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Environment, Food and Rural Affairs Committee

Vaccination against bovine TB

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The Environment, Food and Rural Affairs Committee

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Summary

Tuberculosis in cattle is one of the biggest challenges facing UK farming. It has implications both for public health and for international trade and is estimated to have cost the UK taxpayer £500million over the last decade. It causes a huge emotional and financial strain on farmers whose herds have to be regularly tested and subject to movement controls and whose infected cattle must be slaughtered. In 2012 alone it is estimated that 1% of the dairy herd was slaughtered due to bovine TB.

The aim of our inquiry was to explore the extent to which vaccination can contribute to the control and eradication of bovine TB. While cattle to cattle is the primary means of transmission of the disease, where wildlife populations constitute a reservoir of TB, wildlife to cattle can also be a route of infection. The role of the badger in the spread of bovine TB is an emotive issue but the Government is clear that in order to control the disease in cattle it must also be tackled in badgers.

Vaccination of cattle is currently prohibited under EU law. Defra's 2012 application for in principle marketing authorisation for a cattle vaccine prompted widespread interest in the idea that a vaccine might soon be available, but it has become clear lengthy field trials are required before the EU and OIE would consider amending current rules to allow vaccination to take place. The Government must do all it can to condense the indicative 10-year timetable suggested by the Commission.

Not that vaccination of cattle will immediately solve the problem of bovine TB. The vaccine does not guarantee complete protection from the disease rather it offers a spectrum of protection. Nor does it have any discernible effect on already infected animals. In the short term its use, together with the necessary DIVA test, will be an increased financial and administrative burden on the industry.

An injectable vaccine for badgers has been available since March 2010, but questions remain about its efficacy, and further research of its effect in the field is required. As with the cattle vaccine, the injectable badger vaccine offers a range of protection, has no discernible impact on already infected badgers and is expensive to deploy. For it to be effective a significant number of badgers need to be trapped and vaccinated, over many years. The Government should continue to research methods of discerning whether badger social groups carry infection in order better target deployment of the vaccine. The vaccine has been available for over three years but the Government should now produce a clear strategy for using it

An oral, baited vaccine for badgers would be a cheaper and potentially more practical and effective method of vaccination. However, developing an oral vaccine solution presents a number of challenges; not only does an effective vaccine have to be developed but the right deployment strategy with the right bait must also be determined. An oral vaccine is presently some years away from being available.

For too long the Government's strategy for dealing with bovine TB has been reactive and followed the spread of infection. The increase in cases of bovine TB in cattle demonstrates that the Government needs a strategy that will jump ahead of infection. Cattle vaccination

is a tool that may allow it to do that in the future but for now increased bio-security and rigorous movement controls are vital. It will be no good vaccinating badgers to create a firewall against the spread of infection only for it to be compromised by movement of infected cattle.

We currently rely on a skin test that could miss one in four infected cows. Liver fluke, Johne's disease and even pregnancy may impact on the result of the skin test. While the skin test has served us well, if other more sensitive tests exist, they should be employed alongside it. We accept that the gamma interferon blood test is expensive and not without limitations, but a test that catches infection earlier when animals are less likely to have transmitted the disease is a valuable tool and one that should be deployed as widely as possible. The Government should explore whether it is possible to improve the performance of the test and bring down its cost.

Farmers must be able to reassure themselves that the livestock they bring onto their farms are free of TB. We remain convinced that, alongside enhanced bio-security and movement control, improvements to the testing regime can deliver real benefits.

Our inquiry has shown that the quality of information in the public domain about the availability of the cattle vaccine and oral badger vaccine and the efficacy of the injectable badger vaccine has not been good enough. There is a great deal of interest in this subject and the Government can do better in satisfying it.

1 Introduction

1. Bovine tuberculosis is a disease of global importance and one of the biggest challenges facing the cattle farming industry in the United Kingdom today. It is a disease with public health and international trade implications. It is caused by the bacterium *Mycobacterium bovis (M. Bovis)* which can infect and cause TB in many other mammals than cattle, including badgers, deer, goats, pigs, camelids, dogs and cats. Furthermore, *M. Bovis* has zoonotic potential[1] and in certain circumstances can be fatal in humans.[2] In the European Union, *M. Bovis* accounted for 132 cases of human tuberculosis in 2011, 31 of which were in the UK.[3]

2. Bovine TB is present, and in some areas increasing, throughout Europe, but, with the exception of Ireland, the scale of the problem in the United Kingdom is significantly greater than in any other country in the European Union.[4] In 2011, of those countries with an EU co-financed eradication programme (i.e. those with the greatest problem), proportionately more herds tested positive for bovine TB in the United Kingdom than any other country.

Table 1: Mycobacterium bovis in cattle herds in co-financed non-OTF Member States in 2011[5]

Non-officially free MSs	No. of existing herds	No. of positive herds	% existing herds positive
United Kingdom	106,131	9,620	9.06%
Ireland	116,061	5,002	4.31%
Spain	126,473	1,485	1.17%
Portugal	58,503	267	0.46%
Italy	128,393	488	0.38%

While Ireland, Portugal, Spain and Italy have seen a decrease in the proportion of herds testing positive for bovine TB since 2008, the overall proportion of existing herds testing positive for the disease in the United Kingdom increased from 2.88% in 2008, to 5.58% in 2009, 8.63% in 2010, and 9.06% in 2011. The highest financial contribution from the EU

1 Can transfer from animals to humans

2 In 2009, 10 EU countries reported 133 cases of M. Bovis in humans with mortality at 5.3% (source: http://veterinaryrecord.bmj.com/content/172/12/310.extract)

3 Scientific Report of EFSA and ECDC: The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2011,*EFSA Journal 2013*, 11(4): 3129, 9 April 2013, http://www.efsa.europa.eu/en/efsajournal/doc/3129.pdf

4 Q 103

5 Scientific Report of EFSA and ECDC: The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2011,*EFSA Journal 2013*, 11(4): 3129, 9 April 2013, http://www.efsa.europa.eu/en/efsajournal/doc/3129.pdf

budget to eradicate animal disease (€31m out of €203m) goes to the UK for its bovine TB eradication programme.[6]

3. Bovine tuberculosis is estimated to have cost the UK taxpayer more than £500 million over the last decade and is predicted to cost more than £1 billion over the next 10 years unless there is further action.[7] It causes a huge emotional and financial strain on farmers whose herds have to be regularly tested and subject to movement controls and whose infected cattle must be culled.[8] In 2012 alone more than 8 million tests were carried out on cattle in Great Britain and 37,754 cattle were slaughtered. According to Defra, there are approximately 10 million cattle in the UK: 'a little over two million adult dairy cows in the UK, a little under two million adult beef cows, and about six million younger animals'.[9] In 2012 it is estimated that 1% of the dairy herd was slaughtered because of bovine TB.

4. Bovine TB is primarily a respiratory disease. There are thought to be two principal methods of transmission. Transmission can occur directly through close contact between infected and uninfected animals whereby uninfected animals inhale droplets containing *M. Bovis* bacteria exhaled or coughed by infected animals. It may also occur indirectly through ingestion of water or feed that has been contaminated with excretions or discharges from infected animals. The latter method of transmission is more difficult and more *M. Bovis* bacteria are required to infect an animal by ingestion than by respiration. Both direct and indirect transmission methods potentially occur at pasture and in farm buildings.

5. While bovine TB is transmitted between cattle, it is widely accepted that where wildlife populations constitute a reservoir of *M. Bovis*, wildlife to cattle can be a route of infection though the precise nature of the transmission remains poorly understood. Since the 1970s and the discovery of badgers infected with *M. Bovis*, studies have demonstrated the presence of infected badgers across large parts of the United Kingdom and Ireland, that badgers excrete *M. Bovis*, and that they are a potential source of *M. Bovis* for cattle.[10] The role of the badger in the spread of bovine TB amongst cattle is an emotive issue and their relative contribution a matter of intense debate. As Professor Hewinson, Chief Scientist, AHVLA, told us:

> One of the real evidence gaps is how much TB is given from cattle to badgers, how much TB is given from badgers to badgers, how much TB is given from badgers to cattle, and how much TB is given from cattle to cattle.[11]

The Government has made its position clear that in order to control the disease in cattle it must also be tackled in badgers. In December 2011 the Government announced that it

6 Q 103 and Commission Implementing Decision 2012/761 http://ec.europa.eu/food/animal/diseases/eradication/programme2013/2012_761_eu_en.pdf

7 Defra website, http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/

8 11.5% of herds in England were under movement restrictions in 2011. The average cost of a TB breakdown on a farm is £34,000, of which £12,000 falls to the farmer (source: Defra website, http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/).

9 Defra website, http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/vetsurveillance/species/cattle/

10 Chambers et al, Bacillus Calmette-Guérin vaccination reduces the severity and progression of tuberculosis in badgers, *Proceedings of the Royal Society: Biological Sciences*, 22 June 2011, vol. 278 no. 1713 1913-1920 http://rspb.royalsocietypublishing.org/content/278/1713/1913.full

11 Q 308

would pilot two badger culls. The United Kingdom is not the first country to consider the culling of infected wildlife as a means of combating bovine TB in cattle; the USA (white-tailed deer), New Zealand (brushtail possum) and the Republic of Ireland (badger) have all included this approach in their efforts to control the spread of the disease. The UK is the only EU country to have given its wildlife vector, in this case the badger, protected status.[12] In addition to the pilot culls, the Government announced that

> up to £250,000 a year will be made available over the next three years to support and encourage badger vaccination. The Government has already spent £35 million on developing badger and cattle vaccines since 1994 and plan to spend another £20 million on the development of practical and usable vaccines over the next five years.[13]

6. The aim of our inquiry was to explore the extent to which vaccination can contribute to the control and eradication of bovine TB. When the Government announced plans to pilot a strategy of culling badgers many interested parties questioned why a programme of vaccination, both of cattle and badgers, was not being considered instead. In conducting this inquiry, we set out to question the key people involved in researching, licensing and legislating on a vaccination approach to the prevention of bovine TB and to get on public record their views on the availability, cost and effectiveness of a vaccine for cattle, an injectable vaccine for badgers and an oral vaccine for badgers. We are grateful to all who contributed.

12 The badger is protected under the Protection of Badgers Act 1992 which protects badgers and their setts. It consolidated and repealed the Badgers Act 1973, the Badgers Act 1991 and Badgers (Further Protection) Act 1991

13 Defra website, https://www.gov.uk/government/news/update-on-measures-to-tackle-bovine-tb

2 A vaccine for cattle

7. The vaccination of cattle against bovine TB is currently prohibited under EU law. Bernard Van Goethem, Director for Veterinary and International Affairs at the European Commission, told us 'it is not foreseen in the legislation, because so far the vaccine does not exist'.[14] In a letter to the Secretary of State for Environment, Food and Rural Affairs the Commissioner for Health and Consumers summarised the legislative situation as follows:

> Vaccination against bTB is explicitly forbidden in the EU legislation on disease control (Council Directive 78/52/EEC) and implicitly also in intra-Union trade legislation, as vaccination is not compatible with the provisions for testing and herd qualification (Council Directive 64/432/EEC). EU legislation is fully in line with OIE standards on international trade and can be changed only by the European Parliament and the Council.[15]

Deploying a vaccine in the face of the European ban could lead to a ban on the trade in live cattle, meat and dairy products with other EU countries. In 2011, these trades amounted to £496,000, £490m and £1.2bn respectively. It is likely that countries outside of the European Union would follow the EU's lead.

8. Before legislation and international standards can be changed to allow vaccination to be used as part of a TB eradication programme both the EU and OIE[16] will need to be satisfied that a proposed vaccine is safe and effective and that its use does not compromise the current testing regime.

9. At present, the only vaccine for tackling TB is the Bacille Calmette-Guérin (BCG) vaccine. Studies have shown that the BCG cattle vaccine, as with BCG in other species, does not guarantee complete protection but rather provides a spectrum of protection:

- some cattle will be fully protected;
- some will benefit from reduced disease;
- some will get no protection from vaccination; and
- vaccination does not have a therapeutic effect on cattle that are already infected. [17]

10. A vaccine that reduces the progression, severity and excretion of bovine TB, and thereby the risk of infection and transmission of the disease, would be a valuable tool and successive governments have invested heavily in developing one.[18] Because the BCG vaccine interferes with the mandatory tuberculin skin test used to determine whether a

14 Q 104

15 Letter from Commissioner Borg to the Secretary of State, 14 Jan 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/183229/bovinetb-letter-paterson.pdf

16 World Organisation for Animal Health

17 Defra website, http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/vaccination/cattle-vaccination/

18 Ev 70 [Defra]; Defra's written evidences states that since 1994 Governments have invested more than £43million on vaccine research and development and will have spent a further £15million by the end of this spending review period.

cow is infected with TB, a crucial element of the work on cattle vaccination has been also to develop a diagnostic test to differentiate between infected and vaccinated cattle which can be used alongside the skin test—the 'DIVA test'.[19]

Managing public expectation

11. In 2010, DEFRA stated that it aimed to have the cattle BCG and the DIVA test licensed by 2012 but that 'due to the need to change EU legislation, which is a lengthy process, we anticipate that a cattle vaccine and DIVA test could not be used in the field before 2015'.[20] In January 2012 the Government submitted an application for 'in principle' approval of a marketing authorisation for a cattle BCG vaccine to the Veterinary Medicines Directorate. It said:

> Licensing studies demonstrating the safety and efficacy of BCG have now been completed by Defra's Animal Health and Veterinary Laboratories Agency (AHVLA) and in January 2012 an application for marketing authorisation (required to place a veterinary medicinal product on the market) was submitted to the UK's Veterinary Medicines Directorate (VMD) for assessment. The assessment process may take up to a year to complete and providing it is satisfied with the safety, efficacy and quality data, VMD will be able to confirm that requirements to obtain a marketing authorisation have been met. However, VMD will only be able to grant a marketing authorisation for BCG once the existing EU prohibition on vaccination of cattle against TB is lifted.[21]

12. The application sparked widespread interest that a vaccine might soon be available. Defra's website stated:

> As the science becomes clearer Defra will be in a firmer position in the coming months to begin to discuss with farmers, vets and other interested parties about how the vaccine and DIVA test can be used in the field and the likely implications on different types of farm business.[22]

13. It would be reasonable for anyone considering the above statements to believe that a cattle vaccine for use against bovine TB was just a few years away. That is not the case as correspondence between the Commission and the Government and indeed, evidence taken during our inquiry have made clear.[23] During our final evidence session, Professor Hewinson told us that the 2015 date referred to in the document *The Government's approach to tackling the disease and consultation on a badger control policy* was in fact a date from which field trials for the vaccine and DIVA test might begin. This is an unfortunate misunderstanding for which Defra is responsible. The phrase 'used in the field' cannot reasonably be taken to mean use only in trials.

