivity (infections going unrecognised). We see a strong argument for moving to a more sensitive test (probably the SICT) for surveillance in the High Risk Area (HRA) and Edge Area (EA) to enable the detection of infections in these regions as early as possible. In the Low Risk Area (LRA) the numbers of new infections detected would not justify the increased number of false positives. Such a change would be allowed given current EU rules. Once outside the EU, there would be scope to use either the SICT or caudal fold test (CFT) for herd screening and to retest reactor animals with the interferon gamma test to reduce the number of false positives detected by the more sensitive screening test.

14. Were this change to be made, the number of herd breakdowns would in the short term go up as more infections are revealed. It is very important that policy makers and all stakeholders understand this epidemiological reality and do not misinterpret it as a policy failure.

15. Once infection is discovered in a herd it is important to identify all cattle infected with the bacterium. There are a number of circumstances where there is particular premium on removing infections from herds as quickly as possible. These include herds with persistent and recurrent infections, herds in badger cull areas where it is important to avoid re-infecting wildlife, herds in the EA where preventing geographical spread into the LRA is a high priority, and emerging hotspots of infection within the LRA. Here, combining a skin test, the interferon gamma test and the IDEXX ELISA serological test, should be considered as each test detects some infected animals that the other tests miss. The costs of testing would increase, but the epidemiological benefits in these critical cases would be substantial.

16. The current SICCT, SICT and interferon gamma tests rely on tuberculin – essentially a cocktail of proteins derived from the bacterium that is difficult to standardise. We see a strong argument for investing in better tuberculin quality control. In the medium term, and requiring efficacy and safety tests, the aim should be to replace tuberculin by defined antigens. Such tests would also provide a DIVA (differentiating infected from vaccinated animals) function.

17. There is intensive research on TB testing and diagnostics in both the human and veterinary science worlds. A number of promising tests are in development. Other innovations include the possible bulk-testing of milk for evidence of infection. We see it as very important to make sure that an efficient pipeline is developed to assess the value of new innovations, to carry out field efficacy and safety tests, and where justified to deploy them rapidly. We realise, of course, that the administrative burden of changing test protocols, as well as any consequences for trade, have to be taken into account.

18. Currently, *M. bovis*, the bacterium responsible for bovine TB, is genotyped using information from specific regions of its genome. Recent advances in molecular biology make it now feasible and cost-efficient to move to whole-genome sequencing which we believe should be used routinely. This technique allows disease transmission pathways to be identified with greater accuracy (though cannot of course resolve all issues in identifying sources of infection).

Vaccination and genetic resistance in cattle

19. The BCG vaccine available for cattle provides some but not complete protection against bovine TB. However, vaccinated cattle often test positive for current tuberculin-based tests for the disease and the widespread use of BCG in cattle would compromise surveillance (and affect trade in live cattle and dairy products).

20. In our view, the goal should be for testing to move to DIVA tests (see ¶ 16). Once these are available, then the possible advantages of different models of vaccination deployment should be re-examined. This should involve a cost-benefit analysis that takes into account implications for international and UK trade and business. Recent studies in humans and other primates have explored the potential of improving BCG vaccines and vaccination protocols. Investigation of whether these and future advances carry over to cattle is worthwhile.

21. Progress has been made in understanding the genetic basis of bovine TB resistance in cattle enabling genetic selection for higher resistance. This sensible

approach that will in the long term make a modest but valuable contribution to disease control should, we believe, be supported.

Risk-based trading

22. Defra and the livestock industry are currently investing in the Livestock Information Service (LIS) which will provide information on the movements of all cattle in the UK linked to electronic identification tags. LIS will have multiple functions, of which providing information that can be used in bovine TB control will be one of the most important. We place a very high priority on supporting and implementing LIS, and strongly advise that considerations of how it can be used to combat this disease are taken into account at the design stage.

23. It is now routine to mark horses and pets with microchips and we believe further investigation of the feasibility of this for cattle is warranted. It would reduce the opportunities for fraud and improve traceability. We understand the need to avoid microchips entering the human food chain.

24. Relatively crude indices of the risk of infection of cattle have already been developed and LIS will enable more sophisticated measures. There is, we believe, a very strong argument that these measures should mandatorily be available prior to purchase and at market ring-sides.

25. The number of cattle movements in England is very high and will inevitably be a risk for disease spread. We have not been able to do a full analysis of the regulatory and economic drivers of this level of trading with the time and resources available. We recommend such an analysis is carried out to discover whether there are perverse incentives for movement and if these can be changed as part of post-EU agricultural reforms. The analysis should also test whether movements that increase the efficiency of the industry provide sufficient benefits to outweigh the negative externality of disease spread.

26. Farmers are currently compensated for slaughtered cattle (or might in the future take out insurance against the risk). We believe that there is a strong argument for disincentivising risky trading by reducing compensation (or insurance payments) to reflect trading behaviour. Such adjustments would need to be relatively large to change behaviour.

27. There is evidence that mandatory post-movement testing has reduced the movement of cattle from high- to low-risk areas. Policy makers should consider extending this to at least the EA and to mandate the use of the most sensitive test. We consider that the increased costs of trading that will be borne by the industry is justified by the likely reduction in disease spread.

Disease in wildlife

28. The evidence shows that badgers do transmit bovine TB to cattle and contribute to the persistence of the disease. Ministers have to decide whether the real but circumscribed benefits of culling to the farming industry outweigh the animal welfare and environmental concerns of other stakeholders. This decision must be informed by scientific evidence but inescapably involves a judgement call by ministers.

29. There is evidence that culling badgers perturbs the animal's social structure leading to increased risks of herd breakdowns in adjacent non-culled areas – the perturbation effect. If a decision is made to cull, then carrying it out over sufficiently large geographic areas to reduce the relative effects of perturbation and utilising natural barriers to badger movement, as is done at the moment, is in our view correct. Experience from the Randomised Badger Culling Trial suggests that the benefits of widespread culling repeated annually for four years persist for some years after lethal control stops, and hence we see periodic culling as a more promising strategy than continuous culling beyond four years.

30. Moving from lethal to non-lethal control of the disease in badgers is highly desirable. Though research into other options should continue, we believe that the injectable BCG vaccine is the only viable option currently available. At the moment there is limited information about the relative effectiveness of vaccination and culling on incidence of the disease in cattle, though the results from small-scale vaccine projects in England and large-scale deployment of vaccination in the RoI will help address this. We believe it is very important to maintain flexibility in policy over control of the risk of transmission from badgers to be able to respond to the changing evidence base.

31. If uncertainty about the relative effectiveness of vaccination and culling is not resolved by analysis of the outcomes of existing interventions (in England and elsewhere) then we believe Government should address this need. Culling is currently being carried out, or being planned, in 32 areas, chiefly in the west of England. On the assumption that this goes ahead and that periodic culling rather than continuous culling is adopted (¶ 29), we suggest that after four years of culling Government should consider a programme in which badgers are vaccinated in half of the areas and, after a two-year pause, intensive culling resumes in the other half. The outcomes should be monitored and adaptively managed so should it become clear that vaccination is providing comparable benefits to culling then all areas should adopt it, with the opposite happening if vaccination fails to provide protection.

32. The evidence does not suggest that other wild or feral animals (for example deer, fox, wild boar) pose a substantial national threat to cattle but any opportunity to increase our knowledge of disease prevalence in these species should be taken.

The disease in non-bovine managed animals

33. Bovine TB occurs in other farmed animals, though is less of a problem than in cattle. Defra has recently consulted on improvements in regulations concerning non-bovines (particularly South American camelids such as alpacas) and we support their implementation.

Biosecurity

34. The evidence base about which particular biosecurity measures work is not strong because of the difficulties of carrying out formal experiments for each of multiple different options. Nevertheless, there are many relatively cheap things a farmer can do to separate cattle from badgers, cattle from other cattle on neighbouring holdings, and potentially infected from uninfected cattle. These are 'no regret'

biosecurity options whose take up is disappointingly low. In our view, the issue here is not the availability of information but motivation to discover what can be done and to implement the measures. Above we stress the importance of the industry taking greater ownership of the disease, and we hope this leads to greater uptake of biosecurity. We also underline the importance of farmers' trusted advisors, in particular private veterinarians, giving clear and unambiguous advice on biosecurity.

35. A number of accreditation schemes mandate biosecurity measures while supermarkets also lay down rules for their suppliers. Unifying all these rules relevant to bovine TB in a single guidance set would, we believe, be helpful for farmers and stimulate uptake. Were the single bovine TB authority we discuss in chapter 9 to be created, this would be the natural body to coordinate.

36. Farmers are at present partly compensated for losses due to cattle slaughtered for reasons of disease control. We have examined the relative merits of compensation versus insurance and recommend further exploration of the latter. Because of the issues of adverse selection, Government would need to be involved in setting up an insurance programme (as, for example, it has been in flooding insurance) and in information provision. We envisage a compulsory insurance programme partially supported by Government (replacing compensation) with premiums and compensation designed to incentivise and reward behaviour that reduces the risk of disease.

37. We note recent evidence that the potential for bovine TB to be dispersed by spreading slurry or manure on the land may have been under-appreciated. We believe obtaining more evidence on this transmission route, and then if appropriate mitigating it, is important.

British farming after the CAP

38. In September 2018 the government published the Agriculture Bill and a policy statement on The Future for Food, Farming and the Environment both of which outline a vision for British agriculture outside the Common Agriculture Policy (CAP). A clear direction of travel from indirect subsidy (Single Farm Payment) to "public money for public good" is indicated. The next decade will see arguably the greatest change in British farming since the 1940s and ensuring these changes facilitate bovine TB control will be critical to successful elimination of the disease.

39. Current incentives to hold agricultural land for investment has increased the amount of land rented out for grazing. New rules introducing Temporary Land Associations mean that a farmer renting the land is not required to record cattle movements as long as they are less than 10 miles from his or her farm's central location. We have not been able to analyse fully the extent of this movement but are concerned about the role of short-distance movement in disease spread. We hope that the introduction of the LIS will enable data to be collected on this movement easily without excessively burdening the farmer. Policy makers should consider whether, even with our imperfect current knowledge, reducing local movements in the most critical places for spread (the EA) is justified. Looking to the future, ensuring post-CAP arrangements reduce incentives for local movements would be helpful, though we realise may impact upon the industry.

40. There has been recent discussion about the extent of short-term tenancies in British farming and the disincentive this introduces to investment to increase productivity. We note that these investments include those to reduce the risk of bovine TB and that disease control would also benefit from measures to encourage long-term investment.

Research

41. There are many areas, some outlined in this review, where research has played a valuable role in the battle against bovine TB. The specific need for more research, such as in novel diagnostics, vaccines, genetic resistance and around farmer behaviour, is identified in this report. Research in this field is funded by a variety of bodies and occupies the whole spectrum from largely fundamental to highly strategic. This diversity is a strength. Nevertheless, we believe there would be a benefit from setting up a forum that would better link research funders with the needs of customers of the more applied research. This would ensure that the research had the highest possible impact and value for money.

Concluding comments

42. We conclude with two broad observations. TB is a complex and difficult disease to control, both in humans and in animals. Research over more than a century has provided many insights into the disease and tools to help combat it, and future research will be equally informative. In designing a strategy to control bovine TB in England and progress towards elimination it is important to be flexible and set up systems that ensure new insights from surveillance and research are efficiently incorporated into policy and implementation.

43. Second, we most always remember that this is a disease control campaign with a clear objective and, unfortunately, requiring sacrifices to be successful. Because of the complexities and multiple consequences of the disease – epidemiological, economic and social – it is inevitable that a large series of rules and regulations have had to be put in place. This can foster a philosophy of living with the disease (and the regulations) rather than being part of a disease control campaign. Today, bovine TB incidences in England, definitely in cattle and possibly in badgers, are at best roughly stable. This cannot be allowed to continue. There are no easy answers to reducing disease levels and what is required is new drive and a concerted and concentrated effort by all sectors involved.

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Chapter 1: Introduction

Preamble

1.1. Bovine tuberculosis (bovine TB) is an important disease of cattle which also attacks a broad range of farm and wild mammals. The causative agent is a bacterium, *Mycobacterium bovis (M. bovis)*, and developed infections result in deterioration in condition, milk yield, and meat quality. Bovine TB can infect humans and before milk pasteurisation became standard it was a significant global public health problem, including in the United Kingdom (UK). Today, only a few human infections occur annually in the UK. Infected cattle secrete bacilli which, though the precise modes of transmission are poorly characterised, infect other cattle. There is also two-way transmission between cattle and wild animals. In the UK and RoI, the most important wildlife host is the badger[1].

1.2. Bovine TB is found throughout the world and, amongst high-income countries, it is a particular problem in the UK and RoI. In the UK, the Devolved Administrations (DAs) have responsibility for policy on bovine TB. The disease is particularly prevalent in the west of England, Wales and Northern Ireland while incidents in Scotland are rare and sporadic. The UK administrations work to control the disease within a framework specified by the European Union (EU). Deviations from this framework are at present illegal and would impact the UK's ability to trade cattle with other countries in the EU[2].

1.3. Control of bovine TB in England is based around regular testing of cattle in the nation's herds. A herd that contains cattle that test positive (reactors) is said to experience a herd breakdown and if confirmed it has its Officially TB Free (OTF) status withdrawn. The herd is then subject to movement restrictions (typically cattle can only be sent to slaughter) and is tested more frequently until reactors are no longer present. Reactors are slaughtered and compensation is paid to the farmer. Testing frequency and details of other interventions are different in the High Risk Area (HRA), the Edge Area (EA), and the Low Risk Area (LRA). These areas are set out at Figure 1.1. Government also intervenes to promote biosecurity (for example, discouraging the purchase of cattle with a risk of infection and reducing the probability of transmission from wildlife) and to support research on bovine TB epidemiology, surveillance and vaccination[3].

1.4. When badgers were discovered to be hosts of bovine TB in the UK following investigations on a farm in Gloucestershire in 1971 a programme of badger culling was initiated. This became highly controversial with arguments that it was both ethically wrong and epidemiologically ineffective. The Krebs Report (1997) recommended a large-scale field experiment, the Randomised Badger Culling Trial (RBCT) that ran from 1998-2005. It showed an overall though relatively modest benefit of widespread culling on the incidence of herd breakdowns. Badger culling began again in 2013 at two pilot sites and currently (2018) this has been licensed for 32 sites.

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[1] Further background details of *M. bovis* epidemiology and pathology are given in Chapter 2.
[2] Further background details of bovine TB distribution and European governance are given in Chapter 2.
[3] The interventions described in this and the next paragraph are explored in detail in the core of the report.

1.5. Despite intensive efforts by government and industry the numbers of herd breakdowns in parts of England remains stubbornly high (Figure 1.2). Currently, government spends about £70 million a year on disease control in England with the cost to industry estimated to be a further £50 million. Government also funds a substantial research programme as discussed at Annex 5. Herd breakdowns have major financial and non-financial consequences for affected farms, including on farmer and farm worker health and well-being. The programme of badger culling remains controversial and one major political party is committed to ending culling.

This Review

1.6. In February 2018 the Secretary of State at the Department for Environment, Food and Rural Affairs (Defra) announced a review of bovine TB strategy in England. The intention was to reflect on the progress made with implementation of the current (2014) bovine TB strategy and "to advise on changes to take the strategy to the next phase, in order to maintain momentum towards the government's goal of achieving officially free status in England by 2038". The full Terms of Reference are given in Annex 3 and the members of the Review Panel and their declarations of interest in Annex 2. The Panel began their work in late March 2018.

1.7. With agreement of Defra the Review Panel interpreted their brief as follows:

(i) The Review would be forward looking and revisit past successes and failures only in as much as it helped develop future interventions and strategies.

(ii) The Review would take a broad view of bovine TB in England and reflect not only on the epidemiology of the disease but also the role of the structure of the beef and dairy industries and the way we manage rural landscapes on the incidence of the infection.

1.8. The work of the Panel took place between March and September 2018 at a time when the UK is committed to leave the EU but the final details of the relationship between EU and UK agricultural rules and trade arrangements have not been settled. We have thus not confined ourselves to consider interventions that are in accord with current EU rules though realise, of course, that the viability of some of the options we explore will be influenced by the final settlement.

1.9. Many of the decisions that need to be made about bovine TB control have to take into account the sometimes conflicting views of different stakeholders and so inevitably require judgements to be made by ministers. For example, there is no strictly scientific counter-argument to the claims made by people who consider badger culling to be intrinsically unethical; such issues have to be decided in a democracy by ministers in elected governments. Similarly, the question about the degree to which the state should intervene financially to compensate farmers for bovine TB outbreaks is a question of political economy for which there is no technically 'right' answer. Evidence from the natural and social sciences is very important for placing bounds on feasible strategies and helping policy makers choose amongst different options but cannot by itself determine a single best approach to disease control.

1.10. With this in mind, the approach we have taken in this Review is to consider a series of different options for interventions in different domains that may affect disease transmission. For each option we attempt to weigh up the pros and cons of the different alternatives. We discuss the weight of evidence supporting the efficacy and cost-effectiveness of different interventions, and try to articulate clearly where ministers have to exercise value judgements based on this information. Our 'Summary and conclusions' set out what we believe are some of the most promising approaches.

1.11. As stated above, one of the goals of the Review is to widen the possible set of interventions considered by government (especially in light of the increased autonomy possible outside the EU). Some of the options we explore are thus relatively novel. We point out that in the six-month's time span of the Review, and with the resources available to us, we cannot perform an in-depth analysis of the details of the implementation. We ask readers to concentrate on the big picture and anticipate that careful cost-benefit analysis and a check to avoid perverse incentives would be conducted prior to any implementation.

1.12. Bovine TB is a particularly difficult disease to study and control because of, amongst other reasons: (i) the specific pathology of the disease, (ii) the existence of a nocturnally active wildlife host that spends much time underground, (iii) the difficulty and expense of carrying out large-scale experiments, and (iv) the complexity of the dairy and beef industries in England and in the rest of the UK. Intensive research on the disease in farmed and wild animals, as well as on the closely related human TB pathogen (*Mycobacterium tuberculosis*), will certainly provide new insights in coming years. Bovine TB strategy thus needs to be 'adaptive' and able to respond to new knowledge and technology, as well as to changes in disease prevalence and spatial distribution.

How the Review was conducted

1.13. The Review was conducted by a Panel of five people (Annex 2) acting in a personal capacity and supported by a secretariat provided by Defra. The UK's Chief Veterinary Officer (CVO) attended meetings and offered commentary and advice.

1.14. The Review issued a call for evidence on 24 April 2018 with a deadline of 31 May. We asked for information about evidence-based interventions for bovine TB control (including epidemiological, regulatory, and economic measures). Specifically, we invited submissions on: (i) research considering how to improve the deployment of existing bovine TB control interventions, (ii) potential new approaches and tools and technologies to deal with bovine TB, (iii) approaches taken to control bovine TB in other countries, and (iv) work on human TB that might be relevant to the Review.

1.15. We received 39 responses from a wide range of stakeholders, including public sector organisations, wildlife groups, industry representative bodies, trade organisations, individuals, and research groups. Alongside the request for written submissions, we held a number of face-to-face meetings with a variety of different stakeholders. These sessions allowed us better to understand different perspectives about the disease and in some cases to examine in further detail key issues we identified from the written responses. A summary is provided in Annex 4.

1.16. Whilst our Terms of Reference focused on bovine TB eradication strategy for England, we considered lessons from other countries and engaged with policy makers and veterinarians in the DAs and the RoI. We looked at experience with human TB and the management of other diseases. We took evidence on the technical and operational logistics of different strategies for disease control. We also engaged with wider work underway in Defra to consider future agricultural policy and the farming regulatory and enforcement landscape, especially in the light of the UK's exit from the EU.

1.17. We are very grateful to all those who took the time to engage with us as part of this Review; their input has been extremely helpful.

The organisation of the Review

1.18. Chapter 2 provides some background material on the nature of the disease in cattle, the epidemiology of the disease in its multiple hosts, details of the different tests available to identify bovine TB in cattle, and the current legislative framework for disease control in England. We make no attempt to provide a comprehensive assessment of these topics (though provide an entry to the literature) but consider a number of critical issues underlying our reasoning in discussing the pros and cons of different interventions.

1.19. Chapters 3 to 9 discuss possible interventions to help control the disease. For ease of presentation we divide them into interventions around: (3) surveillance and diagnostics; (4) the disease in cattle – vaccination and resistance; (5) cattle movements and risk-based trading; (6) the disease in wildlife; (7) non-bovine farmed animals; (8) biosecurity, compensation and insurance; and (9) governance.

1.20. In our 'Summary and conclusions' we highlight the factors that we believe should be at the front of decision makers' minds when determining future policy.

Figure 1.1: Risk map for Great Britain (Edge Area boundaries pre-2018)

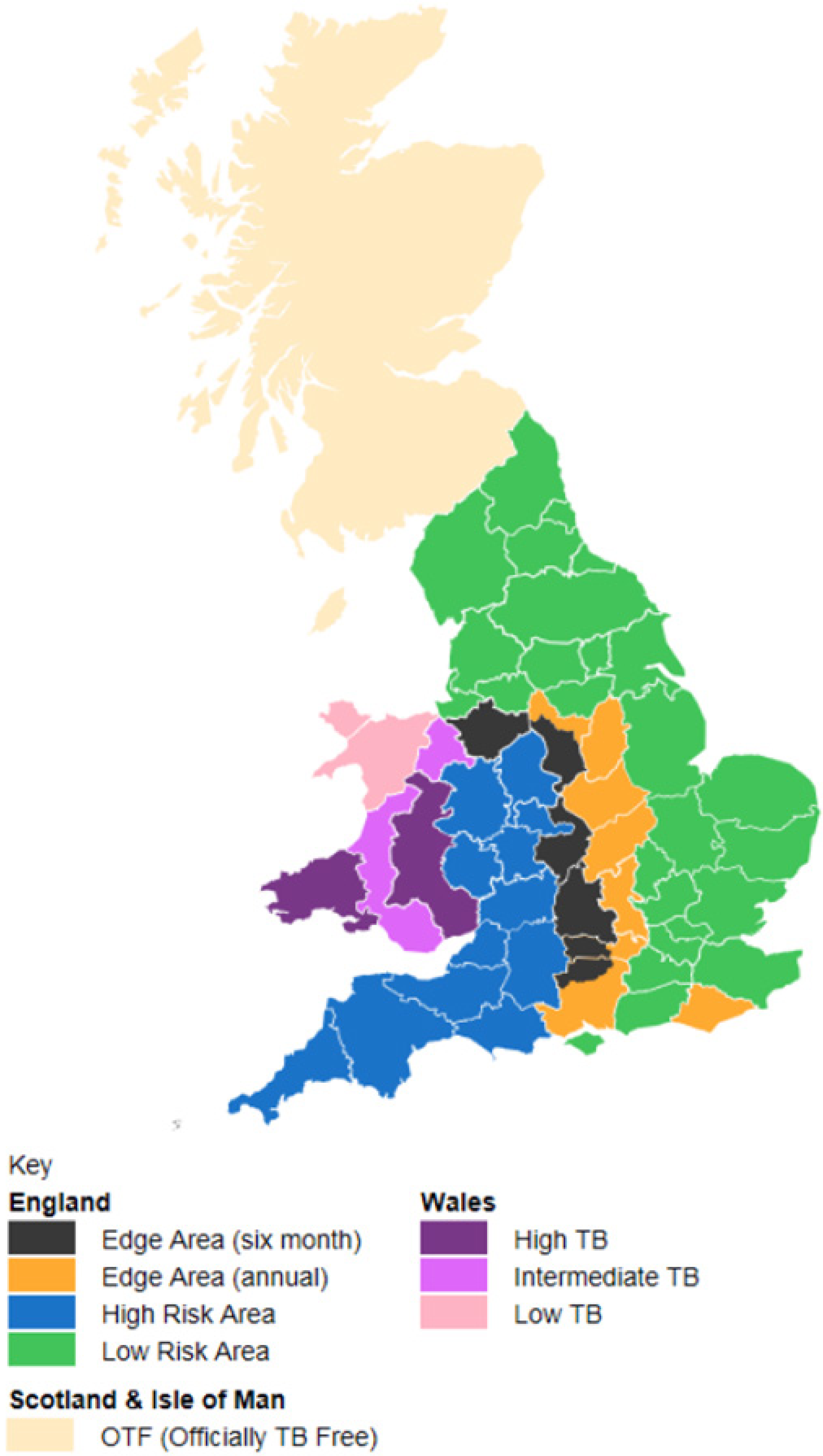
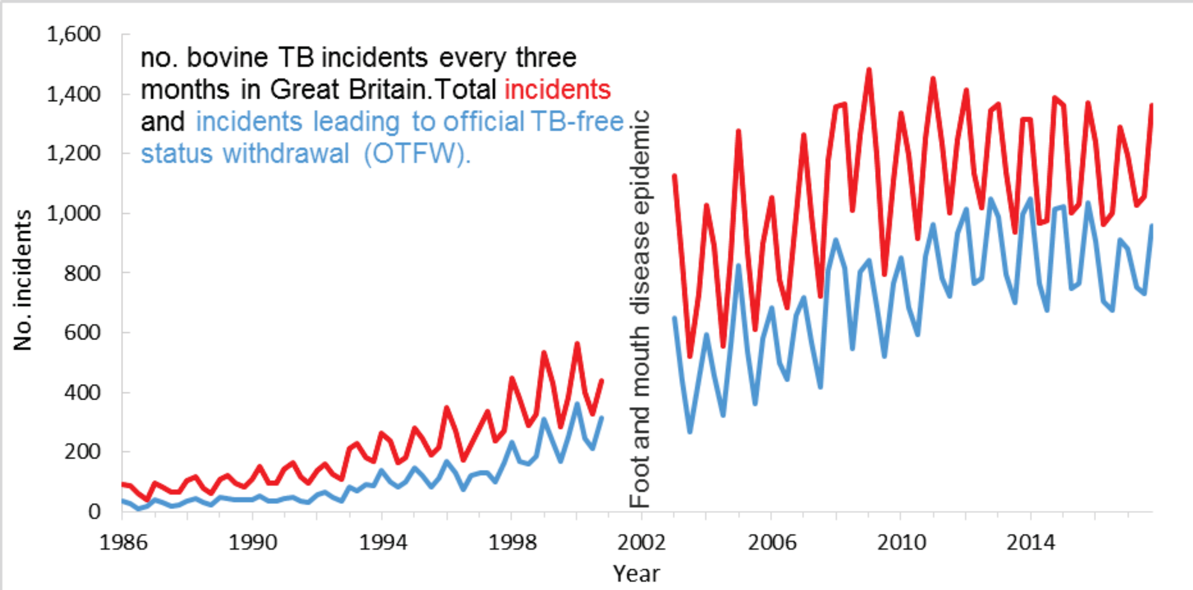


Figure 1.2: Changes in incidence and distribution of bovine TB in Great Britain 1986–2012. (a) Changes in incidence, which varies seasonally. Bovine TB testing was interrupted during the foot and mouth epidemic. (b) Increase in the geographical area affected by bovine TB, 'hot' colours indicating higher densities of farms where disease has been confirmed (official TB-free status withdrawal). Herd density is measured as the number of herds per square kilometre.

(a)



(b)

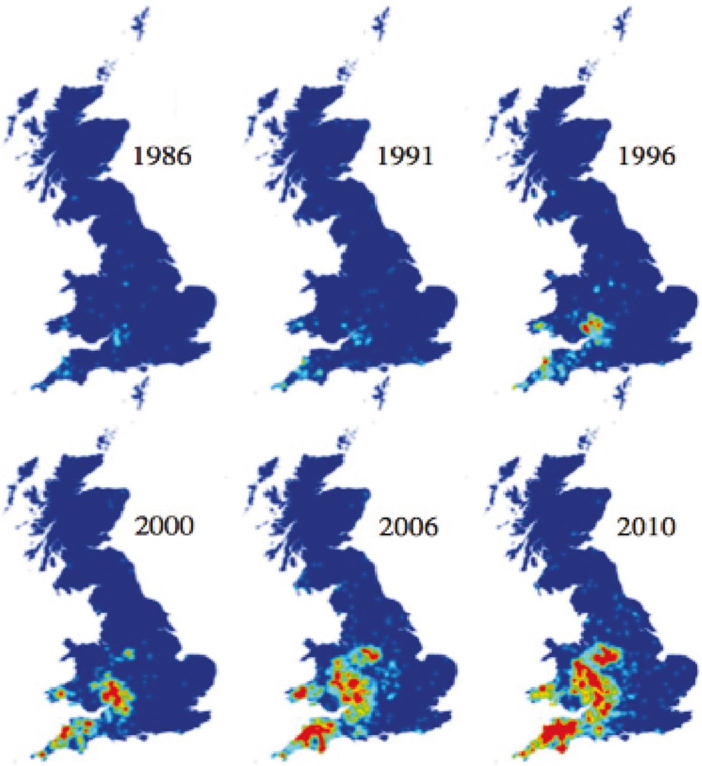
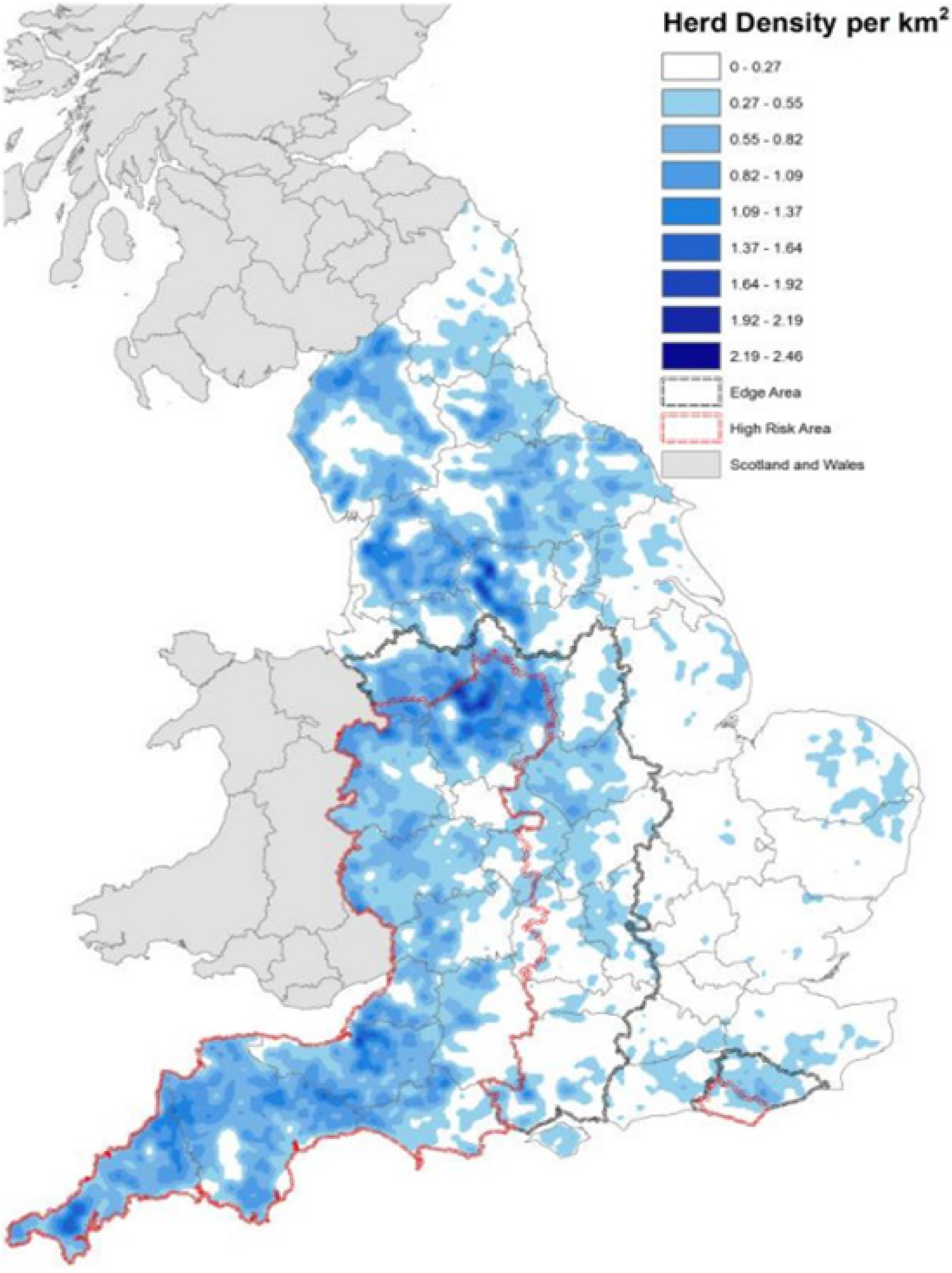
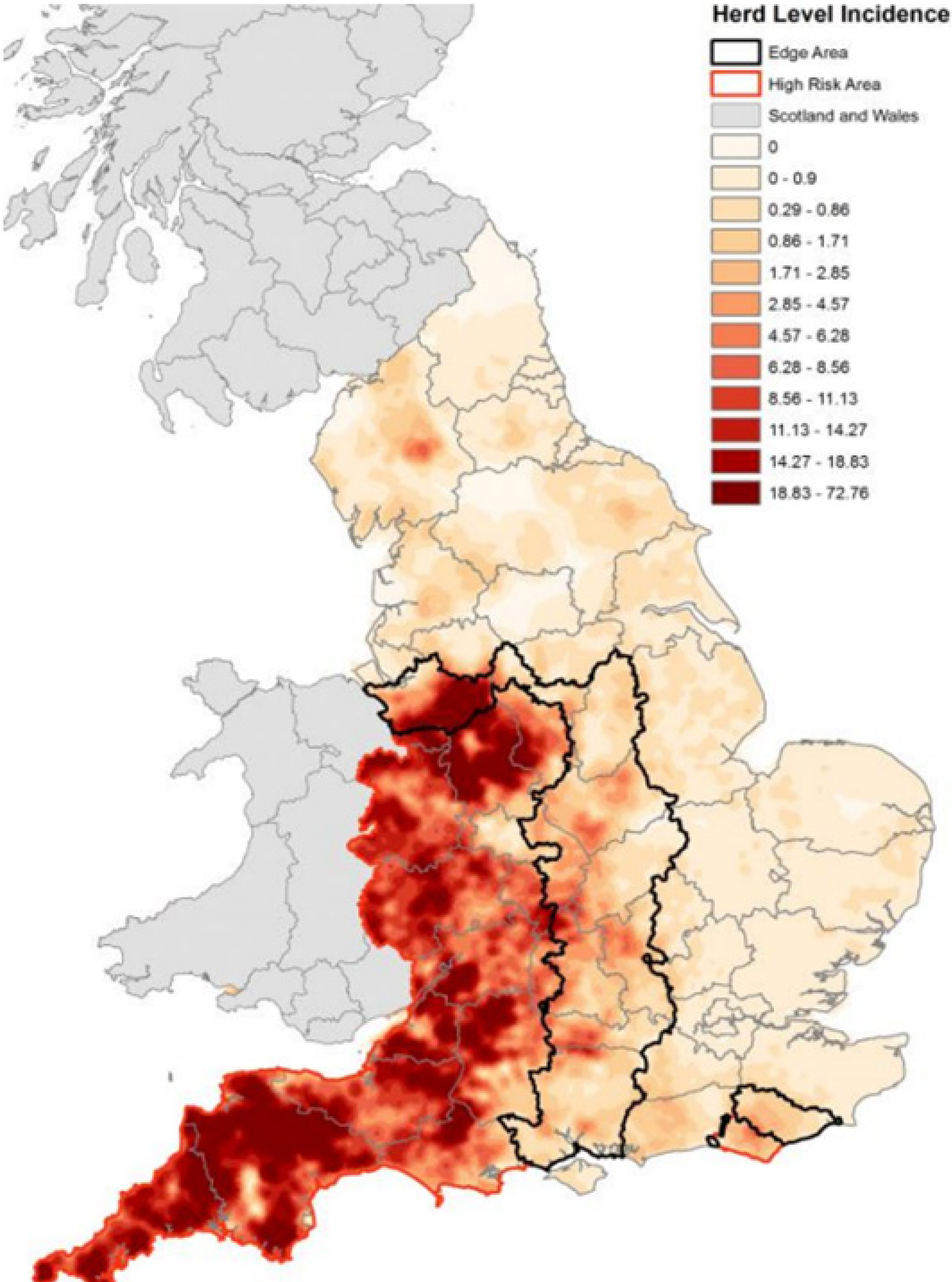


Figure 1.3: Herd density of bovine TB in England, 2017 (Herd density is measured as the number of herds per square kilometre).[4]



[4] Edge Area boundaries were adjusted in 2018, this map reflects the 2017 position.

