Developing a Bovine TB Eradication Programme for England The Bovine TB Eradication Group for England Published: 8 October 2009

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Developing a Bovine TB Eradication Programme for England

EXECUTIVE SUMMARY

- 1. The Bovine TB Eradication Group for England was established by the Government, the farming industry and the veterinary profession in November 2008 to make recommendations to the Secretary of State on bovine TB and its eradication. This report presents the progress we, as the Group, have made in developing a Bovine TB Eradication Programme for England; the risk-based approach we are taking in identifying and assessing new policies; and changes that are being made following recommendations we have made to the Secretary of State.
- 2. Bovine TB is complex: it is a chronic disease, and it takes time for any new measures introduced to lead to a reduction in disease prevalence. An eradication programme is an investment in maintaining trade in cattle and dairy products and protecting public health, but the cost and effort involved should not be underestimated and the timescales for delivering results will be lengthy. This is why we have made short term measures for reducing the impact of TB restrictions on farmers one of our more immediate priorities.
- 3. There is no single measure which will achieve the eradication of bovine TB. We will need to have in place and use a range of tools: effective diagnostic tests; targeted cattle controls; and vaccination for badgers and cattle; and to remain open to the possibility of using badger culling. These tools need to be used in a targeted way to reflect disease risk so we have a proactive approach rather than continuing to play catch-up as we are with the current testing regime. We have defined five areas (high risk; edges of high risk; medium; declining and low risk areas) as a basis for considering and targeting different measures effectively.
- 4. This report is a base from which we can move forward. We have agreed with the Secretary of State a series of changes that should be implemented, and some of these have already been introduced.
- 5. The recommendations which have already been implemented are designed to assist farmers under TB restriction to maintain their businesses. These are:
 - i. Subject to a veterinary risk assessment, the general movement licence can be used to allow movements of unrestricted cattle on to a TB breakdown herd for the duration of a breakdown. This is a change from the previous approach where a new license was required for each movement.

- ii. Movement of cattle to/from breakdown herds will be permitted over longer distances to help facilitate restocking. This is of particular benefit to owners of pedigree and/or organic cattle who can find it difficult to find the right replacement cattle.
- iii. Movement of untested calves (aged under 42 days) direct to slaughter via approved collection centres will be permitted, so reducing the number that have to be killed on-farm.
- 6. These initial changes are small in the wider context of bovine TB. However, they are a start and go some way to reducing bureaucracy for those under restriction and streamlining processes for Animal Health. The measures that will be introduced over the coming months will go further and be targeted both at improving disease control and at helping TB affected farm businesses.
- 7. The most significant changes we have agreed with the Secretary of State are to change the areas on which testing frequencies are set and an interim approach to setting testing frequencies which will be implemented in the coming months. We also recommended and agreed that England's approach to inconclusive reactors needed to comply with European legislation and we have agreed that the policy will be changed to allow only one retest from 1 January 2010. The other recommendations we have made and Hilary Benn has agreed should be implemented are:
 - i. Providing advice on bovine TB to restricted farms (implementation from early 2010);
 - ii. Providing a dispersal sale option for owners of TB breakdown herds (implementation by the end of 2009);
 - iii. Revise testing requirements for entry to and within Approved Finishing Units (AFUs) thereby encouraging more to be set up (implementation by the end of October 2009);
 - iv. Encourage the setting up of more 'quarantine units' as a trade outlet for calves currently killed on farm (implementation by the end of 2009); and
 - v. Providing greater flexibility on the timing of short interval tests in breakdown herds in high risk areas (implementation by the end of October 2009).

- 8. In addition to the changes discussed above we have also agreed, in principle, with the Secretary of State that we need to find a new approach to tackling unconfirmed breakdowns; and, in order to overcome some of the confusion around TB controls, that the terminology around breakdowns will be changed.
- 9. We are confident that the changes described in this report represent a positive first step in the development of an Eradication Programme for England. However, the Group also recognises that real progress towards eradication for those in high risk areas can only be made once measures are in place to tackle disease in wildlife on a large scale. In their absence, we see the additional support to farm businesses under restriction as crucial.
- 10. We are pleased to be able to say that the UK Eradication Plan for 2010 was submitted to the Commission in September 2009 and, while the material covering England within the Plan only represents a small part of what we want to achieve as a Group, we believe it sets a good foundation for the industry in England and the Government to work with colleagues in Europe by making clear to the Commission and other Member States that England (and the UK) are serious about tackling bovine TB. Eradication Plans have to be submitted annually and we aim to play a similarly active role in the future.
- 11. We plan to continue making recommendations and push for measures to be implemented as they are ready. However, as we move forward, it will be important for us to have more opportunities to discuss progress and ideas with those most affected. So, following publication of this report, we plan to meet regularly (approximately every six months) with representatives from key organisations rather than produce regular reports. We would also encourage those wishing to present ideas or discuss issues to contact us at tberadication.group@defra.gsi.gov.uk.

INTRODUCTION

- The Bovine TB Eradication Group for England was established by the Government, the farming industry and the veterinary profession in November 2008 to make recommendations to the Secretary of State on bovine TB and its eradication. This report presents the progress we, as the Group, have made in developing a Bovine TB Eradication Programme for England; the risk-based approach we are taking in identifying and assessing new policies; and changes that are being made following recommendations we have made to the Secretary of State.
- 2. The Group was set-up during a difficult period in the relationship between the Government and the farming industry. The one point on which there was agreement was the ultimate goal: the eradication of bovine TB. This laid the foundation for the Group. A further driver was the need to contribute to a UK TB Eradication Plan for 2010 for submission to the European Commission. While that is an important document, we decided that the main focus of our work needed to be to develop a wide ranging and long term Bovine TB Eradication Programme for England that would have a broader reach than the immediate requirements of the plan for the Commission.
- 3. Developing and implementing a TB eradication programme is a big challenge for the farming industry and for government. Bovine TB is complex: it is a chronic disease, and it takes time for any new measures introduced to lead to a reduction in disease prevalence. An eradication programme is an investment in maintaining trade in cattle and dairy products and protecting public health, but the cost and effort involved should not be underestimated and the timescales for delivering results will be lengthy.
- 4. It will take a number of years for any measures to have a significant impact; in the short term some measures may increase the number of reactors identified and the cost of the disease to Government and the farming industry. It could take as long as twenty years to deliver a significant downturn in the disease. This is not a new point for those familiar with the history of the disease on an international scale. The Australian Brucellosis and Tuberculosis Eradication Campaign (BTEC) took 27 years to eradicate TB; New Zealand's National Pest Management Strategy has been in place for 11 years and, while it has made significant progress, eradication is still thought to be more than twenty years away. England needs to take action now to get on to a path to eradication, and this is why this report looks at the strategic approach we have been developing alongside the more immediate measures we have agreed with the Secretary of State for implementation this year and for 2010.