19 DIVA is an acronym for Differentiating Infected from Vaccinated Animals.

20 *Bovine Tuberculosis: The Government's approach to tackling the disease and consultation on a badger control policy* Defra, 2010

21 Defra website in October 2012

22 Defra website in October 2012

23 Letter from Commissioner Borg to the Secretary of State, 14 Jan 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/183229/bovinetb-letter-paterson.pdf

14. With regard to the application to the VMD for 'in principle' marketing authorisation, Defra's website in October 2012 again gave the impression that the Government's research was further advanced than was, in fact, the case. Professor Hewinson told us that

> the "in principle" application was in fact to tease out what data would be required from the VMD for licensing. ... One of the reasons behind putting in the "in principle" application was to identify what data sets we would need to create in order to get a marketing authorisation. It is, if you like, a dummy run to getting a marketing authorisation.[24]

15. When the application was made, it would have been helpful to public debate if the Government had been clear that it was 'a dummy run' and that years of field trials would likely still be required. Doing so would not have pre-judged the work of the VMD but would have provided a clearer steer on the likely timescale within which a vaccine might be available. We note that the length of time for completion of the assessment process has also changed from 'up to a year' to 'the first half of 2013, in line with normal timelines for such applications'—a potential increase of 50%.[25]

16. **During the last 18 months the debate on the availability of a cattle vaccine for bovine TB has been characterised by a lack of clarity and public misunderstanding. Although it is by no means solely responsible, the Government must accept a great deal of the blame for this. The quality and accuracy of the information that Defra has put in the public domain has been insufficient and inadequate. It is unfortunate that this has led to debate over the timetable for use of the vaccine overshadowing scientific breakthroughs in the development of both the vaccine and DIVA test that should be applauded.**

17. Over recent months it is clear that the Government has recognised that it should do more to inform the public. Professor Boyd told us that the Government is working on a TB eradication strategy that will show 'all the methods that are available for eradication, when they are going to come on line and what their contribution is going to be to the ultimate eradication of TB.'[26] **We await publication of the TB eradication strategy with interest and expect it to include not only information on those methods that are available for the eradication of bovine TB but progress on those in development. The launch of the strategy must be accompanied by a public information campaign to make the position clear in the public's mind and dispel misunderstanding.**

The effectiveness of the candidate vaccine

18. The EU prohibition on cattle vaccination has caused the Government difficulties in collecting scientific data on the performance of the vaccine under UK field conditions. The efficacy of the cattle BCG vaccine has been tested in 'experimentally infected animals, with a mean level of protection (measured as a reduction in visible pathology scores) of 70%' but these studies cannot provide a definite figure for vaccine efficacy when administered to

24 Q 347

25 Defra website in October 2012 and Ev 70 [Defra]

26 Q 422

cattle under field conditions in the UK.[27] Modelling the level of efficacy required for herd immunity, both on its own and in conjunction with other measures such as biosecurity and movement controls is critically important. Such data are crucial to determining whether BCG would be sufficiently effective to justify its use.[28]

19. Small-scale studies have taken place in Ethiopia and Mexico that have shown the protective effect of vaccination to be between 56% and 68%. The AHVLA's study in Ethiopia involved vaccinating calves when between one and 15 days old before they were introduced into a herd containing a large proportion of bovine TB-infected cattle. Defra states:

> Although a relatively small study, vaccination of calves with BCG in this study provided significant protection against strenuous TB challenge by natural transmission. Overall, the protective efficacy of BCG was between 56% and 68% (depending on the parameters selected).
>
> In terms of practical deployment of the vaccine, research results provide evidence that calves as well as older cattle can be protected by BCG vaccination to equal levels. They also suggest that annual revaccination would be desirable. The research results are still under assessment by VMD.[29]

20. Bernard Van Goethem urged us to see first whether vaccination was useful, '... it might only be useful in 65% of the cases ... with all the other measures that we know are efficient, that have been applied throughout the world for decades and we know work; 65% in addition to that: the efficiency is residual, marginal.'[30] Professor Hewinson agreed that cattle vaccination 'is not a magic bullet, it is just another tool' and stressed that while 'you might conceivably get herd immunity' if transmission was entirely from cattle to cattle, that becomes increasingly less likely where there was spillover from a wildlife host.[31]

Next steps

Field trials

21. Both the European Commission and the VMD are clear that additional data are required in order for the availability of the vaccine to progress. The Commissioner for Health and Consumers, Mr Tonio Borg, wrote to the Secretary of State on 14 January 2013 setting out an indicative timetable for the possible use of a vaccine against bovine TB, putting 2023 as a tentative date for a vaccine to be available for general use. However, Commissioner Borg stated that the only candidate vaccine still presents many knowledge gaps,

27 Ev 70 [Defra]

28 Ev w39 [Rethink Bovine TB]

29 Ev 70 [Defra]

30 Q 141

31 Q 333

> in particular concerning the performance of the vaccine (level and duration of protection, protection from disease or infection), safety (possible shedding of the attenuated live pathogen by vaccinated animals), conditions for use (age of animals, type of herd) and suitability of candidate DIVA test(s).
>
> Fundamental scientific information is not yet available on the reliability and feasibility of cattle vaccination accompanied by use of DIVA test(s) that is fundamental for a possible change in the current EU policy on the control and eradication of bTB. Future studies should also address *food safety concerns* (shedding of vaccine strain in milk), *human health concerns* (BCG is the only vaccine available for humans and its use in cattle may lead to the selection of BCG-resistant strains of bTB that may affect also humans) and *animal health and trade concerns* (proper discrimination between vaccinated and infected animals, costs/benefits of vaccination policy, current policy, acceptability of vaccinated animals in international trade).[32]

22. The VMD told us they had already formed their views before the Commission's letter but that they were 'fairly well aligned with the Commission on where additional data is required'. They had 'identified issues around consumer safety, relating to both meat and milk',[33] but that the letter changed things in terms of process. Rather than just list concerns that needed to be satisfied to achieve in principle provisional marketing authorisation, in response to the Commission's request for field trials the VMD would now also provide details of what further data were required before they could issue an Animal Test Certificate.[34] Professor Hewinson explained what experimental data the VMD required:

> looking at whether BCG is excreted in the milk of lactating animals, so further assurance on whether BCG will appear in the milk of lactating animals; looking at how long the BCG persists at the site of injection and whether there is any dissemination of the BCG into tissues, so that there is assurance of the meat and milk products; and the final area is looking at whether there is any reversion to virulence of the BCG vaccine.[35]

Mr Gibbens, Chief Veterinary Officer, Defra, expected 'a cluster of [the assurances required by the Commission] around safety [to] be dealt with as part of the process of the VMD application'.[36]

23. While some of the points made by the Commissioner in his letter have been questioned,[37] it is clear that lengthy field trials are required in order to satisfy the concerns of the EU and OIE.[38] In his indicative timetable the Commissioner forecast the trials to be

32 Letter from Commissioner Borg to the Secretary of State, 14 Jan 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/183229/bovinetb-letter-paterson.pdf

33 Qq 207-8

34 To conduct field trials it is necessary to have an Animal Test Certificate, Q 358

35 Q 423

36 Q 435

37 For example, see http://www.bovinetb.info/vaccination.php for comments on the concerns that widespread use of BCG might encourage BCG resistant strains of TB and Qq 447-9

38 Q 211, Q 331 and letter from Commissioner Borg

large scale and long lasting (possibly 2–5 years).[39] The trials will not be limited to the vaccine. The VMD told us:

> The field trial or field trials will need to look at various aspects of the claims around the vaccine. They will not just be the claims around efficacy per se; they will also be around the DIVA aspects. That is liable to be quite a complex trial.[40]

24. The Commission were also clear that the trials needed to be under EU field conditions.[41] The UK Government's position to date has consistently been that field trials in the UK are prohibited under EU law.[42] This does not appear to be case. As the Minister made clear to us, the position was not one of absolute prohibition, but rather that consent for field trials was unlikely to be granted without the UK being able to demonstrate it had a viable vaccine and DIVA test:

> It is no good going to the Commission asking for a proposal for field trials, until we have not only the vaccine that we have shown to be viable within its limits, and also the diagnostic test, the DIVA test, which we also need to have shown is viable. It is only when all of those factors are in place that we could make a sensible approach.[43]

25. **It is perplexing that the Government has maintained that field trials were prohibited under EU law when, as recent events have shown, this is not the case. We accept that field trials might be permitted only if certain criteria are met, the development of the DIVA test being one of them, but to have stated that legislative change is required is misleading. It would be unfortunate if the Government's interpretation of the legislation had delayed progress in delivering a vaccine.**

26. **We are not convinced that the Government had to wait until all the 'factors were in place' before approaching the Commission. However, while we believe negotiations could and should have begun earlier, we welcome the efforts of the Government and the Commission in coming to an agreement that field trials might take place in the UK. To be able to study the efficacy of the vaccine and DIVA test in UK field conditions is a big step forward and we congratulate the Government on securing this position.**

27. The UK is currently putting together the programme for the field trials in discussion with the Commission.[44] The Commission told us

> You do not design a programme in half an hour. You have to see what you do with the animals. You have to see what you do with the offspring of the animals. You have to see what you do with the meat. You have to control the movement. It is not something you can write on one piece of paper; it will be a heavy programme, which

39 Letter from Commissioner Borg

40 Q 230

41 Q 122, Q 348 and letter from Commissioner Borg; the OIE also require data from UK field trials – see written evidence submitted by Rethink Bovine TB (Ev 39) for discussion of Defra's application to the OIE.

42 For example, Defra's website in October 2012 stated 'Studies to date cannot provide a definite figure for vaccine efficacy when administered to cattle under field conditions in the UK and it is currently not possible to generate these data in the field because of existing EU legislation prohibiting vaccination of cattle against TB'.

43 Q 432

44 Q 124; Q 436

> we are helping the UK to draft, and we are waiting to discuss that with them. I can assure you that they are giving the highest priority to that in the veterinary service in Defra.[45]

28. **It is difficult to envisage Defra designing field trials of the scope and size requested by the Commission without using the commercial herd. In doing so, the Government must take steps to reassure the public that such field trials will not pose a public health risk. The Government must also make sure that farmers volunteering their herds for these trials are not left financially disadvantaged. We look forward to seeing details of the programme for field trials once it is agreed.**

The 10-year timetable

29. Before the programme of field trials can go ahead the Government needs to generate the additional data required for an Animal Health Certificate to be issued.[46] It is already possible to see how the Commission's indicative 10-year timetable which forecasts field trials beginning this year might be at risk of slipping. We pressed the Commission on whether there was scope for the timetable to be compressed:

> Bernard Van Goethem: You can always shrink the timetable, but you have to convince the scientific community and the international community. As I said, it is not only EU legislation; it is also the international legislation, which needs an amendment of the OIE code. That is a quite a lengthy process ... It is possible to shrink it, but field trials are field trials. ... The debate between the scientific community and legislation of course could overlap, so it would be possible to shrink a little bit, but not to reduce it by half, that is for sure.[47]

30. In addition to convincing the EU of the efficacy and safety of the vaccine and effectiveness of the DIVA test, the UK will have to convince the international community, specifically the World Organisation for Animal Health (OIE).[48] Mr Gibbons reassured us that the international guidelines are being looked at in parallel, and discussions with the OIE are already under way.[49]

31. **We welcome the ongoing dialogue between the UK, EU and OIE. A good working relationship is vital to ensuring early success in the development and deployment of a vaccine to help combat bovine TB. The indicative 10-year timetable set down by the Commission is precisely that, indicative. The UK Government should do all it can to condense the timetable without compromising the collection of the robust field data necessary to satisfy the VMD and European and international communities. Once the programme for field trials is agreed we look forward to the Government publishing its own indicative timetable for the use of a cattle vaccine. We accept that such a timetable may be subject to change but any changes must be clearly explained.**

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45 Q 129

46 Q 359

47 Q 138

48 See Q 446 for further explanation of the role of the OIE

49 Q 440

Changing legislation

32. For a cattle vaccine to be available for general use, existing European legislation has to be amended. Mr Van Goethem believed that the political will existed across Europe for this change to occur, partly because other countries may want to use the vaccine but also on grounds of cost: the largest financial support package to eradicate animal disease is spent on the UK and it is therefore in the interests of other Member States for this to change. As Mr Van Goethem pointed out 'What we give to the UK we do not give to other Member States'.[50]

33. Proposals for a new EU Animal Health Law may make it easier to change the rules prohibiting vaccination. The new law, which is currently being drafted, will replace all existing legislation linked to animal health repealing approximately 60 different pieces of legislation. It aims to give an overarching framework on all rules linked to animal health: for trade of animals, eradication of disease, and animal health rules for products.[51] Jacqueline Minor, Head of the Commission Representation in London, considered the new law would be likely to make it easier to change the rules on vaccination:

> Currently they would have to be changed by primary legislation, so it would have to be a proposal for a directive of the Council and the Parliament. Within the framework of the new legislation, once adopted, it would be possible to change the rules on vaccination by a delegated measure, which would be much quicker in principle.[52]

Mr Gibbons assured us that the UK Government have been working to make sure that the draft contains an enabling measure to allow the use of cattle vaccines.[53] **We invite Defra to indicate in its response to this Report, the timetable proposed for the new Animal Health legislation.**

Costs

34. Widespread use of a cattle vaccine and DIVA test will increase the costs of a TB eradication programme, at least in the short term. Professor Hewinson estimated the cost of the vaccine at £5-6 per dose and the DIVA test at £25.[54] Studies have so far suggested that vaccination will be needed annually. Sensitisation to the skin test falls off so that after nine months only 10% of animals test positive as a result of the vaccination. Therefore, it may be that in a TB clear herd only 10% of animals will require the DIVA test - notwithstanding conditions on animal movement. A clear record must be kept of animals vaccinated to ensure the DIVA test is not used unnecessarily. This will add an administrative cost to a programme of vaccination. The use of a vet to ensure that vaccinated animals are correctly identified may add a further charge. Over the longer term Defra models predict vaccination could result in a saving:

50 Q 127

51 Q 152 and Q 163

52 Q 163

53 Q 454

54 Q 377

> The model predicts vaccinating cattle in yearly tested parishes would cost around £170-180 million over the period from introduction in 2012 to the end of the modelled period in 2026. It predicts benefits from fewer breakdowns and less routine testing of between £150-250 million, potentially saving up to one fifth of the costs of the current policy measures. The benefits from vaccinating cattle in yearly tested parishes are likely to justify its costs over this period.[55]

35. **A vaccine that is 65% effective will not immediately solve the problems of bovine TB within the cattle industry. Over the short term, its use will be an additional financial cost and may lead to an increase in the administrative and testing burdens farmers already face. While it will be a useful tool to have, the circumstances in which it might be used, the precise objectives of applying it and levels of protection that would be needed to make vaccination worthwhile need careful consideration. Before deployment the Government must undertake and publish a robust cost-benefit analysis. The analysis must also consider the extent to which EU financial support would be available for such a programme.**

Future vaccines

36. The considerable cost of the DIVA test and vaccine make it all the more important that research continues into a vaccine that does not desensitise animals to the much cheaper skin test. Professor Hewinson explained:

> There are proofs of principle that there are vaccines that do not sensitise to the skin test, but at the moment none of them have proven as effective as BCG on their own. There is ongoing work, but this is long-term; this is not a short fix.