Figure 1.4: Herd level incidence of bovine TB in England, 2017. Herd incidence is the average incidence in the 100 closest herds to each herd location which 'smooths' the effect of political boundaries in England, 2017[5]



[5] Edge Area boundaries were adjusted in 2018, this map reflects the 2017 position.

Chapter 2: Background

Introduction

2.1. This Review does not include a detailed history of attempts to control bovine TB in the UK which are well summarised in a series of earlier reports. There is also a large technical literature in both the natural and social sciences relevant to bovine TB control.

2.2. In this chapter we first provide an overview of the Government's current plans for achieving officially bovine Tuberculosis Free (OTF) status for England as set out in Defra's 2014 Strategy and subsequent updates. More detailed discussion of most individual elements can be found in subsequent chapters exploring current and future interventions.

2.3. We then explore the background of three topics in more detail: epidemiology, diagnostics and testing, and the legislative framework for bovine TB. We do this for two reasons. First, we believe an up-to-date non-technical summary of these topics will be helpful for ministers and policy makers taking decisions about future interventions. Second, they provide context to the rationale behind our discussions of different intervention options.

Overview of current bovine TB strategy in England

2.4. Defra published its Strategy for achieving OTF status for England on 3 April 2014 following extensive public consultation. The Animal Health and Welfare Board for England (AHWBE) and the Bovine TB Eradication Advisory Group for England (TBEAG) contributed substantially to its development.

2.5. The Strategy acknowledged bovine TB as the most pressing animal health problem in the UK with increasing numbers of affected herds. Tackling bovine TB in England is estimated to cost the taxpayer around £70 million a year, with costs to farmers running to a further £50 million. Enabling an economically sustainable livestock industry and reducing the taxpayer bill could be achieved by dealing effectively with the disease, maintaining trade, and achieving OTF status for England incrementally by 2038. The Strategy envisaged non-governmental organisations, farmers, veterinarians, and government working together to free England of TB.

2.6. The Strategy set out a broad range of interventions to fight the disease, including those already available and those in development, such as a cattle vaccine and improved diagnostic tests. It put forward an approach based on stringent cattle control measures, combined with tackling the primary wildlife reservoir through culling of badgers in bovine TB hot spots, with schemes for vaccination of badgers around the edge of those badly affected areas to stop the disease from spreading. The Strategy proposed a stronger focus on biosecurity measures and further work with the farming industry to consider the potential for risk-based trading. It set a range of targets to help with measuring progress towards OTF status.

2.7. The Strategy recognised the need to apply different tools in different herds depending on local circumstances and disease risk, and defined, for the first time, three different risk areas in England. It aimed to preserve the LRA in the north and east of England, stop and reverse the spread of bovine TB at the 'frontier' of the disease (the buffer zone known as the EA), and reduce the level of infection in the HRA, spanning the south-west and west Midlands.

2.8. To date, the principal elements deployed in the Strategy have been cattle movement controls, the detection and removal of infected cattle from herds, and the badger cull. A range of new controls have been introduced since 2014, including: stricter testing protocols for TB breakdown herds (including wider use of the interferon gamma blood test), 31 badger cull zones in the HRA and EA, mandatory testing of cattle moved to herds in the LRA from higher risk areas (post-movement testing), and support for a voluntary herd accreditation scheme. Ministers have said that they want to ensure other tools and interventions, such as cattle vaccination or further developing genetic resistance in the national cattle herd, are ready to be deployed in the next phase of the Strategy to accelerate progress towards the target of achieving OTF status by 2038.

Epidemiology

2.9. Epidemiology is the study of the frequency and distribution of diseases in populations and the reasons why certain individuals become unhealthy whilst others do not. For infectious diseases, mathematical models are typically used to understand their spread through populations and how their transmission may be controlled.

2.10. A very important result from epidemiological theory, of major consequence to the control of all infectious diseases, is that there is a quantity, the 'basic reproduction number', universally termed R_0 (and pronounced R nought), that determines whether a disease will increase or decline in frequency when introduced into a previously uninfected (naïve) population. In the simplest of cases this quantity is the average number of secondary infections arising from a single introduced infection. If this quantity is greater than one, the disease will spread, while if it is less than one it will decline. Understanding the different aspects of the host and pathogen biology that determine R_0 is immensely important in designing control programmes; for example, vaccination strategies. Estimation of R_0 in specific circumstances is typically complex and may need to account for variation between groups or individuals and factors that vary (perhaps randomly) in time or space, but the fundamental insight of a threshold that separates the circumstances under which a disease spreads or declines holds true.

2.11. A disease with R_0 only a little greater than one is, other things being equal, easier to control than a disease where the number is much higher. Analysis of disease transmission can reveal which part of the transmission system can be targeted most effectively to reduce disease spread. Calculations involving R_0 can also be used to study the prevalence of a disease that becomes endemic (i.e. persists in a region at a more or less stable level rather than present only in outbreaks), the rate at which it spreads through space, the fraction of the population that needs to be vaccinated for the disease to decline, and many other processes.

2.12. For bovine TB in the UK, R_0 is a complicated function of: (i) the frequency of transmission between different hosts (cattle-cattle, badger-badger, and cattle-badger in both directions, with other species potentially transmitting as well), (ii) the densities of the different hosts, (iii) the frequency and magnitude of animal movements (both natural and human-facilitated), (iv) the structure of cattle herds and badger social groups, (v) the distribution and survival of bacteria in the environment, and (vi) other factors.

2.13. Several studies have sought to estimate R_0 for bovine TB infections in the joint cattle-badger system in the UK[6]. Not enough is known about the quantitative epidemiology of the disease to construct a highly detailed (quasi-realistic) multi-species model and instead more idealised models were designed to represent the key processes. These studies indicate that R_0 is greater than one but not substantially so (an initial infection causing greater than one but fewer than two further infections on average). This is encouraging as it suggests that a combination of interventions, possibly each of relatively small effect, may combine together to drive R_0 below one. This positive message must be tempered with caution due to the preliminary and approximate nature of the underlying idealised models. Further studies to robustly estimate R_0 would be very helpful.

2.14. An important question is whether bovine TB in badgers is sustainable by itself without further infections from cattle (in other words would R_0 be greater than one in a population of badgers). If R_0 were less than one then were the disease controlled in cattle it would die out in badgers. If this were not the case then it would persist and unless measures in wildlife were taken cattle would continue to be at risk. There is not a consensus amongst epidemiologists about whether R_0 within badger populations is above or below this threshold, though more agreement that it is not substantially below one so the disease would, at best, die out slowly.

2.15. General epidemiological considerations offer some guidance about interpreting new information for bovine TB control. First, improvements in disease control combine non-linearly to affect R_0. Thus an x% reduction in, say, one transmission pathway is unlikely to lead simply to an x% reduction in herd breakdowns – it could be either more or less. A corollary of this is that a proportionally small reduction in one transmission pathway can be more significant than a large reduction in a different pathway; it is important to understand how each contributes to the epidemiology. Second, if R_0 is above but relatively close to one then a combination of interventions, possibly each of relatively small effect, may combine together to push the disease below the threshold at which it declines towards extinction. A corollary of this is that it is not necessarily essential to intervene in every possible way to control the disease. Nevertheless, choosing not to intervene in one way implies that other interventions have to take more of the burden of control and the rate at which disease declines is likely to be slower. Ongoing and future research into bovine TB epidemiology will help make this guidance more concrete.

Diagnostics and surveillance

2.16. Testing cattle and other livestock for the disease is challenging because of the nature of the pathogen and the interaction with its host. We summarise below some of the background biology relevant to discussion of surveillance and diagnostics. Test performance depends on the characteristics of the test used, its

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[6] Cox *et al*. 2005 https://doi.org/10.1073/pnas.0509003102, Brooks-Pollock & Wood 2015 https://doi.org/10.1098/rspb.2015.0374.

correct application, and on the prevalence of the disease in the region or herd being tested.

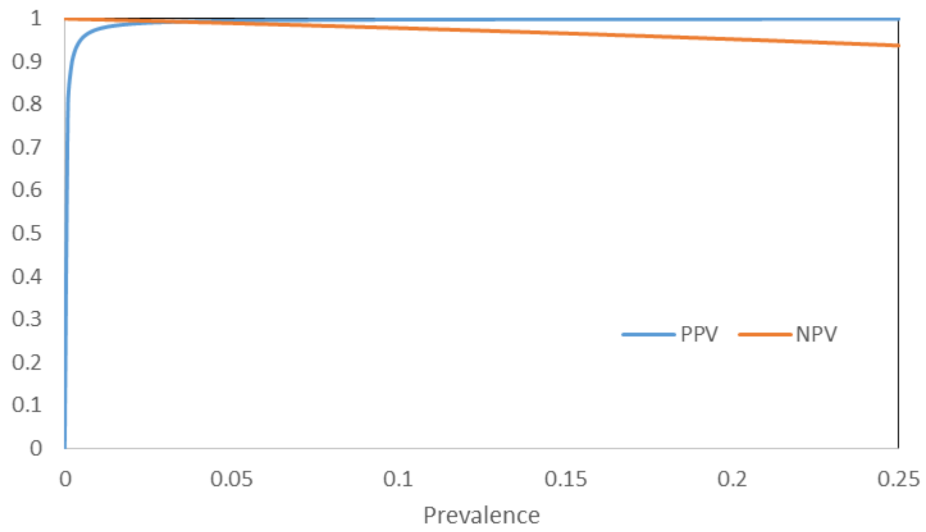
2.17. The performance of a test is based on its ‘sensitivity’ and ‘specificity’. The sensitivity of a test describes its ability to detect all cases of the disease; a sensitivity of 90% means that 9 out of 10 animals with the disease are correctly identified but that 1 in 10 are missed (false negatives). The specificity describes the accuracy of the test in ruling out disease; a specificity of 99% means that 99 out of 100 animals that are not infected will test negative but that 1 out of 100 of them will be incorrectly diagnosed (false positives). Tests differ in both sensitivity and specificity and there is often a trade-off between the two measures of performance.

2.18. The cut-off point, or threshold, of a diagnostic test determines its sensitivity and specificity and can be modified to suit the background of the prevailing epidemiological circumstances. Parallel testing (combining several tests and regarding any positive test result as a positive animal) increases sensitivity, while serial testing (combining several tests and regarding only those animals that test positive by all methods as positive) increases specificity.

2.19. The ‘positive predictive value’ (PPV) of a diagnostic test is defined as the probability that an animal testing positive is truly infected. Conversely, the ‘negative predictive value’ (NPV) is the probability that an animal with a negative test result is truly free from infection. Both of these measures depend on the proportion of the population that is truly infected (the prevalence of infection) as well as the sensitivity and specificity of the test.

2.20. For a given diagnostic test, the higher the prevalence of infection in a population, the higher the PPV and the lower the NPV. In other words, the same diagnostic test for *M. bovis* infection in cattle will not have the same predictive value when used in different infection risk or prevalence areas. For example, in a population of 2,000 with 50% prevalence (i.e. 1,000 infected and 1,000 uninfected individuals) a test with 90% sensitivity and 99% specificity would produce 900 true positives and 10 false positives for a PPV of 900/910 (98.9%), as well as 100 false negatives and 990 true negatives for an NPV of 990/1090 (90.8%). Similar calculations for a population with 33% prevalence (500 infected and 1,000 uninfected individuals) yield a PPV of 97.8% and an NPV of 95.1%. Figure 2.1 shows how PPV and NPV vary as a function of prevalence.

Figure 2.1: The PPV and NPV as a function of prevalence (from 0 to 25%) assuming a sensitivity of 80% and a specificity of 99.98%.



2.21. Due to the effect of stage of infection on test sensitivity, and the differing prevalence of disease in different parts of the country, 'average' predictive values for tests are not useful estimates. Values in different risk areas are important for planning how test results should be interpreted.

2.22. Our best estimates of the animal-level sensitivity and specificity of the main tests for which there are UK data are summarised in simplified form in Table 2.1. There are important caveats in all cases.

Table 2.1: Estimated sensitivity (Se) and specificity (Sp) in cattle of the ante mortem diagnostic tests officially approved for use in cattle in the UK. Single Intradermal Comparative Cervical Tuberculin (SICCT), Interferon Gamma (IFNγ) tests and IDEXX ELISA (Enzyme-Linked Immunosorbent Assay)

Test	Sensitivity	Specificity	Comment and source
SICCT (standard interpretation)	81%	99.98% ±0.004	Se varies between 50-90% depending on the conditions under which it is carried out. Sp Goodchild et al 2015[7]
SICCT (severe interpretation)	85% [95% CI 78-91%]	99.91%±0.013	Se Karolemeas et al 2012[8] Sp Goodchild 2015

[7] https://veterinaryrecord.bmj.com/content/177/10/258
[8] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0043217

IFNγ	90% [95% CI 87.2-92.8%]	96.6% [95% CI 85-99.6%]	Se APHA – animals from known infected herds in GB Sp Ewer and Vordmeier, 2003 (cited in R. de la Rua-Domenech et al 2006[9])
IDEXX ELISA	64.6% [95% CI 59.7 - 69.5%]	98% [95% CI 97.5-98.4%]	Se and SP values according to information supplied by the manufacturer in its OIE registration dossier. Not yet an EU-approved test for TB in cattle

2.23. All current skin tests make use of a cocktail of proteins (termed tuberculin or a Purified Protein Derivative, PPD) obtained from cultures of *M. bovis* (hence PPD-B). If an animal has been previously exposed to this bacterium then it will react to the injection of tuberculin into the deep layer of the skin by producing a local swelling. The precise components of tuberculin that cause this localised allergic reaction are unknown. Though the comparative potency of different batches of tuberculin are tested (on guinea pigs or cattle) against an international standard before their release to the field, there is some residual variation between batches of the product that may affect test results. A Purified Protein Derivate, PPD-A, is prepared in a similar way to PPD-B but uses *M. avium* rather than *M. bovis*.

2.24. The SICCT test involves a comparison of the immune reaction to *M. bovis* and *M. avium* derived tuberculins injected side-by-side into the skin of the animal's neck. An animal is classed as a reactor and removed if the response to PPD-B three days later, i.e. a swelling or lump that can be measured using callipers, is greater than the response to PPD-A by more than 4mm (standard interpretation) or 2mm (severe interpretation). Borderline cases with weak reactions are classified as 'inconclusive reactors'. Since the SICCT test has limited sensitivity, once a herd has been declared infected (a TB breakdown) multiple skin tests must be performed at prescribed time intervals of at least 60 days to increase the probability of detecting all infected animals that remain in the herd. Other strategies employed by Animal and Plant Health Agency (APHA) veterinarians to increase the animal-level sensitivity of testing in TB breakdown herds include: (i) switching from the standard to a severe interpretation of the skin test, (ii) supplementing the SICCT test with the IFNγ blood test, and (iii) removing as 'direct contacts' any negative-testing and inconclusive reactor animals that are considered to be at a particularly high risk of exposure to infection.

2.25. The SICT is the primary test for routine screening of both herds and individual cattle for most of continental Europe; it has a higher sensitivity than the SICCT test. However, sensitisation of cattle to the SICT by exposure to environmental

[9] https://doi.org/10.1016/j.rvsc.2005.11.005

mycobacteria, which can cause cross reactions to the SICT test and lead to false positive results, was reported to be high in the UK and RoI[10]. As a result, in 1972, on the accession of the UK, RoI and Denmark to the European Economic Community (now the EU), it was agreed that the SICCT test (first used in the UK in 1947) could continue to be used in these countries, initially for a transitional period but, from 1980, as an approved EU test. Testing using the SICT is nevertheless required of animals over 42 days old in OTF herds that are destined for export to EU member states.

2.26. The IFNγ test involves taking a blood sample from an animal and stimulating it in the laboratory with bovine and avian tuberculin PPDs that are used for skin testing. The existence of an immune response is assessed by measuring the release of interferon gamma (a cytokine, a signalling protein involved in the development of an immune response). Blood from an *M. bovis*-infected animal will release more interferon gamma in response to bovine tuberculin than to avian tuberculin. This test has higher sensitivity but lower specificity than the SICCT and can identify animals at an earlier stage of infection. It is only approved for use as a supplement to the SICCT test in breakdown herds, with blood samples taken and tested by APHA.

2.27. A slightly different format of the IFNγ test has also been available for some time for use in the UK in specific situations. It differs in including an additional peptide cocktail of *M. bovis*-specific antigens and is less sensitive but more specific than the standard IFNγ test. It is used by APHA in specific circumstances to re-test skin test reactor cattle; for example, in LRA herds with persistent breakdowns.

2.28. Both formats of the IFNγ test have also been available since 2016 for private use by cattle farmers, with prior permission from APHA. For example, this might enable farmers to market their cattle on the basis of high bovine TB health status.

2.29. The Caudal Fold Tuberculin (CFT) test is similar to the SICT except that the tuberculin is injected into the flap at the base of the tail rather than the neck. It is used for herd screening in the USA, Canada and New Zealand with test-positive animals retested using either the SICCT or IFNγ. Until 2010 in the USA, all cattle from reactor herds identified using the CFT test were slaughtered, but because of larger herd sizes in the USA compared to Europe, and the consequent costs of this policy to industry and the taxpayer, the SICCT is now used to identify infected animals in CFT positive herds without whole-herd slaughter. This format of the skin test is currently not approved for use in the EU. There is currently no data on the performance characteristics of the CFT in the UK but there are practical advantages to the test in that it is easier to perform in a cattle crush and there is less risk of injury to the person performing the test.

2.30. All skin and laboratory tests that involve tuberculin recognise an animal as infected because it has developed an immune response to the pathogen. Animals at early stages of infection, before this response has become established, will thus not be detected. Retesting, after a gap of at least 60 days, can help identify these animals, though some of those infected may still be unresponsive.

[10] Allen et al (2018) https://doi.org/10.3389/fvets.2018.00109

2.31. Serological tests detect the presence in blood serum of antibodies produced by the animal against *M. bovis* (the immunological tests discussed so far rely on the presence of immune cell-mediated responses). They are cheaper and quicker than the current tests although their sensitivity may be lower. The sensitivity of serological tests can be boosted by the prior injection of tuberculin between 10-30 days earlier which boosts antibody production in infected animals but not in uninfected ones. At present the IDEXX ELISA[11] test is the only OIE (World Organisation for Animal Health) registered serological test available for the diagnosis of *M. bovis* infection in cattle though other tests are under development. Limited use of the IDEXX ELISA test in the UK has detected an additional 1-3% of infected animals that were skin test and IFNγ negative in (Official TB Free Withdrawn) OTFW herds.

2.32. The tests discussed so far are based on monitoring the animal's response to infection and not the pathogen itself. PCR (polymerase chain reaction) tests detect minute amounts of *M. bovis* DNA and thus reveal the presence of living or recently living bacteria. PCR tests can be very specific if they are based on unique DNA sequences in *M. bovis*. PCR tests can be used to identify bacteria in blood, though the numbers of bacterial cells here are typically small and hence sensitivity is low. PCR tests or growing the bacteria using laboratory culture methods are the only means of detecting bacteria in faeces and in the environment. Culturing *M. bovis* is quite challenging because, amongst other aspects of its biology, it grows slowly compared with other bacteria and there may be low numbers of bacteria in a sample.

2.33. The Actiphage test is a newly developed but not yet validated method of detecting very low densities of *M. bovis*. It involves incubating a blood or milk sample with a specific virus that infects bacteria (bacteriophage) and detecting whether the virus finds a host cell and replicates by PCR. Like the PCR test it detects *M. bovis* directly but unlike this test it only signals the presence of live and viable bacterial cells. The diagnostic performance of this novel test in both infected and TB-free herds needs further research and evaluation in field trials.

2.34. The Dual Path Platform (DPP) immunological blood test can be used for diagnosis of TB infection in badgers. The DPP can be conducted (with different protocols) on whole blood samples (in the field) or on serum samples (under laboratory conditions). The test is used in the 'Test and vaccinate or remove' (TVR) study in Northern Ireland and in the delivery of badger trap and test operations on chronic TB breakdown farms in Wales. The DPP has been estimated to have a sensitivity with serum of 55.3% (95% CI: 38.3 to 71.4) and a specificity of 97.5% (95% CI: 86.6 to 99.9). With whole blood the sensitivity is 52.5% (95% CI: 36.1 to 68.5) and specificity is 97.5% (95% CI: 86.6 to 99.9). The DPP test was signed off as an APHA validated test in February 2018[12].

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[11] IDEXX is the name of a company and ELISA (enzyme-linked immunosorbent assay) a standard serological protocol.

[12] https://gov.wales/docs/drah/publications/180712-delivery-of-badger-trap-and-test-operations-2017-report-en.pdf

Legislation

2.35. Responsibilities for bovine TB eradication are fully devolved to administrations in England, Wales, Scotland and Northern Ireland.

2.36. The EU provides the existing legal framework for bovine TB eradication programmes, comprising legislation on: (i) trade in bovine animals, (ii) EU co-financing of eradication programmes, (iii) animal products for human consumption (meat and milk), (iv) official diagnostic tests and controls, in particular of the manufacture of tuberculin and the performance and interpretation of the skin tests, and (v) bovine animal identification and registration. The main EU regulation on bovine TB is Council Directive 64/432/EEC, which deals with animal health problems affecting trade inside the EU in bovine animals and swine.

2.37. A new EU Animal Health Law will take effect from 2021, introducing a single, comprehensive legislative framework for the EU livestock sector, including bovine TB. The UK government continues to work at EU level on how the new regulation might be implemented. This will also depend on the final post-EU arrangements.

2.38. Domestic Statutory Instruments give effect to the EU rules in England and provide more specific details of compensation payments for cattle compulsorily slaughtered for TB control reasons, testing, movement controls, and enforcement. Further details of domestic and EU legislation relevant to the control of bovine TB are provided at Appendix 1.

2.39. There have been a number of legal challenges to bovine TB policy in England in recent years. Primarily, these have contested decisions about the implementation of wildlife controls under the Protection of Badgers Act 1992. These challenges, and their main outcomes, are summarised at Appendix 2.

2.40. The enforcement of bovine TB regulation, including the roles and responsibilities of Natural England, APHA, and local authorities is discussed in Chapter 9.

Appendix 1: Summary of legislation

The European Union (EU) provides the legal framework for bovine TB control covering: (i) trade in bovine animals, (ii) EU co-financing of eradication programmes, (iii) animals products for human consumption (meat and milk), (iv) official controls, in particular of the tuberculosis EU reference laboratory, and (v) bovine animals identification and registration. Domestic Statutory Instruments (SI) give effect to the EU rules in England and provide more specific detail (e.g. compensation rates, testing, movement controls, and enforcement etc.).

The EU Animal Health Law will take effect from 2021, introducing a single, comprehensive legislative framework for the EU livestock sector. However, the final details of the relationship between EU and UK agricultural rules and trade arrangements after EU exit have not been settled.

Legislation	Summary
Council of Europe - Convention on the Conservation of European Wildlife and Natural Habitats (The Bern Convention) 1979	Conservation of wild fauna and their habitats. Defines the European badger as a protected species. The UK is a member of the Council of Europe (since 1949) and signatory to the Convention (1979) which will continue to apply in the UK post EU exit.
Council Directive 64/432/EEC	Rules for intra-EU trade in bovine animals and swine for breeding, production or slaughter.
Council Directive 77/391/EEC	Requires Member States to develop plans for the eradication of bovine TB and other diseases in cattle.
Council Directive 78/52/EEC	Establishes criteria for EU financial contributions to national TB control programmes. Provides that farmers should be “appropriately compensated” for the loss of diseased animals.
Regulation EU No 652/2014	Provides for the award of grants to EU Member States affected by bovine TB, subject to conditions.

Legislation	Summary
Domestic - The Animal Health Act 1981 c.22	Enables Ministers to make orders to prevent the spread of disease: cleansing and disinfection, biosecurity, animal movements, and imports and exports etc. Establishes a framework for government expenditure to control animal diseases and entitlements to compensation.
Domestic - The Tuberculosis (England) Order, SI 2014/2383, as amended by S.I. 2016/347	Sets out the main TB cattle controls in England. Amended in 2014 and 2016 with additional requirements for TB testing.
Domestic - The Protection of Badgers Act 1992 c.51	Establishes that it is an offence to (or attempt to) kill, injure, or take a badger, or interfere with a badger sett, unless under licence. Sets out exceptions and conditions for granting a licence. Sets out enforcement and penalties for non-compliance.
Domestic - The Veterinary Surgery (Testing for Tuberculosis in Bovines) Order 2005 SI 2005/2015	Permits non-veterinarians to carry out tuberculin testing of cattle.
Domestic - The Veterinary Surgery (Vaccination of Badgers Against Tuberculosis) Order 2010, SI 2010/580	Permits non-veterinarians to vaccinate badgers by injection against tuberculosis, subject to certain specified conditions.
Domestic - Cattle Compensation (England) Order, SI 2012/1379, as amended by S.1. 2018/754	Sets out detailed arrangements for the payment of compensation to dairy and beef farmers where an animal has to be slaughtered under section 32(1) of the Animal Health Act 1981 for bovine TB. Amended by more recent legislation.
Domestic - The Tuberculosis (Deer and Camelid) (England) Order, SI 2014/2337	Specifies disease controls for deer, and camelids (llama, alpaca, vicuna and guanaco).

Legislation	Summary
The Tuberculosis (Deer and Camelid) Slaughter and Compensation (England) Order 2014, SI 2014/2338	Provides for statutory compensation for the owners of deer or camelids when an animal is slaughtered as a result of bovine TB. Amended by subsequent legislation.

Appendix 2: Legal challenges to bovine TB policy in England

The majority of legal challenges (and attempts to bring about a Judicial Review) relating to bovine TB policy in England have been about badger control.

Date	Claimant / Grounds	Outcome / To Note
Feb 2012	The Badger Trust: challenging the 2011 badger control policy in terms of statutory interpretation of powers to cull badgers, powers to issue guidance, and failure to update the impact assessment on all policy options originally consulted upon.	The challenge was dismissed. An appeal judgement also found in favour of the Secretary of State.
Apr 2012	The Badger Trust: whether the proposed culls met the test of “preventing the spread of disease” set out the Protection of Badgers Act, whether the Secretary of State had legal powers to issue guidance to Natural England (NE), and asserting that the cost impact assessment was flawed.	The challenge was dismissed. An appeal judgement also found in favour of the Secretary of State.
2014	The Badger Trust: challenged the decision to allow badger culling in Somerset and Gloucester, arguing there was legitimate expectation of further use of an independent expert panel whilst the culls were still ‘pilots’.	The challenge was dismissed. An appeal judgement also found in favour of the Secretary of State.
July 2018	Mr Langton: challenged the decision to publish guidance on licensing badger culls to prevent the spread of bovine TB, and the subsequent decision to grant two supplementary badger disease control licenses, arguing both were unlawful.	The challenge was dismissed.

Attempted proceedings/Judicial Reviews relating to Badger Culling in England

Date	Claimant / Grounds	Outcome / To Note
Nov 2013	Save Me Trust: Urgent challenge to extension of Gloucester cull period on grounds of ‘unreasonable decision’.	The court said the need for urgency was "not easy to see" so did not give the challenge urgent consideration.
2014	Human Society International v SSEFRA: seeking judicial review for lack of consultation and assessment.	Permission for a Judicial Review was refused.
2015	Save Me Trust v Natural England: challenging the decision to grant three badger cull licences in western Gloucestershire, western Somerset, and Dorset, arguing there was inadequate consultation and no reasonable grounds for culling.	Permission for a Judicial Review was refused.
Sept 2017	Save Me Trust: argued that authorisation of the cull was unlawful - it was not done under the Animal Health Act which provides for certain safeguards.	Permission for a Judicial Review was refused.
Aug 2018	Mr Thomas Langton: consultation on badger culling in the Low Risk Area was unlawful and the 2018 guidance falls outside the powers of the Protection of Badgers Act.	Defra must file their Summary Grounds by 27 September 2018.

Injunctions related to Badger Culling

Date	Summary
Sept 2012	Anti-badger cull website (www.badger-killers.co.uk (“BK.co.uk”) published the personal/work contact details of Defra Ministers and others linked to the proposed badger cull (with implicit incitement to harass them).TSOL obtained an emergency injunction which applies indefinitely and prohibits “Persons Unknown” (and others) from “publishing or disclosing or communicating (or doing or instructing or encouraging or causing or permitting any other person to publish or disclose or communicate) …by whatever means, the personal or work contact details of any person connected with the organisation of or implementation of the badger culls pursuant to the Secretary of State’s policy dated 14 December 2011.”

Chapter 3: Surveillance and diagnostics in cattle

Introduction

3.1. Bovine TB is an endemic notifiable livestock disease and a statutory surveillance and testing programme is in place in the UK in accordance with European and international legislation. This approach is based on the use of a skin test, supplemented in specific cases by the interferon gamma (IFNγ) blood test, to detect infected animals which are then slaughtered. This is combined with carcass inspection of all animals in slaughterhouses.

3.2. This chapter explores whether the current diagnostic and testing regime, underlying surveillance and removing the disease from infected herds, might be improved given advancing knowledge and greater regulatory autonomy after leaving the EU.

Rationale

3.3. An ideal test for a disease recognises every true case of infection and never misdiagnoses a healthy individual. Such tests do not exist for bovine (or human) TB and though this is an area of active research, surveillance and testing regimes have had to be designed using less-than-perfect tests, something that will continue for the foreseeable future.

3.4. Testing cattle and other livestock for the disease is challenging because of the nature of the pathogen and the interaction with its host. We summarise some of the background biology relevant to discussion of surveillance and diagnostics in Chapter 2. Test performance depends on the characteristics of the test used, its correct application and on the prevalence of the disease in the region or herd being tested.

3.5. Existing surveillance regimes underestimate the prevalence of the disease in cattle in England and this hinders control[13]. This conclusion is based on experimental studies using novel tests that are finding more infections than are revealed by the standard accredited tests, and a realisation that the performance of these tests under field conditions may be lower than expected based on their benchmark performance measured under standardised conditions.

3.6. All cattle that react positively to statutory skin or laboratory tests are slaughtered and examined visually for bovine TB lesions. Samples are collected from these animals and efforts are made to culture *M. bovis* from diseased organs or tissues likely to contain the bacterium. Diseased organs may also be examined under the microscope for signs of bovine TB. If *M. bovis* is cultured, then information from DNA genotyping is obtained to help establish the origin of the infection.

3.7. All tests for bovine TB in the UK are done under strict government control. Farmers and their veterinarians are prohibited from testing their animals unless under government authorisation. The reason for this is concern that infected or riskier

[13] Conlan *et al*. 2012 https://doi.org/10.1371/journal.pcbi.1002730

animals discovered by unauthorised testing may be traded to avoid the restrictions associated with a new breakdown being identified.

3.8. All cattle routinely slaughtered (1.26 million each year in England[14]) are examined visually for signs of bovine TB; typically, these are lesions found in the lungs and its associated lymph nodes, or lymph nodes around the head and neck. Where lesions are found, samples are taken and analysed as for test-positive animals. Of all herd breakdowns in the LRA, 40-50% are discovered in this way, though the sensitivity of this form of detection is thought to be relatively low (~50%)[15].

Current policy

3.9. In 2013, England was divided into three risk management areas that differ in terms of the prevalence and epidemiology of bovine TB: the HRA, the EA and the LRA, see Figure 1.1. From January 2018, following a public consultation, a number of changes took effect aimed at re-defining EA boundaries by incorporating as whole counties those that previously straddled the HRA and EA parts of England and increasing the frequency of TB surveillance for herds in the EA[16].

3.10. In the LRA, breeding animals in the majority of herds are tested every four years. Approximately 10% of herds in the LRA are tested annually because of their trading patterns (for example, purchases from the HRA), proximity to a breakdown with lesion or culture positive cattle (radial tests), or for public health reasons. Cattle in intensive indoor beef fattening units are not routinely TB tested. In the HRA, all cattle over 6 weeks old are tested annually (this will change to six monthly from 2020) while in the EA all cattle are tested six monthly or annually (depending on the levels of bovine TB). The SICCT test (¶ 2.24) is used throughout[17].

3.11. If one or more animals test positive (reactors) or are inconclusive, the status of the herd as Officially TB Free (OTF) is suspended (OTFS) and movements other than to slaughter or approved premises for rearing, fattening or finishing are prohibited. Reactors are slaughtered and occasionally other animals in the herd which are considered to be at high risk of bovine TB infection (direct contact animals) are also slaughtered. Inconclusive reactors are retested after 60 days. In rare cases, all the cattle in the herd may be slaughtered if the infection is severe or extensive. Farmers receive compensation for any animals slaughtered because of bovine TB. Testing is repeated at 60-day intervals until the herd is eligible to regain its OTF status.

3.12. If a subsequent test reveals other reactors, or if infection is found in slaughtered animals, then the status of the herd becomes Officially TB Free Withdrawn (OTFW).

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[14] APHA Bovine tuberculosis in England in 2017 (September 2018). https://www.gov.uk/government/publications/bovine-tb-epidemiology-and-surveillance-in-great-britain-2017

[15] McKinley et al. Risk factors and variations in detection of new bovine tuberculosis breakdowns via slaughterhouse surveillance in Great Britain. https://doi.org/10.1371/journal.pone.0198760

[16] http://www.tbhub.co.uk/tb-policy/england/expansion-of-the-edge-area-in-england-and-new-cattle-testing-arrangements/

[17] An overview of the current testing regimes can be found in APHA's 'Bovine tuberculosis in Great Britain in 2017: Explanatory Supplement to the annual reports' (September 2018) – https://www.gov.uk/government/publications/bovine-tb-epidemiology-and-surveillance-in-great-britain-2017

The severe interpretation (¶ 2.24) of the SICCT test is used for these follow-up tests. The herd is then tested at 60-day intervals until no reactors are detected in two successive tests and OTF status can be restored. The IFNγ test is used to supplement the SICCT test in all OTFW breakdowns in the EA and LRA, and in certain circumstances in the HRA where there is a high rate of cattle infection. From April 2017, the IFNγ test may be used alongside the skin test, to help resolve OTFW breakdowns with lesion and/or culture positive animals in the HRA, where any of the following three criteria are met:

(i) APHA concludes that the most likely bovine TB transmission route for the affected herd was contact with infected cattle and measures are in place to prevent further spread of the disease from this source.

(ii) The infected herd is located in one of the areas where at least two annual rounds of effective licensed badger population control have been completed.

(iii) There is clear evidence that repeat skin testing of the herd has failed to resolve a TB breakdown.

3.13. Infections in herds may also be detected other than through regular surveillance: for example, through private tests undertaken prior to movement of cattle out of herds located in the HRA and EA (discussed in Chapter 5 on risk-based trading); through targeted surveillance testing of herds contiguous to OTFW breakdown herds in the HRA and EA; radial tests in the LRA; or ad hoc tests following the detection of animals with suspicious TB lesions at routine slaughter. Once a reactor is identified then the OTFS and OTFW testing procedures described above come into play.

3.14. In line with EU legislation, only the bovine reaction of the SICCT test (see ¶ 2.24) is considered when interpreting the test results in animals intended for export to other EU countries. This rule recognises the reduced sensitivity of the SICCT test compared with that of the SICT test used on mainland Europe. This interpretation is referred to as the 'Intra-Community trade' interpretation, and is in line with Community legislation[18].

3.15. At present, the only testing allowed for bovine TB is ‘statutory testing’, meaning a skin test or any other diagnostic test approved by the Secretary of State[19]. Surveillance and breakdown testing is funded by government. Additional private testing carried out by private veterinarians is allowed at farmers’ expense (mainly pre- and post-movement skin testing, and pre-export skin testing) under a general authorisation. Compulsory post-movement testing in the LRA is generally paid for by the person who brings cattle into the LRA from higher TB risk areas. However, a government-funded whole-herd TB surveillance test can be used as a pre- or post-movement test if its timing makes it possible. Additional, unofficial private TB testing is possible but requires prior permission from APHA. The results of all additional tests must immediately be sent to APHA.

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[18] Council Directive 64/432/EEC.

[19] The Tuberculosis (England) Order 2014 (Statutory Instrument 2383/2014). http://www.legislation.gov.uk/uksi/2014/2383/contents/made

3.16. The complete slaughter of herds is used very sparingly in the LRA where standard skin tests and IFNγ tests fail to achieve a rapid resolution of a serious herd breakdown and APHA decides that infection is severe or extensive. Slaughter of whole herds is generally not considered a cost-effective strategy in the HRA and the EA where reinfection of replacement herds may occur from wildlife or from cattle bought from premises in the HRA or the EA.