- 5. The report first focuses on our work to date in developing an eradication programme for England. While many of us have long had an involvement with the question of what to do about bovine TB, we have used these first 10 months to get to grips with the detail of the epidemiology of the disease, the scientific evidence, TB statistics, the policy options available and the current budget. We have used this information to develop a framework for a risk-based approach and identify review points so we can track progress towards the ultimate aim of eradication.
- 6. We then turn to the changes we have recommended and which will be implemented over the coming year. Measures to reduce the impact of TB restrictions on farm businesses, without materially increasing disease risks, are particularly important since eradication is such a long-term objective. We have worked closely with Animal Health on options, and the first changes were introduced in July this year.
- 7. At the same time we have had to take difficult decisions: we are all too aware of the pressures bovine TB restrictions place on some farmers. We looked hard at the options before making the recommendations to the Secretary of State about strengthening existing controls described in the third part of this report.
- 8. The fourth section discusses bovine TB and badgers. This is the most sensitive and complex issue that we need to cover in an Eradication Programme. In line with our remit, we have been working through issues around both culling and vaccination and looking at the options available to reduce the risk of transmission between cattle and wildlife, while considering the costs and benefits.
- 9. The fifth section outlines our discussion of biosecurity. Biosecurity is good practice whatever the disease and there are specific actions farmers can take to reduce the bovine TB risk. Advice is already available, we have been considering how farmers can access this in the most useful ways.
- 10. The final section of this report looks to the future and our next phase of work. It also outlines how we propose to engage with key stakeholders.

A BOVINE TB ERADICATION PROGRAMME FOR ENGLAND

Bovine TB in England

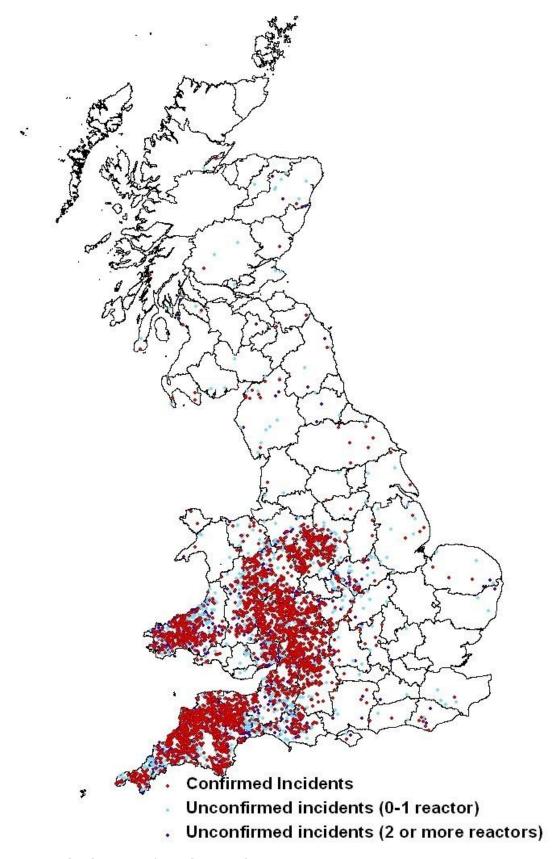
- 11. Bovine TB is the greatest disease challenge facing the cattle industry in England. As the Bovine TB Eradication Group for England, we do not underestimate the scale of the problem: TB testing is identifying thousands of cases per year; the taxpayer spent £84m¹ on bovine TB controls in England in 2008/09; and the costs, both emotional and financial, to individual farmers and the cattle industry collectively, are significant.
- 12. Over the past 10 months we have been working on meeting part of our remit: to produce the England component of an Eradication Plan for the European Commission. The Commission had been pressing the UK for an eradication plan, particularly since the export of TB infected calves to Belgium and the Netherlands in 2008. We met our remit in mid-September 2009 when the UK plan was submitted and hope to hear whether the plan has been approved by November. It has been a challenge to achieve this, but we see the plan as a valuable snapshot of TB controls in 2010. However, the main focus of our work is to develop an Eradication Programme for England for the long-term.

Aims and objectives of the Programme

13. The main aim of the programme we are developing is to eradicate bovine TB from cattle in England. This is easy to state but difficult to implement. Map 1 shows how the level of disease is at its highest in the West and South-West of the country. Badgers are a contributing factor to the disease dynamic in these areas but they are not the only factor; farm practices, cattle movements and the testing regime are strong contributors to how we describe and understand the levels of disease in different parts of England.

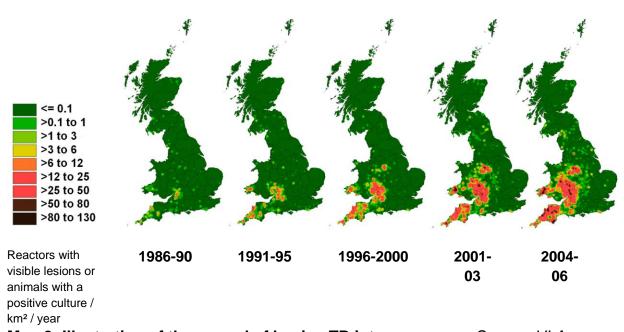
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¹ This is the figure for England but includes some costs for GB (cattle testing and laboratory costs). Total GB expenditure was £108m.



Map 1: New incidents of bovine TB in 2008

14. Consideration of current practice has led us to a key conclusion: the way we test for bovine TB in cattle means we are constantly playing catch-up with the disease. Incidents of bovine TB are found and parish testing intervals are set based on where the testing regime has looked for, and subsequently found, disease. By way of illustration, Map 2 shows the spread of disease over twenty years (1986 – 2006) and how the number of detected incidents and the density of infected cattle (map is of cattle numbers not incidents) has increased through the testing and surveillance regime. In 1986-90, for example, in the West Midlands relatively low numbers of animals had visible lesions or positive culture, though these increased to significant numbers by 2006. This supports the idea that we may need to look for disease outside current annual testing areas on a more frequent basis. As has been shown through Wales' TB Healthcheck², this would mean more disease is likely to be found in areas currently on two, three and four yearly testing.



Map 2: Illustration of the spread of bovine TB into new areas. Source: VLA, January 2009.

http://newydd.cymru.gov.uk/topics/environmentcountryside/ahw/disease/bovinetuberculosis/bovinetberadication/tbhealthcheckwales/;jsessionid=BQDrKwpB9SQKn1V7Fn4FgtChQ1fNF12QkYnQpxL2bKm8pJMLTQyx!-1833824413?lang=en&ts=3

² Further information can be found at:

15. We are convinced that the Eradication Programme for England should take disease risk into account and the way in which areas are treated should reflect the local epidemiology; proximity to high incidence areas; current disease restrictions in place; and whether there is evidence of a wildlife reservoir present; alongside historic incidence of bovine TB. In order to move our thinking forward and consider where policies might be best targeted we have agreed descriptions of geographic areas based on these points: high risk; edges of high risk; medium; declining; and low risk (Table 1).

Table 1: Geographic areas of disease risk

High-risk areas	Established endemic areas: the South-West and West of England, the Midlands and Sussex which are on annual testing and where there is a recognised established wildlife reservoir.
Edge of high-risk areas	Areas at increased risk at the edge of high risk areas in the South-West, West Midlands and East Sussex.
Medium risk areas	Areas in England under restriction but not in the high risk or edge of high risk categories where breakdowns are primarily due to the translocation of infection through cattle movements and there is no evidence of transmission from wildlife. Areas where this would currently apply include, for example, breakdowns in Norfolk, Humberside and Northumberland.
Declining risk areas	Areas where, from an epidemiological point of view, the situation is improving and this is reflected by the area coming off of annual testing and the increasing intervals between routine tests. One of the areas this would currently apply is Cumbria.
Low risk areas	The remaining areas that would not fall within the categories above, which will be on four yearly testing and where herds are not currently under restriction.