The Society of Biology contest that because the current experimental evidence indicates 'BCG vaccination of cattle has only a minor protective effect against infection ... it may be prudent to focus research efforts on developing vaccine protocols that improve levels of immunity obtained with BCG, for example by boosting with defined antigens.'[56]

37. **Even if the cattle BCG vaccine becomes available to use the Government must not stop there. The considerable cost of the DIVA test and cattle BCG mean that research into a vaccine that does not desensitise animals to the skin test must remain an objective. There is also considerable merit in focusing research on improving the immunity offered by the existing BCG vaccine.**

55 *Options for vaccinating cattle against bovine tuberculosis*, Defra, July 2007

56 Ev w31 [Society of Biology]

3 An injectable vaccine for badgers

38. An injectable BCG vaccine for badgers has been licensed for use since March 2010. Its availability is the culmination of 10 years and £11m of government research.[57] BadgerBCG does not confer complete protection from bovine TB and has no discernible effect on already infected animals. A study of infected captive badgers has demonstrated that vaccination can reduce the progression, severity and excretion of the disease. Dr Carter, Senior Scientist at FERA, told us that research conducted in the field supported this conclusion. While the field study was primarily designed to assess the safety of the vaccine and gather the data required to license BCG, the results were consistent with the clinical study.[58] The study showed vaccinated badgers continued to shed TB bacteria but to a lesser extent than unvaccinated badgers.[59]

39. Data from the study also demonstrated that the risk of unvaccinated cubs testing positive for the disease was reduced by 79% when more than a third of the adults in their social group had been vaccinated.[60] This would suggest that not every badger need be vaccinated every year for a vaccination policy to be effective—the vaccine needs to be administered only to enough of the uninfected population to establish herd immunity.[61] What is clear is that the longer the vaccination programme was maintained, the greater would be the benefit realised.

Known unknowns

The badger population

40. The size and spatial variation of the badger population in the United Kingdom is largely unknown as is the level of TB infection in that population. The Randomised Badger Culling Trial (RBCT) demonstrated the degree to which the prevalence of TB can vary between areas. Within the 10 areas studied in the RBCT trial TB prevalence ranged from 1.5% to 35%.[62] Keith Meldrum, a former Chief Veterinary Officer states that 23% of the more than 13,000 badgers put down under a policy of removal in the mid-90s showed evidence of TB during post-mortem.[63]

41. A badger sett survey is currently under way, which will report this summer. The survey will provide an estimate of the density and abundance of badger social and family groups by region. A Defra-funded study planned for this winter will look at the average size of

57 Ev w2 [RSPCA]

58 Q 15; Chambers et al, Bacillus Calmette-Guérin vaccination reduces the severity and progression of tuberculosis in badgers, *Proceedings of the Royal Society: B*, 22 June 2011, vol. 278 no. 1713 1913-1920, available at http://rspb.royalsocietypublishing.org/content/278/1713/1913.full

59 Ev w29 [VAWM], Q 15 and Carter SP, Chambers MA, Rushton SP, Shirley MDF, Schuchert P, et al, BCG Vaccination Reduces Risk of Tuberculosis Infection in Vaccinated Badgers and Unvaccinated Badger Cubs. *PLoS ONE* 7(12): available at http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049833

60 Ev w20 [Humane Society] and Carter et al study

61 Ev w22 [RSPB]

62 Q 14

63 Ev w19 [Keith Meldrum]

badger groups in different landscapes and parts of the country.[64] Neither study will demonstrate the level and distribution of TB in the badger population.

42. Density of population does not necessarily correlate with prevalence of disease.[65] Dr Wilson, Team Leader at FERA, thought that estimating the proportion of the badger population infected with bovine TB would be difficult but that 'measures of prevalence on their own are not particularly useful. What is more useful is looking at how they might vary either regionally or over time.'[66] Professor Hewinson admitted there was an 'evidence gap':

> We do not know whether TB is in badgers in areas where there is no cattle TB, and some of the work in Ireland suggests that there is TB in badgers in both high prevalence and low prevalence areas; it is just the level of TB in those badgers that is the difference.[67]

Efficacy of the vaccine

43. The BadgerBCG vaccine has been available only since March 2010; as Dr Wilson told us 'it is still an embryonic piece of work'.[68] Clinical and field trials have demonstrated a beneficial outcome of using the vaccine but precise efficacy appears difficult to quantify. For example, three tests used in the 2010 study by Chambers et al showed that:

- Vaccination was associated with significant reductions in the incidence of positive Stat-Pak results (73.8%);
- combined Stat-Pak and culture positives (61.4%); and
- the incidence of IFNγ test-positivity was not significantly reduced by vaccination.[69]

The study has led many to state that injectable BadgerBCG reduces positive serological results by 74%.[70] The Veterinary Association of Wildlife Management (VAWM) contest that, saying that the study was 'at best a small scale field study, which only involved 262 animals and which was presumably not designed to assess efficacy' and that while one test showed results of nearly 74%, another using the same data showed no significant

64 Q 13

65 See written evidence from Martin Hancox, Ev w8, for further discussion on this subject and *Bovine Tuberculosis in Cattle and Badgers: Report to the Rt Hon Dr Jack Cunningham MP* by Professor J Krebs and the Independent Scientific Review Group, p46

66 Q 14

67 Q 313

68 Q 52

69 Chambers et al, Bacillus Calmette-Guérin vaccination reduces the severity and progression of tuberculosis in badgers, *Proceedings of the Royal Society: B*, 22 June 2011, vol. 278 no. 1713 1913-1920 http://rspb.royalsocietypublishing.org/content/278/1713/1913.full

70 For example, Ev w27 [Network for Animals], Ev w42 [British Veterinary Zoological Society], Ev w50 [Secret World Wildlife Rescue]

difference.[71] In their written evidence Defra confirm that the study did not produce 'a true efficacy figure'.[72]

44. Since the 2010 study further work has been done reworking the original data using an additional more complex serological test. The 2012 work (Carter et al) states that the

> triple test$_V$ used here is the most sensitive and specific measure of *M. bovis* infection in a live vaccinated badger and so provides confidence that these results are biologically meaningful.
>
> The effect of vaccination on the triple test$_V$ outcome was to reduce the risk of a positive result by 54% in vaccinated individuals. Without *post-mortem* data it was not possible to ascertain what proportion of the triple test$_V$-negative, vaccinated badgers were protected from infection and what proportion still acquired infection, but were not detected using the triple test$_V$. It is unsafe to assume that triple test$_V$ negativity equates to the absence of infection. A greater estimate of vaccine effect (76%) was observed with the dual test. The IGRA (ESAT-6/CFP-10) was absent from the dual test. As the IGRA is more sensitive than either the Stat-Pak or culture at detecting *M. bovis* infection in live badgers, this result was not entirely unexpected.[73]

45. As with the 2010 study, the higher figure from the 2012 work (76%) is widely quoted[74] despite the more sensitive and specific test showing the effect of vaccination was to reduce the risk of a positive result to the lower figure of 54%. **In order for vaccination to be considered part of a strategy to eradicate bovine TB we first need to establish what level of efficacy can be expected. The research undertaken by Chambers et al was vital in gathering the data required to get a badger vaccine licensed and available to use and we congratulate those involved in achieving this aim. To have another tool to use against bovine TB is valuable. However, what is also apparent is that substantial data clearly showing the effect of the vaccine in the field are lacking. Now that a vaccine is available the Government should consider addressing this evidence gap by researching the efficacy of the BadgerBCG vaccine in the field.**

Impact of a programme of badger vaccination on cattle

46. There is no direct evidence that a programme of badger vaccination results in reduced transmission of TB to cattle. Dr Wilson described the lack of data as 'one of the most fundamental knowledge gaps that we have'.[75] Use of the BadgerBCG vaccine is still in its infancy so the lack of such data is not surprising. It is not clear how or whether the Government intends to address this problem. In its written evidence Defra state that to

71 Ev w29 [VAWM]

72 Ev 70 [Defra]

73 Carter SP, Chambers MA, Rushton SP, Shirley MDF, Schuchert P, et al, BCG Vaccination Reduces Risk of Tuberculosis Infection in Vaccinated Badgers and Unvaccinated Badger Cubs. *PLoS ONE* 7(12): available at http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049833

74 For example, Ev w20 [Humane Society], Badger Trust press notice 18 December 2012 http://www.badger.org.uk/_Attachments/Resources/776_S4.pdf

75 Q 38

quantify the contribution 'it is likely we would need to carry out a large-scale field trial (on a comparable scale to the RBCT) the results of which would take many years to collect.'[76]

47. The Government currently funds a Badger Vaccine Deployment Project (BVDP) which covers 120km^2 in Gloucestershire. The project was not set up as a scientific trial but exists to test the deployment of vaccination and train lay vaccinators. The BVDP was originally intended to cover six areas but five of the planned projects were cancelled soon after the current Government took office. Dr Wilson told us that the area in Gloucestershire 'is not large enough in its own right to look at statistical effects of TB on cattle herd breakdowns ... there is no doubt, however, that if all six areas had all been online there would have been more data for us to work with to start looking and addressing questions around what effect this work is having on cattle TB rates ... it is going to be more difficult from the position we are in now to fill the knowledge gap'.[77] **Although they were not originally planned to test the effectiveness of the vaccine or the impact of its deployment on the incidence of TB in cattle, the cancellation of five of the six Badger Vaccine Deployment Projects represents a missed opportunity to collect valuable data on the effect of the badger vaccine.**

48. **The absence of empirical evidence of the impact of badger vaccination on the incidence of TB in cattle is not on its own a reason not to pursue a vaccination strategy. A vaccine that reduces the excretion of *M. Bovis* bacteria is a powerful tool. An effective programme of badger vaccination in areas where badgers are the suspected source of TB in cattle would be expected to reduce transmission of the disease between the species.**

Transmission

49. The discovery of bovine TB in 'closed herds'[78] has led to badgers being identified as a source of TB in cattle. The strength of transmission of *M. Bovis* between badgers and cattle is largely unknown as is the route of transmission.[79] Dr Wilson told us:

> In the past, the feeling was that transmission was more likely on pasture, where cattle come into contact with contaminated excreta from badgers at latrines. Equally, however, we now know from research we have carried out in the last few years that badgers readily enter farm buildings. ... farm buildings represent a high risk area because we know in some circumstances badgers and cattle will come into quite close contact with each other.[80]

76 Ev 70 [Defra]

77 Q 23

78 In this context a closed herd is one without contact with cattle from outside the herd.

79 Q 42

80 Qq 43-4; FERA told the NIA Agriculture and Rural Development Committee that 'Of the 32 farms [studied], 19 had visits from badgers. Some of those had only one or two visits recorded over the whole year, but at the other end of the scale, about 10% of the farms had visits on 70% to 80% of nights. Badgers came on five or six nights a week. It was not just one badger, it was not just one incursion a night, and they were not just travelling through the farmyards; they were going into the farm buildings'. See Northern Ireland Assembly Agriculture and Rural Development Committee Report, *Review into Bovine Tuberculosis*, paras 105-109 for further discussion of badger visits to farm buildings.

50. There is evidence that infected badgers tend to range further than non-infected individuals and the different behaviour pattern may increase the likelihood of the infected badgers encountering cattle.[81] Not everyone agrees that badgers are a cause of TB in cattle. In written evidence Martin Hancox made clear his view that:

> The widely held belief that cows catch TB from badger urine with 300,000 bacilli/cc is wildly improbable. Some 99% drains straight into soil; the rest is disinfected by UV in sunlight within 3 days, so a cow is unlikely to ingest the minimum dose c1million bacilli, ie 3cc of fresh urine.[82]

51. **Although the extent of infection transmitted between badgers and cattle is subject to debate, we believe there is merit in gathering information on potential transmission pathways and we welcome FERA's research project on badger farm visits. Developing and implementing effective badger exclusion methods may prove more cost effective than other measures aimed at addressing the impact of infected badgers on cattle.**

Herd immunity

52. A specific challenge for a vaccination policy is to vaccinate animals before they become infected. As Carter et al (2012) point out:

> This is a particular concern for the vaccination of badgers against TB because they live in close contact with one another and their young do not generally emerge from their underground den (sett) for the first two months of their life. The argument that many badger cubs will become infected during this period (i.e. before they can be caught and vaccinated), has been identified as a key potential constraint on the effectiveness of badger vaccination as a management tool.[83]

53. Analysis of evidence from the four-year field study has shown that where a high proportion of group members were vaccinated, unvaccinated cubs born into those groups were significantly less likely to test positive for TB. Dr Carter told us the most plausible explanation for this is herd immunity:[84] 'the cubs were indirectly protected because a higher proportion of the badgers they were coming into contact with over the course of the study had been vaccinated and had at least received some form of protection from the vaccine.'[85] Results from the field study showed that when more than a third of the social group had been vaccinated the risk to unvaccinated cubs was reduced by 79%.[86] However, Dr Carter explained that owing to a range of factors including prevalence of infection,

81 Ev w31 [Society of Biology] and Qq 44-5

82 Ev w8 [Martin Hancox]

83 Carter et al study, 2012, see earlier footnote for full citation

84 Herd immunity occurs when the vaccination of a significant proportion of a population provides a measure of protection for individuals that have no immunity. It arises when a sufficiently high percentage of the population is protected through vaccination to disrupt chains of infection and therefore stop the spread of disease. Establishing herd immunity is therefore a sought after outcome of vaccination policy.