3.17. In England and Wales, bovine TB testing is carried out by seven Regional Veterinary Delivery Partners (VDPs), commissioned by APHA. Each VDP is contracted to carry out bovine TB testing and disease outbreak response in cattle and non-bovine farmed animals across a defined geographical area. The VDPs chiefly use existing veterinary businesses to deliver services. APHA notifies VDPs of tasks and service requirements and the VDP is then responsible for ensuring that the work is completed either by subcontractors or their own official veterinarian (OV) staff.

3.18. Testing regimes in the DAs are similar, with minor exceptions. In Wales, herds in the Intensive Action Area (IAA) in south-west Wales are tested twice yearly as part of additional cattle controls in place in this high-risk area. Herds in the rest of Wales are tested annually. Scotland, which as a nation has OTF status, operates as if it were a LRA except that over half of herds are identified as ‘low risk’ and as such are exempt from four yearly routine herd testing and monitored through slaughterhouse surveillance only[20]. In Northern Ireland, all herds are tested annually, as a minimum requirement, but some are tested more frequently if they are considered at increased risk.

3.19. The RoI operates an annual testing programme for bovine TB using the SICCT test. All animals in the country are tested for bovine TB at least once a year (with the exception of calves under the age of 6 weeks born on the holding). The Irish programme also includes tests of herds contiguous to TB breakdowns. Ante and post mortem surveillance is carried out at slaughterhouses and detects a high percentage of all breakdowns.

Options for the future

3.20. Outside of the EU, the UK could decide not to carry out statutory testing with individual businesses paying for testing where required for export or if thought cost effective. Meat inspection and pasteurisation of milk would continue to protect public health. We have not considered this strategy further because we believe there is a significant threat of a major increase in the incidence and the prevalence of the disease in cattle. For example, there is clear evidence from the suspension of testing during the 2001 outbreak of Foot and Mouth Disease[21] that without the current surveillance systems there would be a rapid increase in bovine TB in England. This could pose additional risks to farmers and veterinarians and also

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[20] https://www.gov.scot/Topics/farmingrural/Agriculture/animal-welfare/Diseases/disease/tuberculosis/guidance

[21] APHA Bovine tuberculosis in England in 2016: Epidemiological analysis of the 2016 data and historical trends (September 2017) https://www.gov.uk/government/publications/bovine-tb-epidemiology-and-surveillance-in-great-britain-2016

spill over into other animals, including domestic pets with the risk of new routes of infection to humans.

Improving current testing and surveillance

3.21. We consider here the option of maintaining the current schedule of surveillance and testing while taking measures to improve its effectiveness.

3.22. Conducting a SICCT test involves comparing two immune responses (lumps) using callipers (¶ 2.24) and is open to a degree of subjective interpretation. Currently testers must successfully complete a formal training module every two years and carry out at least ten hours of relevant continuing professional development within the two-year cycle. Once the Livestock Information Service (see ¶ 5.29) is in operation and electronic data capture the norm, SICCT measurements using wireless-connected callipers, which automatically standardise the pressure used in measuring skin thickness, could be considered to reduce subjectivity.

3.23. Currently, APHA field audits are used to spot-check the testing performance of the OVs using a risk-based approach informed by test results, late test submissions, and local intelligence. It is possible to estimate statistically the number of positive tests that different veterinary practices are expected to find based on factors such as farm history and geographical region, a capacity likely to be enhanced by the Livestock Information Service and other initiatives discussed in this report. Systematic analysis of performance data to obtain information on testers that are finding unexpectedly more or fewer reactors could be used to target the inspection of testers, as has been successfully implemented in the RoI.

3.24. The use of 'lay-testers' for bovine TB is already allowed for tests carried out by APHA subject to quality control and training. Currently, EU rules do not allow lay-testers to be used by private practices. Specialised lay-testers are less expensive to employ than licensed veterinary surgeons and given the narrow margins on private sector contracts for statutory testing the use of dedicated specialists could provide improved service. Certification of lay-testers would remain with APHA and they would be subject to existing quality control and training measures.

3.25. We note that a very large proportion of Defra, APHA and private veterinarians employed to test for bovine TB are from continental Europe. Severe disruption of this labour force would pose a serious problem for disease control and we understand this is already on Defra's register of risks associated with leaving the EU.

3.26. The tuberculin used in the SICCT test is a complex mixture of proteins and notoriously hard to quality control. There is an OIE initiative to produce a new international standard for PPD-B (¶ 2.23) which has the potential to play an important role for future standardisation of tuberculin potency. Tuberculin quality could be assured or improved by supporting this initiative and through greater use of inspection visits at production sites, and potency assays.

3.27. The frequency with which a herd is tested depends on the risk area (HRA, EA LRA) within which it is located. There are no published criteria and mechanisms that allow these areas to be redefined as the disease geographically spreads or declines. The last changes to EA boundaries took effect from January 2018, following a public consultation exercise launched in August 2016[22]. Faster redefinition of risk areas based on criteria agreed in advance (without consultation every time) could greatly facilitate the adaptive management of the disease.

3.28. We discuss in Chapter 5 the development of farm-level risk scores for use in risk-based trading. The same scores could be used to determine testing frequency, especially in the LRA (an extension of current practice that takes into account trading history).

Improving surveillance and detection of M. bovis infected herds

3.29. A surveillance regime must balance the trade-off between diagnostic sensitivity and specificity (¶ 2.17). There is the option to use a more sensitive test (or combination of tests) that would detect more infected herds and animals within infected herds at the cost of some false positives. Understanding the costs and benefits of such a change is not straightforward because the detection of additional infected herds, or earlier detection thereof, would reduce onward cattle-to-cattle transmission and movement of infected cattle into other herds. The use of these tests would have the greatest value in the EA, the HRA and in emerging hotspots. In the LRA the benefits would be outweighed by the number of false positives.

3.30. Two options for a more sensitive surveillance test are:

(i) The single intradermal cervical tuberculin test (SICT test, ¶ 2.25) is thought to be more sensitive than the SICCT test, and its lower specificity could be mitigated by using the IFNγ test to confirm infection in positive reactor animals (i.e. as a serial test). Such a strategy would require the same number of farm visits but entail additional laboratory expenses.

(ii) The caudal fold tuberculin test (CFT test, ¶ 2.29) is more sensitive that the SICCT test and could be used as the primary surveillance test after the UK leaves the EU. It also has the advantage that it is quicker and safer for the veterinarian to perform. Before such a test could be used, field trials under English conditions would be needed to define test interpretation criteria.

3.31. The SICCT, SICT and CFT tests are known to underperform in animals suffering simultaneous infections. For example, another mycobacterium, *M. avium* subspecies *paratuberculosis*, the causative organism of Johne's disease, is known to complicate the interpretation of the tuberculin test. Replacing SICCT with another test (for example the 'high specificity IFNγ test' which uses specific *M. bovis* antigens, ¶ 2.26) in herds with known or suspected other infections would increase the detection rate of the disease though at an additional financial cost and administrative burden. Clear criteria of what constituted a simultaneous (intercurrent) infection would need to be developed.

3.32. At present, with few exceptions, the frequency of OTF herd testing in England is determined purely by whether a farm is in the HRA, the EA or the LRA. In Chapter 5 we explore the development of indices for the risk of infection of different herds,

[22] Defra consultation on enhanced bovine TB surveillance and controls in the High Risk and Edge Areas of England (August 2016) https://consult.defra.gov.uk/bovine-tb/enhancements-to-hra-edge/

and these indices could be used to determine testing frequency. Scotland already implements risk-based testing which takes into account whether a herd sends many animals to slaughter (where they are examined for infection) and their history of risk-based trading.

3.33. Pre- and post-movement testing could use the most sensitive test to reduce the risk of spreading *M. bovis* infection from one herd to another, particularly when cattle are being moved from the HRA to the LRA. This could be either the SICT (as for trade outside of the UK), or the IFNγ test. The latter is the more expensive test and would require additional laboratory capacity.

3.34. Recent research has shown that it is possible to use serological tests to detect the presence of antibodies to bovine TB in bulk milk[23]. Test sensitivity was low in these studies but if this could be increased and the test was scalable at reasonable cost, it could be used to identify infected dairy herds on a continuous basis and would complement existing surveillance testing.

3.35. About 40-50% of herd breakdowns in the LRA are detected through slaughterhouse surveillance. This could be enhanced by raising awareness of its importance with slaughterhouse workers, financial incentives for good practice and more frequent inspection. Quality assurance could be based on assessing reporting rates against levels predicted from risk areas and slaughterhouse throughput[24].

Increasing the efforts to remove infections from herds

3.36. Tools are available to increase the probability that an infection is removed from a herd that has been declared OTFW. This would benefit the farmer because the risk of a subsequent breakdown due to undiagnosed infections in the herd would be reduced. It would also have the industry-wide benefit of reducing disease spread. Against this, the extra testing would entail costs for the state or the business, and the OTFW status of the herd may be extended not only because more infected cattle are identified but because more false positives occur and are sent to slaughter.

3.37. There are several options to use tests with greater sensitivity than the SICCT:-

(i) The single intradermal cervical tuberculin test (SICT test, ¶ 2.25) has higher sensitivity but lower specificity.

(ii) The caudal fold tuberculin test (CFT test, ¶ 2.29), is also thought to have higher sensitivity but lower specificity than the SICCT test.

(iii) The IFNγ test (¶ 2.26) has higher sensitivity but lower specificity compared to the SICCT test and could be used in all herd breakdowns rather than the more targeted ways in which it is employed at present. This test also has the advantage that it detects animals at an earlier stage of the disease and so its use will identify and remove animals at an earlier stage of disease progression thereby reducing the chance of onward transmission.

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[23] Waters *et al*. 2011 https://doi.org/10.1128/CVI.05343-11

[24] McKinley *et al.* 2018 https://doi.org/10.1371/journal.pone.0198760

(iv) Combining the skin test, the IFNγ test and the IDEXX ELISA serological test (¶ 2.31) to maximise sensitivity, as each test detects some infected animals than the other tests miss. The costs of testing would increase, but this approach might be particularly useful to clear persistent and recurrent herds, herds in the HRA post-cull, the EA and emerging hotspots in the LRA.

(v) There are a variety of new tests under development and active research in this area for both human and bovine TB. Facilitating the validation of promising tests and designing testing regulations so that they can utilise new technology swiftly as soon as they have been validated and accredited is important.

3.38. Animals that test inconclusive to the SICCT test are tested again after 60 days when about 10% are confirmed as reactors[25]. Epidemiological studies of 'resolved' IRs in a high bovine TB prevalence country like the RoI have demonstrated that such animals have significantly higher odds of becoming reactors at a subsequent test in the same or another herd[26,27]. Sending all inconclusive cattle to slaughter would reduce the chance of infection spreading in the herd and to wildlife but would increase compensation costs at least in the short term.

3.39. A more stringent criterion for herds to be declared OTF would be to require two tests, 60 days apart, for OTFS to be removed and three or four tests for OFTW to end. The increased chance of herds being truly free from bovine TB would need to be weighed against the additional costs for the farmer and government. In the final stages of Australia's eradication programme four or five successive negative whole-herd tests were required for disease-control measures to be removed.

3.40. Farmers are not generally allowed at present to conduct additional tests during a herd breakdown, even at their own expense (¶ 3.7). Some farmers would like to employ additional tests (ELISA, Actiphage or PCR, Chapter 2) to accelerate the removal of infected individuals and to better manage within-herd transmission. Because these tests have lower specificity, their use would be discouraged if all positive animals were sent to slaughter. The use of alternative tests could be allowed during breakdowns (with reactors statutorily notified but not necessarily slaughtered) with the herd remaining OTFW until it passed the normal two tests. To participate in this programme farmers would need to apply for and achieve 'earned recognition' status.

3.41. There is evidence to suggest that faecal shedding by cattle plays an important role in the transmission of *M. bovis*[28] and the development of PCR assays (¶ 2.32) to detect animals that are shedding bacteria in their faeces are showing promise though more information is needed on their sensitivity and specificity. If these tests were scalable at reasonable cost, they could be used to complement existing surveillance testing.

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[25] https://www.gov.uk/government/publications/bovine-tb-epidemiology-and-surveillance-in-great-britain-2017
[26] Clegg, T. A. et al. (2011) https://doi.org/10.1016/j.prevetmed.2011.02.015
[27] Clegg, T. A. et al. (2011) https://doi.org/10.1016/j.prevetmed.2011.07.014
[28] McCallan, McNair and Skuce (February 2014). A review of the potential role of cattle slurry in the spread of bovine tuberculosis. https://www.daera-ni.gov.uk/sites/default/files/publications/dard/tb-slurry-lit-review.pdf

3.42. Sometimes infection cannot be cleared from a herd and all animals are culled and compensation paid. This option could be used more frequently to deal with intractable breakdowns, although with very major consequences for the farms involved. Examples of such a case might be breakdowns involving multiple reactors in the LRA caused by high-risk trading, or long-term persistently infected herds.

3.43. After infection is diagnosed in individual cattle, they are kept on farm for a period of up to ten working days before going to slaughter. Reducing this maximum period and mandating their isolation from the rest of the herd would help prevent disease spread, though at costs for both government and the farms involved. To be effective, facilities must be available adequately to isolate cattle and to ensure this would require inspection (see also Chapter 8).

3.44. There is evidence that in rare cases farmers actively break the law in order to increase compensation paid to them during breakdowns, either by manufacturing positive SICCT tests or by changing ear tags so that poorly performing cows are slaughtered and good milkers are retained (though the introduction of DNA ear tags has helped to mitigate this). The latter but not the former will tend to increase disease spread. In ¶ 5.47 we discuss micro-chipping cows, an intervention that would also be helpful in preventing these types of fraudulent activity.

Special issues of new foci of infection

3.45. Herd breakdowns occur sporadically in the LRA and occasionally these turn into foci of infections with a number of neighbouring farms infected and evidence of transmission to wildlife. An example of this is the focus in East Cumbria which began in cattle in 2014 with infections recorded in badgers from 2017 (and which genetic analysis showed was linked).

3.46. Irrespective of decisions made to enhance removal of infections from herds throughout the LRA, the imposition of enhanced measures around developing foci should be considered (see also ¶ 6.36. for control in wildlife).

3.47. For this to work, it must be possible to identify foci and impose a stricter regime quickly. Thus consultation on this strategy should be done in advance and on the principle of the approach, not for each focus identified which would cause delay.

3.48. Whole-herd slaughter is currently used sparingly in the LRA and there is a clear argument against its use in other areas (¶ 3.16). However, it could be used more frequently in the LRA; for example, when there is clear evidence of multiple infections in a herd associated with risky or reckless purchasing behaviours.

Testing and epidemiological intelligence

3.49. Genetic analysis (genotyping) of *M. bovis* has traditionally relied on analysis of restricted regions of variable DNA allowing the identification 'spoligotypes' (a category of genetic variants) and VNTR (variable number of tandem repeat) types. Using a combination of these methods, genotypic analysis can sometimes identify the source of a new focus of infection (for example, genotyping showed that a recent outbreak in East Cumbria probably originated from cattle bought from

Northern Ireland). The cost of sequencing the whole genome of *M. bovis* is decreasing and this allows much more insightful epidemiological investigations for a similar cost. Whole-genome sequencing could be employed routinely to aid epidemiological investigation and control. The greatest benefits would be gained by sequencing a series of isolates from farm breakdowns that persist over several testing cycles, and for multiple isolates to be sequenced in larger breakdowns.

Research & development priorities

3.50. The absence of a cattle test with both high specificity and sensitivity is probably the single greatest barrier to effective disease control. The last few years have seen new tests proposed which are currently in the early stages of commercialisation. There is also a fruitful read across from work on human TB diagnostics. Research and development to characterise the performance of novel tests and explore new options is, we believe, of high priority. Discussions and exploration of novel tests is also hampered by the lack of high-quality data on the true performance of currently available tests in cattle in the UK and filling this evidence gap is, we believe, also a high priority. Such data would facilitate the quantification of the likely costs and benefits of the different testing regimes we explore.

3.51. The establishment of a repository (biobank) of bovine material would greatly assist research and development of new tests. For example, where whole herds are slaughtered and each animal has been multiply tested (SICCT, IFNγ, post mortem inspection and culturing), the retention of material (such as blood sera, peripheral blood mononuclear cells and faeces) would provide a standard sample set to validate future diagnostic tests.

3.52. Further from application are novel approaches to bovine TB detection based on bacterial metabolites and other biomarkers present in cattle blood, breath or faeces. More fundamental research in this high-risk/high-reward area (of the type appropriately funded by Research Councils) is, we believe, justified.

3.53. As discussed in Chapter 4, vaccination using the standard BCG vaccine precludes the normal use of the SICCT test. This has led to the search for other antigens that reveal the presence of an immune response to *M. bovis* but not BCG (so called DIVA – differentiating infected from vaccinated animals – tests). Recent advances in high-throughput molecular biology screening techniques have facilitated this search with promising candidates for skin (like SICCT) and blood (IFNγ) tests. Further research in this area is recommended.

3.54. Development and validation of new diagnostic tests require access to materials and samples from infected farms. Such access is currently restricted by notifiable disease legislation which risks hindering bovine TB control and the development of new commercial products for the international market. Altering the legislation so that it eased the provision of research material while maintaining appropriate levels of biosecurity would be helpful.

3.55. A far better understanding of the excretion and modes of transmission of *M. bovis* between cattle and other species, including the importance of environmental contamination via slurry is needed as a priority. Testing biobanks as described above and sample sets from infected farms to address this evidence gap is a further priority.

Chapter 4: The disease in cattle: Vaccination and resistance

Introduction

4.1. The spread of bovine TB can be reduced by increasing the resistance of cattle to infection by M. bovis. Two, not mutually exclusive, ways to do this are through vaccination or by breeding for increased resistance to infection. We discuss vaccination in wildlife in Chapter 6.

4.2. Vaccination is an important means of preventing infectious diseases that cannot be eradicated in other ways, and in principle this is true of bovine TB in cattle. A vaccine similar to that used for human TB was first trialled in the 1920s and, though it provided some limited protection, it was viewed as a less effective control measure than test and slaughter which became the main control strategy in the 1950s. Because the test used could not distinguish between vaccinated and infected animals, vaccination was discontinued and subsequently made illegal under UK and EU legislation.

4.3. There is evidence that cattle vary genetically in their susceptibility to bovine TB and, once infected, there may be genetic variation in their propensity to spread the infection to other animals. It is thus possible to select for better disease susceptibility and transmission traits as part of cattle breeding programmes.

Rationale for vaccination and breeding for resistance

Vaccination

4.4. The bovine TB vaccine used to date is the Bacillus Calmette-Guérin (BCG) vaccine, the same as that used against human TB. It is prepared from weakened and no longer virulent strains of *M. bovis*. The precise characteristics of a batch of vaccine can be influenced by the strain from which it was derived and how it is processed. Though developed at the beginning of the 20th century, early studies of BCG vaccination provide only limited information about its effectiveness because of variation in vaccine type, dose and delivery, as well as shortcomings in experimental design.

4.5. More systematic studies over the past 25 years have shown that calves are best vaccinated at 2-4 weeks and then revaccinated every 1-2 years to maintain immunity (earlier revaccination can be counterproductive). Optimum dose and comparative BCG strain characteristics have been established.

4.6. Field studies of effectiveness in Ethiopia[29] and Mexico[30] (where local disease prevalences are high) have shown vaccinated cattle are between 30-60% less likely

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[29] Ameni *et al.* 2018 https://doi.org/10.1111/tbed.12618
[30] Canto Alarcon *et al.* 2013 https://doi.org/10.1371/journal.pone.0076418

to contract the disease. If a vaccinated animal becomes infected then disease progression is reduced (fewer and less severe lesions). Experiments in New Zealand where some animals were vaccinated in herds containing reactor-positive cattle (and in the presence of infected wild possums) have shown that the degree to which vaccination reduces infection is in the range of 67-77% depending on how the vaccination was carried out and the age at which the animal was slaughtered and the disease assessed[31].

4.7. If an animal is already infected by *M. bovis* then subsequent vaccination does not alter the course of the disease.

4.8. There is active research on improved BCG vaccines (for both human and animals) and on how to use existing vaccines; for example, on the benefits of intravenous versus subcutaneous injection. Bovine TB control strategies should be flexible enough to make use of these new advances, should they occur.

4.9. A major issue is that BCG vaccination is incompatible with a policy of test and slaughter. Up to 80% of calves that receive the BCG vaccine react to the SICCT (see ¶ 2.24) test 6 months later. Reactivity decreases to 10-20% after 9 months and may disappear completely after 18 months[32]. If the CFT test is used (see ¶ 2.29) 24% react positively 6 months after vaccination though similar levels of false positive reactions between vaccinated and unvaccinated animals are observed after 12-18 months[33].

4.10. A DIVA (differentiating infected from vaccinated animals) test would allow infected animals to be distinguished from those that have been vaccinated. A DIVA test is available based on the IFNγ test using antigens that are not present in BCG[34]. This is also used to diagnose TB in humans. The same antigens are now being used to develop a DIVA skin test[35]. Hence, this is an area of active research and there is a reasonable likelihood of further progress in the medium term. In our view progress on a DIVA test is more likely than the development of a markedly better vaccine.

4.11. A manufacturer for both BCG and a DIVA test will also need to be identified and supplies secured before roll out of vaccination is possible. The licensing process, including testing the safety and efficacy of the vaccine under field conditions, also needs to occur.

Resistance

4.12. Single bulls sire many cows and the probability that their daughters become infected by bovine TB (recorded in APHA databases) can be used to estimate their value in passing on resistance traits. Genetic analysis can then identify genetic markers associated with resistance that can predict the performance of individuals.

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[31] Nugent *et al*. 2017 https://doi.org/10.1016/j.vetmic.2017.07.029

[32] Whelan *et al*. 2011 https://doi.org/10.1016/j.vaccine.2011.05.057 Moodie 1977 Tuberculin reactions in BCG. *British Veterinary Journal,* 133, 642-645.

[33] Parlane *et al*. 2014 https://doi.org/10.1371/journal.pone.0106519

[34] Vordermeier *et al*. 2016 https://doi.org/10.1016/j.vetimm.2016.02.003

[35] Jones *et al.* 2012 https://doi.org/10.1128/CVI.00024-12

4.13. Research by the Roslin Institute (Edinburgh) and Scotland's Rural College (SRUC) has used data on the bovine TB infection status of over 650,000 Holstein cows to identify additive genetic variation in bovine TB resistance. They found resistance to have a heritability of about 9% which is sufficient for the trait to be incorporated in selection programmes for all dairy cattle breeds alongside other production-oriented breeding criteria. Work is currently underway to establish a similar index in beef breeds.

4.14. Improving resistance is a long-term project and not a substitute for interventions that produce quicker results. There is a possibility that *M. bovis* itself evolves to counter selected resistance traits. There is no evidence that improved resistance is negatively correlated with other desirable traits (such as resistance to other diseases or production indices) but this should be considered and monitored.

4.15. Current genetic indices are constructed using data on whether animals react positively to the SICCT test during herd breakdowns. There is a risk that the index may in part reflect the ability to avoid reacting to the skin test, rather than genuine resistance to infection. Further research on the biological mechanism underlying resistance and the role of genes identified by the genetic analysis will be important in excluding this possibility.

4.16. Investigating genetic variation in bovine TB infectivity could help in identifying opportunities to accelerate the reduction of breakdown risk and severity. This would be more challenging than studying resistance as the trait (the propensity to infect other animals) is much harder to measure.

Current policy

Vaccination

4.17. Neither BCG nor any other vaccine is licensed for use in cattle in the UK or the EU. APHA has applied for the licence from the regulator, the Veterinary Medicines Directorate (VMD), necessary for BCG to be used if cattle vaccination were to be permitted. APHA is now addressing specific requirements needed for this approval, including developing protocols for field trials. Since 1998, Government has invested about £40 million into the development of a cattle vaccine for bovine TB and DIVA tests.

4.18. Permission to vaccinate within the EU requires European legislation to be amended. In 2012, the British Government formally approached the European Commission asking for a time schedule for a vaccination strategy to be approved and then implemented through legislation. In its response in January 2013, the European Commission set out a tentative timeline for bovine TB vaccination of cattle in the UK and EU, showing the series of steps that would be needed; including, scientific and veterinary debate on the conditions for use of vaccine, and marketing authorisation procedures. The Commission indicated the necessity of field trials to assess efficacy and safety under European production conditions, and recommendations on the design of suitable field trials were prepared by the European Food Safety Authority[36]. However, to obtain sufficient statistical power

[36] https://doi.org/10.2903/j.efsa.2013.3475

using this approach would likely require, given the prevalence of bovine TB in England, large-scale field trials which might involve 500 farms over 2 years[37]. This may be unfeasible and equivalent information might be obtained more easily using vaccination and challenge experimentation with approximately 200 individual animals.

Resistance

4.19. AHDB Dairy launched 'TB Advantage' in January 2016. This is an index of the degree of resistance to bovine TB that any particular bull is likely to pass on. The index runs from -3 to +3 and if a bull has a score of *x* then *x*% fewer of his daughters are predicted on average to become infected during a breakdown. The score is based on the observed performance of established bulls that have sufficient daughters in the national herd exposed to bovine TB. In addition, for Holstein cattle, genetic analysis (¶ 4.12), allows a score to be given to young bulls or cows that have been genotyped (the index in this case is a little less reliable). Resistance is weakly positively correlated with other traits that farmers use in breeding and hence resistance may have been under recent indirect selection.

4.20. In March 2018, AHDB Dairy announced that they will be partnering with SRUC to embark on two new projects, one in dairy and the other in beef, aimed at further advancing a national database of genetic evaluations and a new genomic prediction tool. This would enable more farmers to identify natural resistance traits and make informed decisions about which cattle they choose to breed, depending on their resistance to bovine TB. The diversity and number of different beef breeds (and their relatively small population size) makes progress in beef genetics the more challenging.

Options for the future

Maintain current vaccination policy

4.21. We interpret the maintenance of current policy as working to obtain approval for BCG vaccination within the rules of the EU, even after the UK leaves the EU. There is considerable uncertainty about the precise testing hurdles that will need to be overcome and the time this will take, and indeed whether either addressing them, or producing a vaccination and testing programme that is cost-effective for farmers to use, is actually possible. Success and speed of progress will also depend on the level of investment in this development work.

Maintain current breeding for resistance policy

4.22. The uptake of TB Advantage is a good example of an industry-led initiative embraced by farmers. Extending the genetic analyses to other breeds is likely to be valuable. Dairy farmers are strongly focused on genetic selection for yield and milk quality as part of the regular process of selecting bulls for artificial insemination. The inclusion of data on TB Advantage on bull reports may encourage farmers to consider other measures that can be taken to protect their cattle against bovine TB, alongside the choice of bull.

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[37] Conlan *et al* 2018 https://doi.org/10.7554/eLife.27694

4.23. Uptake of TB Advantage could in principle be incentivised by including its use in indices used in risk-based trading, insurance or compensation (see Chapters 5 and 8). However, breeding for disease resistance has most value in the long-term so its recent use by a farm may not make a very large difference to a statistically derived index. Crediting herds for using TB Advantage through supermarket or other accreditation schemes that take into account industry-wide benefits is likely to be a better approach.

Deployment of a BCG vaccine

4.24. After the UK leaves the EU, the existing BCG vaccine could be licensed before a DIVA test is validated and licensed. Some preparatory experiments and field trials would be required to address safety and other issues in order to obtain a marketing authorisation licence from VMD.

4.25. The BCG vaccine could be deployed in a variety of ways, and exactly how best to do so would require detailed feasibility studies including epidemiological and economic modelling. One option would be to deploy BCG in higher risk areas (the HRA with or without the EA) and cease current SICCT testing to avoid the costs of increased testing required when vaccinating. Alternatively, animals could be tested just prior to vaccination and then retested again just before revaccination (when the masking effect of BCG would have largely waned, although false positives would still likely occur in larger herds). Thus, testing continues but at a lower frequency than currently in high risk areas with the likelihood of a greater number of false positive reactors. The relationship between vaccination and movement rules would need to be defined. It would not be advisable to allow untested vaccinated animals to be moved to lower risk areas.

4.26. Full details of vaccination would be recorded on the Livestock Information Service (LIS) database (see Chapter 5). Work would be required to determine how the current and past vaccination status of an individual animal or herd would affect risk scores used in risk-based trading or for other reasons.

4.27. Given our current knowledge base there are clear risks in reducing testing and surveillance in favour of vaccination. Close monitoring of disease prevalence, in particular through stepped up post mortem checks to determine the efficacy of vaccination, would be needed.

4.28. The introduction of vaccination would likely impact trade. Trading partners would almost certainly put restrictions on the export of vaccinated animals and possibly on dairy products. If current surveillance programmes were modified, they may not be judged effective enough to allow products to be traded safely internationally. Engagement with the OIE and the regulatory authorities of potential trading partners would be important from the design stage.

4.29. Until the costs of vaccination and its effects on trade and business practices are understood, it is not possible to analyse the economics of vaccination. A careful analysis of its costs and benefits would of course be very important before implementing vaccination and can also guide the value of further investment in this intervention. However, given the probable costs involved, it seems unlikely that farmers would elect to vaccinate and hence a vaccination strategy would need to be compulsory or heavily incentivised. Incentives might include more positive scores on animal or herd risk indices, or the reduction or removal of compensation for unvaccinated animals.

Deployment of a BCG vaccine with DIVA test

4.30. Outside of the EU, the existing BCG vaccine could be licensed and a DIVA test used in surveillance. There are several DIVA test options that could be used immediately; for example, one based on the IFNγ test. Alternatively, given this is an area of particular active research, concentrated investment could be made in optimising a DIVA skin test for deployment in a few years. Any DIVA skin test would need to go through safety and efficacy assessment supervised by VMD under the regulatory arrangements in place after the UK leaves the EU.

4.31. The benefits of vaccination in combination with a DIVA test are greatly influenced by the DIVA test characteristics and costs; a small change in specificity will markedly affect the reduction in breakdown and reactor numbers. This makes further validation work on the DIVA skin test a priority in order to better understand the potential benefits of deploying cattle BCG vaccine. The increased or additional testing likely required in vaccinated cattle may incur substantial costs and could be a major determinant of any economic benefit of vaccination.

4.32. As with deployment of the BCG vaccine alone, this option could be implemented in different ways and detailed feasibility studies would be required prior to implementation. Similarly, engagement with the OIE and trading partners would be important.

Targeted vaccine deployment.

4.33. Instead of blanket vaccination throughout higher risk zones, a strategy of vaccination, or vaccination combined with a DIVA test, could be targeted at critical areas of infection. For example, farms in the EA could be vaccinated, or ring vaccination deployed around clusters of infected farms.

4.34. The same issues of validation, licensing and effects on trade discussed above would also apply to targeted vaccination. Because fewer farms are affected, the effects of any restrictions on trade in animals or animal products would be reduced and less costly to compensate. However, the effects on trade and business for the farmer are likely to be substantial requiring a mandatory programme which in the absence of a stronger evidence base for its value would be unpopular. Engagement with trading partners in advance to understand their response to this intervention would obviously be important.

Research & development priorities

Vaccination

4.35. The major research priority in the broad field of vaccination is the validation and licensing of a DIVA skin test that can reliably and economically identify vaccinated cattle that have become infected. This has the additional and independent benefit of potentially producing a test that is better than the century-old tuberculin-based skin testing approach still used internationally.

4.36. A better vaccine than BCG has proved hard to identify for humans (though some encouraging progress has been made recently) and may be equally hard to find in cattle, making investment in developing better cattle vaccines somewhat speculative. Instead, it may be more profitable to pursue approaches associated with improved BCG efficacy, including the feasibility of intravenous vaccination which has showed improved protection over subcutaneous vaccination against strains of human TB (*M. tuberculosis*) in non-human primates. Should better vaccines be developed for human TB, then the efficacy of these vaccines in cattle should be determined.

4.37. We have an imperfect understanding of the economics of vaccine deployment, farmer attitudes and acceptance of cattle vaccination, and the response of consumers to products derived from vaccinated animals. Research in the social sciences will be valuable in addressing these gaps.

Resistance

4.38. Continued genetic analysis of resistance in multiple cattle breeds to enhance the value of the TB Advantage score will be valuable, enhanced if data can be shared with RoI and Northern Ireland and likely assisted by the LIS. Research to ensure that true resistance and not test avoidance is being identified and selected for is important.

4.39. Researchers in China have recently used genome editing tools to alter a gene in cattle involved in fighting infection, producing some early evidence that the resulting transgenic cattle may have increased resistance to *M. bovis* infection[38]. Carrying out gene editing in cattle will almost certainly become easier in the next few years and, as we learn more about the genetic basis of resistance in cattle (and humans), the opportunities for using this technique to improve resistance will increase. Gene-edited organisms are currently considered genetically modified organisms (GMOs) in Europe but (depending on the precise alteration) not in the USA or Japan.

4.40. None of the national epidemiological bovine TB models currently incorporate genetics. New models that include genetics will be valuable to predict changes in bovine TB prevalence in England over time resulting from genetic improvement alone and in combination with other control strategies.

[38] Gao *et al.* 2017 https://doi.org/10.1186/s13059-016-1144-4

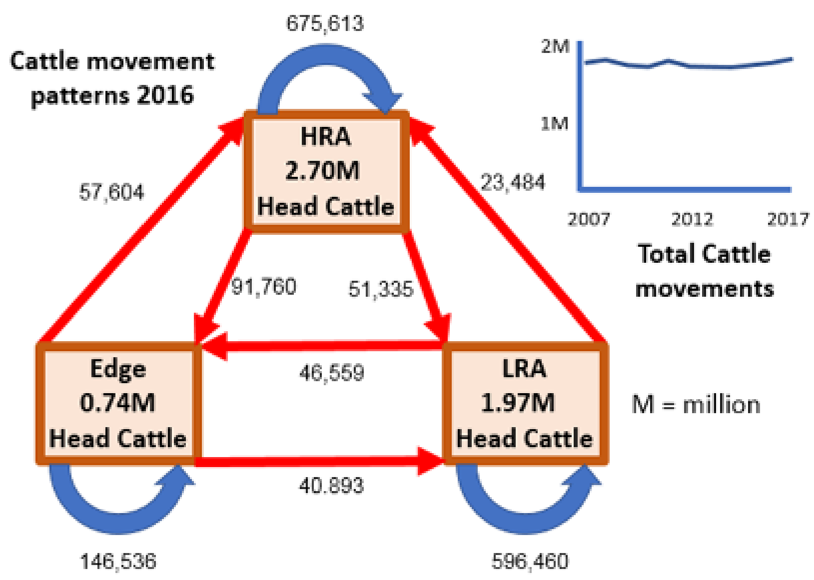
Chapter 5: Cattle Movements and risk-based trading

Introduction

5.1. Movement of infected cattle onto previously uninfected premises is a significant source of spread of bovine TB. This risk is partially mitigated by pre-movement testing of cattle (compulsory since March 2006 throughout the EA and HRA for cattle over six weeks old), though this does not identify all infected individuals. Since April 2016, post-movement testing is compulsory in the LRA for cattle moved from other areas of England and from Wales.

5.2. There were just under 5.5 million cattle on agricultural holdings in England in December 2016. Excluding cattle sent to slaughter (directly or via approved finishing units), which would not spread the disease, a little over 1.7 million cattle were moved within and between different risk areas in England in 2016. Movements between non-contiguous parts of a single farm business, which may be some distance apart, are not included in this figure (see also Chapter 8). This number of movements has remained broadly similar over time and includes substantial numbers moving from higher to lower risk areas (Figure 5.1). Even if a small fraction of the animals that are in transit is infected, the very large number of movements suggests this could be a potentially important source of new infections.

Figure 5.1: Cattle movements in England in 2016



5.3. Cattle movements occur for a number of reasons. Farms often specialise in different stages of the production process: calf rearing, growing, finishing for beef, and milk production. This specialisation and consequent improved industry efficiency requires movement between farms with some cattle moving through multiple farms over their lifetime. Modern farming increasingly monitors the performance of individual dairy cows with low producers being sent to slaughter and replacements being bought in (18-35% of dairy cattle are typically culled from herds each year)[39]. Contracts to supply milk may specify fixed supply amounts incentivising farmers to replace quickly animals that are poorly performing or have died.