16. Using these areas we have concluded that the short, medium and long-term objectives of an Eradication Programme and associated policies need to be tailored to the level of disease risk in an area. For example in high risk areas with established, endemic, bovine TB, eradication of the disease can only be achieved in the long-term and our objective needs to be one which both reduces the incidence of disease and, crucially, its impact on farm businesses.

- 17. The need to better manage impacts of TB on farm businesses was highlighted both from Members' own experiences and our discussions with the Farm Crisis Network following their recent report (*Stress and Loss: a report on the impact of TB on farming families*³). At the same time, any measures introduced should not increase the risk to clean premises, particularly those in the low risk areas, which need to be protected from undisclosed disease moving from high-risk areas.
- 18. At the other end of the scale are low risk areas where the vast majority of herds are not under restriction. The objective here needs to be to make sure testing is used in the most effective way; to improve understanding among farmers and vets about the implications of TB for farm businesses; and to consider options for reducing risk. There is an opportunity now to take advantage of a 'prevention is better than cure' approach and how we can achieve this will be part of our next phase of work.
- 19. We will be continuing to develop the specific objectives of the Programme over the coming months.

How long will the eradication of bovine TB take?

Bovine TB has been a problem for successive governments and the farming 20. industry in England since the 1890s and, international experience shows that it cannot be eradicated overnight; even if all possible measures were to be in place (including culling). International evidence shows that it is not possible to eradicate bovine TB where there is a wildlife reservoir. The Australian Brucellosis and Tuberculosis Eradication Campaign (BTEC) commenced as a national campaign in 1970 and included culling the disease reservoir in feral water buffalo, zoning and cattle movement restrictions and, towards the end of the Campaign, whole herd slaughter. Australia was declared TB free in 1997. New Zealand's eradication campaign is in progress and their local and central Government and industry-funded National Pest Management Strategy has been in place since 1998. The strategy is aimed at achieving eradication in a number of areas where TB is found in wildlife (so-called 'Vector Risk Areas' (VRAs)) and reducing the number of VRAs by 25% by 2025, and is reviewed every 5 years. England is some way behind New Zealand and it is important we identify what can be done, when, and the timescales over which measures could start to have an impact.

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³ The full report can be found at http://www.farmcrisisnetwork.co.uk/latestnews/stress-and-loss-a-report-on-the-impact-of-bovine-tb-on-farming-families

- 21. Timescales were also a concern of the TB Advisory Group. We welcomed their final report⁴ published in April. TBAG's thirty-six recommendations followed almost three years of collecting evidence from experts and discussions with farming, wildlife and veterinary organisations. These have stood us in good stead and we have incorporated their ideas into our work plan.
- 22. We were grateful to TBAG Members for the time they spent with us discussing the way forward and we agree with their view that there needs to be a sense of urgency around what can be done now. In response to this we wanted to be clear what our immediate priorities were and decided that one case we had to put to the Secretary of State was the need for measures to reduce the impact of TB restrictions on farm businesses. At the same time we were under no illusions that existing cattle controls for bovine TB need to be strengthened, and measures to ensure the risk to public health remains low must be maintained and improved where possible, including improving delivery and enforcement of controls (as a general rule no parish on annual testing will be next to four yearly testing parishes); and encouraging preventative measures for all farms, but especially for those in low risk areas. We talk about the progress on these issues later in this report.
- 23. Short-term measures are not enough: eradication of bovine TB is a long-term aim and we need to have an idea of how we can get to that point. We are therefore developing longer term targets to ensure progress on the road to eradication can be assessed at particular points over the next twenty to thirty years. In terms of making the most impact on disease, in the shortest space of time, there is scope for putting in place policies on the edge of high risk areas; and in medium, declining and low risk areas. High risk areas, where disease is endemic in the wildlife population, require longer term targets and delivering a significant impact on disease in these areas is only possible if action is taken to tackle the badger reservoir, with vaccination and/or culling being the main options. However, even with these in place it could take many years before a significant change in disease levels was seen in these areas; until we reach that point we therefore need to make sure farmers regularly under restriction are supported.

⁴ Bovine Tuberculosis in England: Towards Eradication (9 April 2009) http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/tbag-finalreport.pdf

- 24. For the very long-term, we also need to keep in mind that we may need to adapt our approach and policies if measures are not having the expected impact. More positively, once measures begin to have an effect and disease begins to decline decisions may also need to be taken about putting in place tougher measures to sustain progress. As disease does decline we would expect to see a gradual reduction in costs, even before the disease has been eradicated, although we would expect costs to rise during the initial phases of an eradication programme.
- 25. Once actions to tackle the wildlife reservoir begin to have an effect it will be critical to address the undisclosed reservoir of disease in cattle in high risk areas. At that stage, tackling the cattle reservoir is likely to require increasingly stringent cattle controls if we are to continue the progress towards eradication. So, we will need to be prepared to adapt our approach to changes in disease and the impact the eradication programme is having as we move forward.

REDUCING THE IMPACT OF TB RESTRICTIONS ON FARM BUSINESSES

26. TB will take many years to eradicate and this means that some farms will continue to be repeatedly under restriction or under restriction for long periods. For those whose business depends on animals going direct to slaughter (eg fattening units) this has less impact, but for beef and dairy herds that regularly sell animals the restrictions mean they may have to change the approach to their enterprise. For herds that do not purchase cattle ('closed herds') TB restrictions often mean that they have to purchase cattle to maintain their income, which has the potential to compromise herds of high health status. At the same time, the process of putting cattle through the test, waiting for the results, and dealing with reactors puts a significant level of emotional pressure on farming families - and this should not be underestimated. We need to work together to see how farmers facing restrictions can be better supported to deal with the stress and the financial pressures; and to find ways to reduce the impact of TB restrictions on farm businesses.

Changes made to cattle controls since July 2009

- 27. To help reduce the impact of TB restrictions on farm businesses we have worked closely with Animal Health to develop a range of immediate changes that will better support TB affected farmers these build on measures introduced over recent years (e.g. introduction of AFUs in 2002). The Secretary of State agreed our recommendations, and three have already been implemented:
 - i. Subject to a veterinary risk assessment, a general movement licence can be used to allow movements of unrestricted cattle on to a TB breakdown herd for the duration of a breakdown (after first 60 day test). This is a change from the previous approach where a new license was required for each movement on.
 - ii. Movement of cattle to/from breakdown herds will be permitted over longer distances to help facilitate restocking. This is of particular benefit to owners of pedigree and/or organic cattle who can find it difficult to find the right replacement.
 - iii. Movement of untested calves (aged under 42 days) direct to slaughter or via approved collection centres will be permitted, so increasing the trade outlets for stock from TB breakdown herds.

28. These initial changes are small in the wider context of bovine TB. However, they are a start and will go some way to removing some of the layers of bureaucracy for those under restriction and streamlining processes for Animal Health. The measures that will be introduced over the coming months will go further and be targeted both at improving disease control and at helping TB affected farm businesses.