85 Q 20

86 Ev 70 [Defra]

population density, and other environmental factors, 'we cannot say what proportion of the population you would need to vaccinate to achieve herd immunity'.[87]

54. **Herd immunity is a sought after outcome of any vaccination programme. It means transmission of disease is reduced and non-vaccinated animals are given a measure of protection reducing the need for further deployment of the vaccine. The identification of the indirect effect of badger vaccination on unvaccinated cubs is an important step forward in research on the effectiveness of the BadgerBCG vaccine. For herd immunity to occur, a significant proportion of the uninfected badger population must be trapped and vaccinated. The precise numbers depend not only on local factors such as badger population, density and environmental factors but, as importantly, on the efficacy of the vaccine. While herd immunity may mean that not every badger has to be vaccinated every year, we need to be confident, without testing each badger, that herd immunity has developed. Further research on the indirect effect of vaccination is therefore necessary and must be included as part of future evidence-gathering on the efficacy of the vaccine in the field.**

Cost

Deployment

55. Vaccination of badgers is expensive. Defra's current best estimate of the cost of trapping and vaccinating badgers is £2,000-£4,000 per km^2.[88] Costs can vary according to factors such as ease of access to setts, terrain, weather, time of year and experience of personnel. The cost will also depend on factors such as the size of area being vaccinated, density of badgers, frequency of vaccination, and model of deployment. Fixed costs include the vaccine itself, fridges (as the vaccine needs to be kept in cold conditions at all times to remain viable), disposables, traps, vehicles and training. However, as Dr Wilson told us, the largest cost is manpower:

> A badger vaccination round on a farm or something like that would involve a survey, the deployment of the traps—i.e. putting or digging them into place—and then perhaps several days of pre-baiting the traps, which involves repeated visits by staff and operatives going back, with the traps locked open, putting bait in them and getting the badgers used to going in them for food rewards. The final step is to set the traps, go back, check the traps the morning after setting them, vaccinate the animals and release them, and then remove the traps and clean up. That can be a two or three-week programme. Obviously, if you are talking about manpower for that length of time there is clearly a significant cost associated with that.[89]

87 Q 20

88 Ev 70 [Defra]; Gloucestershire Wildlife Trust published a cost range of £41-51 per hectare for their work in 2011 and provide a detailed breakdown of costs in their report *Nature Reserves Badger Vaccination Deployment Programme 2011*, while the Welsh Assembly Government's project cost £3912 per km^2 in its first year.

89 Q 31

Research by the NFU has indicated that even where farmers pre-baited traps on their own land, the cost of vaccination still amounted to £1,736km^2.[90]

56. In 2012, work undertaken by FERA, the Welsh Assembly Government and a number of NGOs led to more than 2,500 badgers being vaccinated.[91] A dozen wildlife organisations now actively deploy the vaccine in England. **Although vaccination is costly, scope exists for economies of scale but this will need a more coordinated national approach to badger vaccination to enable equipment and information to be shared more effectively. There is great enthusiasm among voluntary organisations for deploying the badger vaccine. The Government should not miss the opportunity to use them both to gather evidence and as a resource to carry out vaccination. A first step should be to set up an advisory service to help NGOs plan and deploy a programme of vaccination and to advise what data it would be useful to obtain.**

Identification and surveillance

57. Better targeting of resources is key to reducing the costs of a vaccination programme. Collaborative work undertaken by the University of Warwick's School of Life Sciences and the Government (Travers et al 2012) suggests that Polymerase Chain Reaction (PCR) tests on faeces in badger latrines can determine whether inhabitants of the related sett are infected with bovine TB. While the PCR test will not identify which individual badger has TB, such tests may, when fully developed, prove useful in identifying which setts harbour infected badgers.[92] The research concludes that 'field studies are now required to determine how best to apply the assay for population-level bTB surveillance in wildlife'.[93]

58. Another option is to test captured badgers for infection, releasing only those which tested negative. However, as the BVA made clear, this option could make the problem worse:

> the diagnostics for badger-side testing have a low sensitivity of about 50%. So arguably, in simple terms, for every two infected badgers that are trapped and tested, one will be vaccinated and released and one will be culled and removed. So we still have the disturbance in the badger population from that proportion that has been culled. That can create perturbation. What you have actually done is release infected badgers back into that perturbed population. Potentially you could make the perturbation effect worse than removing badgers on a pure culling exercise alone.[94]

59. **PCR testing of badger faeces has the potential to identify those setts which harbour infected badgers. Doing so will not only enable a vaccination programme to be better targeted and therefore more cost-effective but may also be able to show whether the**

90 Ev w51 [NFU]

91 Ev w22 [RSPB]; In the first year of the Welsh Assembly Government's five year vaccination programme a total of 1,424 badgers were vaccinated over an area of 288km^2 at a cost of £943,000.

92 Ev 46 [IFAW]; Travis ER, Gaze WH, Pontiroli A, Sweeney FP, Porter D, et al. (2011) An Inter-Laboratory Validation of a Real Time PCR Assay to Measure Host Excretion of Bacterial Pathogens, Particularly of Mycobacterium bovis. *PLoS ONE* 6(11). Similar work, funded by Defra, is also being undertaken by Queens University Belfast.

93 *Ibid.*

94 Q 252

vaccination has been successful in creating herd immunity in particular social groups. We recommend that the Government provide funding to explore how this research might be applied practically in the field.

Training

60. Vaccination can be undertaken only by trained vaccinators. The Government has made up to £250,000 a year available over three years to support and encourage badger vaccination.[95] The scheme is aimed at supporting vaccination in the cull pilot areas and to subsidise lay vaccinator training and certification costs for voluntary and community organisations only.[96] Brock Vaccination and the NFU considered that the allocation of funding resources might be better targeted if farmers who wished to undertake the vaccinator training were also eligible for support. We agree. **Farmers are not entitled to funding to complete the lay vaccinator training course despite it being their land on which access is required to undertake the vaccination. This is perverse. The Government should amend eligibility for the course to include farmers.**

61. Gloucestershire Wildlife Trust report that training capacity for lay vaccinators and subsequent certification and licensing is a limiting factor for any significant increase in voluntary deployment: 'in 2013 there are only 50 places on the FERA training course, with 10 places available per course.'[97] **The Government should increase the number of places on its lay vaccinator training course. It would be disappointing if a lack of qualified vaccinators became the limiting factor in a programme aimed at reducing TB in badgers.**

Strategy

62. If cost-effective, a programme of badger vaccination will undoubtedly meet greater support and public approval than culling. It would be unlikely to be subject to public protest and disruption and, while trapping brings with it welfare concerns, a programme of vaccination is more likely than other options to result in a healthy badger population. There is also no evidence of the perturbation effect that is attributed to culling. The efforts of wildlife NGOs, the Welsh Assembly Government and FERA have demonstrated that deploying an injectable vaccine, while expensive, is feasible in limited areas. However, it remains the case that vaccination does not remove and has no effect on already-infected badgers. Indeed, mitigating the effect of the disease through vaccination may increase the survival time of carriers and secretors.[98]

63. Benefits from vaccination would be expected to accrue incrementally over several years as the number of badgers vaccinated increased and infected badgers died off. Although, according to Defra, most individual badgers already infected with bovine TB will die off

95 Defra website, https://www.gov.uk/government/news/update-on-measures-to-tackle-bovine-tb and Ev 70 [Defra]

96 Defra are providing funds to cover 50% of the cost of becoming an accredited and certified lay vaccinator. Farmers are not eligible to apply for funding from this scheme to train as vaccinators. To date, Fera have trained 137 lay vaccinators on the Cage Trapping and Vaccination of Badgers course.

97 Gloucestershire Wildlife Trust Nature Reserves Badger Vaccine Deployment 2012 available at www.gloucestershirewildlifetrust.co.uk

98 Ev w17 [Ian Kett]

within five years, it is likely that annual vaccination would need to last many years more to be successful.[99] For vaccination to produce herd immunity, a significant proportion of badgers need to be captured. The Carter et al research suggested that vaccination reduced the risk of a positive test result by 54% in vaccinated individuals. However, if only 50% of badgers were trapped and vaccinated with a vaccine that is 54% effective then just a quarter of the badger population would have a reduced risk of infection – and that is assuming that those vaccinated were not already infected. The more endemic the disease the more difficult it will be and the longer it will take for vaccination to be effective.[100] **The Government needs to undertake further research in order to have confidence in the level of efficacy to be expected from the vaccine when deployed in the field.**

64. **The development of a vaccine that reduced the level of infection in badgers would be a valuable tool in the battle against bovine TB but, despite 10 years of research and £11million spent in development, it is one that Defra lack a strategy for using. A number of voluntary organisations are deploying the vaccine and, while we commend their actions, in the absence of a clear nationally coordinated strategy this work can only have a limited impact on the wider problem of bovine TB. We are particularly concerned that Defra may miss the opportunity to make use of the enthusiasm that exists in the voluntary sector for badger vaccination.**

65. **Badger vaccination is expensive and no magic bullet. We agree with the Wildlife Trusts that if it is going to make a difference, it needs to be deployed strategically in areas where it is likely to have the biggest impact. The vaccine has been available for use for more than three years. Having developed the vaccine, Defra must now produce a clear strategy for its use.**

99 The British Cattle Veterinary Association has referred to a timescale of 12 years and Paul Livingstone, Technical Manager of the Animal Health Board in New Zealand,has referred to a timescale of 20 years – see www.bovinetb.info for further discussion.

100 *Options for the use of badger vaccines for the control of bovine TB*, Defra

4 An oral vaccine for badgers

66. An oral baited vaccine for badgers that can be laid at setts is likely to be a cheaper and more practical way of vaccinating large numbers of badgers in the wild than an injectable version, primarily because trapping would no longer be required.[101] Its ease of deployment means it is likely to be the only way in which widespread vaccination of badgers can realistically be achieved making its development an important contribution to the long-term eradication of bovine TB.[102] An oral vaccine would also remove the animal welfare costs that come with trapping animals.[103] However, developing an oral vaccine solution presents a number of challenges; not only does an effective vaccine have to be developed but the right deployment strategy with the right bait must also be determined.[104] As the BVA and BVCA outline in their evidence, issues to address include:

- Identifying a palatable carrier substance for the vaccine which the target species will eat but which will not be taken by non-target species;
- Combating the problem of acid degradation in the stomach of the target species;
- Identifying the correct dose of the vaccine, as animals may not eat all of the carrier substance;
- Ensuring that as many members of the target species as possible are reached (particularly cubs) and in sufficient numbers.[105]

67. Work on overcoming these challenges is ongoing. Dr Steve Carter from FERA told us that 'over the last three years we have been trialling candidate baits with biomarkers—not baits with vaccine in them—so that we can look at the rates of uptake of those baits in badger populations' but 'until we have a final product that is ready to take forward to licensing, we cannot answer all of the questions'. [106]

Developing an oral vaccine

68. Since 2005-06 Defra has invested over £6million on research into oral vaccines for badgers, and has budgeted a further £7.5million over the next five years.[107] Professor Hewinson, told us regarding the vaccine itself 'progress is being made. There are a number of formulations that are under investigation' and 'there are some lead candidates that have given proof of principle that oral vaccination can give you similar protection to injectable vaccination'. However, he cautioned that 'none of them are ready for use yet'[108] and 'these

101 Ev w25 [Badger Trust]; Ev w2 [RSPCA]

102 Ev w51 [NFU]

103 Ev w46 [IFAW]

104 Q 388

105 Ev 68 [BVA/BCVA]

106 Q 53

107 Mr Paice, Written Answers (Hansard) 504-505W Bovine Tuberculosis: Disease Control, 14 July 2011; Gloucestershire Wildlife Trust, Bovine TB FAQs

108 Q 388 and Q 391

things take a lot of time. One of the other differences is that every TB experiment takes a year, because the disease progresses so slowly. If you have variation in one experiment, that takes you back a year.'[109]

69. A number of other countries are pursuing an oral vaccine for use on wildlife. The AHVLA is working in partnership with the Republic of Ireland on a field trial that it hopes will give proof of principle that oral vaccination in the field might be possible and create data that could go into a licensing document. Professor Hewinson told us:

> The trial that is going on in the Republic of Ireland is not a trial of how the vaccine would be finally used, so it is not being incorporated in a bait and being up taken up as bait. What they are doing is they are trapping the badgers, anaesthetising them and then injecting the formulation down, so that they swallow the BCG in a formulation. Although it will give you proof of principle of how the vaccine in that formulation might work ... it is not telling you how effective it will be in a bait.[110]

70. The UK is also in discussion with researchers in New Zealand on the oral vaccine project.[111] Indeed, the formulations that have been used in Ireland had been developed in New Zealand for use in addressing the problem of TB in their wildlife vector, the Australian brushtail possum. In New Zealand a lipid-based bait[112] has been developed and trials have shown that when distributed in flavoured sachets the bait is sufficiently stable and palatable to possums to have the potential to be a means of controlling TB in that population.[113] As in Ireland, the proof of principle study in New Zealand included catching the animal and delivering the vaccine into its mouth and, as in Ireland and England, research is ongoing. Research is also under way in southern Spain with field trials aimed at assessing the 'response of wild boar to oral BCG and heat-killed *M. bovis* vaccination under field conditions, gathering information on safety aspects and analyzing the cost-effectiveness of vaccination for TB control in wild boar'.[114] **We welcome the Government's continued commitment toward the development of an oral baited vaccine for badgers. An oral vaccine that is cost effective and easy to deploy is arguably the best means of creating a healthy badger population. It is important that sufficient resources are available in order to accelerate the necessary research required to make an oral vaccine available for use. The Government must also continue to work closely with other countries with similar problems of infected wildlife such as Ireland, New Zealand and Spain.**

109 Q 393

110 Q 391

111 Cross et al, Lipid-formulated bcg as an oral-bait vaccine for tuberculosis: vaccine stability, efficacy, and palatability to brushtail possums (Trichosurus vulpecula), *New Zealand Journal of Wildlife Diseases*, 45(3), 2009, pp. 754–765

112 Edible lipids are thought to protect BCG during transit through the gastrointestinal tract, thus delivering live bacilli to intestinal sites of immune induction.