5.4. The trading patterns of cattle are dynamic, showing seasonal variation with complex relationships between regions and farm enterprises. Approximately 45% of cattle are traded by direct purchase between farms with the rest bought through markets[40]. Live auctions bring together hundreds of cattle from a wide regional catchment. The geographic direction of cattle movements is generally from the west of England to the east. One reason for this is that crops for cattle feed are better grown in the east and it is cheaper to transport cattle to the feed once rather than continuously to move large volumes of feed to the animals.

5.5. Around 20-30,000 live animals are imported each year from the RoI and other parts of northern Europe; mainly female animals going to dairy herds as replacement stock.

5.6. An unknown but likely small proportion of movements will be of known or suspected infected animals, moved to avoid detection. Since 2011, cattle testing positive for bovine TB are DNA tagged to help discourage fraud. The Animal Health and Veterinary Laboratories Agency (AHVLA) found a significant reduction in the numbers of double replacement ear tags being ordered after DNA tagging was introduced suggesting the existence of previous illegal activity.

Rationale for risk-based trading

5.7. In principle, farmers will want to avoid purchasing cattle that are at risk of introducing bovine TB into their dairy or beef herds – that is, they will practice risk-based trading. Simplistically, the farmer will weigh the future financial costs of a breakdown in determining whether or not to purchase an animal with a particular risk profile and if so at price, and this will mean that higher risk cattle are cheaper. There is, however, a possibility that the low price will lead to irrational purchases. In general, the actual behaviour of farmers can be more complicated than a simple rational model predicts and can be affected by attitudes of resignation amongst some farmers regarding their likelihood of avoiding the disease (fatalism)[41].

5.8. There are several reasons why the market may fail to maximise both private and public benefit through current trading practices. For example, the purchaser may have imperfect information about the risk status of an animal at a livestock market. There is of course an incentive for the seller to provide evidence that an animal is at low risk of carrying an infection but no incentive to disclose any information of the opposite. In general, the seller has more knowledge about the animal than the purchaser which leads to an information asymmetry. The provision of more accurate information, particularly at point of sale, would enable risk-based trading. There is an extensive economic literature about the theory of markets in the

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39 https://dairy.ahdb.org.uk/technical-information/animal-health-welfare/cow-culling/#.W6EFD5UUn-c

40 Little *et al*. 2017 http://dx.doi.org/10.1136/vr.103522

41 Cabinet Office Behavioural Insights Team (2017).

presence of information asymmetry and when low-risk sellers should abandon markets for private sale arrangements.

5.9. In addition, not all the costs of a herd breakdown are borne by the individual farmer. First, the farmer is partly compensated for losses. Second, any herd breakdown hinders efforts to control the disease with costs to all farmers while the introduction of the disease to a new area may affect many farms beyond the one involved with the purchase. Restrictions on trading, though they may economically hurt the individual farmer, have wider industry and national benefits. On the supply side these restrictions can include rules forbidding animals from infected or high-risk herds being sent for sale; on the demand side they can include reductions in compensation for reactors that occur on premises that have bought high-risk cattle. Though the latter does not resolve the problem that a farmer's purchasing decisions will only include the costs to their own enterprise (in economics jargon it does not make them internalise the externality), it does increase the costs of risky behaviour to their own business and hence should result in improved practices.

5.10. There is some evidence that a small minority of farmers deliberately send to market animals that they fear may prove positive at the next routine bovine TB test, or swap ear tags to hide infection status. Irrespective of whether this is more than a rare event, the belief that it may occur undermines trust in risk-based trading. Measures to prevent fraudulent trading thus have both a direct and indirect benefit.

5.11. Different types of information can be made available to the farmer at purchase (at ring-side or through a database). Perhaps the most straightforward are: (i) the number of years the herd from which the particular animal is derived has been OTF, or (ii) whether in England the herd is in the HRA, the EA, or the LRA. More sophisticated scores are possible based on more detailed information about the herd's risk factors. Information on every individual bovine animal in the country is held on the Cattle Tracing System (CTS) database maintained by the British Cattle Movement Service (BCMS) and it would also be feasible to derive a risk-score for individual animals that would incorporate their complete history of movement and testing. Information to allow risk-based trading might be provided voluntarily or mandated by the state.

5.12. Modelling the effect of risk-based trading is difficult and requires a variety of different assumptions to be made. A recent study estimated that a voluntary scheme might reduce the number of infected animals traded by 23% (90% CI 22% - 25%) and a statutory scheme by 37% (90% CI 35% - 39%)[42]. While changing the assumptions will affect the exact estimates we suspect the qualitative conclusions from this study are likely to be correct.

5.13. There is broad industry support for risk-based trading, though also some concerns. First, the provision of information at the herd or animal level to allow risk-based trading is an administrative burden for the farmer. Second, some of the risk of infection can be captured by geographic location, the basis of the HRA, EA and LRA classification. Interventions that explicitly or implicitly limited trade between high and low risk areas might lead to two wholly or partially disconnected markets with lower prices in the HRA. A cow on a farm in the HRA that had never had a

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[42] Adkin *et al.* 2016 doi: http://dx.doi.org/10.1016/j.prevetmed.2015.11.021

breakdown would be worth less than an equivalent animal in the LRA (which might have come from a farm that conducted high-risk trades), something that has been described as unfair. A survey of farmers found more support for risk-based trading in the LRA compared to the EA and HRA (which reflects comparative benefits) and for compulsory over voluntary approaches[43]. The lack of support for risk-based trading in the HRA also reflects a belief amongst many farmers that cattle movement is not a significant risk compared to infection from wildlife.

5.14. In May 2013, the industry-led Bovine TB Risk-Based Trading Group recommended the introduction of an (initially) voluntary risk-based trading system supported by a comprehensive, accessible animal-level database providing access to a range of TB risk factors such as movement history, testing history, background prevalence of disease, as well an overall risk rating. It argued for a range of provisions to be introduced more quickly in advance of the database being completed. Defra's 2014 bovine TB Strategy emphasised the importance of risk-based trading and since then a number of measures have been introduced or subject to consultation.

5.15. Risk-based trading has been implemented in several countries:

(i) A statutory scheme ran in Australia from 1970 to 1997. This classified disease risk at the regional level and at the herd level. Regulations specified which herds in each area were free to move to which regions.

(ii) In New Zealand all cattle herds are classified to reflect their TB status. There are three categories: clear, infected or suspended. For example, a herd with a status C6 has been clear of bovine TB for six years, whereas a herd with I9 has been infected for nine years. Suspended status means that the disease is suspected. A herd's bovine TB status can also change to suspended due to receiving stock from an infected herd. Bovine TB status is employed extensively by New Zealand farmers, though its use and interpretation are influenced by local conditions and the degree to which farmers feel empowered to affect their risks of infection[44].

(iii) In the USA, individual states are assigned an accreditation level based on disease prevalence. This determines the testing and other requirements needed to move cattle to another state. Cattle from a state that is accredited as bovine TB free may be moved to another state without restriction; animals from states that are not accredited as bovine TB free must come from accredited herds, or complete specified testing requirements in order to be permitted to move. Owners can achieve accredited bovine TB free status for their herds by following prescribed testing procedures and strict record keeping.

(iv) In the RoI information is available at livestock markets via the Animal Identification and Movement (AIM) database. Prospective buyers are able to see the date of the last bovine TB test for an animal on the display board over the ring at the time of sale. The provision of such data is mandatory.

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[43] *Farmers' attitudes to a risk based trading scheme for cattle in England,* ADAS UK Ltd. (2012)
[44] Enticott 2016 https://doi.org/10.1016/j.jrurstud.2016.04.008

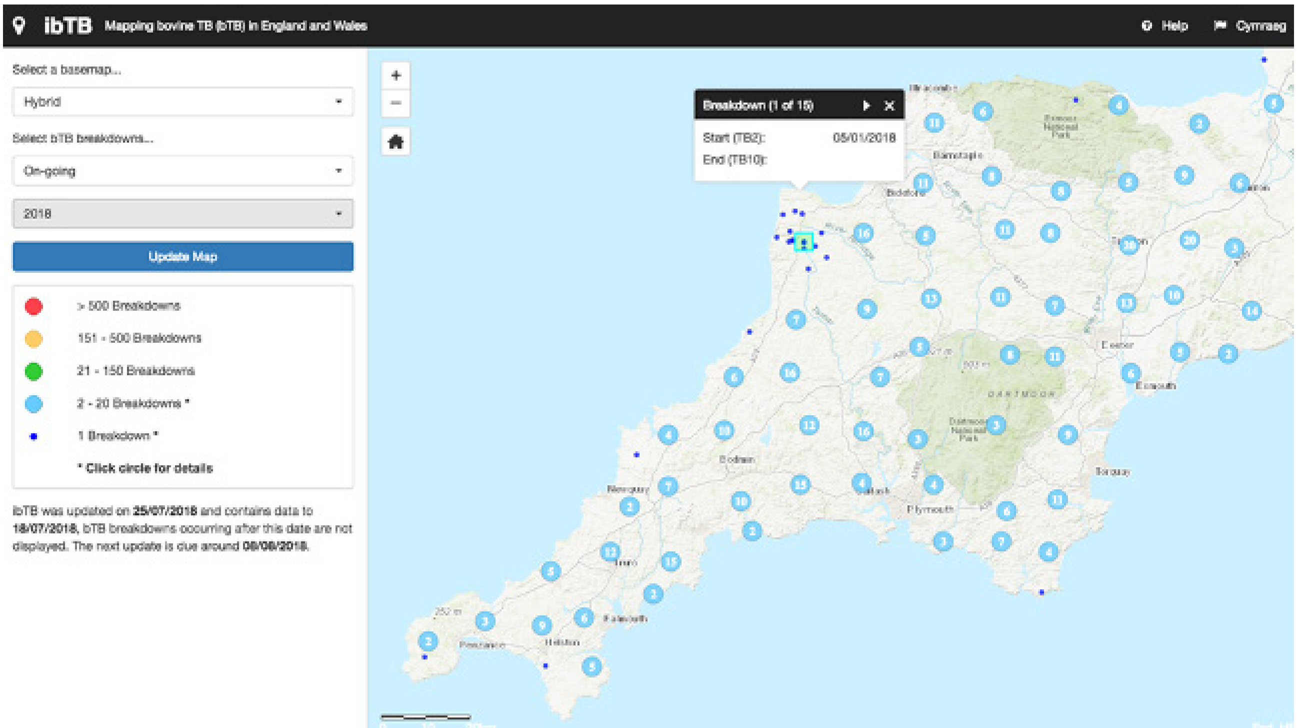
Current policy

5.16. Since 2006, pre-movement tests have been required for all cattle (over six weeks old) on premises subject to annual or more frequent testing unless the herd or movement type meets certain specified exemptions. These include movements direct to slaughter, an Approved Finishing Unit (AFU) or a pre-movement test Exempt Finishing Unit (EFU). The test is paid for by the farmer (though results from regular state-sponsored tests can be used).

5.17. Since 2016, post-movement tests have been required for cattle moving onto premises in the LRA from areas subject to annual or more frequent testing, paid for by the purchasing farmer.

5.18. An initiative to inform farmers about the importance of risk-based trading was introduced in 2015. It stresses the importance of enquiring about the herd-breakdown status of the premises from which animals are purchased, and provides advice about keeping purchased cattle separate and ideally arranging for them to be post-movement tested for bovine TB even when not statutorily required.

5.19. Since 2015 an online interactive tool (ibTB) has been available that provides information on the geographic location of all herd breakdowns in England and Wales (Figure 5.2). Data are available from 2014 and the database can be searched by postcode or County Parish Holding (CPH) number. However, ibTB appears to be of limited use at auctions unless the sale is catalogued in advance (and includes the CPH or postcode which seldom happens) to allow purchasers the opportunity to research vendor bovine TB status[45]. ibTB receives about 100 hits a day but the fraction of these that are farmers using it for risk management is not known[46].



[45] APHA (2015) https://www.gov.uk/government/publications/bovine-tb-epidemiology-reports-2015
[46] http://www.assembly.wales/research%20documents/18-003/18-003-web-english.pdf

Figure 5.2: An illustrative graphic from the online interactive tool ibTB.

5.20. A study of the introduction of ibTB found that it scored highly on different measures of usability. Until recently bovine TB status was confidential, hence the study noted some concerns among the farming community about the accuracy and accessibility of the data. There was also some uncertainty amongst private veterinarians about their changing roles in relation to providing advice on bovine TB control to their farmer clients as information that had previously been private became more available[47].

5.21. Currently, there is no formal requirement for vendors to provide information about their animals' bovine TB status and the level of demand for this from purchasers appear to be limited. Information such as the date of the latest herd bovine TB test comes in the form of a farmer declaration and the veracity of these statements are not assured. Grants were made available in 2014-15 to auction markets to cover half the cost of electronic display equipment to display bovine TB information ringside during cattle sales. About 25% of markets took them up. Our discussions with the industry suggest this reflects a concern of auctioneers that the provision of data on bovine TB status is unlikely to be successful without a more robust source of up-to-date information and greater demand for herd health data from buyers and sellers of cattle.

5.22. The Cattle Health Certification Standards (CHeCS) organisation launched a bovine TB herd accreditation scheme in 2016. Participating farms obtain enhanced biosecurity advice and perform additional post-movement tests beyond regulatory requirements. They receive a score reflecting the amount of time since their last herd breakdown. This can be particularly valuable for herds in the HRA and EA that have never had an infection. However, take up of the scheme has been low with around 60 accredited herds in England to date (mainly high-value pedigree herds).

5.23. From 1 November 2018, government will pay compensation at 50% of the average market price for any animal brought into a herd with a bovine TB breakdown which then fails a test whilst that breakdown is still ongoing. This already happens in Wales and is intended to encourage herd owners to take further steps to improve their disease control. Herds which are CheCS accredited at the time of the breakdown will continue to receive 100% compensation for all compulsorily slaughtered cattle.

5.24. There are further measures under consideration in England:

(i) APHA have developed a herd scoring system based on known and measurable risk factors that could be used in risk-based trading[48]. About one third of all breakdowns can be predicted by the factors included in the model.

(ii) Development of a Livestock Information Service (LIS) as discussed at ¶ 5.29.

5.25. There are some differences between England and the DAs. Wales operates a voluntary 'informed purchasing' scheme, which encourages farmers to share

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[47] Bovine TB in Wales: governance and risk, Gareth Enticott (2018) http://www.assembly.wales/research%20documents/18-003/18-003-web-english.pdf

[48] Adkin *et al.* 2016 http://dx.doi.org/10.1016/j.prevetmed.2015.11.020

information about the bovine TB status of their animals when selling. Northern Ireland has recently consulted on a proposal that the farming industry should lead the adoption of an informed purchasing approach for farmers bringing in stock to their farms. This would involve support to promote information openness and transparency at livestock markets (for example, on the health status of cattle) and increased awareness raising. Scotland has a requirement for pre- and post-movement testing of cattle coming from annually or more frequently tested herds in England and from Wales.

Options for the future

Maintaining the status quo

5.26. Given the evidence that moving cattle can spread bovine TB, existing pre- and post-movement testing almost certainly prevents some new infections. However, the limited sensitivity of the tests used means that not all infections will be identified and purchase of stock, especially from high-risk herds, always carries a risk of introducing infection.

5.27. Existing voluntary schemes such as CHeCS herd accreditation and the use of the ibTB database are poorly taken up by the industry. Though they may benefit individual farm businesses they are unlikely to be having a major effect on the incidence and spread of disease in England. Risk-based trading has not culturally been embraced by large sections of the farming community, in significant part because of lack of confidence in the value of the information available, and also because of an under-appreciation of the risks of purchasing infected cattle[49].

5.28. It is possible that existing measures could be made more effective; for example, by better marketing and a greater understanding of incentivising farmer behaviour. However, we believe more than at present can be done to discourage risky trading.

Improving the information available at purchase

5.29. In spring 2018, Defra announced a major investment to develop the LIS. The service, to be in place from 2019, will use electronic identification tags to identify and record the movements of all cattle, sheep, pigs and goats in the UK. The initiative arises from a joint government-industry working group and has broad sector support. At the time of writing, the details of how the LIS will be constructed and operate are not fully available. However, it is clear that it is potentially an enormously important resource to help all aspects of bovine TB control including risk-based trading.

5.30. LIS is planned to perform multiple functions of which assisting bovine TB control is but one. It is stating the obvious to emphasise that in the design phase it is critically important that the needs of bovine TB control are understood, and that this system should be constructed so that it is intuitive and simple for farmers, veterinarians and other stakeholders to use. The continuing involvement of the National Farmers Union (NFU), the Livestock Auctioneers Association (LAA) and other bodies is important.

5.31. The LIS database should carry the complete location history of each animal as well as other individual-specific information relevant to bovine TB risk such as its

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[49] *Farmers' attitudes to a risk based trading scheme for cattle in England,* ADAS UK Ltd. (2012)

individual testing history and that of other animals in the herds it has been part of. These raw data are of limited use to farmers considering purchasing cattle and must be transformed into a useable index or score. Indices such as those already developed by APHA can be employed immediately but research is needed to utilise the richer data that will be available through LIS. This should begin immediately so that it can inform the design of LIS.

5.32. Though some risk factors can be estimated from information on individual animals, others are a function of farm location (for example, density of wildlife reservoirs). It is important that LIS either includes or can interface with this type of data. Research is needed to see whether estimates of these types of risk factor can be estimated using proxy data (for example, remotely-sensed habitat data might be used to estimate badger densities) and can contribute to the index or score.

5.33. There could be a mandatory requirement that the risk assessment index or score is presented to a potential purchaser before purchase, ideally in both the sales catalogue and on large screens at ring side. Technology would allow ear tags to be scanned and the information automatically uploaded from LIS. A concerted information campaign by the industry and government would be needed to raise awareness and understanding in the farming community. Insights from the behavioural sciences will be valuable in designing the best ways to communicate information to purchasers in the cognitively complex environment of the auction ring. The LAA supports the principle of improving the level of information available to farmers at market provided it is timely, accurate, and reliable.

5.34. As part of the LIS programme all cattle will be electronically tagged. We envisage that in time all farmers will have hand-held scanners that can read an individual animal's identity and in real time communicate with LIS to provide a potential seller or purchaser with an estimate of risk. Insights from behavioural psychology are likely to be helpful in designing the precise interface that elicits the optimum response from the farmer.

5.35. There are a number of potential drawbacks of using LIS for risk-based trading:

(i) Implementation and development of LIS carries significant costs, though these are partially mitigated by the multiple functions it can perform. However, getting LIS to work for bovine TB control will require bespoke investment as described above.

(ii) Despite broad support from industry there will be some farmers who will find LIS intrusive and burdensome. The increasing professionalism of UK farming suggests this will decrease over time but it will be necessary to demonstrate the benefits of LIS to ensure maximum buy-in.

(iii) Government has in the past found it difficult to implement large-scale IT projects. Hopefully this will not be the case here but prudence suggests not relying on the existence of LIS to the exclusion of existing information sources until its delivery is assured. Some of the measures above could be implemented using existing APHA scoring of herd risk profiles in the absence of LIS though in our view this would be a substantially poorer outcome.

(iv) Introducing more information about the risk of infection of individual cattle reduces the demand for the riskiest animals and hence lowers their sale price. This fall in price might undermine moves to reduce risky trading if it encouraged their purchase by farmers with a greater appetite for risk. It is important to consider risk-based trading within the broader context of compensation or insurance for herd breakdowns to avoid perverse outcomes.

Financially incentivising risk-based trading

5.36. Risk-based trading could be incentivised by reducing the compensation paid for high-risk cattle, or cattle from high-risk herds that are purchased and subsequently are tested bovine TB positive. Positive behaviours (absence of risky trading) could be rewarded by enhanced CHeCS scores. The general issue of adjusting compensation to risky behaviour is discussed in Chapter 8.

5.37. Such measures are likely to be unpopular with the industry because they potentially penalise farmers. An argument is that farmers already practice risk-based trading and to penalise them further is unjust. There are two counter-arguments. First, farmers may prefer an immediate gain (reduced price cattle) over future loss (the risk of a breakdown) – i.e. show 'time discounting'. Reduced compensation may help correct this bias. Second, the social benefit of reduced disease incidence and spread may not be internalised in the individual farmer's decision. Reduced compensation may thus bring industry-wide benefits.

Strengthening regulations on movement

5.38. Movement from the HRA or from high-risk premises to the LRA might be forbidden by regulation. A risk cut-off for movement was considered a key element of the successful Australian bovine TB control strategy though in a very different environmental and industry context.

5.39. Even in the HRA there are many farms that have never had a herd breakdown. Preventing them from trading completely might be viewed by the industry as draconian and a lessening of incentives to avoid infection. Trade from herds with OTF status withdrawn or suspended is restricted (e.g. to AFUs or to slaughter) and increasing the extent of this restriction would be viewed as making the burden of a breakdown greater.

Extending post-movement testing

5.40. Government could consider the extension of post-movement testing to the EA in response to increased numbers of herd breakdowns. Enhanced post-movement testing is already part of the CHeCS accreditation scheme requirement. Advice is available to farmers on isolating brought in cattle to ensure that they are not incubating any disease; in particular when buying in cattle from a herd of higher TB risk status. Evidence from Scotland shows that the introduction of pre- and post-movement testing has had a strong deterrent effect on the cattle import trade, albeit in an area of low bovine TB incidence[50].

5.41. Reducing the geographical spread of bovine TB is of high priority and likely to justify the introduction of post-movement testing in the EA despite the costs to the farms concerned. Initial analyses of the introduction of the current post-movement testing regime have suggested it has reduced the numbers of cattle moving from the HRA and the EA into the LRA.

5.42. Post-movement testing will be recorded on LIS and could contribute to the risk score of herds from which animals are sent to market.

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[50] Gates et al. 2013 https://doi.org/10.1016/j.prevetmed.2012.07.016

Enhanced pre- and post-movement tests

5.43. In Chapter 3 we explored the costs and benefits of moving from the SICCT test to other tests, in particular to the SICT or IFNγ tests, which have better sensitivity though in the latter case are more expensive to conduct. These tests could be used for pre- and post-movement testing.

5.44. Using the more sensitive test could be valuable in preventing the most potentially damaging types of movement; for example, from high- to low-risk areas. This would obviously entail costs to individual farmers (we envisage the seller paying for pre-movement and the buyer for post-movement tests) but by internalising the disease costs of risky movements it may increase overall industry efficiency. The use of highly sensitive tests would be recorded on LIS and might contribute to reducing a premises' risk score and hence increase the value of their cattle so mitigating some costs.

Reducing fraudulent movements

5.45. There are a small number of cases of farmers deliberately sending to market animals they know or suspect of being infected with bovine TB, sometimes after illegally swapping ear tags. There is also some concern that individual cattle dealers may be failing to comply with TB testing and animal identification rules. Whether such practices are widespread is unknown, and probably largely unknowable, but the suspicion that it occurs can undermine farmer confidence in risk-based trading.

5.46. Tissue samples that can be used for DNA genotyping are now taken of cattle that test positive for bovine TB. The introduction of this coincided with a drop in requests for replacement ear tags suggesting it had disincentivised fraudulent behaviour. Tissue samples could be taken of all cattle at the time of ear tagging for subsequent DNA genotyping if fraud was suspected or as a spot check (genotyping would not routinely be carried out). The costs of the storage of large numbers of samples would need to be established and a cost-benefit analysis conducted before further consideration of this suggestion.

5.47. Alternatively, Defra could consider replacing or supplementing ear tags with injectable transponders. A scheme to microchip all horses by 2020 has recently been announced and the technology is cheap and technically proven. EU regulations will permit electronic identifiers to replace conventional ear tags from July 2019. Research will be required to ensure that the microchip cannot enter tissues consumed by people or pets (or provision made in the food processing chain to detect microchips in meat).

5.48. Representatives of the industry told us that the farming community were often aware of rare individuals conducting recklessly risky trading behaviour, and that there was a need for a 'whistle-blower phone line' for people to report such behaviour. We believe this is a good suggestion.

Research priorities

5.49. We strongly emphasise the importance of the LIS in providing the data backbone for improvements in incentivising risk-based trading and many other aspects of bovine TB control. We place the highest research and development priority on ensuring from the design stage that the system works to deliver these benefits for disease control. It is imperative that APHA disease specialists are involved from the beginning, and that the system is fully interoperable with other relevant bovine TB data sources.

5.50. The full complexities of the trading history of a farm business or even the lifetime travels of an individual animal are of limited use to farmers making purchasing decisions, especially in the environment of a livestock market. The development of indices describing the risks of purchasing from a particular farm, or the likelihood that an individual animal carries the infection are important, and should be based on the most robust statistical analysis of risk possible.

5.51. Research in the social sciences into how farmers make economic choices regarding cattle purchasing, and how decisions that promote disease control can be incentivised, would be valuable.

5.52. As described in the introduction the amount of cattle movement in the UK is very high. Much of this is due to rational economic reasons. Nevertheless, movements do tend to foster disease spread (not only bovine TB but also other pathogens) and further study to understand movement patterns and to check none are being driven by perverse incentives is warranted.

Chapter 6: The disease in wildlife

Introduction

6.1. The causative agent of bovine TB, Mycobacterium bovis, can infect a broad range of hosts including many species of wildlife. In the 1970s it was discovered that in the UK and the RoI infections were present in wild badgers (Meles meles). To prevent badgers acting as reservoirs of the disease different control measures were introduced, first gassing of badger setts (1975-1982) and then between 1982 and 1997 different forms of direct culling of badgers on and around infected farms.

6.2. The killing of wild badgers has been extremely controversial from the start. A number of civil society organisations with substantial public support have argued that killing badgers under any circumstances is wrong in principle, and that it does not reduce disease in cattle in practice. Through well-organised campaigns, including action to disrupt culling, badger control has become a highly-charged and politicised issue. Bovine TB now has a public salience unlike any other endemic livestock disease.

6.3. A major review of bovine TB control in 1997, chaired by John (now Lord) Krebs, recommended a large-scale, replicated experiment to determine whether badger culling reduced the incidence of the disease in cattle[51]. The RBCT ran from 1998-2005 and showed that proactive culling of badgers reduced confirmed (OTFW) herd breakdowns inside culling areas but increased them among herds within a 2 km belt outside these areas[52]. Reactive culling appeared to increase the number of confirmed (OTFW) breakdowns though its precise interpretation is still debated.

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[51] Bovine Tuberculosis in Cattle and Badgers, Professor John R Krebs FRS and the Independent Scientific Review Group, 1997

[52] Independent Scientific Group on Cattle TB, Final Report, 2007, http://webarchive.nationalarchives.gov.uk/20081108133322/http://www.defra.gov.uk/animalh/tb/isg/pdf/final_report.pdf

6.4. The Labour Government in power when the RBCT reported decided not to implement badger culling. The Coalition Government elected in 2010 instituted industry-led culls of badgers in two areas of the West Country in 2013. Today (2018) culling has been licensed on 32 sites constituting 39% of the High Risk HRA and 2% of the EA. This includes one licence recently granted in Cumbria to eradicate a pocket of infection in both cattle and badgers in the LRA.

6.5. A non-lethal alternative to controlling bovine TB is vaccination. A number of projects involving catching and injecting badgers with BCG vaccine are underway in England, Wales and the island of Ireland. Biosecurity measures aimed at reducing badger and cattle interactions are relatively low cost and strongly encouraged by Defra though there is a poor evidence base for the effectiveness of individual interventions.

Rationale for action on wildlife

6.6. Given a pathogen is present in farmed livestock and wildlife there are three possible epidemiological scenarios (see also ¶¶ 2.9 – 2.15). First, the wildlife species may be a 'spillover' host, only infected because of the disease in livestock and not contributing to further infections of livestock. Control of the disease in wildlife is in this case irrelevant to farming. Second, there may be transmission between livestock and wildlife but the disease is not self-sustaining in the wildlife species alone. Control measures directed at wildlife are in this case helpful but not essential to eliminating the disease in the long term. The third scenario is as the second, except that the infection is self-sustaining in wildlife. In this case the disease cannot be eliminated in livestock without control measures directed at the wildlife species (in the absence of a perfect cattle vaccine or other equivalent measure to completely stop transmission from wildlife).

6.7. There is a scientific consensus that badgers can transmit bovine TB to cattle. The RBCT is the most important replicated and controlled study to date and it showed that proactive (widespread, repeated) badger culling led to a reduction in confirmed (OFTW) herd breakdowns inside culling areas compared to unculled areas (Fig. 6.1). The results of the RBCT are broadly consistent with findings from smaller and less well controlled experiments in the UK and RoI. Recent case studies using whole-genome sequencing of *M. bovis* in new outbreak foci have demonstrated transmission from cattle to badgers. There is no scientific consensus about whether the disease is self-sustaining in badgers. Furthermore, given the difficulty of researching this question, we do not believe it will be answered definitively in the foreseeable future.

6.8. The RBCT also showed an increase in confirmed (OFTW) herd breakdowns in areas surrounding the proactively culled areas (taking the culled and surrounding areas together there was still an overall net benefit but this is less than indicated by reductions in herd breakdowns within the culled areas alone). This increased risk is hypothesised to result from *perturbation*: culling disrupts the badgers' social structure, causing individuals to range more widely. Multiple studies have demonstrated behavioural perturbation but the RBCT is the only evidence that perturbation has an epidemiological effect on disease in both cattle and badgers. To reduce the impact of perturbation, the current industry-led culls in the HRA are mandated to cover a minimum geographic area (100 km^2) and (as in the RBCT) to utilise natural boundaries (coastline, rivers) as much as possible.[53]

6.9. Badgers can be vaccinated against bovine TB using an injectable BCG vaccine approved in 2010. There is also ongoing research on the potential for oral vaccination using baits but this has not progressed to a stage where there is a product ready to be tested for licensing. Vaccination provides some but not perfect protection against infection but does not cure an existing infection, and we do not know the duration of immunity. Because of this and the need to inoculate new cubs, repeated annual vaccination campaigns are thought necessary. It has been shown that vaccinating adult badgers can reduce the risk of infection among unvaccinated cubs in the sett. Vaccination protects the individual animal (direct protection) but by reducing the rate of transmission it can also reduce the risk of badger-to-badger transmission to unvaccinated badgers (indirect protection). There have been no large-scale trials of the impact of badger vaccination on disease risk in cattle comparable to the RBCT.

6.10. Were a field test available that would allow rapid, accurate diagnosis of infection in badgers, a policy of culling infected and vaccinating uninfected animals would be possible. This strategy has been explored in Wales using the DPP (see Chapter 2) antibody test[54]. Of five badgers that tested positive and were culled, more sensitive laboratory tests showed at most one was infected (and subsequent analysis of 35 blood samples suggested two potential false negatives). Results are not yet available for a five-year 'test and vaccinate or remove project' (2014-2018) in Northern Ireland with approximately 300 badgers trapped each year[55].

6.11. Badger numbers could also be reduced (though with a substantial time delay) by controlling their fertility. For example, the possibility of immunocontraception has been considered but not tested at scale. This would involve the use of a vaccine to generate an immune response to some key component of the reproductive system for captured female badgers. The development of 'single-shot' injectable vaccines has improved the potential for practical application in the field.

6.12. Estimating badger density is challenging due to their nocturnal behaviour and because they spend a lot of time underground. There are an estimated 485,000 (95% CI 391,000-581,000) badgers in England and Wales and some suggestion that numbers have increased in recent years.[56] Techniques available for estimating local badger numbers are labour intensive (relying on the frequency of recapturing marked or genetically identified animals) or indirect and relatively inaccurate (counting setts and multiplying by a simple badgers-per-sett scaler). They require quite demanding assumptions to be made about badger movement and behaviour, and they produce estimates with broad confidence intervals making monitoring of badger density reduction programmes difficult.

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[53] The minimum size was originally 150km^2 but was lowered to 100km^2. The rationale for this change is given in paragraphs 3.13-3.15 of Defra's 2015 consultation on guidance to Natural England on licences to control the risk of bovine tuberculosis from badgers: https://consult.defra.gov.uk/bovine-tb/licences-to-control-tb-from-badgers/

[54] https://gov.wales/docs/drah/publications/180712-delivery-of-badger-trap-and-test-operations-2017-report-en.pdf - Animal & Plant Health Agency (APHA) report on the delivery of badger trap and test operations on chronic TB breakdown farms in Wales in 2017 (TBOG0135)

[55] https://www.daera-ni.gov.uk/articles/test-and-vaccinate-or-remove-tvr-wildlife-intervention-research

[56] Judge *et al*. 2017 https://doi.org/10.1038/s41598-017-00378-3

6.13. The Protection of Badgers Act 1992 makes it illegal without licence to kill or injure a badger, and to disturb or damage a sett. Licences to cull or vaccinate in England are issued by Natural England.

6.14. TB has been recorded in other wildlife species in the UK. Of these, the most important is probably deer, but foxes and boar have been found to pose risks elsewhere in Europe, with a single feral boar found to be positive in the UK[57]. We currently have limited information about any risk of these infections to cattle. However, data from nearly 1,000 foxes demonstrated that they had much lower prevalence than badgers[58]. Furthermore, given the large reductions in risk achieved by proactive badger culling within culling areas in the RBCT, and that we know infection is transmitted between cattle, any contribution from other wildlife must be limited, at least on a regional scale.

6.15. Amongst high-income countries, there is a correlation between the persistence of bovine TB as a livestock disease and the presence of wild and feral animal reservoirs. Successful campaigns against bovine TB in Australia and Michigan, USA targeted infections in feral water buffalo and white-tailed deer respectively. In New Zealand, the introduced brush-tailed possum (*Trichosurus 62ulpecula*), itself a pest, is an important reservoir and the object of an active eradication campaign.

Current policy

6.16. Culling in England is currently carried out by industry-led groups, licensed by Natural England. The criteria to obtain a licence to cull are: (i) compliance of farmers with TB statutory controls, (ii) "reasonable" biosecurity, (iii) an area of at least 100 km^2, (iv) high TB risk (HRA or EA), (v) limited (no more than ~10%) land inaccessible for culling, (vi) "reasonable" measures to protect non-participants, and (vii) sufficient funding to undertake four years of culling.[59] Defra advises Natural England on the minimum and maximum cull numbers for each cull with the aims of removing at least 70% of the badger population while ensuring a viable population remains.

6.17. In 2013, two sites were licensed in Gloucestershire and Somerset. One further area (Dorset) was licensed in 2015, seven additional areas in 2016, eleven additional areas in 2017[60] and eleven additional areas in 2018[61]. Annex 6 summarises the number and distribution of current and approved cull sites, and the number of badgers culled each year. There is currently a limit (ten) on the maximum number of new areas that can be licensed per year though Defra has announced (July

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[57] Martin-Atance *et al*. 2005 https://doi.org/10.7589/0090-3558-41.2.435 (Spain).
Michelet *et al*. 2018 https://doi.org/10.3201/eid2406.180094 (France).
Amato *et al*. 2017 https://doi.org/10.1111/tbed.12776 (Italy).
Madeira *et al*. 2017 https://doi.org/10.1111/tbed.12439 (Portugal).
Perez de Val *et al*. 2017 https://doi.org/10.1111/tbed.12368 (Spain).
Foyle *et al*. 2010 http://dx.doi.org/10.1136/vr.c2681 (UK)

[58] Bovine Tuberculosis in Cattle and Badgers, The Independent Scientific Review Group 1997 Table 2.2

[59] https://www.gov.uk/government/publications/guidance-to-natural-england-preventing-spread-of-bovine-tb – Defra, Guidance to Natural England Licences to kill or take badgers for the purpose of preventing the spread of bovine TV under section 10(2)(a) of the Protection of Badgers Act 1992. Criteria to obtain a licence for supplementary badger disease control or for a licence for badger control in the Low Risk Area are defined separately.

[60] https://www.gov.uk/government/publications/bovine-tb-authorisation-for-badger-control-in-2017

[61] https://www.gov.uk/government/publications/bovine-tb-authorisation-for-badger-control-in-2018

2018) that this limit will be kept under review[62]. Authorisation has been granted in 2018 for supplementary culling operations in Gloucestershire and Somerset[63].