Recommendations to be implemented from Autumn 2009

- 29. There are five other measures that we have agreed with the Secretary of State, but which needed further development before being ready to deliver. These are:
 - i. Providing advice on bovine TB to restricted farms (implementation from early 2010);
 - ii. Providing a dispersal sale option, subject to a satisfactory risk assessment, for owners of TB breakdown herds (implementation by the end of 2009);
 - iii. Revise testing requirements for entry to and within AFUs thereby encouraging more AFUs to be set up (implementation by the end of October 2009);
 - iv. Encourage the setting up of more 'quarantine units' as a trade outlet for calves currently killed on farm (implementation by the end of 2009); and
 - v. Providing greater flexibility on the timing of short interval tests in breakdown herds in high risk areas (implementation by the end of October 2009).

Providing advice on bovine TB to restricted farms

- 30. To help farm businesses reduce the risk of repeat TB breakdowns, and also minimise the business impacts of TB breakdowns, it is crucial that they have access to the best available professional, and sharply focused, advice. Farmers do not always realise what a TB breakdown could mean. The experience shared by some of the Members from their colleagues and clients made clear to the Group that the pressure of dealing with a TB breakdown can result in farmers failing to see their way through the problems or even taking decisions that make the problem worse, or that have longer term implications for the health of their herd.
- 31. We recognise that some one-to-one veterinary advice is already provided by Animal Health veterinary and technical case officers for owners of TB breakdown herds. However, we believe it is in industry's and government's best interest to offer more and so we have agreed, in principle, with the Secretary of State that additional government funded veterinary advice could help some herd owners better identify/manage disease risks and develop strategies for minimising the

impact of TB related restrictions. We are pleased to note that Defra is now actively developing options for the provision of veterinary and ecological advice for TB affected farmers, and is also considering business advice options. This work has been given a high priority, the intention being to roll-out the new advice package in early 2010.

32. Animal Health too are proactively looking at how they can enhance their advice service. They are developing clearer guidance on bovine TB through a complete reworking of *TB in Your Herd* – an advisory leaflet provided to all farmers with TB affected herds; and from January 2010 Animal Health Veterinary Officers will spend more time providing one-to-one advice to cattle owners experiencing their first TB breakdown. We were also pleased to hear from the NFU South West that they were applying to the Rural Development Programme for England (RDPE) to fund their own TB advisory scheme for farmers and we have written expressing our support.

Dispersal sales

- 33. We were concerned that the policy to date of discouraging dispersal sales for herds under restriction could cause real problems for small numbers of farmers in particular circumstances eg those that might wish to retire. Two pilot sales in the South-West have shown it is possible to minimise disease risks associated with such sales by, for example, tightly controlling who can purchase. After receiving feedback from Animal Health's working group of auctioneers and farmers we recommended to the Secretary of State that TB breakdown premises that satisfy specified criteria should have the option to hold farm dispersal sales. Movements would only be authorised to other TB breakdown herds that fulfil specified criteria and would be subject to a risk assessment. This will open up the option for a small number of herd owners to sell their whole herd, or a substantial part of the herd, in one day. The option of being able to move animals off to other TB restricted herds on a single animal basis remains available for all TB affected farmers⁵.
- 34. The qualifying criteria and operating controls will be finalised by the Animal Health working group, with the dispersal option becoming operational by the end of 2009.

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⁵ This is permitted following the first 60 day test and a veterinary risk assessment.

Approved Finishing Units

- 35. Approved Finishing Units (AFUs) can be set-up to receive clear tested cattle from TB breakdown herds and are exempt from pre-movement testing. They were introduced in 2002 as a way of increasing marketing flexibility for restricted premises. AFUs could provide a useful outlet for surplus cattle of any age from restricted farms, however only a relatively small number have been established. It has become clear that the biggest barrier to more being established is the requirement for frequent testing, which appears to be disproportionate when the animals are ultimately destined for slaughter. The lack of buyer competition when cattle owners sell to AFUs means that farmers may receive relatively low prices.
- 36. We considered making changes to AFU criteria in some detail because we needed to minimise disease risks while at the same time encouraging the setting up of greater numbers of such facilities. The current requirement for animals to have been clear tested 14 days before being moved to an AFU will be changed a TB test will now be valid, for such moves, for 90 days. This change was first recommended by the TB Advisory Group. We looked further at what could be done in this area, and agreed the following two tier system struck the right balance between facilitating more trade and controlling disease risks:
 - i. AFUs with grazing. These facilities will only be approved in high risk areas and will be subject to 90 day interval testing.
 - ii. AFUs without grazing. These facilities will provide wildlife proof housing and will be subject to testing intervals of 6 months.
- 37. Animal Health are aiming to implement these changes before the end of October 2009.

Calf Quarantine Units

38. Calves from TB restricted herds can be moved to slaughter (directly or via collection centres); to other breakdown herds; or to quarantine units. At the moment, Animal Health can approve quarantine units depending on the disease situation within a breakdown herd and the lay-out of the premises, for example where discrete buildings or separate land mean that specific groups of cattle can be held in isolation. In short, the herd can be divided into distinct epidemiological groups according to infection risk and management practices, enabling their future testing regime to be managed differently. Our concerns arose from the 'one size fits all' approach which failed to recognise the different processes and housing required for rearing calves at different ages and the particular requirements for moving suckler calves and store cattle.

- 39. One option we considered was to allow the continuous 'drip-feeding' of calves into a quarantine unit, however, we concluded that this would undermine any attempt to monitor and control the disease status of the animals within the unit. Following detailed analyses and discussions, we have concluded that two distinct chain systems offer the best way forward: one to facilitate the movement of young dairy calves to slaughter for veal and intensive young bull beef production; and one enabling suckler calves to be sold to be grown-on further and ultimately finished. We anticipate this changed approach will have significant and positive benefits for TB affected farm businesses and, we believe it will be deliverable once approval protocols are in place to manage disease risk.
- 40. Animal Health are now considering what detailed rules and conditions will be needed, with the aim of introducing the revised system before the end of October 2009.

Flexible approach to timing of short interval testing

- 41. For some farm businesses with herds suffering protracted TB breakdowns, the current requirement to complete Short Interval Tests (SITs) at 60 day intervals can prove burdensome, particularly in the summer months if cattle are being grazed away from the main holding. We would like to put in place a more flexible approach. We considered the pros and cons of simply extending the allowable interval between SITs to 120 days (currently the default interval is 60 days) and considered at what point, in these circumstances, the zero tolerance policy (ie no movements allowed) would be applied. While this approach had some attractions we concluded, with advice from Animal Health and Defra vets, that it would risk undermining disease controls too much by increasing the risk of allowing infection to spread unchecked in some breakdown herds. It would also create a very complex system to administer.
- 42. We have, therefore agreed a slightly different approach: one that will certainly introduce a more flexible approach to the timing of SITs (by allowing the majority of farmers in high risk areas to opt for 120 day intervals between SITs if they so wish) but which also protects herd-owners and government from the impacts of extensive spread of TB within a herd. The change means that movements from restricted herds to slaughter; to red markets; or to other restricted premises will be permitted for 90 days after a SIT. Once 90 days have elapsed since a completed SIT, Animal Health will complete a risk assessment of the herd if that risk assessment produces a satisfactory result, movements would be permitted (under special license) for a further 30 days (total: 120 days).
- 43. This approach will be introduced by the end of October 2009.