113 Ev w2 [RSPCA]

114 Beltran-Beck et al, Progress in Oral Vaccination against Tuberculosis in Its Main Wildlife Reservoir in Iberia, the Eurasian Wild Boar, *Veterinary Medicine International*, 10 July 2012

Timescale

71. Defra state that 'Until the results of the necessary, ongoing further research are known we cannot be certain of the timescale within which an effective and affordable oral badger vaccine may be available. As of now, no product is ready for licensing.'[115] **Progress towards an oral vaccine for badgers is evident but one will not be available in the near future. Further scientific information is required before a candidate vaccine might be taken forward to be licensed. The most cost-effective means of deploying the vaccine which will maximise uptake among the target badger population and minimise consumption by other species also remains to be fully identified.**

Magic bullet

72. As we noted in the previous chapter, while a worthwhile pursuit, vaccination should not be considered a magic bullet. An oral vaccine may prove more cost effective than an injectable version but it is not a complete solution. As with the injectable version currently available, a programme of oral vaccination would take some time to be effective. When asked about herd immunity Professor Hewinson told us:

> [the] logistics are very difficult ... modelling suggests that this would take many, many years to achieve, so vaccination would not be a quick fix especially as, when you are vaccinating badgers, you are leaving infected animals, so the vaccine does not cure preexisting infection. The time it takes for a vaccine to start having an effect in a wildlife population is dependent on the infected badgers dying off and then getting more protection. Any vaccination strategy focusing on badgers would need to be, I would say, quite widescale and longterm.[116]

73. This view is supported by Dr Paul Livingstone, Technical Manager of the Animal Health Board (AHB) in New Zealand, who, in April 2009, told the website bovinetb.info, 'to eradicate TB from badger populations through vaccination will mean annual vaccination of badger populations for some 4 - 5 badger generations or around 20 years - which is some commitment.'[117] Dr Carter told us that 'we would recommend annual vaccination, not because badgers need to be revaccinated annually but because there is a fairly quick turnover of cubs each year. Each year, you would want to go out and vaccinate the new recruits into the population'[118]. **Even if an oral vaccine becomes available it is unlikely to be an immediate or complete solution in combating bovine TB in badgers. If herd immunity could be achieved it would take many years and considerable effort and expense. That is not to say that it should not be considered; it is the most likely means of creating a healthy badger population, but it is important that these caveats are understood by all those interested in this subject.**

74. **Defra has a clear responsibility to keep the public informed of scientific progress toward developing an effective oral vaccine. It has so far failed to do so adequately.**

115 Ev 70 [Defra]

116 Q 387

117 Bovine TB info website http://www.bovinetb.info/newzealand.php

118 Q 56

Reticence about publishing indicative timescales is understandable but there is scope for Defra to improve information available. Basic details of trials, such as their purpose and length, and updates on progress should be available and easily accessible to the public.

5 Other issues

75. The focus of our inquiry was on the availability of vaccines for bovine TB for use in cattle and badgers. A number of other issues were, however, raised during the course of our inquiry which we consider here.

Tuberculin skin test

76. Two diagnostic tests are used in the UK for screening cattle herds for bovine TB. The primary screening test is the mandatory single intradermal comparative cervical tuberculin (SICCT) test - commonly known as the skin test. Additionally, the ancillary gamma interferon (γ-IFN) diagnostic blood test has been used since 2002 alongside the skin test in certain prescribed circumstances in the UK. A failure of a screening test to recognise infection means that infectious cattle remain in the herd.

77. The mandatory skin test has a sensitivity of between 60-80% - i.e. it can miss up to 40% of infections.[119] Johne's disease, liver fluke, pregnancy and even the diligence of the tester can affect the result of the skin test. The gamma interferon test has a higher sensitivity than the skin test and will therefore detect more positive infections (c90%). It is faster and can give an earlier indication of infection, meaning that animals can be identified before they have had a chance to transmit the disease.[120] However, the gamma interferon test has limitations. It is expensive, at £30 per test plus transport costs to the laboratory, compared with £3 for the skin test.[121] Its specificity is also lower than the skin test – 3 in 100 animals would be false positive compared with 1 in 1000 for the skin test.[122] The Roslin Institute suggest that the gamma interferon test 'could be used more extensively to assist in clearing herds of infection in the high risk areas.'[123] Professor Hewinson agreed:

> Your earliest infection is detected by gamma interferon response, when you have lesions and very few bugs, and where you cannot find any sign of infection. That does not mean the infection is not there; it just means that you are identifying animals at that very early stage, before they have developed disease and become infectious. For me, the ideal test would be to identify animals that have no visible lesions because that means they are less likely to have transmitted disease. By the time they have developed lesions, they are more likely to have spread disease.[124]

78. Queens University Belfast noted in giving evidence to the Northern Ireland Assembly Agriculture and Rural Development Committee that the gamma interferon test used by

119 Q 243

120 The first response to infection is a gamma interferon response. As the disease progresses a skin test response is seen and much later an antibody response (Q 329).

121 Q 323

122 Specificity is the ability of a test to correctly identify an animal that is free of infection - a false positive is where the test incorrectly identifies an uninfected animal as infected. Sensitivity is the ability of a test to identify infected animals – a false negative is where the test incorrectly identifies an infected animal as uninfected. Both are important, the lower the specificity the more likely infected cattle remain in the herd, while lower sensitivity may mean cattle are sent to slaughter and herds put under movement controls unnecessarily.

123 Ev w37 [Roslin Institute]

124 Q 329

DARD[125] is now out of patent and that there might be an opportunity to develop a cheaper 'generic' blood test.[126] Also in evidence to that Committee, the Agri-Food and Biosciences Institute suggested a number of ways in which the test could be improved.[127]

79. **The testing regime is central to the control and eradication of bovine TB in this country. It is frustrating to hear government officials acknowledge that the current testing regime misses infectious cattle when they have a test at their disposal with a greater sensitivity. We accept that the gamma interferon test is expensive but the Government must explore whether it is possible to use the test more widely than is the case at present. Doing so may help the Government to get ahead of the spread of infection and begin to bear down on the disease.**

80. **Now that the gamma interferon test is out of patent it seems to us timely for the Government to explore whether it is possible to improve the performance of the test and reduce its cost.**

Movement controls, biosecurity and local knowledge

81. In evidence to us, officials from the European Commission were adamant that movement controls and biosecurity were key to reducing the bovine TB footprint in the United Kingdom. From 1 January 2013 tighter controls on cattle movement and changes to the testing regime came into force. These new measures were brought in on the back of a 2011 Commission audit which was critical of the UK's existing Bovine tuberculosis eradication programme. Neil Blake, past president of the BCVA told us that greater use could be made of local vets, as he argued is the case in Wales where they give advice on biosecurity and disease control, not just in endemic areas but in TB-free areas, 'You are trying to get ahead of the problem again. You are trying to offer advice that reduces the risk of disease spreading and also advice to try to limit the damage of ongoing transmission of disease on the farm'.[128]

82. **The Government should explore the possibility of integrating local vets into strategies for improving farm biosecurity and disease control. The local vet is well placed to know what is going on in a particular herd and will be familiar with the area and trusted by the farmer. We are mindful that this may lead to extra costs for farmers and this must be included in any consideration of such a strategy.**

125 Department of Agriculture and Rural Development

126 Northern Ireland Assembly Agriculture and Rural Development Committee Report, *Review into Bovine Tuberculosis*, Minutes of evidence, 1 May 2012

127 Northern Ireland Assembly Agriculture and Rural Development Committee Report, *Review into Bovine Tuberculosis*, para 42

128 Q 267

6 Conclusion

83. Vaccination is not a panacea that will solve overnight the problem of bovine TB in cattle and badgers. The impact of the available injectable vaccine for badgers is unproven in the field, an oral vaccine for badgers is several years away and it may be 10 years before a cattle vaccine is available for use and at present we do not know how effective such a vaccine might be under UK conditions.

84. Vaccination is expensive and labour intensive. It must therefore be deployed strategically where it is likely to have the biggest impact. It is disappointing that although an injectable vaccine for badgers has been available for use since March 2010, the Government still does not appear to have a clear strategy for deploying it. This situation must not be repeated if either an oral vaccine for badgers or a cattle vaccine becomes available to use.

85. For too long the Government's strategy for dealing with bovine TB has been reactive and followed the spread of infection. The increase in cases of bovine TB in cattle demonstrates that the Government needs a strategy that will jump ahead of infection.[129] Cattle vaccination is a tool that may allow it to do that in the future but for now increased biosecurity and rigorous movement controls are vital. It will be no good vaccinating badgers to create a firewall against the spread of infection only for it to be compromised by movement of infected cattle.

86. We currently rely on a skin test that could miss one in four infected cows. Liver fluke, Johne's disease and even pregnancy may impact on the result of the skin test. While the skin test has served us well, if other more sensitive tests exist, they should be employed alongside it. We accept that the gamma interferon blood test is expensive and not without limitations, but a test that catches infection earlier when animals are less likely to have transmitted the disease is a valuable tool and one that should be deployed as widely as possible.

87. Bovine TB is costing the British tax payer millions of pounds a year but the cost is not solely financial. The emotional distress that herd breakdowns bring to farmers and their families can be immense. Farmers must be able to reassure themselves that the livestock they bring onto their farms are free of TB. We remain convinced that, alongside enhanced biosecurity and movement control, improvements to the testing regime can deliver real benefits.

88. Throughout this inquiry we have been impressed by the scientific research that has and is taking place to discover solutions to the problem of bovine TB. A variety of ongoing research projects could make a real difference to the eradication of bovine TB in the United Kingdom, these include: PCR testing to determine infected badger setts, a new type of test that can identify more cases of bovine TB in cattle after slaughter, and work on a vaccine that does not interfere with the skin test. It is crucial that the Government continues to invest in research.

129 Q 256

89. Bovine TB is an emotive subject. Our inquiry has shown that the quality of information in the public domain about the availability of the cattle vaccine and oral badger vaccine and the efficacy of the injectable badger vaccine has not been good enough. There is a great deal of interest in this subject and the Government must do better in satisfying it.

Conclusions and recommendations

A vaccine for cattle

1. During the last 18 months the debate on the availability of a cattle vaccine for bovine TB has been characterised by a lack of clarity and public misunderstanding. Although it is by no means solely responsible, the Government must accept a great deal of the blame for this. The quality and accuracy of the information that Defra has put in the public domain has been insufficient and inadequate. It is unfortunate that this has led to debate over the timetable for use of the vaccine overshadowing scientific breakthroughs in the development of both the vaccine and DIVA test that should be applauded. (Paragraph 16)

2. We await publication of the TB eradication strategy with interest and expect it to include not only information on those methods that are available for the eradication of bovine TB but progress on those in development. The launch of the strategy must be accompanied by a public information campaign to make the position clear in the public's mind and dispel misunderstanding. (Paragraph 17)

3. It is perplexing that the Government has maintained that field trials were prohibited under EU law when, as recent events have shown, this is not the case. We accept that field trials might be permitted only if certain criteria are met, the development of the DIVA test being one of them, but to have stated that legislative change is required is misleading. It would be unfortunate if the Government's interpretation of the legislation had delayed progress in delivering a vaccine. (Paragraph 25)

4. We are not convinced that the Government had to wait until all the 'factors were in place' before approaching the Commission. However, while we believe negotiations could and should have begun earlier, we welcome the efforts of the Government and the Commission in coming to an agreement that field trials might take place in the UK. To be able to study the efficacy of the vaccine and DIVA test in UK field conditions is a big step forward and we congratulate the Government on securing this position. (Paragraph 26)

5. It is difficult to envisage Defra designing field trials of the scope and size requested by the Commission without using the commercial herd. In doing so, the Government must take steps to reassure the public that such field trials will not pose a public health risk. The Government must also make sure that farmers volunteering their herds for these trials are not left financially disadvantaged. We look forward to seeing details of the programme for field trials once it is agreed. (Paragraph 28)

6. We welcome the ongoing dialogue between the UK, EU and OIE. A good working relationship is vital to ensuring early success in the development and deployment of a vaccine to help combat bovine TB. The indicative 10-year timetable set down by the Commission is precisely that, indicative. The UK Government should do all it can to condense the timetable without compromising the collection of the robust field data necessary to satisfy the VMD and European and international communities. Once the programme for field trials is agreed we look forward to the

Government publishing its own indicative timetable for the use of a cattle vaccine. We accept that such a timetable may be subject to change but any changes must be clearly explained. (Paragraph 31)

7. We invite Defra to indicate in its response to this Report, the timetable proposed for the new Animal Health legislation. (Paragraph 33)

8. A vaccine that is 65% effective will not immediately solve the problems of bovine TB within the cattle industry. Over the short term, its use will be an additional financial cost and may lead to an increase in the administrative and testing burdens farmers already face. While it will be a useful tool to have, the circumstances in which it might be used, the precise objectives of applying it and levels of protection that would be needed to make vaccination worthwhile need careful consideration. Before deployment the Government must undertake and publish a robust cost-benefit analysis. The analysis must also consider the extent to which EU financial support would be available for such a programme. (Paragraph 35)

9. Even if the cattle BCG vaccine becomes available to use the Government must not stop there. The considerable cost of the DIVA test and cattle BCG mean that research into a vaccine that does not desensitise animals to the skin test must remain an objective. There is also considerable merit in focusing research on improving the immunity offered by the existing BCG vaccine. (Paragraph 37)

An injectable vaccine for badgers

10. In order for vaccination to be considered part of a strategy to eradicate bovine TB we first need to establish what level of efficacy can be expected. The research undertaken by Chambers et al was vital in gathering the data required to get a badger vaccine licensed and available to use and we congratulate those involved in achieving this aim. To have another tool to use against bovine TB is valuable. However, what is also apparent is that substantial data clearly showing the effect of the vaccine in the field are lacking. Now that a vaccine is available the Government should consider addressing this evidence gap by researching the efficacy of the BadgerBCG vaccine in the field. (Paragraph 45)

11. Although they were not originally planned to test the effectiveness of the vaccine or the impact of its deployment on the incidence of TB in cattle, the cancellation of five of the six Badger Vaccine Deployment Projects represents a missed opportunity to collect valuable data on the effect of the badger vaccine. (Paragraph 47)

12. The absence of empirical evidence of the impact of badger vaccination on the incidence of TB in cattle is not on its own a reason not to pursue a vaccination strategy. A vaccine that reduces the excretion of M. Bovis bacteria is a powerful tool. An effective programme of badger vaccination in areas where badgers are the suspected source of TB in cattle would be expected to reduce transmission of the disease between the species (Paragraph 48)

13. Although the extent of infection transmitted between badgers and cattle is subject to debate, we believe there is merit in gathering information on potential transmission pathways and we welcome FERA's research project on badger farm visits.