6.18. The total cost of current culling operations is estimated to be £0.6 million per area over four years (see Table 6.2 below for a further breakdown).[64]

Table 6.1: Breakdown of costs of badger culling per area (over 4 years)

Natural England	Processing licence applications and monitoring compliance with licence conditions	£116k
APHA	Training, mentoring and advice	£140k
Defra	Equipment (e.g. communications and positioning)	£20k
Police	Maintaining public order and safety	£210k
Industry	Surveying, preparation and coordination and delivery	£140k

6.19. Analysis of herd breakdowns in the two years following the start of the initial industry-led culls showed a 58% (95% CI 49-66%) reduction in herd breakdowns in the Gloucestershire cull area and a 21% (95% CI 13-28%) in Somerset[65]. In Somerset, a significant 38% (95% CI 9-75%) increase in herd breakdowns was found in the 2 km buffer area surrounding the cull site but not in Gloucestershire (9% reduction, 95% CI 23% reduction – 7% increase). These results are qualitatively consistent with those of the RBCT. Annual TB monitoring data and results for each badger control licensed area and their buffer areas up to the end of 2017 have recently been published which appear consistent with the earlier results (full analysis is underway and will be published later in the year)[66].

6.20. In May 2018, Defra announced that culling will be allowed in the LRA in the rare event that disease in badgers is linked with infected herds[67]. The objective is to stamp out infection quickly and prevent further spread within wildlife and cattle. One such licence has been granted for culling in 2018 over an area of 190 km^2 in Cumbria.

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[62] An additional area was licensed in 2017 and 2018 as permitted in the licensing guidance to Natural England.

[63] Supplementary culling enables farmer-led licensed badger control in England to continue, to preserve the disease control benefits expected in areas where successful culls have been completed over at least four years.

[64] https://www.gov.uk/government/publications/bovine-tb-badger-control-policy-value-for-money-analysis/badger-control-policy-value-for-money-analysis-2018

[65] Brunton *et al*. 2017 https://doi.org/10.1002/ece3.3254

[66] https://www.gov.uk/government/publications/bovine-tb-incidence-of-tb-in-cattle-in-licenced-badger-control-areas-in-2013-to-2017

[67]https://www.gov.uk/government/publications/guidance-to-natural-england-preventing-spread-of-bovine-tb

6.21. Culling has been the subject of several judicial reviews. These have largely centred round the interpretation of statutory powers, the procedural correctness of consultations and the accuracy of cost-benefit analyses underpinning decisions related to the culling operations. Further details are included in Chapter 2, Appendix 2.

6.22. The Badger Edge Vaccination Scheme (BEVS) was set up to promote vaccination in the EA where the possibility that badgers may be contributing towards the spatial spread of the disease is of particular concern. The initial scheme in 2014, which supported six volunteer groups, was suspended the following year because of global BCG vaccine supply problems. The scheme was relaunched in 2017 (BEVS 2) when vaccination in three areas was licensed and is now underway. A small number of privately funded vaccination groups have been licensed and operate independently of the BEVS.

6.23. There is currently no systematic surveillance of bovine TB in wildlife. Some surveying occurs during the investigation of new foci, in particular in the LRA, and as part of specific research projects.

6.24. In the RoI, herd breakdowns with three or more reactor cattle are investigated by a state veterinarian and if infection by badgers is suspected, and badger activity and the presence of setts found, a trapping programme is initiated. Badgers within a 2 km radius of the affected farm are trapped and culled, with the aim of reducing badger densities to 0.5 badgers km^2 (average pre-cull densities in farmland are 2-3 badgers km^2).

6.25. Beginning in 2009, the RoI carried out large field trials of a BCG vaccine in badgers given orally in a lipid formulation. They showed that vaccination confers protection to badgers and reduced incidence rates in badger populations exposed to the disease[68]. These results were consistent with those observed in England using intramuscular injection of a BCG vaccine (BadgerBCG)[69]. In 2018, a policy was announced of replacing culling by BCG vaccination by injection in areas where badger densities had been reduced. This is starting in the field-trial areas and will be extended to other parts of the country. Culling may still be used in cases of serious and persistent breakdowns.

6.26. In 2014, Northern Ireland began a five-year research project to describe the effects of implementing a 'Test and Vaccinate or Remove' intervention on badgers, in an area of high badger and cattle density and with high levels of bovine TB in cattle. In addition, it will quantify costs and field logistics of implementation. A single intervention area in County Down (about 100 km^2 in size) will be compared with a number of similarly sized 'control areas'. The field activities will conclude in late 2018, with the project anticipated to report in late 2019. In Wales, there is an ongoing project to explore the feasibility of catching badgers and then culling or vaccinating depending on the results of a bovine TB test performed in the field (see ¶ 6.10).

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[68] Gormley *et al*. 2017 https://doi.org/10.1371/journal.pone.0168851

[69] Chambers *et al*. 2011 https://doi.org/10.1098/rspb.2010.1953 Carter *et al*. 2012 https://doi.org/10.1371/journal.pone.0049833

Options for the future

Continuing with current policy.

6.27. We interpret current policy as encouraging industry-led culling campaigns in the HRA and EA, potentially relaxing the limit on the number of new culling areas allowed per year. Ultimately all parts of the HRA and EA where the required majority of landowners were willing to take responsibility for culling would, over time, be included.

6.28. Evidence from the RBCT and initial analyses of the industry-led culls indicate that current policy would reduce the number of herd breakdowns, compared to not culling. Whether culling in addition to current cattle controls can reverse the increasing trend in bovine TB in England is not known, but it does represent an important option to help in controlling the disease.

6.29. It is likely that the farming industry would be more willing to accept other interventions that could negatively affect dairy and beef profitability if they believed that the threat of transmission from badgers was being robustly addressed.

6.30. The implications of scaling up badger culling operations over time would be an increase in the costs set out in Table 6.2. Costs might not increase in direct proportion to the number of areas. It is a shared goal of Defra and the Home Office that policing duties should eventually become a normal activity and so not incur additional costs, though this does assume that the frequency of protests and direct action (including illegal activity) will decline. Costs to government and industry are likely to decrease, as lessons are learnt and efficiencies or improvements are identified and implemented.

6.31. Were culling to be extended to the majority of the HRA and EA then the number of badgers culled per year would rise substantially from today's numbers. If there were 40 cull areas in operation (based on 10 new areas per year and 4 years of culling in the first instance), then we might expect roughly 40,600 badgers to be culled each year[70] (roughly 8% of the estimated badger population in England, see ¶ 6.12). For comparison, 10,979 badgers were culled over the course of the RBCT between 1998 and 2005 (including both proactive and reactive culling). This ongoing level of lethal control would not be acceptable to some (possibly large) sections of the public, and the costs of policing could be substantial.

6.32. Current policy is to reduce badger density by at least 70% but estimating badger densities is difficult and inaccurate (¶ 6.12). It is unclear the degree to which region-wide badger culling would affect the viability of the species in these areas and what the large-scale ecological effects would be.

6.33. Reducing badger numbers will have consequences for other species in the local area. Culling in the RBCT (which was limited to 100 km^2 areas) was associated with increased numbers of foxes and hedgehogs[71]. Badgers are omnivores (with a particular preference for earthworms) and inhabit highly modified farmland ecosystems. Reducing their densities will have complex direct and indirect ecological effects with some species increasing and others decreasing in abundance.

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[70] Extrapolating from the average of 1014 badgers culled per area in 2017 in areas 3-21; areas 1 and 2 were excluded from this calculation as undergoing supplementary culling, see Table 6.3

[71] Trewby *et al*, 2008 https://doi.org/10.1098/rsbl.2007.0516

6.34. The requirement that farmers come together and co-finance culling campaigns can cause tension when some farmers feel pressurised to agree to culling, and those that do not are viewed as free-riding. Culling is not possible in some areas where major landowners (for example the National Trust) have policies not to permit it. One possibility would be for badger vaccination to be conducted within cull areas on farms or areas where culling is not accepted.

6.35. The potential for perturbation to increase the risks of herd breakdowns in adjoining areas is a particular issue in the EA because of the importance of preventing the spread of bovine TB into the adjoining LRA. The presence of physical barriers, limiting or preventing badger movement into adjacent areas, is an example of an argument in favour of allowing culling in a particular part of the EA.

6.36. Herd breakdowns, typically caused by the importation of infected cattle, occur periodically in the LRA[72]. Stopping the disease from becoming established in these areas and spreading further is a priority and Defra has already announced it will allow industry-led culling campaigns in these circumstances. The geographic extent of the cull should be large enough to reduce the possibility of further spread of infection through any perturbation effect (see ¶ 6.8).

Stopping culling (without the introduction of other wildlife control measures)

6.37. Stopping culling would cease the killing of a wild animal and address the concerns of a sizeable constituency that believes it is unacceptable.

6.38. It would achieve substantial savings in terms of licensing and surveying. Depending on the future extent and nature of action to disrupt culling it would save on policing costs. Culling expenses would be saved, benefitting the industry locally.

6.39. Stopping culling (without the introduction of other measures) would mean that an important source of transmission to cattle would not be addressed. To achieve a comparable reduction in incidence in cattle more stringent interventions to reduce transmission between cattle would be required than if culling were allowed, which would negatively affect industry. If bovine TB can persist in badger populations (which is not known, ¶ 6.7) then the risk of transmission from wildlife would remain unless a fully protective cattle vaccine were to become available.

6.40. There are no proven biosecurity measures to protect herds and give farmers confidence their herds are protected. The willingness of the dairy and beef industry to cooperate with other disease control measures might be reduced if a proven source of infection is not tackled.

Stopping culling and replacing by vaccination

6.41. As in the last option, stopping culling would cease the killing of a wild animal and address the concerns of a sizeable constituency that believes it is unacceptable.

6.42. Vaccination does not remove infectious badgers from the countryside and so does not immediately affect the risk to cattle. However, over time vaccination will reduce the number of badgers that contract the disease. We would expect that this would yield some reduction in the risk of badger-to-cattle transmission though this effect has not been measured. Even if bovine TB can persist in badger populations then

[72] https://www.gov.uk/government/publications/bovine-tb-epidemiology-and-surveillance-in-great-britain-2016 (page 109)

vaccination has the potential to reduce transmission so that in the absence of transmission from cattle the disease in time dies out, though this is not certain.

6.43. Laboratory studies with captive badgers have shown that BCG vaccination by injection reduces TB lesions caused by *M. bovis* infection[73]. Field studies involving BCG vaccination of over 800 wild badgers resulted in an approximately 74% reduction in the proportion of badgers testing positive to the antibody blood test for infection in badgers[74]. However, as the blood test is not an absolute indicator of bovine TB infection, these results cannot be taken as a reliable measure of vaccine efficacy. The field study also showed an indirect protective effect of BCG vaccination on unvaccinated cubs born into vaccinated social groups if more than a third of the adults within the social group were vaccinated[75].

6.44. Vaccinating badgers with injectable BCG requires them to be trapped and handled by trained personnel. Costs in the BEVS have been reduced through voluntary labour but it is unlikely that this could scale up to a national programme. As badgers must be vaccinated annually (including both revaccination of individuals and vaccination of newly trapped individuals) on-going costs are likely to be substantial (one estimate puts this at £2,250 per km^2 per year)[76]. Consideration could be given to reducing costs using alternative capture methods, subject to careful consideration of the welfare (and potentially health and safety) impacts of these methods compared to those of currently used badger traps[77].

6.45. It is not clear what level of industry buy-in could be achieved without evidence of the impact of badger vaccination on the incidence of bovine TB in cattle. Testing the impact of vaccines is thus of great importance. There is an argument that if vaccination replaces culling motivated by reasons other than efficient disease control, then the state should shoulder more of the expense.

6.46. It is not certain whether a viable and cost-effective oral vaccine (using baits) could be developed. Were it possible, the costs of trapping and handling badgers might be avoided. However, distributing baits to ensure sufficient badgers are vaccinated may be difficult and require large number of baits containing high doses of BCG. It would be important to ascertain whether cattle that consumed oral vaccine would test bovine TB positive.

Stopping culling and replacing by fertility control

6.47. This option shares with vaccination the advantage of avoiding killing a wild animal, as well as the disadvantages of not removing infected animals immediately and the expense of a continuing campaign of badger capture and handling.

6.48. Reliable fertility control for badgers is not currently available although research continues to test potential options. A study in 2015 explored the use of an injectable immunocontraceptive vaccine, GonaCon, to generate infertility in badgers. This led

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[73] Lesellier et al. 2011 https://doi.org/10.1016/j.vaccine.2011.03.028
[74] Chambers *et al*. 2011 https://doi.org/10.1098/rspb.2010.1953
[75] Carter *et al*. 2012 https://doi.org/10.1371/journal.pone.0049833
[76] Defra Impact Assessment 2011: Measures to address bovine TB in badgers https://www.gov.uk/government/publications/measures-to-address-bovine-tuberculosis-in-badgers-impact-assessment
[77] Defra report (2005) - Review of effectiveness, environmental impact, humaneness and feasibility of lethal methods for badger control" discusses badger restraint methods. http://webarchive.nationalarchives.gov.uk/20081108133322/http://www.defra.gov.uk/animalh/tb/isg/pdf/final_report.pdf

to an immediate fall in cub production, but the effects of the vaccine declined in the second and third breeding seasons[78]. Further testing in the field to explore its potential as a tool for badger control, to understand the potential interaction between the efficacy of BCG and GonaCon, and to incorporate a vaccine into a self-administered bait have been identified as next steps to assess this intervention's viability.

6.49. Naturally occurring reproductive suppression in badgers limits the number of females that breed, but more than 75% of adult females carry blastocysts (very early stage embryos) each year and can potentially breed. It is likely that a high proportion of females would need to be caught and treated before population numbers began to decline, increasing costs and logistic requirements.

6.50. It is not clear how low the population needs to be before transmission to cattle is affected (as in culling). Given the increased ranging of badgers observed in areas subjected to culling, the effectiveness of fertility control could vary depending on the culling history of the local area.

Periodic intensive culling

6.51. Current badger culling licences last for four years though supplementary culling beyond this period has been approved in two areas (¶ 6.17). Continuous culling obviously results in more badgers being culled but there are also arguments for periodic culling with a pause between campaigns.

6.52. There is evidence from the RBCT that the greatest benefits from repeated, widespread culling occur in the first two years after culling is stopped (Figure 6.1). This suggests that a periodic culling regime might have the same disease reduction effects at lower costs. Such a regime would involve culling for four years, not culling for two, and then resuming culling again. Badger populations would increase during the break in culling so when it resumes it would need to be more intensive than the maintenance culling assumed in the supplementary cull licences. It is thus not clear how many fewer badgers would be killed with periodic culling, compared to four years of culling plus supplementary culling.

6.53. These arguments are based on analysis of the RBCT, and though this is the best experimental study of the consequences of culling, it is not certain that the detailed pattern of herd breakdowns it found can be extrapolated to culling carried out in a different way. It is not possible to say what would have happened in proactively culled RBCT areas had they all been culled continuously for seven years. However, it is clear from the data that substantial post-cull benefits were achieved during years in which no culling costs were incurred.

6.54. A two-year pause in culling after the initial four years would lead to savings in operational costs for the industry-led consortia running the culls. Setting up these consortia involves logistical and financial challenges, in particular around obtaining legal and financial commitments from local farmers. If periodic culling were implemented, it would be important to ensure that this did not result in extra regulatory and compliance burdens on the consortia that might reduce rates of participation and incur extra costs.

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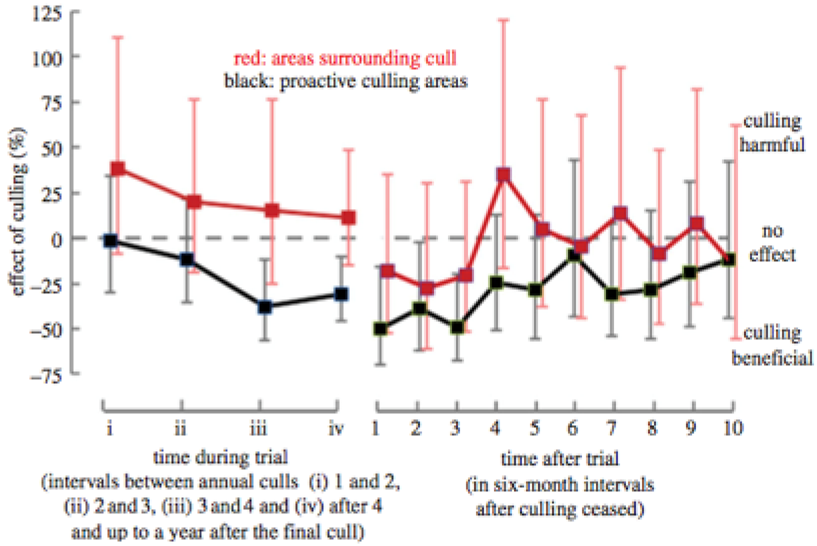
[78] SE3277 Evaluation of the potential for GnRH and BCG vaccines to contribute to the management of bTB in badgers

Figure 6.1 – Key results from the Randomised Badger Culling Trial, as summarised in Godfray *et al*. 2016 (https://doi.org/10.1098/rspb.2013.1634)



(i) The black lines show the percentage difference (with 95% confidence limits) in new confirmed herd breakdowns between sites subjected to proactive culling compared with no-cull areas. The red lines show the same information for land up to 2 km outside the proactive culling area compared with land up to 2 km outside the no-cull trial areas.

(ii) Estimates at particular time points can be read from the graph. There are various ways to summarize these data; averages and confidence intervals for three time periods are as follows:

	average % change			
	proactive culling area		areas surrounding cull	
time period	central estimate (%)	95% confidence interval	central estimate (%)	95% confidence interval
during trial	−23	−12 to −33	+25	−1 to +56
after trial	−28	−15 to −39	−4	−26 to +24
entire period	−26	−19 to −32	+8	−14 to +35

The averages involving the post-trial period include 5 years of data; choosing a different time span would affect their values.

(iii) The figures above are a comparison of cull and non-cull sites, and hence represent relative differences. As background incidence was rising throughout the monitoring period, absolute reductions in rates of new confirmed cattle herd breakdowns (compared with historical rates) would be smaller than the relative reductions shown here, and absolute increases would be larger than the relative increases shown here.

(iv) RBCT culling had no impact on approximately 30% of cattle herd breakdowns, which are unconfirmed.

Using culling to reduce badger densities and then replacing with vaccination (and/or possibly fertility control).

6.55. Substantially reducing badger densities by culling over a large area means that the risk of transmission to cattle is reduced at the cost of continuing lethal wildlife control. Once the lower density is reached, annual vaccination could reduce the likelihood of the badger population from becoming a similar threat again to cattle, even if the populations rebound. Fertility controls could also potentially be introduced to prevent or reduce the extent of population rebound (with the challenges described in ¶ 6.47 et seq.).

6.56. The advantages and disadvantages of culling, vaccination and fertility control applied singly also apply to this combined strategy (and its added complexity may be a further disadvantage). The combination of using lethal control in the short term while explicitly phasing out culling may be seen to be a compromise between groups arguing for and against culling (though still unacceptable to those who view culling as an absolute wrong).

6.57. Were rapid and more accurate tests of badger infections in the field to become available, a variant on this strategy would be to test and cull any infected badger rather than vaccinate. This is currently being implemented with imperfect diagnostic tests on a small scale in Wales and in a 5-year trial in Northern Ireland (see ¶¶ 6.26). More evidence is required to assess the feasibility of this strategy.

Comparing the benefits of periodic intensive culling and intensive culling followed by vaccination

6.58. The absence of an estimate of the impact of badger vaccination on the incidence of bovine TB in cattle herds is a key information gap that hinders evidence-based policy-making. For example, vaccination provides one of the few possible exit strategies from the policy of large repeated culls, yet we cannot say today whether it is feasible. Modelling studies can provide some insights into this question, but cannot provide definitive answers because of our uncertainty about the underlying epidemiology. We see it as very important to obtain new evidence on vaccination, though without compromising current control efforts.

6.59. There are currently 31 large areas that have undergone at least one year of intensive industry-led culling. Only two of these (Areas 1 and 2; Annex 6) have received supplementary culling following the initial four years of culling. There is an opportunity now to consider further the future of areas subjected to repeated intensive badger culls and to obtain evidence on the effectiveness of badger vaccination.

6.60. In ¶¶ 6.51 – 6.54 we explain why we see periodic intensive culling as a more promising strategy than continuous culling beyond four years. If this argument is accepted, then we suggest that after the initial four-year intensive cull half the cull areas are allocated to vaccination and the other half to periodic culling. The areas would be allocated randomly to the two treatments. Vaccination would begin immediately and continue annually while culling would resume after the two-year pause.

6.61. Herd-breakdown rates would be monitored in the two treatments to compare the effectiveness of culling versus vaccination. Prior to the start of the trial ‘break points’ would be defined that would end the experiment (a procedure common in medical trials). Thus, if the data showed vaccination was failing to provide sufficient protection by a predefined time it would be abandoned and culling resumed; conversely, if it provided comparable protection to culling then all areas would switch to vaccination.

6.62. We envisage that, like the current industry-led 4-year culling programmes and the two examples of supplementary culling, the resumed culling would be funded and organised by local farmers. However, we think Government will need to fund the post-culling vaccination in these areas until sufficient evidence has been accrued robustly to inform a decision on the superiority of either approach. While this is an additional funding burden for the state, it should be viewed as an investment to provide an expanded evidence base to inform future policy. Ministers will need to decide on whether this investment is justified.

Farm-led culling

6.63. In Chapter 9 we explore the possibility of farmers being asked to take more responsibility for disease control on their premises and restricting the role of government to statutory testing and empowering farmers to act. As part of this reassignment of responsibilities farmers could conceivably be allowed to apply for individual licences to control badgers on their premises (subject to appropriate welfare standards).

6.64. Because decisions to cull badgers would be made by farmers with a detailed knowledge of the local cattle population and its risks, the control would be more targeted and cheaper. The total number of badgers killed would likely be lower than in area-wide culling, although this would depend on the number of farms undertaking culls.

6.65. It is known that culling causes disruption of badger social structure and data from the RBCT suggests that this can lead to increased herd breakdowns in the areas surrounding a large-scale cull (¶ 6.8). There is thus a risk that farm-led culling might cause the dispersal of infected badgers and herd breakdowns on neighbouring properties and so it would only be possible if farmers could not be held responsible for local herd breakdowns. There has been no specific experiment to test the effect of farm-led culling but analysis of data collected in high-risk areas as part of the RBCT provides no support to the idea that small-scale culling might reduce risk to local cattle, suggesting instead an increased risk.

Research priorities

6.66. It is not clear what drives the ongoing spread of bovine TB into the EA. Epidemiological analysis, informed by genetic analysis of *M. bovis* samples from infected cattle and from infected badgers detected in surveillance studies, is a research priority to understand this. The work will benefit from the application of recent advances in whole-genome sequencing and analysis (and its reduction in costs).

6.67. Better understanding of the prevalence of infection in badger populations in different areas could inform prioritisation of areas to receive interventions to limit badger-to-cattle transmission. It could also provide insight into differences observed in the impacts of badger culling on local TB incidence in cattle, such as seen between Somerset and Gloucestershire[79].

6.68. Continuing research on optimising injectable BGC vaccines in badgers is important. Analysis of the outcomes of badger vaccination programmes in the RoI and Northern Ireland, and the incorporation of lessons learnt into English bovine TB strategy, is a very high priority. Though the feasibility of oral vaccination using baits is less clear, research supporting new approaches and into methods of avoiding cattle eating oral vaccines should be considered.

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[79] Brunton *et al*. 2017 https://doi.org/10.1002/ece3.3254

6.69. Initial work on an immunocontraceptive for badgers in 2016 established an initial proof of principle[80]. Further investment may be justified as new approaches are put forward.

6.70. Ecological studies of the consequences of reducing badger densities (by culling or fertility control) on other species (for example foxes[81]) should be undertaken given the key roles played by badgers in their local ecosystems.

6.71. The social attitudes to culling in the farming community should be understood. In particular, does control of badgers (whether through culling, vaccination or fertility control) incentivise better biosecurity or the reverse? Within the RBCT, farmers all knew whether they were in a culling area or not so the effects observed would have included any impact of culling on the local farmers' behaviour. Were farmers in culling areas to relax biosecurity, thinking the risk is already reduced, then the full potential of culling to control disease would not have been observed. The same applies to all badger-related control measures.

Chapter 7: Non-bovine farmed animals

Introduction

7.1. Non-bovine farmed species, including deer, goats, South American camelids (SACs: alpacas and llamas), pigs and sheep, are susceptible to M. bovis infection to varying degrees. The reported incidence of the disease in these species is very low (¶ 7.20), and the risk of them passing on the disease to humans, cattle and wildlife is generally considered to be low.

7.2. There is no statutory bovine TB surveillance programme in place for these species, but there is a duty to notify to APHA the suspicion of bovine TB in carcases or identification of *M. bovis* in samples taken from carcases or live animals. There is a statutory duty on keepers and veterinarians to notify suspicion of bovine TB in live deer.

7.3. For deer, goats, pigs and sheep, the risk of human infection is through close contact with infected animals or their carcases (respiratory and cutaneous transmission) and, in the case of dairy goats and sheep, consumption of unpasteurized milk (digestive transmission). For SACs, the risk of human infection is from close contact (mainly through spitting). Human cases of *M. bovis* infection contracted from non-bovine farmed animals are very rare.

7.4. Because there is no statutory surveillance programme for these species, there is uncertainty around the true prevalence of infection. The Advisory Committee on Dangerous Pathogens *M. bovis* Working Group[82] has advised that should *M. bovis* cases in non-bovine species at slaughterhouse increase in frequency, then the risks

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[80] http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=17952&FromSearch=Y&Publisher=1&SearchText=fertility
[81] Trewby *et al*, 2008 https://doi.org/10.1098/rsbl.2007.0516
[82] http://www.hse.gov.uk/biosafety/gmo/acdp-m-bovis-working-group.pdf

should be reviewed. There has been no consistent increase in the frequency of *M. bovis* infection detected in these species at slaughterhouse between 2011-2017 (see Table 7.1).

Table 7.1: Animal specimens that were culture positive for *M. Bovis*

Species	2011	2012	2013	2014	2015	2016	2017
South American Camelids	17	45	36	34	39	20	30
Sheep	35	20	3	1	7	2	4
Goats	0	2	7	29	0	27	7
Pigs	44	20	35	18	23	31	24
Deer	23	17	27	24	34	29	29
Other	22	12	30	26	42	30	11

7.5. Domestic pets can be infected with *M. bovis,* but again cases are thought to be rare. The risk of infection to these species comes from ingestion; for example, drinking unpasteurised infected cow's milk, eating carcases of infected animals, and direct or indirect contact with infected farm animals or wildlife (badgers or, in rare cases, deer).

Rationale for action on other farm-managed species

7.6. Recent veterinary risk assessments[83] conclude that non-bovine farmed animals in the UK are largely 'spillover' hosts: individuals are at risk of becoming infected from the major carriers of *M. bovis*, mainly in areas of the country where *M. bovis* infection is known to be endemic. Non-bovine species vary in the extent to which the disease is able to persist in their populations. Given the right conditions, they can also infect other animals and herds of the same species (e.g. via movements of undetected infected animals between holdings). However, the current consensus is that bovine TB in non-bovine farmed animals and pets would gradually disappear if the infection could be brought under control in cattle and badgers.

7.7. There is uncertainty about the true prevalence of *M. bovis* infection in non-bovine farmed animals because data come chiefly from slaughterhouse inspection and post mortem examinations in veterinary laboratories which, as in cattle, have a relatively low sensitivity compared with live testing. However, the presence of potential non-bovine hosts on (or near) cattle farms affected by bovine TB breakdowns is of concern for disease control.

7.8. Except where noted below, the SICCT test (¶ 2.24) is used to test for bovine TB in other farmed animals though currently it is only internationally recognised for use in

83 https://consult.defra.gov.uk/bovine-tb/tb-in-non-bovine-farmed-animals-call-for-views/

deer, goats and SACs. In species where skin testing is difficult, such as pigs and farmed deer, the results of slaughterhouse post mortem examinations may be taken into consideration when decisions are made on whether to lift restrictions from infected herds.

7.9. SACs tend to be kept on dedicated farms and purchased at specialist and direct farm-to-farm sales. Most incidents of bovine TB in SACs in England (see Table 7.2) occur in the HRA and the EA. Cases of bovine TB transmission within and between SAC herds have been recorded, but not to other animals (except, very rarely, to humans in close and frequent contact). There is no mandatory requirement to identify, register or report SAC movements in GB. Some infected animals display extensive and severe pathology and can be highly infectious.

7.10. Pre-movement testing (SICCT or SICT, ¶¶ 2.24 & 2.25) is required when trading SACs between EU member states and most third countries. However, skin tests perform poorly in SACs and bovine TB has been difficult to diagnose in live animals until recently. New serological tests have been validated by APHA, and are now approved for use in the UK in conjunction with the skin tests and, in some cases, as standalone tests.

7.11. Deer are susceptible to bovine TB and low levels of infection have been detected in farmed deer in the UK (see Table 7.2), mainly in the HRA and the EA. Deer are moved from parks and farms to provide breeding stock for new or existing herds or for finishing, or from farms to specialist slaughterhouses, though in much smaller numbers compared with cattle. Deer must be moved under licence with animals identified using an ear tag. Surveillance entails compulsory notification of suspect clinical cases and passive surveillance at slaughterhouses. Cases of bovine TB transmission between deer herds through infected animal movements have been recorded in the UK, and experimental studies have shown that the disease can be transmitted from deer to cattle, with free-ranging and captive deer implicated in the spread of bovine TB in cattle in the USA, Canada, RoI and New Zealand (EFSA 2008)[84]. The SICCT is used to test for bovine TB in deer with a minimum between-test interval of 120 days.

7.12. Data suggest that the prevalence of bovine TB in goats is low (Table 7.2). There are some large commercial milking herds but many goats are kept on hobby farms or as pets. Goats are longer-lived than cattle, increasing the risk of disease progression and transmission within herds. This has led to a small number of serious ('explosive') bovine TB incidents involving large commercial dairy goat herds in the HRA. Movements of goats to or from farms must be recorded. Surveillance relies on compulsory notification when disease is suspected in carcases, post mortem reports, passive surveillance at slaughterhouses and targeted skin testing of goats adjoining or co-located with cattle herds affected by lesion- or culture-positive bovine TB breakdowns. Goats kept as pets or in petting zoos pose a potential route of transmission to humans.

Table 7.2: Non-Bovine Reactors slaughtered (England)[85]

[84] EFSA, 2008. Scientific report on „Tuberculosis testing in deer". Panel on Animal Health and 671 Animal Welfare, Question No. EFSA-Q-2006-179, Adopted on 30 January 2008. Annex to the 672 EFSA Journal 645, 1-34.

[85] https://www.gov.uk/government/statistical-data-sets/other-tb-statistics

Species	2011	2012	2013	2014	2015	2016	2017
South American Camelids	79	393	75	55	201	37	297
Sheep	2	62	22	0	0	1	5
Goats	2	2	165	431	1	755	4
Pigs	3	5	8	3	0	16	0
Deer	44	3	16	3	5	6	0
Other (mainly pets [cats and dogs] and the occasional sample from exotic mammals kept in zoos, safari parks).	0	0	0	0	0	0	2

7.13. The reported incidence of bovine TB in sheep is very low (Table 7.2). There are no reports of sheep infecting other species of farmed animals and no evidence of disease spread from sheep to wildlife in the UK. Evidence suggests that sheep are only likely to become infected when the level of challenge is relatively high, and infection within the flock is unlikely to be sustained without contact with a local cattle or wildlife reservoir[86,87]. Clinical signs of disease are very rare in live sheep and surveillance relies on statutory post mortem reporting, isolation of *M. bovis* and slaughterhouse surveillance. The SICCT test is used to test for bovine TB in sheep.

7.14. The incidence of bovine TB in pigs caused by *M. bovis* infections has increased slightly in recent years in GB, but overall remains very low (Table 7.2). There is no evidence of spread of *M. bovis* from pigs to cattle. The majority of cases in pigs in recent years have been detected in areas of endemic bovine TB, caused by the same genotype of *M. bovis* as local cattle infections. With direct contact between pigs and cattle rarely reported, this suggests pigs are mainly infected by wildlife[88].

7.15. The number of tuberculous pigs found on the same infected unit is generally very low, which suggests limited within-herd transmission. The risk of disease entering the pig population is greatest for pigs raised in outdoor systems where there is greater opportunity for contact with *M. bovis* in wildlife, or on farms with limited biosecurity. However, pigs are susceptible to a number of highly contagious diseases, which has led the industry to adopt relatively strong biosecurity standards which will help mitigate risks from bovine TB.

7.16. There is a statutory requirement to identify, register and report movements of pigs. These movements often occur as part of all-in-all-out (AIAO) management systems that keep animals together in groups closely matched by age, weight, production stage and condition. Animals from different groups are not mixed during their stay on the farm. AIAO systems are thought to reduce disease risks from other animals and the environment as individual barns or pens can be emptied and sanitized

[86] Cousins et al. 2001 Rev. sci. tech. Off. int. Epiz., 20, 71-8
[87] Marianelli et al. 2010 https://doi.org/10.1177/104063871002200319
[88] Bailey et al, 2013 https://doi.org/10.1016/j.tvjl.2013.08.035

between groups. The SICCT test can be used to test for bovine TB in pigs, though there is no legal requirement for testing in the context of international trade except for the export of germinal products to some third countries such as China.

7.17. Sporadic incidents of bovine TB in non-bovine farmed animals have been documented in other countries; for example, goats and alpacas in Spain and RoI, and sheep in North-western Spain. The OIE Terrestrial Code outlines the requirements for trade in non-bovine animals. For countries without bovine TB-free status, a surveillance system must be in place as part of the regulation of live deer export. For other species, a mandatory system of disease notification must be in place and exports should only be from bovine TB-free herds.

7.18. Limited authorisation has been granted in the UK to use an inactivated MAP (*Mycobacterium avium* spp. *paratuberculosis*) vaccine (Gudair) in sheep and goats to help control Johne's disease. The vaccine may interfere with the interpretation of the SICCT and SICT tests for bovine TB as it tends to elicit a cross-reaction to *M. bovis* and *M. avium* tuberculins. The vaccination status of the animal must be noted when testing sheep and goats for bovine TB; in the event of a bovine TB breakdown, decisions are taken on a case-by-case basis to account for this (for example, removing the animals as direct contacts, switching to more severe interpretation of SICCT results, or opting to use SICT tests).

7.19. Only a very small number of *M. bovis* infections in pets, mostly cats, are recorded each year. Public Health England (PHE) has assessed the risk of cats spreading bovine TB to humans as very low.

Current policy

7.20. There are about 20 million non-bovine farm animals in England, the vast majority pigs and sheep. In 2017, 308 non-bovine animals were slaughtered as TB reactors or direct contacts. High numbers of goats slaughtered in 2013, 2014 and 2016 are the result of APHA's decision to undertake whole herd slaughter on individual large commercial milking goat herds with persistent and widespread bovine TB problems.

7.21. There is no statutory surveillance programme for bovine TB in farmed non-bovine species equivalent to that in cattle and so there is uncertainty around the true prevalence of *M. bovis* infection in non-bovine farmed animals. A voluntary surveillance scheme is in operation for SACs, mainly for individual animals moved between holdings. There are no active bovine TB testing programmes for deer, pigs, goats or sheep though Defra and APHA have discussed with the pig and farmed deer sectors possible trials for the validation of bovine TB blood tests in those species. Validated blood tests could speed up the resolution of bovine TB incidents in species where skin testing is impractical or unreliable. Testing (at government expense) is normally carried out in SACs, goats and captive deer co-located with, or in close vicinity to, infected cattle; or which have been moved from premises where *M. bovis* infection has been confirmed by culture.

7.22. There is a statutory duty immediately to notify to APHA the suspicion of disease in non-bovine carcases, in live deer, or when *M. bovis* is identified by laboratory examination of a sample from a live animal or carcase. Cases are usually identified, post mortem, through meat inspection or laboratory examination. APHA places the remaining animals in the herd of origin under movement restrictions pending bacteriological culture results. If those results are positive for *M. bovis* the affected herd is tested for bovine TB at government's expense until testing or slaughter surveillance has demonstrated the absence of infection. Contiguous or radial targeted bovine TB testing takes place around such herds, directed by APHA.

7.23. Since 2017 non-bovine animals removed by APHA for bovine TB control purposes in England attract statutory compensation payments at fixed rates, depending on the species and category of the animal[89].

7.24. Government works with various sectors groups to raise awareness among farmers of the risks of *M. bovis* infections in non-bovine species and measures that can be taken to reduce them. In 2016, Defra consulted on the need for more stringent interventions against the disease in non-bovines; for example, measures to enhance reporting and surveillance, and to require veterinary inspectors to investigate where there is suspicion of bovine TB in live animals or carcases.