STRENGTHENING EXISTING BOVINE TB CONTROLS

44. We have been working through the testing and surveillance programme for bovine TB to understand in more detail how it works and identify ways where disease risks could be better managed or a different approach taken. Largely the system works well, although the demands on vets, farmers and the taxpayer are considerable in terms of time, stress and money. We have focused particularly on the retrospective way testing intervals are set within EU legislation (which means we are not getting ahead of the disease) and the confusion caused by the terminology used to describe TB breakdowns (the commonly held misconception that unconfirmed breakdowns mean that cattle either have not been infected or have somehow become immune).

Changes for 2010

- 45. We have looked hard at the changes needed to strengthen the current testing and surveillance programme to prioritise action which could make the most difference while balancing the effect of any changes against the potential impact on the industry, the cost to Government and the consequences if we did nothing. We have been particularly concerned that there is a risk with the current approach that the full extent of disease across England and within breakdown herds is not being disclosed and therefore not being removed, and also that it leads to misunderstandings over the TB status of herds.
- 46. Following our recommendations to Ministers the three specific areas where changes will be made for 2010 are:
 - Testing areas: a decision to change the area on which testing frequencies are set;
 - ii. Establish an interim approach to setting testing frequencies; and
 - iii. Inconclusive reactor policy: change to allow only one retest.

Testing areas: a decision to change the area on which testing frequencies are set

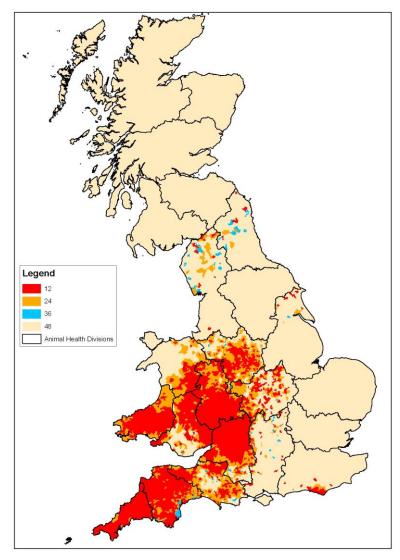
47. We concluded that, in a worsening disease situation, there are several problems with the current Parish Testing Interval approach. Firstly, it is apparent that parishes are too small a unit on which to assess risk and reach decisions on routine testing frequencies. This results in a "scatter-gun" pattern of testing intervals (even with local veterinary discretion) and does not present a coherent and consistent picture for TB surveillance, for example with four yearly tested parishes next to annually tested parishes. Secondly, testing frequency is based on the historical TB incidence and follows the spread of infection, rather than the current TB situation and trends. These points mean

- that testing frequency does not truly reflect or respond to risk of TB infection for herds within some parishes and regions.
- 48. We agreed that work should be put in train to develop an approach whereby testing frequencies are set on the basis of local epidemiological risk. This is consistent with the view from the European Commission and their *Bovine TB Subgroup* of the *Task Force on Monitoring Animal Disease Eradication*. This will take some time to develop so we recommended to the Secretary of State that an interim approach is implemented for 2010.

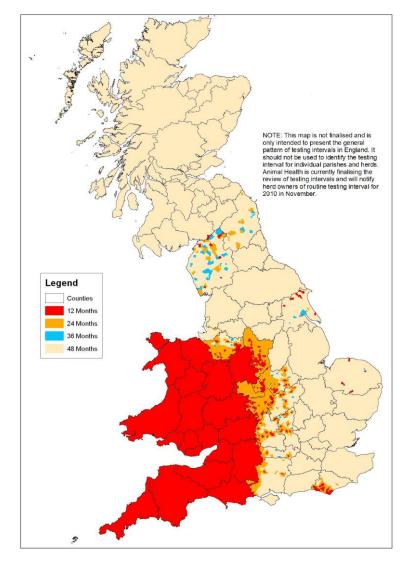
Interim approach to setting routine testing frequencies

- 49. The interim approach to setting routine testing frequencies for 2010 steps away from the current approach of retrospectively setting routine testing frequencies at parish level (Map 3a), towards a more epidemiological and proactive risk-based assessment (Map 3b). It will reflect the current local risk of infection for cattle herds and ensure a more coherent picture for bovine TB surveillance. Animal Health halted the annual Parish Testing Interval review process earlier this year while we were developing this approach and the following principles have been applied in setting the new routine testing frequencies.
 - Where risk of and actual infection is high, ie the TB endemic areas in the South-West and Midlands there will be annual testing across whole counties.
 - ii. The northern and eastern edge of this endemic core area will be separated from the low incidence regions of England by a continuous 'buffer zone' of 2-yearly routine testing interval, so that annual and four yearly testing areas do not adjoin. Where TB incidence and other data warrants it, this buffer will encompass whole counties adjoining the core area; otherwise, the buffer zone will be a two parish (approximately 10 km) wide strip. Within this 2-yearly testing buffer zone, small areas (based on administrative boundaries) may be placed on annual testing if local incidence is higher.
 - iii. Immediately to the east of the buffer zone, where a parish is placed on annual testing due to disease incursion it has been surrounded with a 2-yearly testing buffer, since these counties are considered of potentially higher long term risk than counties in the far North and East of England further from the endemic wildlife infected areas.

- iv. In addition, the small area in the South-East of England along the East Sussex coast, which has historically sustained a low but endemic TB incidence linked to badger infection will be on a background of 2 yearly routine testing, with annual testing in smaller areas where herd incidence and risk are higher.
- v. The rest (North and East) of England, where the incidence and risk of TB has historically been very low with any disease associated with the movement in of infected cattle and there is no evidence of a wildlife reservoir of TB, will remain on background 4 yearly routine testing. Exceptionally, any individual parishes in this area that have suffered recent incursions of TB due to movements of infected cattle, should temporarily be placed on more frequent testing, without buffering.
- vi. This is consistent with the Group's view of different geographic areas of TB risk (in table 1, page 9). The interim approach will result in a more consistent approach to setting test intervals. It will be particularly important in ensuring that the surveillance and control programme can get ahead of, rather than trail, the spread of infection.
- vii. Animal Health will be writing to individual farmers in November once the local veterinary review of the proposed testing intervals has been undertaken. This could mean that there may be changes to the indicative intervals shown in this progress report.
- viii. This will mean extra costs to Government for testing of around £1.7m per year, as well as extra compensation expenditure (estimated at around £1.1m). Approximately 4,000 additional herds will be required to premovement test. Whilst we recognise that this will impose an additional cost for these farmers if they wish to move cattle, it offers significant additional protection against the risk of TB spread from cattle movements both locally and nationally. Despite the increased costs, the pattern of testing under the proposed interim approach is considered by Defra and Animal Health vets to be a more accurate reflection of TB infection risk and to offer greater protection from the spread of TB to areas that are currently free of the disease.