Developing and implementing effective badger exclusion methods may prove more cost effective than other measures aimed at addressing the impact of infected badgers on cattle. (Paragraph 51)

14. Herd immunity is a sought after outcome of any vaccination programme. It means transmission of disease is reduced and non-vaccinated animals are given a measure of protection reducing the need for further deployment of the vaccine. The identification of the indirect effect of badger vaccination on unvaccinated cubs is an important step forward in research on the effectiveness of the BadgerBCG vaccine. For herd immunity to occur, a significant proportion of the uninfected badger population must be trapped and vaccinated. The precise numbers depend not only on local factors such as badger population, density and environmental factors but, as importantly, on the efficacy of the vaccine. While herd immunity may mean that not every badger has to be vaccinated every year, we need to be confident, without testing each badger, that herd immunity has developed. Further research on the indirect effect of vaccination is therefore necessary and must be included as part of future evidence-gathering on the efficacy of the vaccine in the field. (Paragraph 54)

15. Although vaccination is costly, scope exists for economies of scale but this will need a more coordinated national approach to badger vaccination to enable equipment and information to be shared more effectively. There is great enthusiasm among voluntary organisations for deploying the badger vaccine. The Government should not miss the opportunity to use them both to gather evidence and as a resource to carry out vaccination. A first step should be to set up an advisory service to help NGOs plan and deploy a programme of vaccination and to advise what data it would be useful to obtain. (Paragraph 56)

16. PCR testing of badger faeces has the potential to identify those setts which harbour infected badgers. Doing so will not only enable a vaccination programme to be better targeted and therefore more cost-effective but may also be able to show whether the vaccination has been successful in creating herd immunity in particular social groups. We recommend that the Government provide funding to explore how this research might be applied practically in the field. (Paragraph 59)

17. Farmers are not entitled to funding to complete the lay vaccinator training course despite it being their land on which access is required to undertake the vaccination. This is perverse. The Government should amend eligibility for the course to include farmers. (Paragraph 60)

18. The Government should increase the number of places on its lay vaccinator training course. It would be disappointing if a lack of qualified vaccinators became the limiting factor in a programme aimed at reducing TB in badgers. (Paragraph 61)

19. The Government needs to undertake further research in order to have confidence in the level of efficacy to be expected from the vaccine when deployed in the field. (Paragraph 63)

20. The development of a vaccine that reduced the level of infection in badgers would be a valuable tool in the battle against bovine TB but, despite 10 years of research and £11million spent in development, it is one that Defra lack a strategy for using. A

number of voluntary organisations are deploying the vaccine and, while we commend their actions, in the absence of a clear nationally coordinated strategy this work can only have a limited impact on the wider problem of bovine TB. We are particularly concerned that Defra may miss the opportunity to make use of the enthusiasm that exists in the voluntary sector for badger vaccination. (Paragraph 64)

21. Badger vaccination is expensive and no magic bullet. We agree with the Wildlife Trusts that if it is going to make a difference, it needs to be deployed strategically in areas where it is likely to have the biggest impact. The vaccine has been available for use for more than three years. Having developed the vaccine, Defra must now produce a clear strategy for its use. (Paragraph 65)

An oral vaccine for badgers

22. We welcome the Government's continued commitment toward the development of an oral baited vaccine for badgers. An oral vaccine that is cost effective and easy to deploy is arguably the best means of creating a healthy badger population. It is important that sufficient resources are available in order to accelerate the necessary research required to make an oral vaccine available for use. The Government must also continue to work closely with other countries with similar problems of infected wildlife such as Ireland, New Zealand and Spain. (Paragraph 70)

23. Progress towards an oral vaccine for badgers is evident but one will not be available in the near future. Further scientific information is required before a candidate vaccine might be taken forward to be licensed. The most cost-effective means of deploying the vaccine which will maximise uptake among the target badger population and minimise consumption by other species also remains to be fully identified. (Paragraph 71)

24. Even if an oral vaccine becomes available it is unlikely to be an immediate or complete solution in combating bovine TB in badgers. If herd immunity could be achieved it would take many years and considerable effort and expense. That is not to say that it should not be considered; it is the most likely means of creating a healthy badger population, but it is important that these caveats are understood by all those interested in this subject. (Paragraph 73)

25. Defra has a clear responsibility to keep the public informed of scientific progress toward developing an effective oral vaccine. It has so far failed to do so adequately. Reticence about publishing indicative timescales is understandable but there is scope for Defra to improve information available. Basic details of trials, such as their purpose and length, and updates on progress should be available and easily accessible to the public. (Paragraph 74)

Other issues

26. The testing regime is central to the control and eradication of bovine TB in this country. It is frustrating to hear government officials acknowledge that the current testing regime misses infectious cattle when they have a test at their disposal with a greater sensitivity. We accept that the gamma interferon test is expensive but the

Government must explore whether it is possible to use the test more widely than is the case at present. Doing so may help the Government to get ahead of the spread of infection and begin to bear down on the disease. (Paragraph 79)

27. Now that the gamma interferon test is out of patent it seems to us timely for the Government to explore whether it is possible to improve the performance of the test and reduce its cost. (Paragraph 80)

28. The Government should explore the possibility of integrating local vets into strategies for improving farm biosecurity and disease control. The local vet is well placed to know what is going on in a particular herd and will be familiar with the area and trusted by the farmer. We are mindful that this may lead to extra costs for farmers and this must be included in any consideration of such a strategy. (Paragraph 82)

29. The Government should explore the possibility of integrating local vets into strategies for improving farm biosecurity and disease control. The local vet is well placed to know what is going on in a particular herd and will be familiar with the area and trusted by the farmer. We are mindful that this may lead to extra costs for farmers and this must be included in any consideration of such a strategy. (Paragraph 82)

Formal Minutes

Tuesday 4 June 2013

Members present:

Miss Anne McIntosh, in the Chair

Iain McKenzie
Mrs Mary Glindon
Ms Margaret Ritchie

Draft Report (*Vaccination against bovine TB*), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 89 read and agreed to.

Summary agreed to.

Resolved, That the Report be the Second Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Tuesday 11 June at 2.30 pm

Witnesses

Tuesday 12 February 2013

Page

Dr Gavin Wilson, Team Leader and **Dr Steve Carter**, Senior Scientist, Food and Environment Research Agency — Ev 1

Prof Trevor Drew, Lead Scientist for Virology, Animal Health and Veterinary Laboratories, **Alick Simmons,** Deputy Chief Veterinary Officer,Defra — Ev 8

Tuesday 26 February 2013

Bernard Van Goethem, Director for Veterinary and International Affairs, DG Health and Consumers,**Francisco Reviriego,** Head of Sector, Disease Control and Identification in Unit SANCO/G2 Animal Health, **Koen Van Dyck,** Head of Unit SANCO/G4 Food, Alert System and Training, European Commission, and **Jacqueline Minor,** Head of the Commission Representation in London — Ev 14

Wednesday 27 February 2013

Jackie Atkinson, Director of Authorisations, and **Anna-Maria Brady,** Head, Biologicals Team, Veterinary Medicines Directorate — Ev 23

Carl Padgett, Past President, British Veterinary Association, and **Neil Blake,** Chair, Government/Agencies Liaison Working Group, British Cattle Veterinary Association — Ev 30

Wednesday 6 March 2013

Prof Glyn Hewinson, Chief Scientist, and **Simon Hall,** Veterinary Director, Animal Health and Veterinary Laboratories Agency — Ev 40

Tuesday 19 March 2013

David Heath MP, Minister of State for Agriculture and Food, **Prof Ian Boyd,** Chief Scientific Adviser, **Nigel Gibbens,** Chief Veterinary Officer, Defra, **and Prof Glyn Hewinson,** Chief Scientist, Animal Health and Veterinary Laboratories Agency — Ev 54

List of printed written evidence

List of additional written evidence

(published in Volume II on the Committee's website www.parliament.uk/efracom)

List of Reports from the Committee during the current Parliament

The reference number of the Government's response is printed in brackets after the HC number.

Session 2013–14

First Report	Draft Dangerous Dogs (Amendment) Bill	HC 95

Session 2012–13

First Report	Greening the Common Agricultural Policy	HC 170 (HC 654)
Second Report	The Water White Paper	HC 374 (HC 602)
Third Report	Pre-appointment hearing: Chair of the Water Services Regulation Authority (Ofwat)	HC 471-I & -II
Fourth Report	Natural Environment White Paper	HC 492 (HC 653)
Fifth Report	Desinewed Meat	HC 120 (Cm 8462)
Sixth Report	Draft Water Bill	HC 674
Seventh Report	Dog Control and Welfare	HC 575 (HC 1092)
Eighth Report	Contamination of Beef Products	HC 946 (HC 1085)

Session 2010–12

First Report	Future Flood and Water Management Legislation	HC 522 (HC 922)
Second Report	The Marine Policy Statement	HC 635
Third Report	Farming in the Uplands	HC 556 (HC 953)
Fourth Report	The draft National Policy statement (NPS) on Waste Water	HC 736
Fifth Report	The Common Agricultural Policy after 2013	HC 671 (HC 1356)
Sixth Report	Implementation of the Common Fisheries Policy: Domestic Fisheries Management	HC 858 (HC 1485)
Seventh Report	Pre-appointment hearing: Chair of Gangmasters Licensing Authority	HC 1400-I & -II
Eighth Report	EU proposals for the dairy sector and the future of the dairy industry	HC 952 (HC 1548)
Ninth Report	The Welfare of Laying Hens Directive—Implications for the egg industry	HC 830 (HC 1664)
Tenth Report	The outcome of the independent Farming Regulation Task Force	HC 1266 (HC 1669)
Eleventh Report	The draft National Policy Statement for Hazardous Waste	HC 1465 (HC (Session 2012–13) 540)
Twelfth Report	EU proposals for reform of the Common Fisheries Policy	HC 1563-I & -II (HC (Session 2012–13) 108)

Oral evidence

Taken before the Environment, Food and Rural Affairs Committee

on Tuesday 12 February 2013

Members present:

Miss Anne McIntosh (Chair)

Richard Drax	Iain McKenzie
George Eustice	Sheryll Murray
Barry Gardiner	Neil Parish
Mrs Mary Glindon	Dan Rogerson

Examination of Witnesses

Witnesses: **Dr Gavin Wilson**, Team Leader, Food and Environment Research Agency, and **Dr Steve Carter**, Senior Scientist, Food and Environment Research Agency, gave evidence.

Q1 Chair: Good afternoon and welcome. Thank you very much indeed for agreeing to participate in our inquiry into bovine tuberculosis vaccination. May I ask, just for the record, if you would please say who you are and where you are from? I will ask Dr Wilson to start.
Dr Wilson: I am Gavin Wilson. I am a wildlife biologist. I am Team Leader of the research team at Woodchester Park Outstation, which is part of the Food and Environment Research Agency's wildlife programme. The team does a range of research, primarily funded by Defra, on issues such as badger vaccination, farm biosecurity and primary research on badgers and badger ecology.
Dr Carter: My name is Steve Carter. I am Senior Scientist at the Food and Environment Research Agency. My main area of work is in the research and development of TB vaccines for badgers. I have worked on both the injectable and, now, on oral vaccine.

Q2 Chair: Thank you. I should declare that I have the headquarters of FERA at Sand Hutton in my constituency. I am extremely proud of the work that you do. May I say at the outset thank you for accommodating the hastily rearranged change of time owing to the business in the main Chamber? We are extremely grateful for that.
Can I just ask at the outset whether we are the only member state in the European Union that has given badgers protected status?
Dr Wilson: Yes, that is correct.

Q3 Chair: Do you think this has an influence on the number of badgers in the population?
Dr Wilson: That is a very difficult question to answer. We do not have the data to say for sure.

Q4 Chair: When was the last national badger survey called?
Dr Wilson: The last national badger survey—of England, Wales and Scotland at that time—was conducted in the mid-1990s. The fieldwork was carried out from around 1994 to 1996–97. To update the information that came out of that, a similar study is being carried out at the moment and is due to report this summer.

Q5 Chair: Is there any particular reason why, given that the previous national badger survey was 10 years before, there was no badger survey in England, Scotland and Wales between 2004 and 2007?
Dr Wilson: Primarily, there was no funding for it. There was no particular call to repeat it.

Q6 Chair: So there was no funding under the last Administration for a badger survey to take place? As far as you are aware, was there any particular reason why there had not been another 10-year survey?
Dr Wilson: As far as I am aware, there is no particular reason why it did not take place. The original idea behind the national badger survey was to repeat it approximately every 10 years. However, I have no real answer why the question of repeating it did not come up until recently.

Q7 Chair: So the last known figures for the badger population are way out of date.
Dr Wilson: Yes, they are now; that is right.

Q8 Iain McKenzie: Going back to the question about Europe, could you expand somewhat on the badger population? Not being a wildlife expert, regarding the spread of badgers across Europe, are they indigenous to several countries? Are they found just in the countries of Northern Europe or are they spread throughout?
Dr Wilson: Yes, the Eurasian badger is widespread throughout Europe. However, for the most part we think they are probably more abundant in this country than in most of the rest of that range. They occur, for example, in southern countries such as Spain, but in generally lower densities than here in most of Spain.

Q9 Chair: Do you think there is a correlation between protected status and the large number of badgers in this country.
Dr Wilson: As I say, I do not know whether we have the data to answer that question.
Chair: Who would have the data to answer that question?

Dr Wilson: It is very hard to correlate what effect the protected status of the badger has on the growth of the badger population. It is very hard to make those correlations.

Q10 Chair: It just seems odd that Ireland and the UK are the only countries in the European Union with a significant problem with bovine TB and that we are the only countries in the European Union that give them protected status. It would appear that this is a bit of a coincidence.

Dr Wilson: It is hard to say whether that is a coincidence or whether they are linked.

Dr Carter: It is probably worth adding that the particular characteristics of their habitat do differ in England from a lot of places in continental Europe—land use certainly does. There is that as well as a longer history of the persecution of badgers across Europe. Neither of us have the data to be able to say what impact protected status has had on badger numbers in this country.

Dr Wilson: In answer to that question, it would be interesting to look at what the population status was before the protection came into place.

Q11 Chair: That, however, was way back in the 1970s. Land-use practice will have changed hugely.

Dr Wilson: Yes, exactly. There are many factors that affect badger population size and density—primarily, habitat, availability of food and badger sett sites. All of these things play into what size of badger population can be supported.

Q12 Chair: Do you think, then, it was a surprise in summer last year when it became clear in areas like Gloucestershire and Somerset that the badger population was as big as it then appeared?

Dr Wilson: We know that badger population densities vary a lot. It is a very patchy population. Although they are widespread across Britain, some areas have very high densities, particularly the south of England and Wales, less so in the eastern parts of the country and the north. Even though the overall density is one thing, in certain pockets there may be quite variable densities compared to somewhere nearby. When our national badger survey reports this summer, we will have a better idea as to whether the figures that were generated in those areas were in line or otherwise with the broader picture.