7.25. The consultation proposed additional steps to enhance disease control for non-bovines through: (i) isolating animals and restricting movements, (ii) requiring operators of markets, shows etc. to manage risks posed by animals exposed to bovine TB, (iii) requirements for bovine TB testing at specified intervals, and (iv) applying rules and requirements for testing, treatment and vaccination to all non-bovines. Responses to the consultation raised concerns about the protection of rare breeds, and the efficacy of TB testing in pigs. No changes in current policy have so far resulted from this consultation, except for the introduction of new statutory compensation rates for slaughtered non-bovine animals.

7.26. In England, any live testing of domestic pets for bovine TB is voluntary and done at the owner's expense. Tuberculin skin tests are unreliable in cats and dogs and there are no official validated blood tests for bovine TB in these species (an experimental IFNγ release assay for cats and dogs is offered on a commercial basis by an Edinburgh-based private diagnostic laboratory). Defra and APHA strongly recommend the destruction of pets with confirmed *M. bovis* infections due to the lack of licensed drugs to treat infected animals and the protracted courses of antibiotics that would be required.

7.27. APHA and PHE provide guidance on minimising the risk of human infection to keepers of non-bovine animals with confirmed *M. bovis* infections. This review has not considered the issue of bovine TB in companion animals.

Options for the future

Continue with the current regime

7.28. The incidence of bovine TB (*M. bovis* infections) in non-bovine farmed animals is considered relatively low based on the number of reactors slaughtered through passive surveillance (see Table 7.2). Because there is no statutory surveillance system in place there is considerable uncertainty around the true prevalence of *M. bovis* infection in these species, but at present they appear to play an insignificant

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[89] The Tuberculosis (Non-bovine animals) Slaughter and Compensation (England) Order 2017. (see: http://www.legislation.gov.uk/uksi/2017/1254/contents/made)

role in the transmission of *M. bovis* infection to cattle and badgers. This suggests that the costly interventions introduced for cattle, including routine surveillance testing, would be disproportionate. Incidence remains fairly static in most species, but a number of premises have been subject to long-term restrictions. This places a burden on individual businesses.

7.29. There is concern that because of the absence of regular testing there may be more infections in non-bovines than is currently appreciated though the number of observed cases from passive surveillance at slaughterhouse and veterinary laboratories does not appear to be going up. Further, legislation for the control of bovine TB in non-bovine species has developed in piecemeal fashion, remains unconsolidated, and can be unclear to industry and challenging to enforce.

Consolidation of legal provisions

7.30. Consolidation of current rules, as suggested in the consultation on non-bovines in 2016, to make a more coherent and transparent regulatory regime would make it simpler for businesses to comply and regulators to police and enforce. A unified bovine TB Order for non-bovines would set out rules and duties around (i) reporting suspicion of the disease; (ii) veterinary enquiry; (iii) government mandated and private testing; (iv) vaccination and therapeutic treatment; (v) biosecurity; (vi) movement and risk-based trading (vii) compensation, and (viii) financial responsibilities.

Targeted measures where there is a risk of human infection

7.31. Dairy sheep flocks and goat herds kept to produce unpasteurised milk and dairy products for human consumption, or non-bovine animals to which the public are exposed on petting farms, zoos or similar establishments, pose an infection risk to humans. This could be reduced by annual testing of animals on such premises.

7.32. Though the risk to humans is currently understood to be very low, the reputational risk both to the farming and recreational sectors involved are great and may justify such intervention. Research and development of appropriate tests would be needed for species where a sensitive and specific validated test is not currently available.

Introduce stricter controls on movements of non-bovines

7.33. The introduction of the Livestock Information Service (Chapter 5) would facilitate the introduction of control measures for non-bovine species. The inclusion of SACs would facilitate surveillance, tracing of contact animals and monitoring of movement testing. There have been some cases of secondary bovine TB incidents (including in the LRA) caused by movements of infected alpacas, goats and farmed deer from the HRA. Mandatory pre- and post-movement testing would reduce the risks of translocating bovine TB between herds via movements of infected SACs, managed deer and goats. Validated tests for bovine TB are available for these species. Such testing could be funded by the respective industries, as is presently the case for the movement testing of cattle.

Introduce stricter measures for bovine TB breakdowns in non-bovines

7.34. In Chapter 3 we discuss means of ridding infections more quickly from cattle herds after a breakdown. These measures could be applied, suitably modified, to non-bovines, subject to cost-benefit analysis. As with cattle this could help the farmer and reduce the risk of onward transmission of *M. bovis* infection. Implementing this strategy would require the development of suitable validated tests for different species, where these do not currently exist (see also Research Priorities ¶ 7.37).

Applying to non-bovine species the full range of bovine TB controls that currently apply to cattle

7.35. Such interventions would clearly reduce the risk of bovine TB in species other than cattle. However, the costs of introducing current cattle controls across all species would be very great for Government and place a substantial burden on the different industry sectors.

7.36. Selective species could be subject to measures similar to those that currently apply to cattle if the incidence of the disease was thought to warrant it in future. Such an option would form a part of an adaptive management approach to bovine TB control.

Research priorities

7.37. Development of better (blood-based) tests for some non-bovine species (chiefly pigs and deer) is a research priority. Given the poor performance of skin tests (SICCT, SICT) in some non-bovines, research into the development of alternatives would be valuable. Better tests for pigs are particularly important because a rise in prevalence in this species could have significant effects on exports of British pig meat to some key international markets such as China and India.

7.38. Development of rapid molecular diagnostics based on PCR would speed up the identification of *M. bovis* in pathology samples from suspicious lesions discovered at slaughterhouse inspection or during post mortem surveillance of non-bovine farmed animals. This would minimise the interval between detection of the index case and testing of the herd of origin (or withdrawal of precautionary movement restrictions, if the sample proved PCR or culture negative).

Chapter 8: Biosecurity, compensation and insurance

Introduction

8.1. This chapter discusses several issues that involve the farmer. These include the implementation of biosecurity measures to lessen the risk of transmission amongst cattle or from wildlife to cattle, and how farmers are protected from the risks of herd breakdown and loss of cattle to slaughter through compensation or insurance. It also explores some issues of how the structure of the farming industry may affect disease transmission.

8.2. Taking biosecurity measures on farms to limit the spread of bovine TB represents an important element of management practices that can be implemented by farmers through sanitation, surveillance and organisational integration[90].

8.3. An incidence of bovine TB on a farm has substantial economic (and other) consequences for the farmer. Currently part of the economic loss is met through compensation paid for by the state. There are alternative models of helping farmers cope with the disease, including insurance schemes with state support.

Rationale for action

Biosecurity

8.4. Quantitative information on transmission pathways is difficult to obtain which makes it hard to judge the most important routes of infection to address through biosecurity interventions. There have not been large-scale, replicated and controlled trials of biosecurity interventions, and the information that does exist is largely correlative and based on investigation of individual bovine TB breakdowns. In 1999 the TB99 questionnaire was introduced to be used by the then State Veterinary Service Veterinary in interviews with farmers and herd managers after every breakdown[91]. The information today is gathered through a similar process using the Disease Report Form (DRF), which replaced the TB99 in 2004.

8.5. Because of the inadequacies of the readily available data, the rationale behind many biosecurity measures is thus precautionary or, when relatively cheap to implement, a 'no regret' option. In many cases, biosecurity measures recommended for Bovine TB overlap with recommendations for the control of other diseases such as Johne's Disease.

8.6. Herd size is the single most common risk factor for bovine TB in Britain[92]. However, it is probably not size, per se, that determines the greater susceptibility of larger

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[90] Hinchliffe *et al*. 2012 https://doi.org/10.1111/j.1475-5661.2012.00538.x

[91] The TB99 process is described in some detail in: Independent Scientific Group on Cattle TB (2007) *Bovine TB: The Scientific Evidence, A Science Base for a Sustainable Policy to Control TB in Cattle*

[92] Brooks-Pollock, E., & Keeling, M. (2009) https://doi.org/10.1016/j.prevetmed.2007.11.001 Carrique-Mas, J. J., Medley G. F., & L. E. Green (2008) https://doi.org/10.1016/j.prevetmed.2007.11.001

herds, but practices that tend to be more associated with larger herds such as purchasing activity, farm size, number of premises and neighbouring herds[93].

8.7. Transmission between cattle may occur through direct contact, through close contact and the inhalation of bacteria in aerosol droplets, or through feed or grazing contaminated by infected faeces or slurry. Calves may contract bovine TB from infected colostrum or milk.

8.8. Transmission to and from badgers and other wildlife is thought most likely to occur through environmental contamination rather than from direct contact[94]. Infected badgers can shed bacteria, and badger presence on cattle grazing, drinking from water troughs, and entering cattle sheds to forage for food, are all considered possible routes of transmission.

8.9. The feasibility of implementing different biosecurity measures depends on the farming system being operated. For example, it is easier to insulate indoor-housed dairy cows from badgers than those that graze on grassland, but cattle-to-cattle transmission is likely to be more frequent in the close confines of cattle sheds. Feeding pasteurised colostrum to calves is more practical in intensive dairy systems than in single-suckle beef herds.

8.10. Because of the challenges in identifying routes of transmission, demonstrating the efficacy of biosecurity to the farming community has been difficult. There is evidence that farmers are unconvinced of the need for biosecurity measures, or do not feel empowered and hence are fatalistic about the risk of bovine TB infection[95]. A similar issue also affects private veterinarians, who play an important role in recommending biosecurity measures to farmers, as they are less inclined to advise on biosecurity take-up if the demonstrable efficacy of such measures is lacking[96]. There is evidence that implementation of badger but not cattle biosecurity measures is more likely on farms that have experienced bovine TB[97], an indication that many farmers view badger-cattle transmission as more important than cattle-cattle[98].

Structure of the farming industry

8.11. Investment in biosecurity and other types of capital improvement are influenced by ownership models. For example, there are a range of tenancy agreements from Full Agricultural Tenancies (FAT) with long-term security, through Farm Business Tenancies (FBT) with an average occupancy of around four years[99], to short-term contract farming arrangements which typically last less than two years (and grazing arrangements that are even shorter). Responsibility for investment to reduce disease risk may be complicated; for example, tenants are typically responsible for

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93 Broughan, J. M., Maye, et al (2016) https://doi.org/10.1016/j.prevetmed.2016.05.007
94 Woodroffe, R., et al (2016) https://doi.org/10.1111/ele.12654
95 Maye, D., Enticott, G., Naylor, R., Illbery, B., & Kirwan, J., (2014) https://doi.org/10.1016/j.jrurstud.2014.07.001
96 Gunn, G.J., Heffernan, C., Hall, M., McLeod, A., & Hovi, M. (2008) https://doi.org/10.1016/j.prevetmed.2007.12.003
97 Farmers were asked about measures taken in the previous twelve months: Brougham et al; op.cit.
98 Ibid.
99 CAAV (2018) *The Annual Agricultural Land Occupation Surveys for Great Britain*. It should be noted that the survey is based on the evidence from local associations of the CAAV and therefore many informal local arrangements are not covered

fences that can prevent contact with neighbouring herds or badger setts, while landlords are responsible for buildings that should be badger-proof. Tenants on short-term leases will have limited incentives to invest in biosecurity capital. Rents are usually lower in FATs than shorter-term FBTs[100], which reduces the incentive to landlords to make expensive capital investments given the low return on capital.

8.12. There has been a recent increase in the extent to which individual farms are fragmented into non-contiguous holdings. These satellite holdings may have been purchased from other landowners or they may be farmed through a tenancy or other agreement such as a grazing licence or Temporary Land Association (TLA). For example, in England and Wales, since the scheme began in 2016, 13,109 TLAs have been approved on CPHs which have an active cattle unit out of a total of 16,019 TLAs approved for all species[101]. One driver of this trend has been an increase in farm purchase by people only wanting to live in the farm house or who carry out restricted 'hobby farming' on a subset of the land.

8.13. Another driver has been the way that the CAP's Basic Payment Scheme (BPS) and UK tax law have encouraged landowners that no longer wish to farm (or who have bought the farm for an investment) to retain ownership of land but let others use it for grazing or cropping on a range of short-term tenancies or share/contract farming arrangements[102]. Farmers entering into these arrangements are thought to be exploiting local economies of scale though one of the few studies of fragmentation (in Brittany) found an association of fragmentation with lower profitability[103]. The significance of fragmentation for bovine TB is largely as a result of the increased opportunity it provides for contacts with cattle from contiguous herds, which has been associated with an increased risk of disease transmission[104]. In another study, the distance of the furthest fragment rather than fragmentation alone increased the likelihood of a recent bovine TB incident on beef farms; there was less evidence of the significance of fragmentation on dairy farms[105].

8.14. Both beef and milk can be produced under a range of different systems. Beef cattle may derive from unwanted calves from the dairy industry or from pure beef suckler cow herds. In broad terms, beef cattle are fattened (finished) in one of three different systems: 'intensive', usually indoors and reliant on concentrates and conserved forage (12-15 month finishing time); 'semi-intensive', where the animals are outdoors in the summer and indoors in winter utilising grass, conserved forage, cereals and concentrates (15-20 months); and 'extensive' based on forage and grass (more than 20 months). Many beef systems are straw-based so that farm-yard manure rather than slurry is produced though some of the larger modern intensive finishing units will be slurry-based.

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100 The legal arrangements for rent review are governed by two separate pieces of legislation. The Agricultural Holdings Act 1986 provides for statutory rent arbitration for FATs. The Agricultural Tenancies Act 1995 for FBTs allows greater contractual freedom including opt-out of statutory arbitration. FBS data show FAT rents in 2016 averaged £181 per hectare as against £219 under FBTs, a £38 per hectare or 17% difference.

101 Source: APHA data.

102 Winter, M. and Lobley, M. (2016) http://www.princescountrysidefund.org.uk/downloads/research/is-there-a-future-for-the-small-family-farm-in-the-uk-report.pdf

103 Latruffe, L., & Piet, L. (2014) https://doi.org/10.1016/j.agsy.2014.05.005

104 Johnston, W. T., et al (2011) https://doi.org/10.1016/j.ijid.2011.08.004; Karolemeas, K., et al (2011) https://doi.org/10.1016/j.prevetmed.2011.06.004

105 Broughan et al (2011) op.cit.

8.15. In dairying, there is a continuum from systems that produce milk primarily from grass, some using the New Zealand system of intensive paddock grazing for up to 10 months of the year, through to indoor systems based on conserved forage (maize or grass) and concentrates (the vast majority slurry-based). There are now relatively few extensive small dairy herds as part of a mixed farm system though there has been a growth of interest in organic micro dairies. Also, the once common straw-based dairy herds on arable farms are fewer in number. Dairy systems can also be differentiated by whether they calve at one time or continuously.

8.16. The implications of different systems for bovine TB are complex. On the one hand intensive systems facilitate a reduction in the risk from wildlife and can reduce cattle-to-cattle transmission through, for example, pasteurising colostrum. On the other hand, grass-based extensive systems can reduce close cattle-to-cattle contact. For example, one study has associated lack of outside shelter for cattle at pasture with a reduced risk of a breakdown, interpreted to be because of the reduction of opportunities for cattle to be in sustained close direct contact[106].

8.17. The proportion of farms using cattle farmyard manure as opposed to cattle slurry has remained roughly constant over the last five years, and in 2017 47% of surveyed farms used manure and 16% slurry[107]. They are not, of course, mutually exclusive categories as some farms will use both.

8.18. The importance of farm contractors as a source of both labour input and specialist machinery has increased in recent decades and many livestock farmers use contractors who move from farm to farm for tasks such as slurry spreading, silage making and hedge cutting. In a survey of over 1,000 farmers in the south-west, over 90% of dairy farmers and 85% of livestock farmers used contractors[108]. The movement of slurry tankers without being washed or cleansed within and between farms was identified as a potential risk factor in an outbreak of bovine TB in Cornwall nearly 45 years ago[109]. A recent study in Northern Ireland found an association between increased risk of bovine TB and the use of contractors for spreading slurry[110] .

8.19. Common grazing lands are areas, typically moorland, where multiple livestock holders have the right to graze. There clearly is an opportunity for herds to mix and bovine TB transmission to occur on commons. Rates of herd breakdown amongst Dartmoor graziers are slightly higher than for the rest of Devon[111] though this could be due to a correlation with a third factor. Grazing of commons can be important in the management of habitats, including those important for biodiversity, and the

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[106] Johnston et al 2011 op. cit

[107] https://www.gov.uk/government/statistics/british-survey-of-fertiliser-practice-2017

[108] Nye, C. (2018). https://ore.exeter.ac.uk/repository/handle/10871/33119

[109] Richards, R. (1972). *Inquiry into Bovine Tuberculosis in West Cornwall*. MAFF, London; cited in McCallan, L. McNair, J and Skuce, R. (2014) *A Review of the Potential Role of Cattle Slurry in the Spread of Bovine Tuberculosis,* Agri-food and Biosciences Institute, Belfast. https://www.daera-ni.gov.uk/sites/default/files/publications/dard/tb-slurry-lit-review.pdf

[110] O'Hagan, M.J.H., Matthews, D.I., Laird, C. & McDowell, S.W.J. (2013) *Bovine Tuberculosis Study, County Down, Northern Ireland 2010-2011*, Department of Agriculture, Environment and Rural Affairs.

[111] APHA data.

Open Spaces Society has raised concern about the imposition of restrictions on common grazing[112].

8.20. Individual and social barriers to behaviour change including the greater uptake of biosecurity measures have been identified in qualitative research with farmers[113]. An important aspect is the lack of perceived behavioural control over disease spread. If farmers do not believe they have a degree of control over TB, they are less likely to implement recommended measures[114]. Another individual aspect is the tendency to discount the long-term benefits of investing in biosecurity; because the benefits of enhanced biosecurity may not be seen immediately and therefore receive less weight in decision-making compared to the immediate needs of the farm business[115]. Among the social barriers, two stand out: the lack of a perceived social norm for biosecurity and the engrained social practices that shape how farmers approach their daily routine[116]. Farmers do not operate in isolation and if neighbouring farms are not seen to be performing biosecurity, the impetus for action is reduced. Evidence shows that many farmers take pride in their accumulated expertise, so that the implementation of new or under-utilised biosecurity measures may require a fundamental shift to traditional approaches.

8.21. There are some issues that contribute to the difficulty farmers may face in complying with biosecurity conditions. For example, there is the question of the cost of biosecurity measures requiring capital expenditure in relation to the low profitability of many beef and some dairy enterprises, and the wide range in economic performance across the two sectors. Put simply, some farmers have a greater capacity to make the necessary capital investments than others. In particular, the level of debt is a critical issue for any business considering an investment.

8.22. A wide range of debt circumstances face farmers and this is captured in the notion of 'gearing' which is defined as total liabilities as a percentage of net worth. A low ratio suggests that the farm business is more likely to be able to meet its investment needs from earnings. The average gearing ratio for all farm types in 2016-17 was 10%. There are lower average ratios amongst livestock grazing businesses as this is not a capital-intensive sector. The dairy sector has relatively high ratios with 10% of dairy farms having a gearing ratio value of over 40% (see Figure 8.1). Tenanted farms have an average gearing ratio of 29%, whilst owner occupied farms had an average ratio of 7% (Figure 8.2).

8.23. There is not a straightforward relationship between gearing and the likelihood of farmers making biosecurity investments. Much will depend on the attitude of an individual famer to both debt and the need for biosecurity investment. Some with low debt may be averse to investment and borrowing in any circumstances. Some with high debt will see the necessary investment as merely a modest addition to an

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112 https://www.oss.org.uk/bovine-tb-control-and-commons/
113 Fisher, R. (2012) http://eprints.glos.ac.uk/1178/
114 Ibid.
115 Garforth, C.J. (2015) https://doi.org/10.1111/zph.12189
116 Escobar, M.P., & Buller, H. (2014). Projecting social science into Defra's animal welfare evidence base: A review of current research and evidence base on the issue of farmer behaviour. http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=18442

already high debt burden. However, there will be some for whom any additional debt is seen as highly undesirable and therefore the high level of debt in parts of the dairy sector is a cause of concern.

Figure 8.1 Distribution of Gearing Ratio by farm type[117]

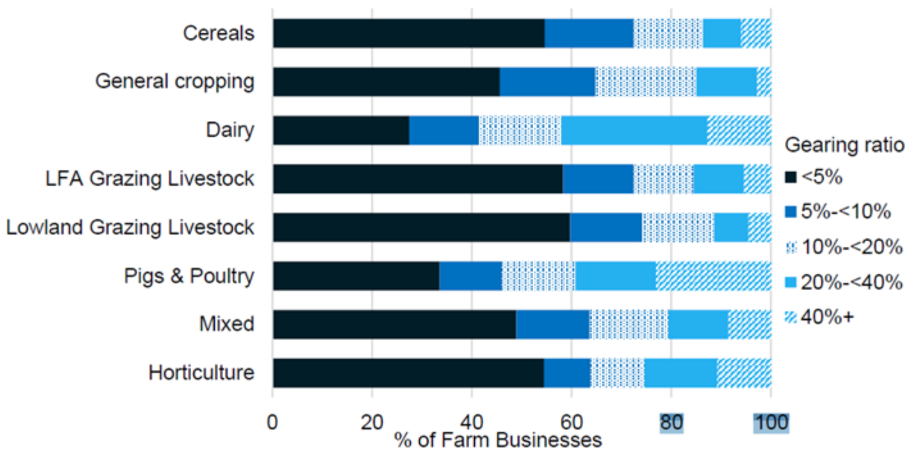
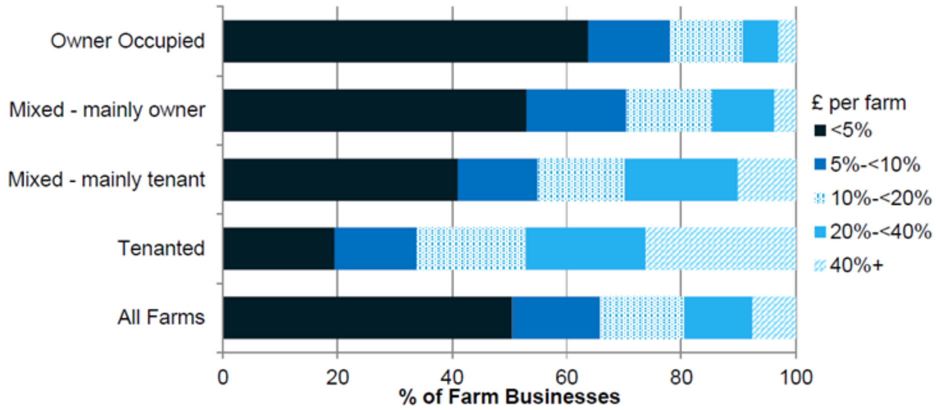


Figure 8.2: Distribution of Gearing Ratio by farm tenure[118]



Compensation

8.24. Several arguments are used to justify the payment of compensation to farmers for the losses occurred due to bovine TB. The first is that for the benefit of the industry (and to a lesser degree public health) robust measures are taken to test for bovine TB and to slaughter infected animals beyond those that an individual farmer would take for the good of his or her business. The second is that the farming industry is being asked by society to refrain from doing certain things that otherwise it would want to do, in particular engage in more extensive culling. The continued presence

[117] Defra, Balance sheet analysis and farming performance, England 2016/2017. https://www.gov.uk/government/statistics/historic-balance-sheet-analysis-and-farming-performance-england

[118] Ibid.

of protected badgers on farmland can be viewed as a minimum standard, akin to basic animal welfare, or as a merit good provided by the farming community that justifies recompense. Third, the unusual prevalence of bovine TB in the UK places the industry at a competitive disadvantage which compensation helps redress. Fourth, government may wish in general to support the dairy and beef industry for the direct benefits it brings, as well as the indirect benefits for rural economies. We return to issues of industry versus government support for bovine TB control in Chapter 9.

8.25. Setting the right level of compensation is important to avoid generating perverse incentives. If the level is too high then farmers may lack incentives to reduce the risk of disease, and in rare cases may fraudulently claim animals are diseased. Setting the level too low would, in addition to causing financial stress to the farmer (assuming no other mitigating strategies such as insurance are available), incentivise poor compliance with disease surveillance. An analysis of Farm Business Survey data shows that there is no significant difference in average farm business income or the likelihood of having negative income between farms with cattle that had a bovine TB compensation payment in 2014-15 to 2016-17 and those that did not (whether or not Basic Farm Payments are included). Similarly, there is no significant difference in income between cattle farms in each of the three bovine TB risk areas (HRA, EA and LRA)[119]. These data do not, of course, reveal anything about the levels of stress, anxiety and business disruption suffered by many farmers due to bovine TB[120].

Insurance

8.26. An alternative means of providing mitigation of financial loss is through insurance. The cost of insurance could be met wholly by the individual business, it could be subsidised by a regional or nation-wide levy, or it could be subsidised by the state. The insurance programme could be run by the private or public sector, or by some hybrid model.

8.27. Compensation is akin to insurance with a zero premium and one could transition from compensation to insurance by introducing a premium. An advantage of an insurance scheme is that variable premiums could be introduced to incentivise behaviours likely to reduce disease incidence. Currently such behaviour is incentivised by reducing compensation in some circumstances which is a much coarser instrument. Making variable premiums work effectively requires experience and access to relevant information by the insuring body.

8.28. Successful insurance schemes must avoid 'adverse selection' and 'moral hazard'. Adverse selection is the tendency for those most at risk to purchase insurance while those less at risk do not. This is a particular issue with bovine TB because of its concentrated geographical distribution. It is typically countered by Government

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[119] Clothier, L. and Betts, C. (2018) Loss of Direct Payments: Assessment of vulnerability of farms with cattle in bTB risk areas and farms that have had bTB compensation payments, Internal Defra paper. The analysis used a subset of data for farms with cattle from the Farm Business Survey for 2014/15 – 2016/17. The analysis compares cattle farms that have had a bovine TB compensation payment with those that have not and provides a comparison between the 3 bovine TB risk areas (HRA, EA and LRA). The risk areas used are those in place from January 2018.

[120] Farm Crisis Network (2009) *Stress and Loss: A report on the impact of bovine TB on farming families,* Northampton, FCN. http://www.tbfreeengland.co.uk/assets/4200

interventions such as making insurance compulsory or subsidised. Moral hazard is the tendency for those insured to take riskier behaviours (as also occurs with compensation). The introduction of behaviour-related premia can help counteract this.

8.29. Evidence provided to us from the Government Actuary's Department (GAD) explains the circumstances when government might usefully intervene in the commercial insurance market. In addition to the above, one of these is when a commercial insurance market may exist in the future, but requires initial government intervention as insurers may be unable or unwilling to participate due to a lack of experience and reliable models, or a relatively small number of risks to be insured. The bovine TB case would appear potentially to fit into this category.

Current policy

Biosecurity

8.30. Since 2016 APHA has issued bovine TB farm level reports routinely to farmers in all cases of new bovine TB breakdowns[121]. The report presents a collated view of historical data on the herd held by APHA and the Rural Payments Agency (RPA). It is intended to help farmers understand the causes of bovine TB in their herd and assess the potential for changes to their husbandry practices to mitigate future risk. Farmers are encouraged to share the report with their veterinary surgeon and seek support and advice.

8.31. In addition, in some circumstances APHA visits take place to investigate the circumstances of breakdowns and assess the likely risk pathways for infection. Data are gathered through DRFs that are typically compiled by veterinarians based on observations during visits to gather epidemiological data and using information provided by the farmer, sometimes supplemented by existing APHA and CTS data for that farm. Much of the information is gathered in the form of free text which is costly to transcribe and store electronically.

8.32. In the HRA, DRFs are completed in approximately 60% of cases. This is made up of two groups: (i) a random sample of one in three new breakdowns and (ii) a proportion of the remaining breakdowns based on a triage process to focus on the high priority cases that can benefit from a DRF. In the EA, DRFs were completed for all new breakdowns until very recently – now, in Cheshire, due to the number of breakdowns, a triage process (similar to the one deployed in the HRA) has been introduced to target interventions. In the LRA, DRFs are completed for all new breakdowns. Farmers have the option to share some of the content of the DRF with their private veterinarians. Data gathered from DRFs and other systems are fed into the Farm Level Report provided to all farmers within seven weeks of a new breakdown.

8.33. Extensive information about biosecurity is provided on AHDB's bovine TB Hub. The component devoted to biosecurity includes a Bovine TB Biosecurity Five-Point Plan[122] that focuses on (i) restricting contact between badgers and cattle; (ii)

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[121] APHA Briefing Note 14/16 Provision of bTB herd reports to new breakdowns in the High Risk and Edge Area of England http://apha.defra.gov.uk/documents/ov/Briefing-Note-1416.pdf

[122] http://www.tbhub.co.uk/biosecurity/protect-your-herd-from-tb

managing cattle feed and water; (iii) preventing infected cattle entering the herd; (iv) reducing risk from neighbouring herds; and (v) minimising infection from cattle manure. The TBAS (see Chapter 9), funded for an initial 3-year period, also provides biosecurity advice through farm visits and a telephone advice service.

8.34. Different accreditation and certification schemes mandate different biosecurity measures. For example, in the case of spreading slurry or farmyard manure, the Red Tractor Scheme recommends a minimum of four weeks before grazing resumes with ideally eight weeks for adult livestock and six months for young stock. By contrast, the Biosecurity Five-Point Plan recommends a two-month no-grazing interval for all cattle. The Five-Point Plan recommends the storage of manure for at least six months, before spreading on pasture, but the Red Tractor Scheme, whilst noting the importance of storage, does not specify a time period.

8.35. The most important accreditation scheme by take-up is the Red Tractor Scheme's 'Farm Health Plan' [123] (75% of livestock farmers participating in 2018 compared to 65% in 2017[124]). Table 8.1 compares the biosecurity measures recommended by the different schemes.

8.36. It is a condition of badger culling licences (see Chapter 6) issued by Natural England that "practicable, proportionate and appropriate" biosecurity measures are implemented for the duration of any licence[125]. Natural England assesses compliance by reviewing the mechanisms the culling companies put in place to ensure their participating farmers implement required biosecurity; for example, the extent of the information they provide farmers and engagement with local veterinarians. Natural England also carries out limited inspection. In the cull areas, 30-55% of farms receive APHA epidemiological investigations and Natural England targets a further ~5% for their inspections which focus in particular on preventing badger-to-cattle transmission. If non-compliance is found, 'advisory' or 'required' improvement notices are issued.

8.37. Funded through the Rural Development Programme for England, the 2018 Countryside Productivity Scheme (CPS) provided small capital grants for, among other things, badger-proof feed troughs (which cost ~£300 each), badger-proof lick holders (~£100), calf-milk pasteuriser/dispensers (~£7,000), and a machine to inject slurry into the soil surface (~£22,000). Grants were awarded between £3,000 and £12,000, covering up to 40% of eligible costs. [126] The CPS is a competitive scheme and the majority of the range of eligible items are not related to biosecurity. The new grants announced recently to tackle ammonia pollution may be helpful in terms of reducing the risks associated with slurry spreading[127].

[123] See Red Tractor Beef and Lamb Health Plan Template: https://assurance.redtractor.org.uk/contentfiles/files/Mocked_up_completed_health_plan.pdf

[124] Defra Farm Practices Survey 2018: https://www.gov.uk/government/statistics/farm-practices-survey-february-2018-greenhouse-gas-mitigation-practices

[125] Defra (May 2018) Guidance to Natural England: Licences to kill or take badgers for the purpose of preventing the spread of bovine TB under section 10(2)(a) of the Protection of Badgers Act 1992. https://www.gov.uk/government/publications/guidance-to-natural-england-preventing-spread-of-bovine-tb

[126] Prices from Annex 3 of the 2018 Countryside Productivity Small Grant Scheme Handbook.

[127] https://www.gov.uk/government/news/3m-support-scheme-launched-to-reduce-air-pollution-from-farming

8.38. For the purposes of bovine TB control, a farm is considered to be a unit with a single CPH number associated with a permanent registered holding. Land permanently acquired within a 10-mile radius (an area of over 300 square miles) of the registered holding can be associated with the same CPH number. Cattle movements within parcels of land in the same CPH do not need to be notified to the British Cattle Movement Service (BCMS). If a herd breakdown occurs, the whole CPH is placed under restrictions, though movement can still occur within the CPH. Farmers can apply to have non-permanently held land within the same area associated with the CPH through a TLA arrangement which lasts a year and can be renewed[128].

Table 8.1: Biosecurity Recommendations

Biosecurity Measure	Biosecurity five-point plan	Red Tractor-Beef	Red Tractor - Dairy	Xlvets	RSPCA - Dairy	Morrisons
Restricting contact between badgers and cattle:						
Find out if badgers visit your farm	✓					
Introduce barriers to prevent badgers accessing cattle	✓			✓		✓
Limit access of cattle to badger latrines and setts	✓					✓
Managing cattle feed and water:						
Badger-proof feed stores, troughs & mineral licks	✓	✓	✓	✓		
Don’t put feed on the ground at pasture and clean up spillages	✓					
Use clean, fresh water and badger-proof water troughs	✓					
Only feed waste milk to calves if it has been boiled or pasteurised	✓					✓

[128] https://www.gov.uk/government/publications/apply-to-register-temporary-use-of-land-to-keep-livestock

Biosecurity Measure	Biosecurity five-point plan	Red Tractor-Beef	Red Tractor - Dairy	Xlvets	RSPCA - Dairy	Morrisons
Preventing infected cattle entering the herd:						
Ask for TB history information before you buy new cattle	✓			✓	✓	✓
Post-movement test cattle entering the herd	✓			✓		✓
Isolate all higher-risk cattle before they enter a herd	✓			✓	✓	✓
Reducing risk from neighbouring herd:						
Check local TB breakdown data online at www.ibtb.co.uk	✓	✓	✓			
Put in place effective barriers between neighbouring herds	✓			✓		✓
Avoid sharing equipment or vehicles with other farms	✓			✓		
Avoid sharing cattle grazing with other herds	✓					
Reducing risk from neighbouring herd:						
Store manure for a long period before spreading on your farm	✓	✓	✓			
Only spread manure on arable land or pasture that is not going to be grazed by cattle for at least two months	✓	✓	✓	✓		✓
Minimise aerosols and contamination of roadways when spreading	✓					

Biosecurity Measure	Biosecurity five-point plan	Red Tractor- Beef	Red Tractor - Dairy	Xlvets	RSPCA - Dairy	Morrisons
Don't spread manure from other farms	✓			✓		

8.39. Since 2014, pre-movement testing also applies for cattle moving from HRA and EA holdings to common grazing in any of the three risk areas. Pre-movement testing is also required for all cattle moving from common grazing in the HRA and EA to a holding in any of the three risk areas, though exemptions allowing testing back on farm, can be made by local Commoners' Associations or groups of cattle graziers that have agreed a TB Control Plan[129]. Such plans, which may vary between each common (for example, to reflect that grazing practices and risks will vary from common to common), must be agreed in advance with APHA. All approved Control Plans would be expected to include a commitment to record cattle movements to and from the common.

Compensation

8.40. A large part of the financial risk of a herd breakdown is currently borne by the state through its payment of compensation, though this does not cover all the loss of income experienced by the farm business. Compensation for cattle slaughtered for bovine TB, is calculated under the Cattle Compensation (England) Order 2012 (based upon average livestock market prices for the relevant categories) and the Individual Ascertainment of Value (England) Order 2012. Compensation rates are adjusted monthly based on real market data from the preceding months. Sales data for around 1.4 million cattle are collected each year to support valuations. The 2012 Compensation Order amended an earlier 2006 Order, but both were based on compensation at average market value rates. The use of an average rather than an actual valuation of the affected stock means that some famers are over compensated and others under compensated for their actual losses. Compensation is only for the loss from animals slaughtered. It does not take into account the extra costs associated with retaining animals under movement restriction or loss of income, for example due to lower milk sales. Previously, farmers were paid 75% of the average market value of an animal slaughtered.

8.41. In England, compensation is reduced on a sliding scale where there has been a delay of more than 60 days on the part of the keeper in arranging for the TB testing of cattle herds. From 1 November 2018, a 50% reduction in compensation will also apply to:

(i) Animals that cannot be processed for human consumption at a slaughterhouse because they fail to meet required standards of cleanliness[130].

[129] Exeter AHVLA, Dartmoor Commoners' Council and the Dartmoor Hill Farm Project (2014) TB Control Plan for Dartmoor.