Map 3a: Current Parish Testing Intervals (used in 2009)



Map 3b – Illustration of possible testing intervals for 2010

Inconclusive reactor policy: change to only allow one retest

- 50. In England and the rest of the UK up to two skin re-tests of inconclusive reactors (IRs) have been allowed for many years. The only exception to this policy in GB has been the animals in 1 or 2 yearly tested non-breakdown herds with two inconclusive tests which, since October 2006, have been gamma interferon blood tested in order to more quickly resolve their TB status (ie if positive to the blood test, these twice IRs in 1 and 2 yearly tested herds are automatically removed without further skin testing). Around 45 – 50% of these twice IRs are being removed as gamma positive animals. Historically when TB incidence was low there was a lower risk that IRs were infected with bovine TB (as opposed to showing a cross-reaction to avian TB). However, with the worsening disease situation, it is apparent that IRs are now more indicative of the true level of infection, as evidenced by the gamma interferon blood test results and numbers of animals cleared on re-testing but then disclose as reactors or repeated IRs at subsequent tests. By moving to a single re-test of IRs it ensures that infected animals are removed more rapidly and reduces the likelihood of future breakdowns in that herd and the risks of disease spread.
- 51. This has the added benefit of bringing us into compliance with EU Directive 64/432/EEC (as amended), which requires all (standard) IRs to the skin test (disclosed in both breakdowns and non breakdown situations) to be classed as reactors and slaughtered if they do not pass their first re-test. It is therefore a pre-requisite if a UK eradication plan is to be accepted by the European Commission. We understand this to be the IR policy adopted in all other EU Member States, including the Republic of Ireland. Wales and Scotland changed their IR policy to comply with the Directive on 1 March 2009.
- 52. We considered the epidemiological evidence which showed that herds with inconclusive reactors were likely to become confirmed breakdowns in the future. It is clear to us that submitting an eradication plan which contains rules which are not compliant would be counter-productive and lead to rejection of the plan. Following our recommendation, from 1 January 2010 inconclusive reactors will only be allowed one retest before being taken for slaughter.
- 53. The measures could identify an additional 1,000 reactors per year meaning additional costs of testing (£1.2m) and compensation (£0.9m) per year, which would be met by the Government. However, there would be enhanced disease control benefits through the earlier identification of infected animals and prevention of further breakdowns in the future.

Recommendations requiring further work

- 54. In addition to the changes discussed above we have also agreed, in principle, with the Secretary of State that we need to find a new approach to tackling unconfirmed breakdowns; and, in order to overcome some of the confusion around TB controls, the terminology around breakdowns will be changed.
- 55. The current approach to unconfirmed breakdowns (where no visible lesion is detected at post mortem examination or *Mycobacterium bovis* grown through tissue culture) creates misconceptions about the disease status of the herds involved and does not accurately reflect the levels of risk in some of these herds. This is not helped by the use of the terms confirmed and unconfirmed to describe the herd breakdown status. This can be incorrectly taken to mean that animals in the herd only have TB if 'confirmed' but do not have TB (or are 'false positives') if 'unconfirmed', when in fact the infection is present in *both* cases.

Changing the approach to unconfirmed breakdowns

- 56. In endemic areas total (confirmed and unconfirmed) breakdowns are a truer reflection of the level of infection than the current practice of using confirmed alone, and there is evidence that unconfirmed breakdowns could be a good indicator of an emerging TB problem which should be tackled more aggressively. These are often in herds or areas with a history of TB breakdowns and the more rapid lifting of restrictions through a reduced testing regime for unconfirmed breakdowns presents a risk that TB will not be cleared from the herd. A change in approach would mean that under some circumstances an outbreak with only unconfirmed reactors would be handled as a confirmed breakdown (or OTF-status withdrawn under proposed changes to terminology set out below). By maintaining herds under TB restrictions and associated controls for longer and subjecting them to more testing will help ensure a herd is cleared of infection. This is already accepted practice in other European countries and Northern Ireland where multiple unconfirmed reactors in a herd result in a breakdown being dealt with as if confirmed.
- 57. We are convinced that a change of approach to unconfirmed breakdowns is required, however, further work is needed to develop recommendations on a revised approach. The policy will need to be tailored to reflect differences in risk between high and lower risk areas. This will include work to identify the factors which would lead to an outbreak with only unconfirmed reactors becoming confirmed, determine the numbers of herds such a change might affect, and the likely cost of a change in policy. We will make further recommendations on the shape of a new policy once further analysis and assessment of costs and benefits have been completed.

Changes to TB Breakdown Terminology

- 58. TB policy in England currently describes a TB breakdown as "confirmed" or "unconfirmed" depending on results of post-mortem and bacteriological examinations carried out predominantly on animals disclosed as reactors to the immunological TB screening tests (skin test, gamma interferon blood test). A TB breakdown is "confirmed" following identification of typical TB lesions or isolation of *M. bovis* in the carcases of at least one test reactor, or after isolation of the bacterium in visible lesions from "slaughterhouse cases" detected in the course of normal meat production.
- 59. The current terminology focuses on the ability to detect demonstrable evidence of disease in slaughtered animals and assumes that post-mortem examination and culture represent the "gold standards" for establishing *M. bovis* infection. There is a fairly widespread misconception that skin or gamma-interferon test reactors with no visible TB lesions and a negative culture result represent false positive reactions to the ante-mortem TB screening tests and are thus being killed unnecessarily. The use of 'confirmed/unconfirmed' adds to this misconception because, while culture and post-mortem are gold-standards methods for TB disease, they are not sufficiently sensitive to identify all TB infected cattle, particularly those in the early stages of TB. The tuberculin skin test and gamma interferon blood test are both immunological tests and are more sensitive for this purpose and are fairly specific with low risks of substantial numbers of false positives (an explanation of TB test sensitivity and specificity can be found at annex B). So, 'unconfirmed' can mean 'undetected' through gross carcase examination or culture of a sample of animal tissues. In short, 'confirmed/unconfirmed' are neither the right language to use nor accurate descriptors of the TB status of a herd or a reactor animal.
- 60. The alternatives that we have recommended and will be put in place are from the language used in Annex A of Directive 64/432: 'Officially TB Free' (OTF), 'OTF suspended' or 'OTF withdrawn' to describe the TB status of a herd and this terminology refers to where a herd is within the surveillance/control process and its trading status. Use of this language will help tackle misunderstandings about whether an animal/herd has TB or not and make the testing and restriction process much clearer.
- 61. How this terminology would apply is described in Annex C and this shows that using EU Directive designations would largely be an administrative change rather than a material one. The change of terminology would not preclude also having information available on whether the laboratory tests for a herd or individual animals showed whether *M. bovis* had been detected or not. Using OTF herd status descriptors would also help make the implications of the outcome of a TB test clearer.

62. This change of terminology would be relatively straightforward to introduce and Northern Ireland has introduced this change already. However, the link to establishing a different approach to unconfirmed breakdowns means it makes sense to wait and introduce the changes together.

BOVINE TB AND BADGERS

63. Dealing with the reservoir of bovine TB in badgers in some areas of the country is, without doubt, the most sensitive and complex issue within the development of the Eradication Programme. International evidence shows that bovine TB in cattle cannot be brought under control or eradicated in areas where the risk from wildlife is not addressed. While Members have very clear personal views on this issue we approached our consideration of policy options within the wider context of developing an Eradication Programme for England and the different levels of disease risk. We will also keep abreast of strategies in other countries around the world that have a wildlife reservoir of bovine TB that is compromising the control of the disease in cattle.