Q13 Chair: What is the timeframe for those reports?

Dr Wilson: There are two steps to the population assessments that are currently being carried out. There is a large sett survey being carried out at the moment, which will report in July or August this year, I believe. This will give us estimates of the density and abundance of badger social and family groups by region. In parallel with that, we have our research project, which is a Defra-funded project to look at the average size of badger social groups and the variability in size of badger family groups in different landscapes and parts of the country.

The two things together will combine to give us good estimates of badger populations in the different parts of England and Wales. Regarding the social group size project, the main bulk of the field work will take place in this coming winter and will report the following spring. There is a two-stage reporting process.

Q14 Chair: If you do not have that information, you may not be able to answer the next question: what proportion of the badger population is infected with bovine TB? Have you found it varies across the country?

Dr Wilson: Yes, that is right: it is a difficult question to answer. In terms of proportion, if you are talking about the prevalence—the percentage of badgers that are infected with bovine TB—the only information we have is from research projects such as the randomised badger culling trial and some small-scale research projects like the long-term research project at Woodchester Park in Gloucestershire and the badger vaccine study, which was part of the licensing project. We know that it is variable, even between those small-scale studies. We will not be able to say much more about badger populations in other parts of the country where they are not being sampled.

Chair: The incidence of TB in badgers could be significantly greater than we know?

Dr Wilson: Yes; we just do not know. This is a question we will not be able to answer for the parts of the country where we are not sampling badgers.

Dr Carter: To add some numbers to that, in the RBCT the prevalence in the 10 areas in the first year of proactive culling ranged from 1.6% to 37.2%. However, there are different ways of estimating prevalence. In the RBCT, the animals were killed and post-mortems were carried out. Prevalence was estimated through culture analysis, but if you do an advanced post-mortem, you look harder and you find more disease. At Woodchester Park, in the study Gavin has mentioned, the badgers are not killed; we rely on live tests. You get a completely different measure. The actual measures of prevalence on their own are not particularly useful. What is more useful is looking at how they might vary either regionally or over time. They vary both spatially and temporally.

Q15 Sheryll Murray: Could you just tell me how effective an injectable BCG (Bacillus Calmette–Guérin) vaccine is in reducing TB in the badger population?

Dr Carter: Yes, I will take that one. The best direct evidence we have of the protective effect comes from experimental work that was not carried out by ourselves but another Government agency, the Animal Health and Veterinary Laboratories Agency. If you want very detailed information on it, it is best to talk to somebody there. Professor Glyn Hewinson is also due to give evidence.

However, very briefly, in animals that were vaccinated with BCG and then challenged with—exposed to—TB, under those experimental conditions, the study demonstrated the animals' BCG did not prevent them from becoming infected, but it significantly reduced the progression and severity of the disease, which is essentially their overall disease burden or infectiousness. That is the direct evidence we have of the protective effect.

Together with colleagues at AHVLA, we also carried out a field study, which was a badger vaccine field study that was primarily designed to assess safety. It was done to gather the safety data required to license BCG. This was done in an area of Gloucestershire, where we looked at a much larger sample of wild badgers. These badgers were not killed and post-mortemed. We relied on the live test to infer their infectious status. The results from this were consistent with a protective effect of BCG in badgers.

We have recently done a more detailed analysis. The first analysis we did has been published and reported. We divided the population into two groups: vaccinate groups and control groups. We tested all the animals when they were first caught, so any animals that were already infected—as indicated by the live test—were omitted from the analysis. At the end of the study, we looked to see how many animals in the two groups went on to test positive to a range of tests.

Q16 Sheryll Murray: What happened to the infected animals that you found?

Dr Carter: Infected animals, if they fell into a vaccinate group, would have still been given the vaccine, because it was a field study where we were looking at the effects of vaccination on a wild population. We did actually try to see if we could get evidence of what happens when you vaccinate an animal that is already infected, but the power was not sufficient to give us any hard and fast figures on that. There was no evidence, however, that vaccinating an animal that is already infected either has a beneficial effect or any negative effect.

Q17 Sheryll Murray: Were those animals then released back?

Dr Carter: Yes. This was a field study; its primary purpose was to generate data to apply for the licence application.

Q18 Sheryll Murray: Why do you not test trapped badgers for TB? Infected animals could then be removed, leaving only uninfected ones to be vaccinated. Why were they released again?

Dr Wilson: You are asking about trapping animals, testing them, establishing their disease status and, if they are uninfected animals, vaccinating and releasing them or, if they test positive, removing them. I assume that is what you are asking.

Sheryll Murray: Yes.

Dr Wilson: That is an intuitively appealing approach, because it sounds like it surgically removes infected badgers and releases the rest. There are challenges around that. There are two areas where it becomes less simple than it sounds on the face of it. One is that it is difficult to catch all the animals. We deploy traps. Badgers are reasonably trappable, but it is hard to catch them all. We will miss some and some of those might be infected animals. There are also limitations around the diagnostic test for TB, particularly ones you can do trap-side in real time. The issue with that is you may get a negative result for a positive animal, wrongly categorise it and then release it.

Q19 Sheryll Murray: In that respect, it is very similar to cattle.

Dr Wilson: The risk in that is that we know—from the randomised badger culling trial experiment—that culling badgers and disrupting what is quite a stable social pattern of badger population may lead to a perturbation or disruption of that population and may actually have negative effects in terms of TB transmission between badgers.

Badgers may move around more because dominant animals may have been removed. They try to re-establish the social structure, potentially exacerbating disease effects rather than having the desired effect. One thing we do not have a lot of information about is when this effect might be triggered—i.e. how many animals would need to be removed before that effect starts to come into play. There are knowledge gaps around that.

Q20 Sheryll Murray: Do you think it is possible to achieve herd immunity and, if you do, what percentage of the badger population would need to be vaccinated? How often and how long would a programme need to last?

Dr Carter: The best field evidence we have of herd immunity comes from the same study I talked about, the field-safety study. It was not designed to measure herd immunity in badgers, but we were able to look for an indirect effect of the vaccine. On the one hand, the study confirmed the results that we saw in the laboratory—or it was at least consistent with the direct protective effect of the vaccine. However, we were also able to look at how likely unvaccinated animals born into vaccinate groups were to test positive for TB using these live tests. In groups where a high proportion of group members had been previously vaccinated, we found that unvaccinated cubs born into those groups were significantly less likely to test positive to a panel of fairly sensitive diagnostic tests. As Gavin said, however, all the live tests have limitations.

We attribute this to herd immunity. There are other potential mechanisms, such as the transfer of antibodies derived from the mother or the transfer of BCG, but we think both of these are unlikely. The most plausible explanation is herd immunity. The cubs were indirectly protected because a higher proportion of the badgers they were coming into contact with over the course of the study had been vaccinated and had at least received some form of protection from the vaccine.

We cannot get a precise figure from that. We cannot say what proportion of the population you would need to vaccinate to achieve herd immunity. It would depend on a whole range of factors: for example, the prevalence of infection in the population, which, as I said at the beginning, varies quite widely from area to area. It would depend on all sorts of other factors, like badger population density and possibly other environmental factors. However, we saw those effects over a period of three years post-vaccination, although we only saw significant effects in the cubs; we did not see a significant effect in adult badgers. That may take longer.

Q21 Sheryll Murray: How similar is the badger BCG vaccine to the human one? With the human one, you do a Heaf test before you carry out the vaccination. Could you just explain to me whether the badger one is similar?
Dr Carter: It is essentially the same vaccine, but it is a much stronger dose. It is 10 times the human dose. I am not sure Heaf tests are even used any more with humans, because they are not very reliable indicators. It is, however, essentially the same vaccine. The main purpose of the field study that we carried out is to demonstrate that the vaccine did not induce any adverse effects in the badgers. We did a range of work to look at that. We observed badgers over a period of 24 hours after they had been vaccinated. We recaptured them a couple of weeks after they had been vaccinated.
We think the vaccine probably works in a very similar way as in humans. BCG in humans is variable in its effectiveness. We expect to see a range of protection with badgers in the field: some animals will be completely protected; some animals will have partial protection, where they still become infected but they are less infectious because their disease progression and severity is reduced; and there will be some animals where the BCG just does not have any effect, particularly animals that are already infected.

Q22 Iain McKenzie: Are some breeds of cattle more susceptible to this disease than others? If they are, has this been factored in to the equation of assessment?
Dr Wilson: I think that question is probably better put to Professor Hewinson, who will be much better placed to answer it.
Chair: We will have them in separately.
Dr Carter: We just work on the badger side; it is complicated enough.

Q23 Richard Drax: Is your area in Gloucestershire large enough to produce the statistical evidence you need? What benefit might have been gained if more areas had been analysed? As I understand it, five were cancelled; there were going to be six.
Dr Wilson: That is right.
Richard Drax: Is your area big enough to get the right evidence and should more areas have been used?
Dr Wilson: The short answer to the first part of your question is, no; it is not large enough in its own right to look at statistical effects of TB on cattle herd breakdown rates.
Yes, the initial plan for the badger vaccine deployment project was for six areas: that area plus another five. It was never set up as a scientific trial. It was originally designed to kick-start an industry in badger vaccination and build the capacity of trained expertise in the country. There is no doubt, however, that if all six areas had been online there would have been more data for us to work with to start looking and addressing questions around what effect this work is having on cattle TB rates.

Q24 Richard Drax: Did you say Gloucestershire was or was not large enough?
Dr Wilson: No, it is not large enough.

Q25 Richard Drax: How large do you think it should be? How large is it? Remind me of the size of it.
Dr Wilson: The Gloucestershire area is about 120 sq km.

Q26 Richard Drax: How large do you need? What would you like it to be?
Dr Wilson: If you wanted to look at the effects of badger vaccination on cattle, you would have a number of areas. You would do a replicated trial. You could do something like the randomised badger culling trial, which comprised 10 treated areas with 10 untreated and matched controls. It is that that gives it statistical rigour.
At the moment, we are not in a position to look at what impacts the badger vaccination work is having on cattle. Given where we are, with piecemeal bits of badger vaccination happening and slowly building up, we are looking at ways of adaptive management, where we look at that data and try to see whether it can be used, as things build up and as time goes on, to look at the statistical effects.

Q27 Richard Drax: Would you have got the statistical results you need quicker if you had had more areas?
Dr Wilson: Yes, with the caveat that it was not designed as a trial to do that. There would have been more replicated large areas of badger vaccination with which to look at that data, so, yes.

Q28 Richard Drax: This is going to take longer and not get the results you want necessarily as quickly as you want them?
Dr Wilson: Yes. It is going to be more difficult from the position we are in now to fill the knowledge gap that we have, which is the effect that badger vaccination has on cattle TB rates.

Q29 Richard Drax: Can we move on to perturbation? I am sure you know what that is. The question is whether there is any evidence that your vaccination programme causes this. If not, might it be because the badgers are used to seeing humans around in the areas that you are testing?
Dr Wilson: Perturbation is disruption because of, say, removing badgers from the population, from an otherwise relatively stable social structure. With vaccination, because we are not removing animals and disrupting what social hierarchies are there, we do not have any evidence of this, and we do not think it has any marked perturbation effect, because we release the animals. The animals are not taken away; they are just vaccinated at the point of capture and then released quickly.
The main reason we think this is because we have a lot of experience, from long-term studies over 30 years, of capturing animals, sampling them for TB to study the epidemiology and then releasing them. In our long-term study in Gloucestershire, the disease picture in the study site has stayed very stable. The disease has stayed in the same places throughout that study site, which suggests that perturbation is not

happening and there is not a general mixing and spreading of the disease.

Q30 Richard Drax: Very briefly, if I may, it is argued that culling causes perturbation. From the work you have done, do you agree with that?
Dr Wilson: The evidence from the randomised badger culling trial was the main reason the increase in cattle TB rates around the areas that were culled was attributed to culling. It was attributed to greater badger movement, the perturbation of the badger population, with ongoing consequences for contact rates and disease transmission between badgers and between badgers and cattle.

Q31 Iain McKenzie: Could you enlighten us as to the cost of vaccination? Could you break it down for us, especially in relation to manpower?
Dr Wilson: I can do that for injectable vaccination. Do you mean around training?
Iain McKenzie: If you could just give us a quick itinerary of what the vaccination costs, followed by training, manpower and trapping, etc.
Dr Wilson: The components of a vaccination programme are an initial survey to find out where badger setts are and where badger activity is, which is where you want to deploy traps. There are some fixed costs. You obviously need to have badger traps and vehicles to take the traps around. There are things around the vaccine itself and vaccine fridges. The vaccine needs to be kept in cold conditions at all times in order to remain viable, so that requires fridges for transport. There are these fixed hardware costs.
The largest part of the cost is the manpower. A badger vaccination round on a farm or something like that would involve a survey, the deployment of the traps—i.e. putting or digging them into place—and then perhaps several days of pre-baiting the traps, which involves repeated visits by staff and operatives going back, with the traps locked open, putting bait in them and getting the badgers used to going in them for food rewards. The final step is to set the traps, go back, check the traps the morning after setting them, vaccinate the animals and release them, and then remove the traps and clean up. That can be a two or three-week programme. Obviously, if you are talking about manpower for that length of time there is clearly a significant cost associated with that.

Q32 Iain McKenzie: Could that cost be reduced if you had voluntary assistance offered?
Dr Wilson: Yes, definitely.

Q33 Iain McKenzie: Would it be acceptable to have voluntary assistance step forward and reduce the cost for the taxpayer—and also for the farmers—to alleviate the biggest cost, which is manpower?
Dr Wilson: Yes, very much so. There are certain parts of the process that have to be carried out by trained and accredited people—i.e. people who have trained and have a licence to set traps and to deploy vaccines. However, there are other parts of that process, such as just transporting traps to places. Perhaps the longest part of the process is repeatedly pre-baiting the traps, which is a fairly straightforward process but is key to catching as many animals as possible for your efforts. You may have to do that for seven or 10 days, but that does not have to be done by an accredited person or an expert. That could be done by volunteers, perhaps, because it is a very straightforward process.

Q34 Iain McKenzie: To continue the theme of cost, I am reading here that 2,500 badgers were vaccinated in 2012. Is that suggesting the vaccination programme could be rolled out to a bigger area? If so, how much do you reckon such a programme would cost?
Dr Wilson: I am not sure quite where that figure comes from. I know that in our study with vaccination—
Dr Carter: It is combined with Wales.
Dr Wilson: I think that may combine the Welsh vaccination programme as well. Presumably, all the badgers that have been vaccinated in England and Wales in this year would perhaps be around that number. I do not know what the total cost of that is. Clearly, one of the major challenges about wider deployment of badger vaccination is around the fact that it is a relatively laborious process. It is fairly involved and has a cost associated with it. There is a challenge there about how we find the resources to do that. When I say resources, I mean both in terms of expertise and finances. There may be cost-sharing models between stakeholders involved in this issue that may be able to fund it.