[130] https://www.food.gov.uk/business-guidance/cleaner-cattle-and-sheep

(ii) Animals brought into a breakdown herd that are subsequently found to be bovine TB reactors or direct contacts (i.e. other animals in the herd which APHA consider to be at high risk of being infected with TB) before the herd regains OTF status. This reduction will not apply to herds registered to a CHeCS (see Chapter 5) accredited bovine TB health scheme.

Options for the future

Improving the biosecurity evidence base

8.42. Current DRFs do not cover all the information that may be valuable in understanding disease transmission and helping to improve biosecurity advice. APHA has developed a new much more comprehensive version of the DRF in an electronic and more usable format though it has not yet been tested in a pilot. Testing and rolling out the new form would improve the evidence base underlying biosecurity measures.

8.43. Farmers do not always fully collate and utilise all the evidence available to them. One example of how farmers and veterinarians can work together to assemble and analyse the necessary data is the online tool, 'MyHealthyHerd'[131], a web-based health management tool to help measure, manage and plan for animal health on-farm. The infectious disease module helps farmers to develop control measures for a range of endemic diseases, including Johne's disease and bovine TB. The bovine TB component requires further development, however, and there has been only limited demand from farmers to date. There is potential for greater use of MyHealthyHerd or equivalent products in preventing disease spread, particularly where there have been no recent breakdowns and therefore no APHA involvement.

Measures to reduce risk of transmission from badgers

8.44. Extensive information about biosecurity is available on the TB Hub and on the websites of the different certification and accreditation schemes. A free advisory service (TBAS) with a special focus on biosecurity is also available to some farmers. Hence, farmers have access to the best current advice should they choose to look for it. To improve awareness of this information and service, sources of trusted advice to farmers (private veterinarians, representatives of certification schemes, and APHA inspectors) could be encouraged or incentivised to be more proactive in stating the importance of biosecurity, and the existence of some cheap 'no regrets' interventions. This might be done by targeted information campaigns and the provision of training courses.

8.45. Previous government initiatives empowering private veterinarians to produce tailored biosecurity advice and monitor its effectiveness have been associated with increased take-up of biosecurity, increased farmer satisfaction with biosecurity, and reduced risk of introducing disease[132]. These initiatives could be extended and the provision of bespoke advice facilitated through analysis of information collected by APHA in completing the revised DRFs.

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131 http://www.myhealthyherd.co.uk/

132 Royal Veterinary College (2013) Assessment of tailored farm-level biosecurity strategies for beef suckler farms in England and Wales. Defra commissioned project, SE4007.

8.46. Farmers may find their biosecurity measures scrutinised on multiple occasions; for example, during the DRF process in the event of a breakdown, from the TBAS if advice is taken up, through certification schemes, and from Natural England when it undertakes checks on biosecurity compliance as a condition of issuing badger culling licences.

8.47. As illustrated in Table 8.1, current information and advice from multiple sources can be somewhat inconsistent. Given some farmers' and local veterinarians' lack of belief in the efficacy of biosecurity measures, even slight inconsistencies may act against efforts to change behaviour through awareness raising. Biosecurity advice across government, delivery bodies, and certification and accreditation schemes could be coordinated, with greater data-sharing, to reinforce a coherent message across sources. In Chapter 9 we discuss the potential for a single body to undertake functions currently carried out by APHA, Natural England and other organisations. If this idea were adopted it would facilitate a more consistent approach to biosecurity.

8.48. There is anecdotal evidence of inadequate compliance with biosecurity conditions by a minority of farmers within badger culling areas. Where this is the case, compliance could be enforced more strongly, with licences withdrawn if this cannot be achieved. It could also be a condition of the cull licence that biosecurity measures are maintained for a reasonable specified period after the end of the cull; a condition that would be binding on successors if the land changed hands.

8.49. In discussing risk-based trading (Chapter 5), and compensation and insurance below, we explore the possibility of creating farm-level indices of the risk of bovine TB infection. Such indices could include measures of the take-up of biosecurity measures. Farms could be credited for engagement with TBAS and other sources of biosecurity advice, as well as the existence of a biosecurity plan that would be subject to inspection.

8.50. The major accreditation and certification schemes, as well as some supermarkets, already mandate some measure of farm-level biosecurity. For example, Sainsbury's ensures that all domestic farmers who supply its red meat and dairy products meet the relevant Red Tractor Assurance standards at a minimum. The latest standards for beef producers require effective on-farm biosecurity measures to prevent the spread of disease and protect food safety and animal health, including a documented Farm Biosecurity Policy. These measures could be 'levelled-up' and compliance coordinated and simplified.

Improving inspection

8.51. Farms are inspected as part of farm assurance schemes, for producer assurance, and to assess bovine TB biosecurity measures (including possible new measures suggested elsewhere in this Chapter). There are opportunities to join up and combine such inspections, not only those relating to bovine TB but also those concerned with other aspects of farming.

Measures to prevent local cattle-to-cattle transmission

8.52. The emphasis in biosecurity advice could be broadened to encompass more cattle-to-cattle transmission risk reduction measures, such as reducing the risk of contact between contiguous herds through wider buffers between holdings. We see a particular issue on parcels of land separate from the main holding but sharing the same CPH. Especially when these fragments are short-term FBT or TLAs there may be little incentive to invest in biosecurity measures.

8.53. At present the registration of a TLA requires no evidence of the extent of buffers against surrounding land, nor is information required on the category of livestock associated with the TLA or other contiguous holdings. Thus, a TLA could be authorised for a farmer to graze high-risk, low-value animals adjacent to a farm with high-value pedigree or dairy cattle. Options that could be considered to reduce the risk of movement to TLAs spreading the disease include confining TLAs only to sheep in the HRA, not allowing cattle on TLAs if they adjoin existing cattle farms, and mandating adequate buffers as a condition of a TLA. We understand the potential financial and regulatory implications of these measures and the need for further cost-benefit analysis.

8.54. More generally, cattle farmers could be discouraged from taking on parcels of land not contiguous with the main holding, especially on TLAs applying to seasonal grazing licences or informal gentleman's agreements and short term FBTs. The phased reduction of CAP direct payments up until 2027 is likely to reduce the current incentive for existing farmers, already beyond retirement age, to 'sell' grass keep on an annual basis whilst still retaining their subsidy payments.

8.55. There are a number of other reasons, related to the tax system, why short-term letting arrangements remain attractive to some land occupiers. This includes land owned for investment, residential or recreational purposes by non-farmers[133]. Government could consider providing tax breaks on rental income for longer-term agricultural lettings, a model that has been used successfully in the Republic of Ireland to shift the market away from very short-term lets towards longer-term leases. Tenancy legislation could also be amended to de-risk longer-term leases for agricultural landlords. Government could encourage industry bodies to be more proactive in providing best practice advice to land agents and other professional advisors on the benefits of longer-term lets for both landlord and tenants to encourage a culture shift away from off the peg short term agreements.

Increased focus on slurry and manure

8.56. *M. bovis* can survive in stored slurry for up to 6 months[134]. The risk of spread of disease through slurry can be addressed by giving more emphasis to the injection of slurry into the soil. This could become a condition for those (mostly dairy) farmers with slurry systems in the HRA. The extension of schemes providing capital grants for slurry injectors would be helpful with such grants made available not only to farmers but also to agricultural contractors, who undertake much slurry spreading. In addition to reducing risks of disease, slurry injection has other

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133 Strutt & Parker's Farmland Database for 2013-17 shows an average of 43% of farm sales were to non-farmer buyers, accounting for 55% of the land marketed. These include lifestyle buyers and private investors. Source: www.struttandparker.com/knowledge-and-research/the-rise-of-non-farmers-in-the-farmland-market.

134 Scanlon, M.P. & Quinn, P.J. (2000a). The survival of *Mycobacterium bovis* in sterilised cattle slurry and its relevance to the persistence of this pathogen in the environment. Irish Veterinary Journal 53 (8), 412-415.

important advantages such as reducing ammonia pollution[135] and the risk of run off after heavy rain. The cleansing of contractor machinery between farm visits could be made mandatory in future.

8.57. Instead of spreading on land, the use of slurry in high temperature (thermophilic) types of anaerobic digestion could be incentivised. The advantages and disadvantages of on-farm or local anaerobic digestion are complex because of the capital requirements to set them up, the need for a steady supply of feed material which has consequences for both farm economics and local infrastructure, and the presence of customers for digestate (often the farmer) and biogas. We do not go into these issues beyond noting that the potential disease-control benefits should be included in these calculations.

8.58. If farmyard manure from cattle is spread directly onto the land, there is a risk of disease transmission. Composting for a minimum of 30 days and turning is recommended as temperatures of 50^{o} C are needed to destroy *M. bovis*. Composting has other benefits including reduced weed seed and pathogen burden, extended range of time and area for spreading, and less risk of water pollution. These benefits need to be balanced against the potential for greater gaseous and leachate losses during the storage and turning of manures[136]. Composting farmyard manure could be made mandatory or could contribute to biosecurity indices used in incentivising good disease control measures. Capital grants could be made available for the infrastructure required for composting.

Moving from compensation to insurance

8.59. The compensation scheme for herd breakdowns could be transformed into a mandatory insurance scheme. The premiums would be made up of two parts, one determined by geographical zone (either the existing HRA, EA or LRA categorisation or something that evolved from it) and the other a variable component that is influenced by farmer behaviours such as degree of risk-based trading, adoption of biosecurity measures, and engagement in measures to control the disease in wildlife (for example culling or vaccination). The two components represent risks that the farmer has no control and some control over.

8.60. The component of the premium that represents the risks that a farmer has no control over could be subsidised by government (effectively a re-designation of the compensation payment). Alternatively, the cost of the premium could in total or in part be transferred to the industry. The industry through a levy might equalise the premiums paid by farmers in the different geographical risk zones, or businesses in high-risk areas may be asked to pay more. There is an economic argument for risk-related payments in that it encapsulates the true costs of the disease and might discourage beef and dairy farming in areas of greatest bovine TB prevalence. Against this is the welfare argument that the higher premiums may make any type of farming inviable in certain areas, with knock-on effects on employment and the viability of rural economies.

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[135] http://www.neiker.net/la-inyeccion-el-mejor-metodo-para-reducir-las-emisiones-de-amoniaco-procedentes-de-la-aplicacion-de-purines-en-tierras-agricolas/?lang=en

[136] Department of Agriculture and Food Studies University of Plymouth (2000) Enhancing the effective utilisation of animal manures on-farm through compost technology, Report to MAFF.

8.61. The premiums paid by individual farmers would have a component that incentivises disease control behaviour. In Chapter 5 we discuss the development of a farm-level index to be used in risk-based trading and this could also be used in determining insurance premiums. The extent of biosecurity measures taken by a farmer should also influence the premium. There are different ways this could be implemented – for example the business could declare a level of biosecurity that affects premiums and be subject to inspection or be recognised for joining existing accreditation schemes that mandate and monitor high levels of biosecurity.

8.62. It would be important that the differential in premium between businesses that implement strong and poor disease avoidance measures are large enough to incentivise the former actions. In principle this differential could be established with no net change in Government expenditure on bovine TB were current spending on compensation to be reallocated to insurance.

8.63. The government has a role in providing information to facilitate risk-based trading that is essential for the insurance scheme to produce positive outcomes. The scheme itself is likely best to be run by the insurance industry. A detailed feasibility study would need to be done to ascertain the financial viability of the scheme. Government has relevant experience in setting partially subsidised insurance schemes, for example the 'Flood Re' programme that limits home insurance costs to households in particularly flood-prone areas.

Making compensation more dependent on risk-avoidance behaviour

8.64. The last section described how an insurance premium for losses to bovine TB could be made dependent on an index of farmer disease avoidance actions (for example related to risk-based trading, biosecurity and wildlife control). Currently, compensation is reduced to 50% of market value in circumstances that penalise particularly risky behaviours. The index could be used to make reduction in compensation more graded and more dependent on farmer decisions.

8.65. Part of the rationale for compensation is to reduce hardship for farmers who are already financially challenged. Directly assisting such farmers through income supplements or hardship grants (as happens in the RoI) would be one way to address this. It has advantages in decoupling assistance from incentives to improve biosecurity and in allowing assistance to be better targeted. A disadvantage is that it may disincentivise poorly performing farmers from leaving the industry. Assistance could be provided directly by Government or working through agricultural charities such as the Farming Community Network (FCN).

Research and development priorities

8.66. There is a need for continuing research on *M. bovis* transmission and how it can be reduced by biosecurity measures. This includes transmission between cattle and to and from cattle and wildlife. Further study of the role of slurry and manure is particularly important and will be facilitated by modern molecular technologies. This is difficult research that produces incremental rather than break-through results but which can material contribution to disease outcomes.

8.67. Some groups of farmers actively seek advice on biosecurity and willingly implement biosecurity measures on their farmers; others are much less willing. A wide variety of economic, social and behavioural factors lie behind these differences and social science research is needed into how better to encourage behaviour change in farmers with a poor track record in biosecurity.

Chapter 9: Governance

Introduction

9.1. Control of bovine TB in England is an epidemiological challenge but one that is situated in the broader context of the structure and socio-economics of the farming industry and its relationship to the state. The relative effectiveness of different disease control interventions is influenced by these economic and social factors and it is a mistake to view the problem as purely scientific and technical.

9.2. This chapter discusses some of the governance issues concerning bovine TB control. More than any other topic explored in this review, questions concerning governance often involve judgements that in a democracy rightfully are made by ministers. We respect this distinction and aim to highlight the advantages and disadvantages of different options that decision makers need to take into account.

9.3. A discussion of governance is particularly pertinent at the present time with the UK leaving the EU. Much of bovine TB governance is currently determined by EU legislation and directives, and there will be more freedom of action outside the Union. Of course, the degree to which British actions will need to mirror those of the EU will not be known until the departure negotiations are completed.

9.4. We consider in this chapter a variety of different issues concerned with the governance of bovine TB control in England. These include the relative roles and responsibilities of the state and the farming industry, and exactly where regulatory and control functions should be situated.

Rationale for different governance models

State involvement

9.5. Bovine TB is a notifiable disease under EU and domestic legislation. The state originally became involved in bovine TB control because of the risk of transmission to humans (prior to pasteurisation and meat inspections bovine TB caused significant mortality and morbidity in people). While that risk has receded, the disease remains a veterinary issue as infected cattle suffer loss of condition, welfare status and economic value. However, an important reason government remains involved is because of consequences of the disease for international trade. Trade is impacted because other countries protect their national herds from infection by import restrictions on live animals and cattle products, and statutory or government measures are required to maintain freedom of trade.

9.6. Of the notifiable endemic diseases of cattle in the UK, bovine TB is the only one with a substantial wildlife reservoir (the badger) protected by binding international conventions and domestic legislation. Government is thus inescapably involved with any measures to control the disease in wildlife.

9.7. An important justification for state intervention is that there is a collective benefit of coordinated action to control disease that might not happen if responsibility was left to individual farmers. There are short-term advantages of reducing the impact of disease, for example by sending suspected infected animals to market, and costs to biosecurity and other disease avoidance interventions. Hence, without a set of regulations imposed by Government there is a relatively high likelihood of a substantial increase in bovine TB prevalence. Indeed, there is clear evidence from the suspension of testing during the 2001 outbreak of Foot and Mouth that without the current surveillance systems there would be a rapid increase in bovine TB in England.

9.8. Outside the EU it would be possible for the UK Government to remove the disease's notifiable status (with or without relaxing protection of the badger) and transfer all responsibility to the industry. Public health would be protected by pasteurisation and meat inspection. However, increased incidence in cattle could pose additional risks to farmers and veterinarians and also spill over into other animals. Because of the risks of increased disease prevalence just outlined, and because of the possibility the disease would spread to other hosts, including domestic animals with the possibility of human infections, this is not considered further here.

Payment for bovine TB control

9.9. Currently about 60% of the total costs of bovine TB control measures are paid for by the state and the rest by the industry. The arguments for state involvement (in addition to regulation) on bovine TB control are: (i) that control of the disease is a public good in that it reduces the (low) risk of human infection by *M. bovis*; (ii) without this subsidy beef and dairy farming in some parts of England would be uneconomic leading to farm closures and harm to the local rural economy that would have ramifications beyond farming, (iii) other governments provide state support for bovine TB control and so the UK also doing so ensures a 'level playing field' for our industry and (iv) collecting money from industry to support bovine TB control is complicated and might increase the total costs of combatting the disease.

9.10. There are also arguments that the industry should pay more for bovine TB control: (i) absence of the disease benefits beef and dairy farmers providing private benefits to the farmer that should be paid for by the groups that gain from it; (ii) implicitly subsidising beef and dairy production distorts economic signals and leads to resource allocation inefficiencies, for example the continuation of beef or dairy farming in locations where it would otherwise be unprofitable; and (iii) government payment for control implies government responsibility for the disease and the resulting lack of ownership of the disease by the industry can reduce the impetus to implement disease control measures.

9.11. Decisions about the economics of bovine TB control have to be made in the context of overall support for farming in England. Currently, beef and dairy farmers receive support from Pillar One of the Common Agricultural Policy through the Basic Payment Scheme (BPS) administered by the Rural Payment Agency (RPA). This is an area-related payment that provides 38% of farm business income for the average English dairy farmer and more than 90% for the average English beef farmer[137]. Since 1 January 2014, poor compliance with bovine TB testing regulations has been penalised by a reduction in Pillar One payments as part of "cross compliance" requirements administered by the RPA.

9.12. Defra has set out in its Agriculture Bill and accompanying policy document, *Health and Harmony: the future for food, farming and the environment in a Green Brexit*[138] (September 2018), a direction of travel for what will replace the BPS after the UK leaves the EU. Increasingly public money will be allocated to payment for public goods. Technically, public goods are non-rival and non-excludable (everyone enjoys them and use by one person does not preclude that by another) and include things such as cherished and biodiversity-rich landscapes, or environmental flood control measures. Food itself, though colloquially a good thing for the public, is in the technical sense a private good as farmers receive market rewards for its production.

9.13. It is likely that the provision of animal welfare standards, including the absence of disease, beyond that which maximises private economic benefits, will be included within a broad categorisation of public goods. Though technically not a public good in the strict economic sense, the provision of high welfare standards to meet public demand, as interpreted by government, is a merit good that might fall within a future CAP replacement scheme[139].

Ownership of disease control programmes

9.14. There is a consensus that responsibility for control of bovine TB is shared by government and the industry. But there is also evidence that the major role played by government leaves the industry feeling disempowered and engenders a feeling of fatalism amongst some farmers which views the disease as an 'act of nature' that they can do little to prevent. Most groups we talked to, both inside and outside the farming industry, expressed concern and dissatisfaction with bovine TB control ownership.

9.15. This is a particular issue in the UK where there is a wildlife reservoir that is responsible for a fraction of herd breakdowns. Because unrestricted culling of badgers has never been permitted it is possible for some stakeholders to characterise the problem as unsolvable and attribute responsibility for the continuing presence of the disease to government because of the restrictions on culling it has imposed. The strength of debate about badger culling is understandable given the strong and profoundly held views of many groups that oppose it, but the attacks on the farming industry (by some but by no means all opposed to culling) has tended to reinforce a feeling of powerlessness in the industry.

9.16. Other countries have adopted policies to reinforce shared responsibility. The country most similar to England and the DAs is the Republic of Ireland where it is estimated that farmers pay 38% towards the cost of bovine TB control, with the state contributing 50% and EU funding the remaining 12%. The Irish Government,

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[137] Health & Harmony Evidence Compendium, p.35.

[138] The future for food, farming and the environment: policy statement (2018)

[139] Animal welfare, economics and policy. Report on a study undertaken for the Farm & Animal Health Economics Division of Defra by Professor John McInerney February 2004.

as part of its strategy to eradicate bovine TB by 2030, has established a Stakeholder Forum tasked with developing policies to help achieve this goal. It will advise on: (i) how best government and industry can work together; (ii) the development of new policies and interventions; and (iii) how the programme can be appropriately and sustainably funded on the basis of a formal objective evaluation of benefits and cost.

9.17. New Zealand is a country that has made major progress in reducing the incidence of bovine TB. Important to this was setting up TBfree – a research and operational bovine TB control programme with a distinct legal status. The programme is jointly funded by industry and government (60% and 40% respectively for the 2016-20 period). Its key functions include disease management, movement controls, wild animal control, research, and engagement with farming communities and conservation groups. In considering lessons of TBfree for the UK, several major differences between New Zealand and the UK need to be taken into account. First, amongst high-income economies, New Zealand (with Australia) has gone furthest along the path of removing subsidies and other support for its agricultural industry, and farming after tourism is the country's largest earner of foreign currency. Second, the wildlife reservoir in New Zealand is the introduced brush-tailed possum which is also a significant threat to the country's biodiversity. There is relatively little opposition to lethal control of possums.

Bovine TB and regulatory reform

9.18. Concurrent with the work of this review, Dame Glenys Stacey is leading a review of Farm Inspection and Regulation. Its terms of reference are to identify ways in which regulation can be improved and burdens on farmers can be reduced, while maintaining and enhancing animal, environmental and plant health standards. An interim report was produced in July 2018 and the final report is expected by the end of December 2018.

9.19. An important interim conclusion is that farm regulation in the UK would benefit from the creation of an independent regulator with considerably more flexibility in setting standards and assessing compliance, and with a greater range of enforcement powers from notices and advice through civil and criminal penalties. Such a body would take over many functions currently carried out by Defra arm's length bodies as well as some Local Authority responsibilities.

9.20. Approximately 45% of all farm visits are concerned with bovine TB, obviously concentrated on beef and dairy farms. For these farmers the large majority of interactions with regulators concern this disease. The interim report does not conclude there are too many farm visits but emphasises the importance of well-designed, flexible regulation that is trusted and accepted as necessary by both the industry and other stakeholders. The report also highlights the importance of appropriate penalties for different types of non-compliance, the role of licensing to allow innovation and novelty, and the link between standards set by the state and farm assurance schemes.

9.21. The broader questions of holistic farm regulation are beyond our remit and will be considered by the Farm Inspection and Regulation review's final report. However, we have discussed these issues with Dame Glenys and in this chapter explore options for changing regulation along the lines the interim report suggests.

The veterinary profession

9.22. The veterinary profession plays a very major role in the control of bovine TB. Veterinarians are involved: (i) within Defra and its arm's length bodies in advising on policy and in implementation; (ii) in private practices advising farmers day-to-day on diagnosis and disease risk; (iii) in the specialist companies contracted to carry out bovine TB testing; (iv) as Official Veterinarians in slaughterhouses reporting suspicion of TB in a carcase to APHA; and (v) through their professional bodies such as the British Veterinary Association (BVA) and the British Cattle Veterinary Association (BCVA) that represent the profession in discussions on disease management and control.

9.23. Farm veterinarians are a trusted source of information to farmers and build relationships with their clients which can be hugely important in advising on all aspects of animal health and welfare. This close working relationship and detailed local knowledge makes them ideally placed to help farmers avoid bovine TB and, when herd breakdowns occur, to get rid of the disease as quickly as possible. While this relation sometimes works very well, we were often told that some farmers do not ask veterinarians for disease control advice, and their veterinarians do not proactively offer it. Instead, there is the belief on both sides that the farmer must just follow the statutory procedures laid out by APHA and that there is nothing that can be done to affect disease outcomes. A regulatory rather than a disease-control mind-set. We believe the veterinary profession has a critical role in overcoming this fatalism and improving effective bovine TB control.

9.24. Routine testing for TB was in the past undertaken by farmers' private veterinarians, who were then paid by government. Now, routine bovine TB testing is contracted out to the private sector which often means that testing is not done by farmers' own veterinarians, reducing opportunities for engagement on bovine TB between farmers and their veterinarians. The use of para-veterinary professionals as Approved Tuberculin Testers (ATTs) to perform tuberculin skin testing of cattle has been permitted in Great Britain since 2005. To date this has been restricted to a small number of suitably trained APHA staff under the supervision of an APHA veterinarian. Defra has recently consulted on extending the use of ATTs in England so that private veterinary businesses also have the option of deploying them to carry out bovine TB skin tests. ATTs would have to meet qualifying criteria and complete specified training.

9.25. The results of statutory testing for bovine TB are only communicated to farmers and not to their private veterinarian; this includes the comprehensive APHA information pack. This is in contrast to results from other laboratory investigations conducted by APHA laboratories which are communicated to both farmer and veterinarian. Farmers often perceive information overload when bovine TB is diagnosed on their farms. The formal APHA information pack for their farm often gets lost in this deluge and the opportunity for discussion with their private veterinarian regarding best disease control and prevention is thus forgone.

9.26. In England, routine testing is now organised by five Veterinary Delivery Partners contracted to work over defined geographical areas. Quality assurance is the responsibility of APHA, who provides training and can also conduct unannounced spot checks during testing. The arrangements in the DAs are different. In Wales, local veterinary practices are contracted to do routine testing, organised by two

Veterinary Delivery Partners. This a deliberate strategy to help support the profession economically in rural areas and to maintain a link between veterinary practices and disease control in client herds. In Scotland routine bovine TB testing is delivered by private veterinary surgeons qualified as “Official Veterinarians”. In Northern Ireland, the Department of Agriculture, Environment and Rural Affairs (DAERA) contracts private veterinary practices to carry out a minimum of 90% of routine bovine TB testing. High risk testing is done by DAERA employed veterinary surgeons.

9.27. In the Republic of Ireland, measures have been put in place to assure the adequacy of routine bovine TB testing by private veterinarians through unannounced field inspections. The Irish Animal Health Computer System records details of all bovine TB testing carried out in the field and summarises the individual performance of each veterinarian on a quarterly and annual basis against peers’ performance, including local disease detection rates, the number of inconclusive test results, and the number of test reports submitted late. A numerical risk-based weighting is used for each aspect of performance measured; the bottom 10% of performers are selected for special investigation as high risk and are subjected to additional practice and field inspections[140].

Current policy

The economics of bovine TB control

9.28. Currently (2016-17), Government spends around £70M annually on bovine TB control in England. This comprises: compensation (£33M); wildlife control (£9M); TB testing (£23M); and research (£4M through Defra with additional funding by the Research Councils as discussed at Annex 5).

9.29. The average cost of a TB breakdown (officially TB-free status withdrawn OTFW) in England is around £37,000 of which £22,000 is borne by Government mainly as compensation for animals compulsorily slaughtered and the costs of testing. The remaining £15,000 represents consequential losses carried by farmers, including disruption to business through movement restrictions. Costs vary greatly amongst farms depending on their ability to adapt and mitigate. In addition to the direct financial costs of herd breakdowns, there is evidence of significant mental stress to farmers and their families after herd breakdowns.

9.30. Farmers currently pay a production levy on dairy and meat products that is administered by the Agriculture & Horticulture Development Board (AHDB). The current rate for milk is 0.06p per litre and for beef £5.40 per head, of which the producer pays £4.05 and the slaughterhouse/exporter the rest (with calves £0.16 per head). AHDB owns and provides a “TB Hub”, paid for from the levy, a website on which it publishes advice on biosecurity and herd health (¶ 9.34). AHDB Dairy also publishes “TB Advantage,” a genetic index aimed at helping dairy farmers make informed decisions on selecting breeding stock which may have improved resistance to bovine TB (Chapter 4).

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[140] Duignan *et al.* 2012 Quality control in the national bovine tuberculosis eradication programme in Ireland, *Rev. sci. tech. Off. Int. Epiz.*, 31, 845-860

9.31. Future costs to industry for each new cull area have been estimated at £0.14m per area over four years (Chapter 6). Total government costs for each new cull area have been estimated at £0.48m per area over four years – including costs to Natural England (£116,000), APHA (£140,000), Defra (£20,000), and for policing (£210,000)[141].

Ownership of bovine TB programmes

9.32. To foster broad ownership of bovine TB control efforts, Defra has set up a number of consultative bodies. It also carries out extensive consultation on proposed new interventions prior to their implementation.

9.33. The Bovine TB Eradication Advisory Group for England (TBEAG) is an expert group tasked with helping implement the 25-year strategy to eradicate bovine TB in England. It advises on funding and budgetary issues and on compliance with EU legal requirements. It also takes an active role in communicating and explaining any changes in policy to stakeholders as well as engaging regularly with the farming industry, the veterinary profession and wider stakeholders. The Animal Health and Welfare Board for England (AHWBE) has strategic oversight of Defra policy and delivery in England in relation to animal health.

9.34. The TB Hub is a joint industry initiative, supported by AHDB, APHA, the BCVA, Defra, Landex (a consortium of higher education colleges with interests in farming), and the NFU. It provides practical advice for beef and dairy farmers on dealing with bovine TB on their farm, covering everything from biosecurity measures to understanding trading rules. It provides access to the ibTB service (Chapter 5), which has the latest information on local bovine TB outbreaks in England and Wales.

9.35. The TB Advisory Service (TBAS) is a free service in the HRA and the EA that helps farmers improve farm biosecurity and reduce risks associated with cattle movements. It has been funded by Defra through the Rural Development Programme for England (RDPE) for a three-year period ending in September 2020. Eligible farmers in the HRA and the EA of England can receive an advisory visit to their farm and there is also a telephone advice line. The service is currently provided by the Origin Group.

9.36. An increasing number of counties have active TB Eradication Groups (TBEG). These are unofficial and variable in structure, but frequently build effective alliances between interested farmers, private veterinarians, APHA veterinarians and wildlife groups. In some cases they have provided useful discussion fora and have been effective sources of local information for farmers.

9.37. Government routinely consults widely before the implementation of new policies. Best practice is that consultations should include an assessment of the costs and benefits of the options being considered and their impact on particular groups, and that government departments should explain how responses have informed policy. To reduce the risk of 'consultation fatigue' recent guidance emphasises that

[141] https://www.gov.uk/government/publications/bovine-tb-badger-control-policy-value-for-money-analysis/badger-control-policy-value-for-money-analysis-2018

consultations should be well-targeted and informative, and not conducted just for the appearance of engagement.

9.38. Defra regularly consults on different aspects of bovine TB policy, seeking views and evidence to inform future decisions. Since December 2016, formal written consultation exercises run by Defra have included proposals on: (i) introducing licensed badger controls in the LRA, (ii) simplifying testing in the HRA, (iii) plans to implement a supplementary form of badger control after an initial four-year period of culling, (iv) introducing enhanced bovine TB surveillance and control measures in the HRA and the EA, and (v) introducing more effective control measures to reduce the risk of bovine TB in non-bovine animals. These consultations typically run for a 12-week period. It is normal practice for Defra to publish a summary of responses to each consultation and explain how these might influence future policy.

Bovine TB regulation and enforcement

9.39. As the delivery body for Defra, APHA is the interface between the industry and government. They are primarily responsible for: (i) ensuring that disease control measures are implemented in England in line with government policy; (ii) providing expert veterinary and scientific advice to industry in relation to bovine TB; and (iii) monitoring and promoting compliance.

9.40. APHA does not have an enforcement section and does not employ investigators or enforcement officers. Under the Animal Health Act 1981, the responsibility to enforce all aspects of domestic bovine TB legislation remains with local authorities. This includes:

(i) ensuring compliance in cases of overdue bovine TB tests;

(ii) investigating and undertaking enforcement action where pre-movement testing rules are not complied with;

(iii) taking appropriate enforcement action in cases where bovine TB testing has been required by notice and is not carried out;

(iv) enforcing the removal of bovine TB reactors where a refusal has occurred;

(v) enforcing licence conditions, movement restrictions, isolation requirements, etc.; and,

(vi) conducting investigations prompted by suspicion of illegal movements, interference with relevant testing, and cattle identification concerns (including where the DNA of a slaughtered bovine TB reactor does not match the sample taken at the test).

9.41. The 2014 bovine TB Strategy for England emphasised the importance of maintaining high levels of farmer compliance with bovine TB controls. Because compliance is the responsibility of local authorities it is difficult to get overall statistics about enforcement. Our discussions with different stakeholders suggest that the resources allocated to compliance vary greatly across different local authorities and are affected by the extent of competing pressures on LA budgets.

9.42. Natural England has a dual role in providing advice as the Government's statutory adviser on the natural environment and nature conservation, as well as assessing and issuing licence applications to cull or vaccinate badgers to prevent the spread of bovine TB. Its role as a licensing authority is to help ensure any proposed cull is effective, safe and humane.

Options for the future

Continuing with current policy.

9.43. The regulation of bovine TB has to change as we leave the EU and European legislation no longer applies in the UK. The default option is to incorporate European legislation into domestic legislation and to mirror future changes in EU rules. Current governance arrangements could continue substantially unchanged.

9.44. The chief advantage of this option is that it minimises change and disruption to the industry. This is not to be underestimated given the frequency with which new rules and regulations have been introduced in recent decades. Against this must be set the reality that efforts to control bovine TB in the UK are currently failing to achieve strong progress, and that while the presence or lack of specific interventions is clearly partly responsible, blame is also likely to lie with the overall governance of disease control measures.

9.45. TBEAG (¶ 9.33) has played an important role in bringing together different stakeholders to coordinate bovine TB advice to Defra under the strong chairmanship of John Cross. An example of its success is the development of the Livestock Information Service proposal (see Chapter 5). TBEAG's continuing involvement in developing England's bovine TB strategy will be very helpful. We also see an important role at a more local level for TB Eradication Groups to share best practice and disseminate information.

9.46. Relationships between the farming industry and the NGOs opposed to culling are clearly difficult, and in the past have been quite confrontational. We acknowledge the recent efforts on both sides to establish dialogue and hope it is possible for this to continue.

Improving provision of bovine TB advice

9.47. There is extensive information available on bovine TB both on Defra's website and on TB Hub (¶ 9.34). We find it well-written and accessible. Farmers who are motivated to look for information will find much that they need on these sites.

9.48. TBAS (¶ 9.35) is a potentially important initiative currently in a trial phase. Should it prove successful there will be a strong argument for its continuation. The current aim is to carry out 2,400 advisory visits to farms over the three-year project but it will be important to assess the quality of advice given not just the number of visits. TBAS is being delivered by a private sector veterinary practice who also provide veterinary services to clients in the region served. Concerns have been expressed that this may lead to conflicts of interest (or that other practices may discourage their clients from registering). Such issues should be considered in evaluating the success of the programme. How TBAS visits might best be coordinated with other farm advice visits should also be considered.

9.49. Efforts could be made to encourage farmers to consult their expert private veterinarians more often to plan how to avoid or tackle the disease. Currently, APHA disease reports are sent to farmers rather than their private veterinarians. These contain a mass of invaluable information, but are difficult to interpret without help from veterinarians. Ensuring the latter received the report would increase the likelihood of the disease report findings leading to action on farm and help foster farmer-veterinarian collaboration.

9.50. The DAs and RoI have adopted policies that maintain greater links between the implementation of bovine TB control policy and local veterinarian practices than is the case in England. There is a balance to be struck between the economies of scale of providing bovine TB testing at regional levels and the risk of disengagement of local veterinarians. Future policy should consider lessons from the DAs and RoI, and will benefit from consultation between the veterinary profession, farming groups and government.

Sharing the costs of disease control between industry and government

9.51. As described above (¶ 9.28), approximately 60% of the costs of disease control are currently borne by government and the rest by industry. There has been a trend for the industry to be asked to pay a larger fraction of the burden, for example to contribute substantially to the current badger culling programme. The precise allocation of costs between Government and farming is a decision for ministers but we discuss here what the consequences and implications for disease control might be of more of the costs being borne by industry.

9.52. In principle the costs of disease control could be spread evenly across the beef and dairy industry or concentrated on the most high-risk businesses. All of the extra expense could be borne before the farm gate as a production cost (where most likely to incentivise disease-control behaviour) or some could be moved further along the value chain. Different options would have different effects on UK beef and dairy competitiveness and on meat and dairy prices.

9.53. Arrangements that placed greater burdens on high-risk farms would affect the viability of beef and dairy farming in areas of high disease risk. It might be argued that stopping cattle farming in areas where it is not financially profitable when all costs are accounted is economically sensible, and it would remove centres of infection from which the disease could spread to other areas. Against this is the reality that in many of these areas there is no alternative economic model of farming so in the absence of other sources of funding (such as payment for public goods) the land would likely come out of agriculture. From a strategic national point of view, allowing farms to go out of business due to a disease that might in the future be controlled might be seen as suboptimal. For those farms that stayed in business, the extra financial burden of disease responsibility may make them unable to afford anything more that the statutory minimum to help control the disease.