Badger Culling

- 64. The Government's policy remains that licences will not be issued to cull badgers for bovine TB control in England, although the Secretary of State has made clear publicly and in discussion with us that he remains open to the possibility of revisiting this policy under exceptional circumstances, or if new scientific evidence were to become available. Our remit includes considering any such exceptional circumstances or new scientific evidence that might arise relating to the established policy on badger culling for control of TB.
- 65. We have considered the evidence the Secretary of State took into account in making his decision on badger culling: the scientific evidence (Randomised Badger Culling Trial (RBCT) including further analysis by Professor Christl Donnelly; international approaches); the cost benefit analysis; security advice from the police; research into methods of culling; the current potential of tests based on the polymerase chain reaction (PCR) technique; public acceptability; and practicality. We concluded that the option of badger culling needs to remain open but we cannot, at this stage, make a clear case for change based on scientific evidence which has emerged since the Secretary of State's decision or exceptional circumstances. We will keep this position under close review since results emerging from the ongoing post-RBCT analysis led by Christl Donnelly and Helen Jenkins of Imperial College still show an overall benefit⁶. We have also agreed that we need to make sure options are available so, if the position were to change, culling could be carried out in an effective and cost efficient way.

⁶ Christl Donnelly and Helen Jenkins discussed their emerging findings during the <u>8th meeting of the Group on 13 March 2009</u>.

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66. TB in badgers is also relevant to the Eradication Plan and we were grateful to the Commission for taking the time to discuss with us their views on the wildlife reservoir of bovine TB. They made clear that they expected an eradication plan to consider measures to address the disease risk from badgers, however, there was no specific requirement for culling. After discussion with the Secretary of State we agreed that the statement about wildlife controls in the England part of the Eradication plan would keep culling open as a future option for tackling disease in badgers alongside the work being done on vaccines and biosecurity. Our work will continue on options for using all tools as part of the range of measures to eradicate bovine TB in cattle.

Vaccination

- 67. The Bovine TB Vaccines Programme represents an investment of over £22 million by taxpayers in research and development of TB vaccines for cattle and badgers since 1998, with a further £20 million announced by the Secretary of State in 2008. Cattle vaccine is the easiest to develop and deliver, but current European legislation makes it illegal to vaccinate cattle. The most optimistic date for availability of BCG (Bacille Calmette-Guérin) for use in cattle alongside an approved test to Differentiate Infected from Vaccinate Animals (a 'DIVA' test) is estimated to be 2015. Badger vaccination is an innovative approach to TB in wildlife but has the opposite problem to a cattle vaccine: there are challenges in developing and delivering vaccines, but the legal barriers are more easily overcome. The injectable BCG is expected to be licensed for use in badgers next year and the earliest estimated date for oral BCG to be available is in late 2014. The Group has acknowledged that the vaccination of either badgers or cattle with a vaccine that is only partially effective, and which will be deployed in an already infected population, will take a long time to have a significant impact.
- 68. From the discussions we have had with experts we are convinced that vaccination will be an important tool in the toolbox. We see value in vaccination for badgers for the long-term because it has been shown to have a protective effect in badgers when, under experimental conditions, they were given a much higher dose of *M. bovis* than would be expected in the field (approx. 10⁴ organisms). This was demonstrated by decreased severity of disease, restricted dissemination of infection and lower bacterial burdens in lungs and thoracic lymph nodes⁷. Vaccination with BCG has also been shown to generate protective immunity in mice, guinea pigs, monkeys, rabbits, cattle, ferrets, brushtail possums, white-tailed deer and elk⁸.

⁷ Corner et al., 2008 Tuberculosis 88: pp601-609.

⁸ Murphy et al., 2008 Tuberculosis 88: pp344-357.

- 69. We know that vaccination alone is not the solution: there is no single measure that will eradicate bovine TB. We need a range of tools that can be used to target the epidemiology of the disease in a particular area; that can be tailored to any progress made with the disease (eg if it is declining in an area); and can be applied to different farming conditions (geography, type of farm business, and so on). This is why culling cannot be ruled out, but also why it is short-sighted to dismiss vaccination simply because large-scale use is too far away. In the long term vaccination would also have the potential to deliver an exit strategy to culling if culling were to be used.
- 70. In terms of proactive action on badgers and bovine TB, the approach close to being available is use of injectable BCG in the form of the Badger Vaccination
 Deployment Project
 9. We had several discussions with the project team about where the project should take place and the reasoning behind running a practical deployment project, rather than a scientific trial. Using what we have as soon as we can is a positive approach, but we must be realistic in our expectations: it is planned for vaccination to take place at Government expense over a total of 600km² of cattle land and this is a small proportion of the areas affected by bovine TB so the impact on the epidemic as a whole will be small. Nevertheless, we were comfortable that the project aims to achieve as much as it can in a relatively short amount of time and we advised on which areas would be the most appropriate for badger vaccination at this time. The Secretary of State accepted our recommendations and the project is now being rolled out in these areas. We have asked to be kept updated on the project and will continue to provide guidance where needed.
- 71. While the use of vaccines for badgers and cattle on a large scale is some considerable distance away, they have potential and another available tool can only be helpful. Our concern is how more extensive the disease may have become before a large-scale vaccination programme could be rolled out. This is one of the reasons why badger culling must remain on the agenda.

http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/vaccination/bvdp.htm

⁹ Further information can be found at:

BIOSECURITY

- 72. Biosecurity is important in the prevention and control of disease generally and is part of the practice for farm management. However, the term biosecurity means different things to different people. We use the term to mean any measures to prevent or reduce the risk of disease in cattle and this can incorporate on-farm management practices or husbandry measures. As an early part of our work we discussed the current advice available which was developed by the Husbandry Working Group¹⁰ in 2006 with the two Members of our group who were involved in the work providing the background.
- 73. The main principles from the Husbandry Group's conclusions were the importance of cattle based controls as biosecurity measures and how secure feed storage could contribute to minimising cattle and badger contact and reduce the risk of disease transmission. We agree with these conclusions and, in view of no additional evidence suggesting different avenues to pursue we do not plan to expand the advice available. We will, however, draw on any new evidence as it becomes available in the future (for example the current Defra funded Fera (the Food and Environment Research Agency), formerly the Central Science Laboratory (CSL)) project exploring measures to keep badgers away from cattle in and around buildings¹¹).
- 74. The organisations represented on the Husbandry Working Group have also tried to communicate the advice in various forms to farmers and vets, however, we concluded this had met with limited success. As a result one of our recommendations to the Secretary of State, mentioned earlier in this report (see page 14), has been to provide funding for the provision of advice to farmers under TB restrictions for over 12 months and those experiencing their first TB breakdown.
- 75. Members' experience from Foot and Mouth in 2001, where financial and business management advice was given priority over veterinary advice; evidence from the Husbandry Working Group's research¹²; and Wales' biosecurity pilot have shown that the key to getting this right is the involvement of vets. Vets have an important role as trusted experts in providing advice to clients; and farmers' general preference is to discuss rather than be bombarded with leaflets and paperwork so time with their vet is key. At the same time vets' understanding about the disease and the science behind the testing regime

http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/husbandry_background.pdf

¹⁰ For further information on the Bovine TB Husbandry Group see http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/abouttb/protect.htm

Defra project SE3119: An experiment to assess the cost-effectiveness of farm husbandry manipulations to reduce risks associated with farmyard contact between badgers and cattle. 'Search Defra Projects' using '3119' as key word at: http://www.defra.gov.uk/evidence/science/index.htm

¹² The Husbandry Group's background document can be found at:

needs to be up-to-date so they are in the best possible position to talk about disease risks specific to a particular farm. We believe this is crucial to helping farmers manage being under restriction in high risk areas and to encouraging farmers in lower risk areas to manage disease risk through their herd management practices.