9.54. The New Zealand model of asking the industry to assume the major share of disease control costs has been accompanied by a significant shift in the determination of policy to the independent industry body. The resultant ownership of the problem by industry has been very helpful in forging a consensus amongst farmers to adopt useful measures that at least in the short-term are costly to their businesses. Following that model in the UK, with its undoubted advantages, is much harder because of the differences in the wildlife reservoir. Whereas in New Zealand there is a broad consensus that the industry can undertake the type of possum control it thinks best, there would no such consensus in the UK; for example, one major political party is committed to halt culling. Whether full industry ownership of the disease in cattle is possible when government determines the policy on control in wildlife (and this may change over time) is not clear.

Setting up an independent regulator

9.55. As discussed above (¶ 9.18), the interim report of the Farm Inspection and Regulation review argues that farming could be regulated more effectively and efficiently by independent regulatory arrangements that allowed for adaptive approaches, tailored to each of government's aims for farming. We explore that suggestion here within the context of our remit on bovine TB though realise that to take this forward a full options appraisal would need to be done comparing this with the status quo and perhaps a New Zealand-type industry-led option (¶ 9.54).

9.56. The regulatory, licensing, inspection and compliance activities concerning bovine TB currently associated with APHA, Natural England and local authorities could be vested in a new body with greater independence from Defra. Using the terminology in the Farm Inspection and Regulation interim report we refer to this as the 'regulator' though emphasising this body's important disease control role. Responsibility for general policy would remain with Defra (which we believe is essential because of the requirement for ministerial judgement about many of the decisions that have to be made) which would set the goals for the consolidated body to achieve. The interim report of the Farm Inspection and Regulation review envisages all bodies involved in farm regulation being brought together so as to capitalise on synergies and economies involving farm visits. Though much activity involving bovine TB involves specialist activities such as testing for the disease, there are opportunities for synergies in using inspection visits as opportunities to advise on a broad range of issues of importance to the farmer including disease control.

9.57. Current advice on best practice in regulation supports the independence of regulators. In the context of bovine TB there is a belief amongst environmental NGOs that government is unduly influenced by lobbying by the farming industry, while the industry complains of the reverse. Though government would still set the goals for disease control, its day-to-day implementation by the regulator would be immune from this real or perceived interference. The remit of the regulator would be drawn up carefully to encourage it to engage impartially with the industry and other stakeholders in shared ownership of the problem and to avoid regulatory capture by any of the interested parties.

9.58. The regulator would carry out the statutory duties around bovine TB control now carried out by a number of different bodies. With the increased freedom possible after leaving the EU, the regulator would be empowered to interpret more flexibly and adaptively disease control rules. Working with industry it would develop standards for cattle trading and biosecurity, and develop the type of indices of farmer behaviour needed for the innovation in risk-based trading (Chapter 5) and insurance and compensation (Chapter 8) discussed earlier in this review. It would be responsible for licensing, including for wildlife culling and vaccination (Chapter

6), and to allow innovative approaches to disease control using newly developed test (Chapter 3).

9.59. The regulator would have broad powers of enforcing compliance and the flexibility to use them in a way that is perceived as fair and impartial and which generates confidence in the farming community. Thus, minor infringements would be dealt with by warnings or directives with more serious incidents attracting enforceable undertakings, civil penalties or licence withdrawals. The body would have the ability to act through legal power and criminal prosecution as a last resort.

9.60. The final report of the Farm Inspection and Regulation review is due to be submitted in December 2018 and will then be considered by ministers. Were government to decide on a broad-based independent regulator as flagged by the interim report, the activities we discuss here would naturally fall within it. But were this suggestion not accepted then a narrower body with a brief to act on livestock disease in general or just on bovine TB should be considered.

More use of licensing

9.61. As described in Chapter 3, farmers are prohibited from using non-statutory tests for bovine TB, either when they are free from the disease, or when they are restricted during breakdowns, even when they wish to pay for them. This reduces the potential for them taking ownership of the disease and its prevention on their farms. Greater flexibility in allowing licensed use of alternative tests in cattle farms to improve both prevention and control – and importantly, to enable reductions in within-herd transmission – seems to have great merit. We understand the potential for non-statutory tests to be misused and envisage farmers have to achieve “earned recognition” to be allowed to do so.

Consultation frequency

9.62. Consultation with industry and other stakeholders is an important part of bovine TB control and of achieving shared ownership of the problem. At the moment consultation is relative frequent which risks “consultation fatigue” and slows the rate at which policy can adapt to changing conditions. Excessive and slow consultation was raised with us by many of the stakeholders we spoke to. An alternative is to consult less frequently and at a higher level on broad strategy, mechanisms of adaptive management and direction of travel.

9.63. The chief advantage of such a change is that it could enable operational decisions to be made more swiftly as circumstances change and new evidence emerges. It would allow disease control to take a more adaptive management approach. Speed of action will be particularly valuable in circumstances such as when a new focus of bovine TB appears in the LRA and quick action is required to stop establishment.

9.64. On the negative side, it may be harder to achieve consensus amongst stakeholders for actions that are not described in detail. There is also the risk for multiple interpretations of more high-level policy that could undermine shared ownership. We are aware that changes in the nature of consultation may involve some changes to legislation that stipulates types of consultation.

Annex 1: Acronyms and definitions

95% CI: 95% Confidence Interval
AFU: Approved Finishing Unit, used to channel cattle from bovine TB restricted herds to slaughter
AHDB: Agriculture and Horticulture Development Board
AHVLA: Animal Health and Veterinary Laboratories Agency, former executive agency of Defra (now part of APHA)
AHWBE: Animal Health and Welfare Board for England
AIM: Animal Identification and Movement database (in Republic of Ireland)
APHA: Animal and Plant Health Agency
ARAMS: Animal Movement and Reporting Service
ATT: Approved Tuberculin Testers
BCG: Bacillius Calmette-Guérin, which is used to manufacture tuberculosis vaccines
BCMS: British Cattle Movement Service
BCVA: British Cattle Veterinary Association
BEVS: Badger Edge Vaccination Scheme
Biosecurity: Procedures or measures designed to reduce the risk of transmission of infectious diseases
Bovine Tuberculosis: An infectious disease in cattle caused by *Mycobacterium bovis (M. bovis)*
BPS: Basic Payment Scheme (administered by Rural Payments Agency)
Breakdown: Detection of exposure to *M. bovis* infection in a herd (e.g detection of a bovine TB reactor or signs of possible bovine TB at post mortem). This is followed by breakdown control procedures; the duration of a breakdown depends on the successfulness of the breakdown measures to clear the infection from the herd
BVA: British Veterinary Association
CAP: Common Agricultural Policy
CFT test**:** Caudal Fold Tuberculin Test - tuberculin is injected into the flap at the base of the tail rather than the neck
CHeCS: Cattle Health Certification Standards
CPH: County Parish Holding, a unique number to describe the land and buildings that people use for keeping livestock, including livestock kept as pets.
CPS: Countryside Productivity Scheme - provides funding for projects in England which improve ***productivity*** in the farming and forestry sectors and help create jobs and growth in the rural economy.
CTS: Cattle Tracing System
CVO: Chief Veterinary Officer
DA: Devolved Administration (Wales, Scotland, Northern Ireland)
Defra: Department for Environment, Food and Rural Affairs
DIVA: A test used to **d**ifferentiate **i**nfected from **v**accinated **a**nimals
DNA: Deoxyribonucleic acid, the hereditary material in humans and almost all other organisms.
DPP: Dual Path Platform, an immunological blood test that can be used for diagnosis of TB infection in badgers.

DRF: Disease Report Form
EA: see Edge Area
Edge Area: The edge of the HRA where the disease is not yet considered to be endemic and disease prevalence is lower than in the HRA but there is a great likelihood of further geographical spread of bovine TB out of the HRA.
EFSA: European Food Safety Authority
EFU: Exempt Finishing Unit, a route for beef producers to finish cattle without the need for a pre-movement test
ELISA: Enzyme-linked immunosorbent assay, a test that can be used to detect either antibody (Ab) or antigen such as viral proteins.
Endemic disease**:** A disease which is continuously present in a specific population
Epidemiology: A study of the distribution and dynamics disease in a population
EU: European Union
FAT: Full Agricultural Tenancies
FSA: Food Standards Agency
FYM: Farm Yard Manure
Genotype: A genetically distinct strain of a specimen or species
Herd Prevalence: This statistic can be expressed in different ways but depicts the proportion of herds that are affected by a disease/condition in a specific population
High Risk Area for bovine TB**:** An area defined geographically in which cattle herds have a greater likelihood of experiencing a bovine TB breakdown. It includes geographical areas in which there is a relatively high herd prevalence of bovine TB
Home range: The specific geographic area where a specific animal or pathogen (for example, a genotype of *M. bovis*) is typically detected
Host: Animals which can routinely become infected with a pathogen (for example, *M. bovis*) if exposed
HRA: see High Risk Area
IAA: Intensive Action Area (South West Wales)
ibTB: Interactive map showing the locations of bovine TB breakdowns
IDEXX: IDEXX Laboratories
IFNγ: Interferon Gamma, see Interferon Gamma Assay
Incidence: This statistic reflects the number of cases of infection or disease in a population as a rate per time unit.
Inconclusive reactor: An animal which gives an inconclusive reaction to the tuberculin skin test as defined in Council Directive 64/432/EEC
Index infection (or case): The first infection (or case) in a herd or area
Interferon Gamma Assay: A rapid (24-hour) whole blood in-vitro assay to detect immune response to *M. bovis* infection for the diagnosis of bovine TB
IR: see Inconclusive reactor
LAA: Livestock Auctioneers Association
Lesions: Characteristic tubercles or larger abscess-like structures typically found in lymph nodes and organs such as the lungs, liver and spleen
LIS: Livestock Information Service
Low Risk Area: An area defined geographically in which cattle herds have a lower likelihood of experiencing a bovine TB breakdown. It includes geographic areas with very

low herd prevalence of bovine TB and where the disease is not believed to be maintained by badgers and is primarily caused by cattle movements
LRA: see Low Risk Area
Mycobacteria: A family of bacteria which includes *Mycobacterium bovis*
Mycobacterium avium (M. avium): A bacteria which causes tuberculosis in birds and swine, and is responsible for the *mycobacterium* avian complex (MAC) in humans.
Mycobacterium bovis (M. bovis)**:** One of the bacteria which causes tuberculosis in cattle. It can also infect other mammals including humans and wildlife.
Mycobacterium tuberculosis (M. tuberculosis): One of the bacteria which causes tuberculosis in humans
Natural England*:* An executive non-departmental public body responsible to Defra, which administers applications for licences under the Badger Protection Act 1992
NFU: National Farmers Union
NGO: Non-governmental Organisations
NPV: Negative predictive value, the proportion of negative diagnostic test results that are true negative results.
OIE: World Organisation for Animal Health
OTF: "Officially Bovine Tuberculosis Free" as defined in Council Directive 64/432/EEC. OTF status may apply to herds, regions or Member States
OTFS: "Officially Bovine Tuberculosis Free" status of herd is suspended, as defined in Council Directive 64/432/EEC. This status is used for those cattle and herds where the infection is not confirmed by culture of *M. bovis*
OTFW: "Officially Bovine Tuberculosis Free" status of herd is withdrawn, as defined in Council Directive 64/432/EEC. This status is used for those cattle and herds where the infection is confirmed by culture of *M. bovis* or by finding typical lesions in a carcase of an animal
OV: Official Veterinarian, a private veterinarian permitted to undertake official controls such as tuberculin skin testing
PCR: see Polymerase Chain Reaction
Perturbation: Disruption of badger social organisation or structure which causes badgers to range more widely than they would normally and come in contact more often with other animals (including both cattle and other badgers).
PHE: Public Health England
Polymerase Chain Reaction: Technology to amplify a single or a few copies of a piece of DNA in order to allow easier detection of a particular pathogen by its DNA
Post Movement Test: A tuberculin skin test applied to an animal after it has moved between premises
PPD-A: Purified Protein Derivative, extract of *Mycobacterium avium;* tuberculin.
PPD-B: Purified Protein Derivative, extract of *Mycobacterium bovis*; tuberculin.
PPV: Positive Predictive Value, the proportion of positive diagnostic test results that are true positive results
Pre Movement Test: A tuberculin skin test applied to an animal before it has moved between premises
Prevalence: see Herd Prevalence
R&D: Research and Development

RBCT: Randomised Badger Culling Trial, a scientific study carried about from 1998 – 2005 to quantify the impact of two forms of culling badgers on TB incidence in cattle
RDPE: Rural Development Programme for England
Reactor: An animal which gives a positive reaction to the tuberculin skin test as defined in Council Directive 64/432/EEC
Reservoir Host Population: A population in which the pathogen is endemic and from which infection is transmitted to a particular target population
RoI: Republic of Ireland
Routine herd testing: The programme of routine surveillance testing of breeding cattle in herds using the tuberculin skin test in line with Council Directive 64/432/EEC. Routine herd testing is applied to four-yearly tested herds
RPA: Rural Payments Agency
SAC: South American Camelids, for example alpacas and llamas
SE: Sensitivity (of a test – ability to detect all cases of disease)
Severe Interpretation: A more rigorous interpretation of the tuberculin skin test (than the "standard interpretation") in line with Council Directive 64/432/EEC
Short Interval test: The intensive testing of all cattle in breakdown herds using the tuberculin skin test in line with Council Directive 64/432/EEC
SICCT: Single intradermal comparative cervical test. See tuberculin skin test
SICT: Single intradermal cervical test. See tuberculin skin test
Single Farm Payment: An agricultural subsidy paid to farmers in the EU
SP: Specificity (of a test – the accuracy of the test in ruling out disease)
Spillover Host Population**:** A population which can become infected with the pathogen but from which the infection is not transmitted to a particular target population.
SRUC: Scotland's Rural College
Standard Interpretation: The routine interpretation of the tuberculin skin test in line with the Council Directive 64/432/EEC
Surveillance: The collection of health data to detect disease in a population by using diagnostic or clinical methods. For bovine TB in England, formal surveillance is carried out with frequent, whole or routine herd testing, by pre-movement testing of all cattle of 42 days of age, leaving premises in the HRA and by inspecting all cattle carcases slaughtered commercially for post mortem signs of bovine TB
TB: Tuberculosis
TBAS: Tuberculosis Advisory Service
TBEAG: Bovine Tuberculosis Eradication Advisory Group for England
TBEG: Bovine Tuberculosis Eradication Groups, county level local groups
Test Interval: The period of time between routine or whole-herd tuberculin tests
Therapeutics: Pharmaceutical agents (drugs) licenced for use in treating human or animal diseases
TLA: Temporary Land Association, associates a permanent County Parish Holding with land or a building within 10 miles of the CPH's main livestock handling area.
Tuberculin: Mycobacterial proteins used in tests to detect bovine tuberculosis
Tuberculin skin test: A diagnostic test measuring an animal's reaction to injection(s) of tuberculin carried out in line with Council Directive 64/432/EEC.

TVR: A wildlife intervention research study in Northern Ireland, looking at the effects of implementing a test and vaccinate or remove intervention on badgers
UK: United Kingdom, comprising Great Britain and Northern Ireland
USA: United States of America
VDP: Regional Veterinary Delivery Partners
VMD: Veterinary Medicines Directorate, an agency of Defra
VNTR: Variable Number of Tandem Repeat, a location in a genome where a short nucleotide sequence is organized as a tandem repeat
Whole herd testing: The testing of all cattle in herds using the tuberculin skin test in line with Council Directive 64/432/EEC. Whole herd testing is applied routinely to annually tested herds and to breakdown herds

Annex 2 – Register of interests

This register records declarations of interests relevant to the remit of the bovine TB Strategy Review.

Professor Sir Charles Godfray CBE FRS (Chair)

- Director of the Oxford Martin School, University of Oxford (current employer)
- Imperial College London (past employer & Honorary Principal Research Fellow)
- Chair, Defra Science Advisory Council
- Trustee Director, Rothamsted Research & Lawes Trust
- Science Advisory Council, Natural History Museum
- Trustee, Food Foundation
- Research in laboratory currently funded by National Environment Research Council (NERC), the Foundations of the National Institute of Health (USA), Bill & Melinda Gates Foundation, the Open Philanthropy Foundation and by the Wellcome Trust
- Current and recent committee service for GoScience (BEIS), Global Challenge Research Fund, Defra, Welsh Government, Biotechnology and Biological Sciences Research Council (BBSRC), Soil Association, European Landowners Association, Royal Society, Royal Commission for the Exhibition of 1851, Bill & Melinda Gates Foundation, Balzan Foundation, Heineken Foundation, and Scottish Government.
- Participant (remunerated) at Nestlé Conference 2016

Professor Christl Donnelly CBE FMedSci FRS

- University of Oxford (current employer)
- Imperial College London (current employer)
- Deputy Director of the World Health Organization (WHO) Collaborating Centre for Infectious Disease Modelling, Imperial College London
- Council member (trustee), Royal Statistical Society
- Committee service for the Royal Society, Academy of Medical Sciences and Royal Statistical Society
- Research currently funded by MRC, National Institute for Health Research, BBSRC, Wellcome Trust, DfID.
- Consultant on the Defra-funded APHA-led research project: Developing a surveillance system to report TB in cattle herds exposed to badger control in England - SE3131
- Consultant to provide statistical and epidemiological analysis and interpretation to Prof Marian Stamp Dawkins, University of Oxford (from 2016)
- Current PhD students funded by NERC, Engineering and Physical Sciences Research Council, Wellcome Trust, Commonwealth Studentships, Imperial College London Presidents Awards.
- Expert group member (statistics) for the Infected Blood Inquiry
- Expert panel member, Council for Science and Technology Review on Modelling: Opportunities for Growth, Productivity and Resilience
- Working group member, World Health Organization (WHO) Blueprint Plan of Action - Designing a vaccine efficacy trial during Public Health Emergencies: Towards the development of guidelines and interactive tools

- Member (2012-2016), International Council for Science (ICSU) Scientific Committee on Health and Wellbeing in the Changing Urban Environment –
- Co-author of Principles of Applied Statistics (Cambridge University Press) with Sir David R. Cox and of Statistical Aspects of BSE and vCJD: Models for Epidemics (CRC Press) with Prof Neil M. Ferguson.

Professor Glyn Hewinson

- Lead Scientist for Bovine Tuberculosis, Animal & Plant Health Agency
- APHA (current employer until 16 December 2018)
- Aberystwyth University (future employer from 17 December 2018)
- Imperial College (Visiting Professor)
- Jenner Institute, University of Oxford (Jenner Fellow)
- OIE expert on Bovine Tuberculosis
- Chair of the Global Research Alliance for Bovine Tuberculosis (GRAbTB)
- Defra TBEAG member
- University of Surrey Veterinary School – member of External Advisory Committee
- Public Health England (PHE) – member of Strategic Oversight Group for the implementation of Whole Genome Sequencing of Pathogens
- PHE Porton – member of External Science Review Panel
- Research currently (or recently) funded by: Defra, BBSRC, Bill & Melinda Gates Foundation, ZELS (NERC, BBSRC, ESRC, DfID, MRC), Wellcome Trust, European Commission EU - FP7

Professor Michael Winter OBE

- University of Exeter (current employer)
- Board member, Natural England
- Board member, Rothamsted Research
- Board member, UK Joint Nature Conservation Committee
- Member, Natural England Science Advisory Committee
- Chair, UNESCO North Devon Biosphere
- Current or recent research funded by Defra, Prince's Countryside Foundation, BBSRC, NERC, Devon County Council.
- Chair (2014-16), Uplands Alliance
- Visiting Programme Director (2010-15), Food Security, Wilton Park, Foreign Office

Professor James Wood

- University of Cambridge (current employer)
- Animal Health Trust (previous employer and previous charity trustee)
- Honorary Research Fellow, Zoological Society of London
- Council member, Royal College of Veterinary Surgeons
- Director and Charity trustee, British Equine Veterinary Association Ltd
- Director, Equine Veterinary Journal Ltd
- Charity Trustee (chair), Survival International
- Science Advisory board member, Animal and Plant Health Agency
- Science Advisory board member, Roslin Institute

- Member, Defra Bovine TB Eradication Advisory Group for England
- Member, Defra Science Advisory Council
- Member, Veterinary Schools Council
- Director, Southoe Consultancy Ltd
- Research currently (or recently) funded by Alborada Trust, Wellcome Trust, BBSRC, Ecosystem Services for Poverty Allieviation Programme (NERC, BBSRC, Economic and Social Research Council, Department for International Development (DfID), Medical Research Council (MRC)), Zoonoses and Emerging Livestock Systems (NERC, BBSRC, ESRC, DfID, MRC), RAPIDD, Humane Society International, International Fund for Animal Welfare, European Commission EU-FP7, European Food Safety Agency (registered expert), Defra – directly and through BBSRC (all on bovine TB), MRC, Gillings Family Foundation

Annex 3: Terms of reference

The Bovine Tuberculosis Strategy review is initiated by, and will report to, the Secretary of State for Environment, Food and Rural Affairs.

1. Purpose

To reflect on progress being made with implementation of the bTB Strategy and consider how to take the Strategy to the next phase. Advise on what further actions might be prioritised now to ensure we maintain progress towards our target of achieving Officially Free status for England by 2038.

2. Objectives

The review will:

- consider and advise on the opportunities for improved application, enhancement or acceleration of the interventions set out in the Strategy, including cattle vaccination, oral badger vaccination, improved genetic resistance and improved diagnostic tests, or to deploy new tools and/or technologies to fight the disease

- consider how delivery is monitored and how impact of the Strategy is evaluated (and what that tells us about progress of the disease and the dynamics of its spread), and make recommendations as to whether and how these can be improved

- advise on gaps in the available evidence and disease control tools. Recommend options to address these (including the application of epidemiology and research) to achieve the aims of the Strategy

In implementing the review, the review team should also take account of:

- the structure of the farming industry and the rural environment

- the sustainability, scalability, deliverability and cost-benefit trade-offs of interventions

- wider work underway in Defra to consider future farming policy and the farming regulatory and enforcement landscape, in light of the UK's exit from the EU

- lessons learnt from the experiences of the Devolved Administrations and from the strategies deployed by other countries to tackle and eradicate bovine and human TB and other diseases

3. Scope

The review will consider all the drivers for disease spread and how they might be addressed. The focus will be on the bTB eradication strategy for England only. It will consider this as a system of intervention to control the disease and advise on how this could be improved.

The review will not re-visit the rationale for current interventions in the Strategy. It will take a prospective and not a retrospective view. It is not a review of badger culling.

4. Roles and responsibilities

The review will be led and overseen by Professor Sir Charles Godfray FRS. He will be supported by a small core working group to which Professor Christl Donnelly FRS, Professor James Wood, Professor Michael Winter and Professor Glyn Hewinson have been appointed. All reviewers have been selected for their skills, competence, expertise, and experience of operating at a strategic level and impartially.

The UK Chief Veterinary Officer, Christine Middlemiss, will work closely with the core group to provide her expertise and a government perspective. Whilst the core group will consider her views, they will retain ownership of the final report and will not need to secure her agreement or align the report to her views.

5. Ways of working

The Chair will be responsible for overseeing the strategic direction and progress of the review and delivery of the final report. The Chair will work closely with the CVO and the Director of Animal and Plant Health who will oversee the review within Defra. Progress reviews will be conducted monthly.

The Chair, with advice taken from the core working group, may seek to access wider expertise dependent on need.

The review will be supported by a Secretariat within Defra, and by staff within Defra and the relevant agencies throughout.

A communications strategy and stakeholder engagement/management plan will be developed. All communication with the media will be undertaken through Defra Communications Team.

6. Timing

The review will commence in March and is due to be completed by end September 2018.

7. Reporting

An evidence-based report will be submitted to Defra Ministers for consideration, detailing the findings of the review. The final report will be published in due course.

Annex 4: Summary of stakeholder engagement

We ran a call for evidence from 24 April 2018 to 31 May 2018 to help inform the bovine TB Strategy Review work.

We sought information about evidence-based interventions (including epidemiological and regulatory/economic measures) for bovine TB control. In particular:

- research aimed at improving the deployment of existing bovine TB measures;
- potential new approaches and tools/technologies to deal with bovine TB;
- approaches taken to control bovine TB in other countries; and,
- work in the field of human TB that might be relevant to the Review.

Call for evidence outcome

We received 39 responses to the call for evidence. These were submitted by a mixture of individuals and organisations, including farming and veterinary groups, NGOs and academics.

We carefully considered all the submissions received and used this evidence to inform our final report.

Issues raised

Key themes raised in response to the call for evidence were:

Risk-based trading

Several responses discussed the role of cattle movements in spreading bovine TB and the potential for risk-based trading to mitigate this risk.

Biosecurity

Some respondents highlighted issues of on-farm biosecurity and whether this could be incentivised and improved.

Vaccines

Several responses discussed the potential role of cattle and badger vaccines in terms of effective disease management. Work is needed to develop these tools and explore how best to deploy them.

Surveillance and diagnostics

A number of responses called for further work to improve the identification of the disease, including support for new/novel diagnostic tests.

Using genetic techniques

Several organisations highlighted the potential to breed for disease resistance, with some suggestions for future research.

Badger Culling

There was a range of views about the need for badger culling, its humaneness and effectiveness, including how Government might develop an exit strategy.

Environmental factors

Some responses discussed the role of slurry and soil in terms of disease transmission.

International experience

Responses highlighted good practice in Australia, New Zealand and other countries; for example, approaches to risk-based trading and governance.

Human TB

Several submissions highlighted relevant research in the field of human TB.

Bovine TB in other farmed species

Some responses discussed the need for further action to identify and control the disease in a wider range of species.

Information

A few responses raised the potential of big data, artificial intelligence and better use of analysis and statistics. These could help with monitoring and better targeting of efforts to control the disease.

Role of retailers

Some organisations felt that the large supermarkets could play an important role in influencing farmers and consumers and encouraging good practice.

Other novel suggestions

Some responses highlighted novel tools and techniques to detect bovine TB and reduce disease risks.

Stakeholder Meetings

The Review team also met with a number of stakeholders throughout the course of the Review process. This included individuals and organisations linked to farming, environmental and wildlife protection and the veterinary profession, NGOs, Government and academics.

Annex 5: Bovine TB Research Spending (2014/15 to 2018/19)

Defra funds a substantial bovine TB research programme. This includes:-

- developing vaccines for use in both cattle and badgers;
- developing improved diagnostic tests for cattle;
- exploring epidemiological factors influencing the prevalence and persistence of bovine TB in cattle and wildlife;
- investigating risk factors for the development of the disease in cattle; and
- undertaking economic and epidemiological analyses of bovine TB control strategies and the overall impact of the disease.

Between 2014/15 and 2018/19, Defra funded 45 individual research projects and invested approximately £21 million in its bovine TB Research and Development programme. The research budget covers England, Wales and Scotland.

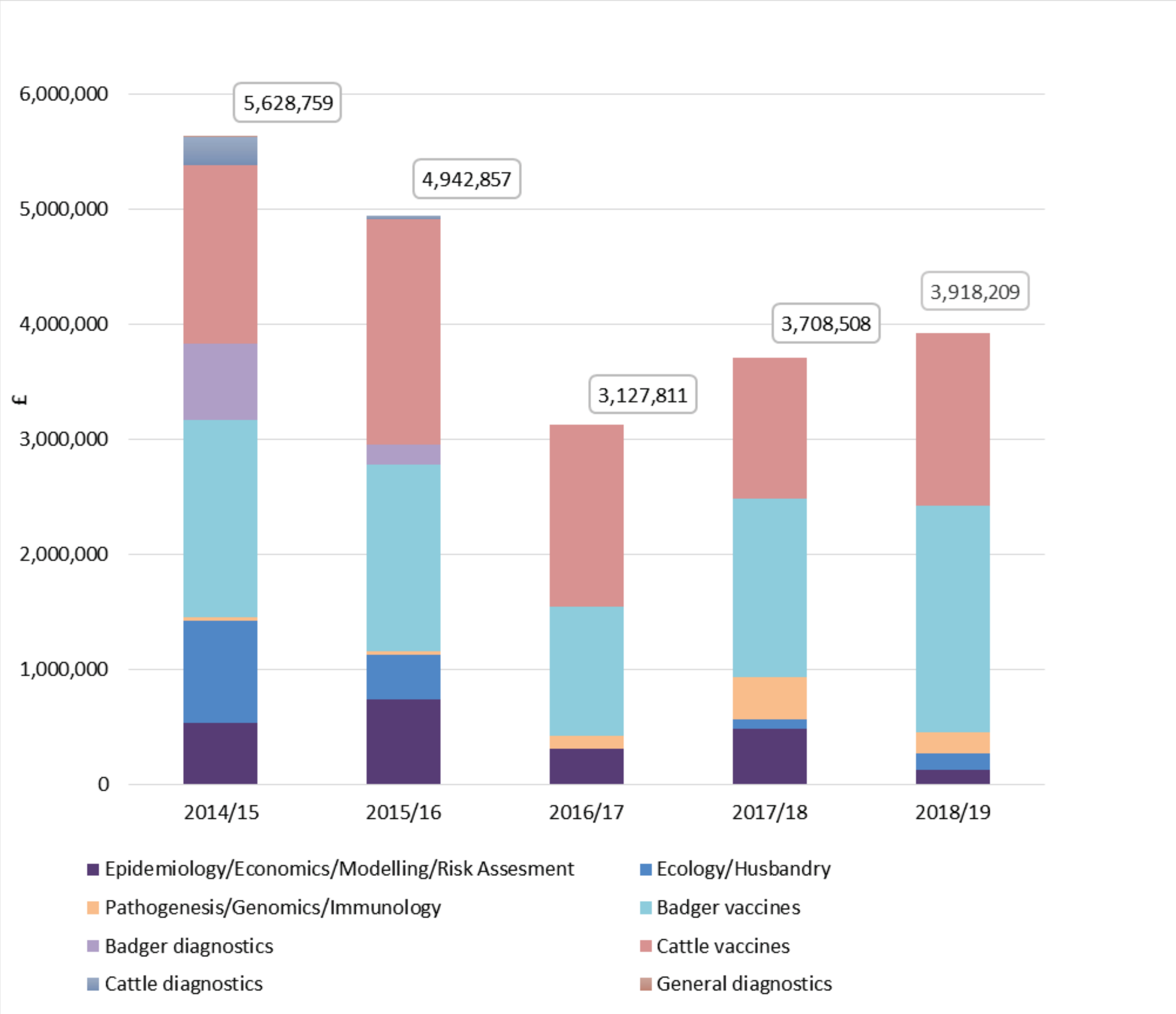
Figure An5.1 provides a breakdown of research expenditure by Defra since 2014 in the following areas:

- epidemiology, economics, modelling and risk assessment;
- pathogenesis, genomics and immunology;
- cattle vaccines and related diagnostics;
- cattle diagnostics;
- badger vaccines and related diagnostics;
- badger diagnostics; and
- general diagnostics (i.e. multi-species projects).

In 2014, Defra collaborated with the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) and the Biotechnology and Biological Sciences Research Council (BBSRC) on a £7 million programme aimed at improving knowledge of bovine TB biology. The programme is focused on addressing knowledge gaps, developing new non-animal models to study disease, and developing novel control and eradication strategies.

The live portfolio of BBSRC awards at 1 April 2018 relating to bovine TB covers 18 active projects with a total commitment of £10.9 million. Other Research Councils have also invested in bovine TB research in recent years. The Natural Environment Research Council (NERC) funds research on the occurrence of bovine TB in wild populations and transmission to other species. The Medical Research Council (MRC) has made a number of strategic investments in long-term bovine TB research programmes which may produce new cross-cutting approaches, tools and technologies.

Figure An5.1. Defra bovine TB research spend by scientific area, 2014/15 to 2018/19



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

Annex 6 – Areas of licensed badger control

Figure An6.1. Map of 2018 badger culling areas in England (number and approx. size*)

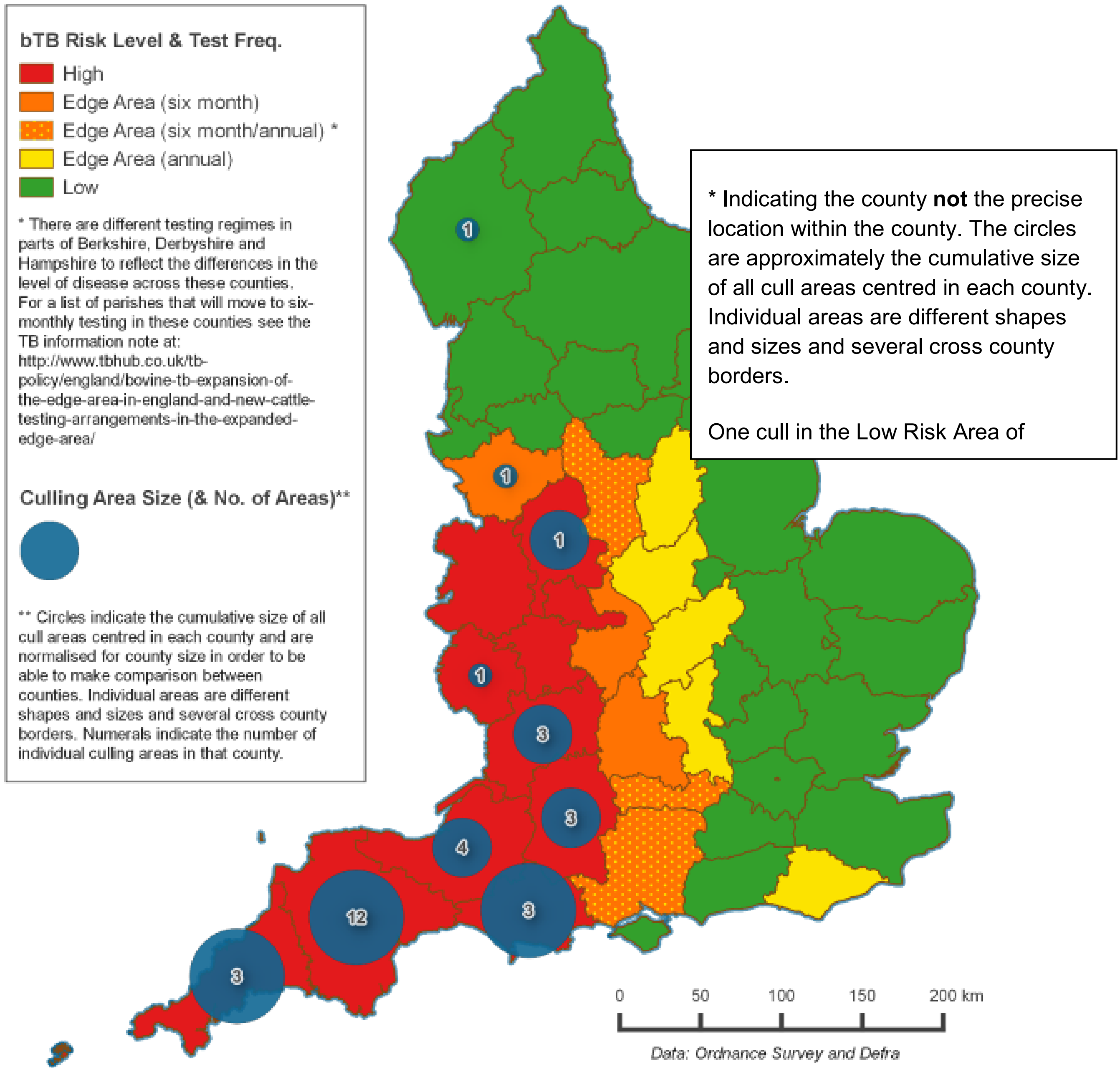


Table An6.1. Number of badgers culled per year (2013 - 2017)

	2013	**2014**	**2015**	**2016**	**2017**
Area 1 – Gloucestershire	924	274	432	252	172
Area 2 – Somerset	955	341	279	217	91
Area 3 – Dorset			756	502	257
Area 4 – Cornwall				711	213
Area 5 – Cornwall				851	358
Area 6 – Devon				2038	727
Area 7 – Devon				833	246
Area 8 – Dorset				3000	1166
Area 9 – Gloucestershire				1858	1012
Area 10 – Herefordshire				624	394
Area 11 – Cheshire					736
Area 12 – Devon					1874
Area 13 – Devon					1237
Area 14 – Devon					708
Area 15 – Devon					763
Area 16 – Dorset					3450
Area 17 – Somerset					1123
Area 18 – Somerset					489
Area 19 – Wiltshire					2252
Area 20 – Wiltshire					1040
Area 21 – Wiltshire					1229

Key: Shading indicates culling did not occur in these areas/years. Highlighting indicates culling has occurred under a licence for supplementary badger control.