76. The advice package needs further development before it is implemented in 2010 and, in the meantime, we welcome any initiatives to share biosecurity advice and information about bovine TB such as the NFU South West's RDPE application (see page 15, paragraph 32). The workshops held as part of the early stages of the Badger Vaccine Deployment Project have also given vets a useful opportunity to ask questions and discuss the disease with Animal Health and Defra. More significantly the British Cattle Veterinary Association (BCVA) is already running workshops for vets on bovine TB and we encourage other farming and veterinary organisations to consider what role they could play.

LOOKING FORWARD

- 77. We are confident that the changes described in this brief report represent a positive first step in the introduction of an Eradication Programme for England. However, the Group also recognises that real progress towards eradication for those in high risk areas can only be made once measures are in place to tackle disease in wildlife on a large scale. In their absence, we see the additional support to farm businesses under restriction as crucial.
- 78. Part of the remit of the Group was to contribute to the English component of the UK Eradication Plan for submission to the European Commission. We are pleased to be able to say that the Plan was submitted in September 2009 and while it only represents a small part of what we want to achieve as a Group, we believe it sets a good foundation for the industry in England and the Government to work with colleagues in Europe by making clear to Member States that England (and the UK) are serious about tackling bovine TB. Eradication Plans have to be re-submitted annually and we aim to play a similarly active role in the future.
- 79. Throughout this report we have referred to further work that we already have underway, such as identifying additional approaches to protecting low risk areas; provision of advice to farmers; analysis of unconfirmed breakdowns; and considering options around badger culling. We are also mindful that there is a potential disease risk to cattle from goats and New World camelids (llamas and alpacas). The disease risk is low, however, we plan to consider any future policy proposals for managing the disease risks to cattle from goats and camelids. Alongside this shorter-term work, we also intend to make progress on more fundamental ideas such as targeting different measures more strategically at different areas of the country and considering the implications of the approaches being taken in Scotland, Wales and where appropriate Northern Ireland.
- 80. We plan to continue making recommendations and implementing measures as they are ready. However, as we move forward, it will be important for us to have more opportunities to discuss progress and ideas with those most affected. So, following publication of this report, we plan to meet regularly (approximately every six months) with representatives from key organisations rather than produce regular reports. We would also encourage those wishing to present ideas or discuss issues to contact us at tberadication.group@defra.gsi.gov.uk.

ANNEX A: Remit of the Bovine TB Eradication Group for England

The Bovine TB Eradication Group for England has been set up to make recommendations to the Secretary of State on bovine TB and its eradication. The membership of the group includes representatives from Defra's Food and Farming Group, Animal Health, the farming industry and the veterinary profession, and it is convened and facilitated by Defra.

The Group may invite other experts to contribute to its work as necessary, including other industry bodies and wider interest groups. It will also draw on the advice of the Commission's TB Task Force.

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

A priority output from the work of this group will be a series of measures which can be submitted to the European Commission for approval as part of a formal eradication plan. The group may wish to make recommendations on other issues as they arise, and Defra may also choose to refer specific issues to the group.

The group will look at the options available to address infection in cattle and to reduce the risk of transmission between cattle and between cattle and wildlife, and consider costs and benefits in making recommendations for action.

It will consider options for using vaccination in cattle and badgers. It will also consider any exceptional circumstances or new scientific evidence that might arise relating to the established policy on badger culling for control of TB.

In carrying out this work the Group will have full access to information on Defra's TB budget and be able to make recommendations on its use within Defra's funding ceilings. It will also be able to make recommendations for additional expenditure where these can be supported by a robust business case.

Members of the Bovine TB Eradication Group for England:

- Andy Biggs (veterinary profession)
- Gabrielle Edwards (Defra)
- Nigel Gibbens (Defra)
- Brian Harding (Defra)
- Bill Harper (farming industry)
- David Maughan (farming industry)
- Rob Paul / David Harris (Animal Health)
- Carl Padgett (veterinary profession)
- Kevin Pearce (farming industry)
- Jan Rowe / Paul Griffiths (farming industry)

The Bovine TB Eradication Group for England met for the first time on 27 November 2008 and has met seventeen times up to and including 9 September 2009.

ANNEX B: TB testing sensitivity and specificity

Specificity is the ability of a test to correctly identify **non-infected** animals as **negative** (the higher the **specificity** the lower the probability of **false positives**).

Sensitivity is the ability of a test to correctly identify **infected** animals **positive** (the higher the **sensitivity** the lower the probability of **false negatives**).

Analysis has shown that the *TB skin test* has a **specificity** of 99.9% (i.e. correctly identifies 999 out of 1000 negative animals); and a **sensitivity** of approximately 80% (range of 77-95%; i.e. correctly identifies 8 out of 10 positive animals). Following a review of the published literature the *gamma interferon blood test* has been determined to have a **specificity** of 97% and a sensitivity of 71-94% (taken at the median 88%).

ANNEX C: Changing TB Terminology

- 1. How the change in TB terminology from confirmed/unconfirmed to the EU Directive designations of: Officially TB Free (OTF); OTF suspended and OTF withdrawn (see pages 24 and 25 of the main report) would apply are described below. This shows that using EU Directive designations would largely be an administrative change rather than a material one.
- 2. Suspension of Officially Tuberculosis Free (OTF) status occurs whenever a positive skin or gamma blood test result occurs, or suspect lesions are detected at routine meat inspection (a slaughterhouse case), or Inconclusive Reactors (IRs) are found in a herd with recent history of infection, before any laboratory examination has been completed (also with zero tolerance of overdue tests). The status remains suspended until either the test reactors are slaughtered and at least one of them shows typical TB lesions at PM examination, or *M. bovis* is detected in tissue samples from reactors without lesions or from slaughterhouse cases when the OTF status changes to withdrawn (or TB breakdown "confirmed"). By contrast, if all PM/laboratory results are negative, OTF status is restored. This is done either immediately (in the case of slaughterhouse cases) or following a single herd test with negative results (in the case of test reactors).
- 3. Once imposed, a **suspension** can only be lifted if the laboratory examinations in all the test reactors and slaughterhouse cases have been completed, and following removal of all the reactors, the herd has had one further skin test with negative results (without reactors or IRs).
- 4. OTF status moves from **suspended** to **withdrawn** whenever typical lesions are found in a test reactor and/or *M. bovis* has been detected by culture on laboratory examination or (i.e. TB breakdown "confirmed"). Withdrawal of OTF status/confirmation of a breakdown requires the herd to give negative results at two consecutive skin tests performed at minimum intervals of 60 days and triggers a series of additional control measures such as: severe skin test interpretation; cleansing and disinfection; origin and spread tracings; testing of contiguous herds; and, in some instances, the deployment of the gamma-interferon parallel blood test.

Note: OTF status is also **suspended** when a surveillance test becomes overdue and is restored when clear test results are received.