Q35 Iain McKenzie: You expect to find a number of funding sources to cover vaccination?
Dr Wilson: Yes, that is right.

Q36 Richard Drax: What is the Government doing to assess the impact of BCG on the incidence of TB in cattle? What is being done in that regard?
Dr Wilson: There was a research call in this recent call for research funding to fund a research programme looking at modelling the potential effects—i.e. mathematical predictions of the effects of different badger vaccination deployment strategies and what impact those will have in cattle. That is yet to pick up. The proposals are in and the decisions are still to be made.

Q37 Richard Drax: So no work has been done?
Dr Carter: It is worth clarifying that there is no empirical data on the contribution that vaccinating badgers has on the incidence of TB in cattle. As Gavin said earlier, there is an evidence gap at the moment.

Q38 Richard Drax: It is rather a serious evidence gap, is it not?
Dr Wilson: Yes, it is definitely one of the fundamental knowledge gaps that we have. We have started very preliminarily looking at the possibility, as I mentioned to you before, of recruiting areas in a more standardised way: badger vaccination is being done in a kind of piecemeal way at the moment.

Q39 Richard Drax: Is there a lack of co-ordination, organisation and other things? Are you saying that it is all a bit bitty and a bit piecemeal?

Dr Wilson: I suppose, other than the programme we run in Gloucestershire and the Welsh one, it is not a Government co-ordinated initiative at the moment.

Q40 Richard Drax: Is this because it is early days still? Is there not some concern that people want answers to this? The farming community, the animal conservationists, we all want answers to this. There is a slight urgency to this, is there not?
Dr Wilson: It is early days; that is part of it. Like I say, we are starting a very small-scale initiative to look at the possibility of studying the cattle data.

Q41 Richard Drax: However, a small-scale initiative—as you said earlier to my previous question—is not really big enough to find the answers we need.
Dr Wilson: We will establish, once we have gone through this process, how much badger vaccination we need to have done before we can start looking at whether there are impacts from that.

Q42 Richard Drax: There are a few holes there. Can I move on to the transition from badgers to cattle? Where is this happening most, in your opinion? Where is this transmission taking place? I understand from the evidence that farms have been sampled and what people did not think was happening—badgers literally coming nose to nose with animals—is happening more than farmers thought. Is that right? Where is the biggest proportion of transmission happening, do you think?
Dr Wilson: We do not know where transmission happens. It probably happens in different ways. In some areas one route of transmission is probably more important, compared to another.

Q43 Richard Drax: Yes, but is it buildings? Is it the pasture?
Dr Wilson: Both of those areas are possibilities. In the past, the feeling was that transmission was more likely on pasture, where cattle come into contact with contaminated excreta from badgers at latrines. Equally, however, we now know from research we have carried out in the last few years that badgers readily enter farm buildings.

Q44 Richard Drax: Particularly sick ones, I understand. The research has shown that sick ones, in particular, tend to go into buildings, because food is easier to get and they do not have to wander so far. Is that right?
Dr Wilson: That is right. There is some very small-scale, intensively studied evidence that suggests that infected badgers have slightly different behaviour patterns that may bring them into contact with farm resources more often. It is only on a very small scale. What we do have on a slightly larger scale, however, is the farm biosecurity work that our team has been involved in, which led to a quite extensive study, using surveillance cameras, of how often badgers entered farm buildings.

Q45 Richard Drax: Overall, briefly, you think it is more likely in the pasture than in the buildings?
Dr Wilson: I have no evidence on which to base whether it is more likely in either of those areas; obviously, both places are risk points.
Dr Carter: It is virtually impossible to trace where transmission has actually taken place, but we think that farm buildings represent a high risk area because we know in some circumstances badgers and cattle will come into quite close contact with each other.
Dr Wilson: In our most recent study, 60%—
Chair: We will move on. We are expecting a vote at four, I am afraid.

Q46 Iain McKenzie: On training, how many people are you able to train as vaccinators each year? What are the costs of enrolling them on these courses?
Dr Wilson: The training is built into our vaccination programme at Gloucestershire. We run about five courses a year. On each course we can train about 10 people, so we have a capacity of around 50 at the moment. It is a four-day course. The cost to attend the course is currently £750.

Q47 Iain McKenzie: What does the course have in it? Or, more to the point, what would you say it does not have in it that it should have?
Dr Wilson: The course has an instruction on how the vaccine should be dealt with and handled and the background to the legal responsibilities people have when they are deploying and working with the vaccine. The biggest component of the course is around the field work. People come on the course and get shown how to put traps down and how to assess badger activity and then they go and vaccinate badgers on two or three mornings on the course. It is very much a hands-on course, which is what it has to be in order for them for them to be able to go away and actually do it themselves.

Q48 Iain McKenzie: I am also told that there is funding available from the Government—£250,000. Why are farmers not entitled to that funding that is available from the Government for training?
Dr Wilson: As I understand it, the funding is available to the voluntary and community sectors. That would really be a question for Defra and policy as to why it is directed there. I do not feel well placed to answer that.

Q49 Iain McKenzie: Can you say what the level of co-ordination is between Government and the various NGOs?
Dr Wilson: Again, I do not feel particularly very well placed to answer on their behalf about how much co-ordination there is.

Q50 Iain McKenzie: Are you aware of any?
Dr Wilson: It is early days and, yes, I think it is growing.

Q51 Iain McKenzie: At this moment in time, what does take place?
Dr Wilson: As far as I am aware there have been early discussions about potential stakeholder involvement in this area, but I do not know the details.

Q52 Iain McKenzie: Is this a very early-stage discussion?
Dr Wilson: Yes, very much so. It is worth bearing in mind that the whole thing is at an early stage. The vaccine was licensed in 2010 and therefore is still an embryonic piece of work.

Q53 Sheryll Murray: Could we move onto oral vaccine? What benefits would an oral vaccine have for badgers? What would it offer and what progress has been made towards developing one? I am conscious of time, so if could also ask you to comment on the Ireland trials of an oral vaccine. Do you have regular contact and discussions with your colleagues in Ireland? Why do they appear to be so far ahead of us in this area of research?
Dr Carter: The benefit that we hope it would bring is that a vaccine delivered in an oral bait that can simply be put out at the badger setts would be more practical and cheaper. We do not have any evidence yet that this would be the case because it is in the early stages of research.
I think it is fair to say that there has been a lot of work done. Defra have invested a lot of money in the research into an oral vaccine for badgers, but there are a lot of challenges, partly to do with the vaccine itself being a live vaccine—i.e. it needs to be kept alive in the bait, which requires that you get the formulation right. That particular area is one that the AHVLA are working on. It also has to be demonstrated to be safe and efficacious in the badger and there are whole hurdles of regulatory requirements that need to be overcome to be able to even start the process to get an oral vaccine licensed.
My and FERA's particular involvement in it has been looking at the best way to deploy a vaccine to make it as cost-effective as possible. The two work-streams are working in parallel. Until we have a final product that is ready to take forward to licensing, we cannot answer all of the questions, but over the last three years we have been trialling candidate baits with biomarkers—not baits with vaccine in them—so that we can look at the rates of uptake of those baits in badger populations.

Q54 Sheryll Murray: You have not mentioned your colleagues in Ireland. Is there communication between the two of you and do you share experience?
Dr Carter: Do you mean the field trial where they are trialling vaccine in the field? These are not oral baits, but this is a vaccine delivered orally to badgers in the field. They are also involved in some oral bait work as well, but the two areas are different.
If you mean the field trial, in Ireland they are essentially looking—it is proof of principle, as much as anything—to see how effective a vaccine a delivered in the field would be. They have a field trial where they have delivered vaccine over a large area to some animals; other animals are controls. In that study, I would not say they are further ahead because we have already carried out a field study in England that has demonstrated results consistent with the laboratory work and a consistent protective effect of the vaccine in the field. In Ireland, they have a similar aim. The difference there is that, at the end of the study, the badgers will be killed, so they can do post-mortems on those badgers to get more information on the efficacy of the vaccine.

Q55 Chair: Can I just ask how often you would expect to have to vaccinate a badger?
Dr Carter: The truth is that we do not know how long any protective effect of the vaccine lasts.

Q56 Chair: You do not even have that information?
Dr Carter: No, but we do not really know that in humans either. There is some work going on in Ireland where they are looking at duration of immunity, but in the field study we vaccinated badgers on an annual basis, so the field data that we have of the protective effect is a result of badgers being vaccinated annually and we would recommend annual vaccination, not because badgers need to be revaccinated annually but because there is a fairly high turnover of cubs each year. Each year, you would want to go out and vaccinate the new recruits into the population.

Q57 Chair: Have you had any discussions at all with the people preparing the cattle vaccination to build up a picture of how effective both would be at controlling TB?
Dr Carter: I have not had any conversations with them. Has there been modelling done looking at both?
Dr Wilson: There has not been any that we have been involved in. These considerations are definitely very much still in the early stages.

Q58 Chair: Are you surprised that between 1985–88 and 1994–97 social groups increased by 24% and badger setts increased by 43%? Would you expect a similar rise to have taken place between now and 1988?
Dr Wilson: Given the biology of the badger, such a change in the population is not surprising; it is feasible. However, I have absolutely no idea what to expect of the updated survey and the comparison, whether that was a trend that is ongoing or whether that was a trend that was near the top of its cycle and is coming back down again. We will find out.
Chair: I know that Sheryll Murray would like to come in, but if we are interrupted by the bell we will have to break off.

Q59 Sheryll Murray: I will be very quick, Chair. I notice that in New Zealand such vaccines were deployed successfully to control bovine TB in possums. Have you looked at the New Zealand methods as well and has that helped you in any way?
Dr Carter: That was a field trial; it was a proof-of-principle study to see how effective vaccinating the possums was. It was not done through the delivery of bait. It was done in the same way as in Ireland, where they catch the animal and essentially squirt the vaccine into their mouth. It provided useful information, but we are separately in discussion with researchers in New Zealand on the oral vaccine project.

Q60 Iain McKenzie: Quickly, pricewise, does the oral vaccine cost the same, less or more than the injection?
Dr Carter: We have no idea at this stage, because we do not know what the final bait will be.
Chair: I think that is a "no". Dr Carter, Dr Wilson, thank you very warmly indeed for being so generous with your time and accommodating our delayed start, for which we are very grateful. We are enormously thankful to you. We stand adjourned; we invite the other witnesses to take their place, so that we can recommence as quickly as possible after the division.

Examination of Witnesses

Witnesses: **Professor Trevor Drew**, Lead Scientist for Virology, Animal Health and Veterinary Laboratories Agency, and **Alick Simmons**, Deputy Chief Veterinary Officer, Defra.

Q61 Chair: Good afternoon and welcome. Thank you very much indeed for participating in our thoughts on Schmallenberg. For the record, could you introduce yourselves and give your positions?
Professor Drew: My name is Trevor Drew. I am Head of the Virology Department at the Animal Health and Veterinary Laboratories Agency
Alick Simmons: Good afternoon. My name is Alick Simmons, and I am one of Defra's directors with responsibility for, amongst other things, new and emerging diseases of livestock. I am Deputy Chief Veterinary Officer as well.

Q62 Chair: Thank you. I am most grateful. Obviously, I represent a large sheep-producing constituency, so I am delighted you are here with us. Were you able to quantify the impact on the economy from the outbreak of Schmallenberg virus in the last period?
Alick Simmons: When we were aware that the virus was likely to be coming to Britain, based on modelling information from the near continent, we set up the means to understand the cost to both industry and Government. We have not tried to quantify the total cost to industry. What we have done is understand in general the average impact per affected farm, extrapolate from there and compare it with diseases such as foot rot, lameness in cattle, bovine virus diarrhoea and a number of other endemic diseases to put this into perspective. The conclusion we have reached is that, even if our estimate of the impact—that is, in numbers of affected animals per flock or herd—was at the extreme end of the estimates, the cost to the national herd and flock is still substantially less than the majority of endemic diseases that plague the national flock and national herd.

Q63 Chair: You will be aware that the price for sheep has collapsed; obviously, the loss could be fairly desperate for hill farmers at this time. Professor Drew, you nodded.
Alick Simmons: The price of sheep and lambs has fallen in this spring or late winter. There are a number of factors that influence that. I am not an agricultural economist, but I think oversupply, a need to unload stock from farms where winter feed has started to run out because of the particular poor forage year and a number of other factors have contributed to this. I do not believe that Schmallenberg disease has influenced the price of sheep.

Q64 Chair: How many cases of Schmallenberg have there been so far this year, and how widespread do you believe the disease to be?
Professor Drew: It is important to point out that the monitoring we have been doing of numbers of cases has really been with the objective of tracking the spread of the disease, not as part of any sort of assessment of the prevalence of the disease or the number of cases. That said, we have recorded the total number of holdings as being 1,211. The holdings where there have been malformed foetuses and serology in sheep has been 377. The number of holdings where there have been foetuses, serology and acute disease in cattle is 834 so far.

Q65 Chair: Could there potentially be underreporting of the problem? Should it be made a notifiable disease?
Alick Simmons: I wonder if I could come in here, Chair. Using the term "underreporting" implies that we are seeking to get comprehensive information about the spread of the infection through the national flock and herd. We have not set out to do that. The figures my colleague has just quoted are almost certainly a substantial underestimate of the number of herds and flocks that have been exposed to infection. We know, because of work we did last autumn, that there is evidence of infection in every rural English county. It is almost certain that the number of several hundred farms that we know have been infected—where the virus has been either isolated or there is previous evidence of infection through serology, which is looking for antibodies—is a substantial underestimate. I would emphasise that we have not attempted to quantify the actual prevalence or numbers of affected herds. We did not feel that was appropriate.

Q66 Chair: Is that because of the cost of obtaining the information?
Professor Drew: It is rather more that we did not see there was a particular value to the farmer in actually counting the number of cases. What we do know, both from our own observations but also remembering that the disease was spreading very rapidly in Europe, is that the European message was that in a very short time virtually all cattle and sheep would seroconvert. Certainly, that is the data that is coming out of Europe and our own studies.

Q67 Sheryll Murray: What is the impact of Schmallenberg on non-pregnant adult cattle and sheep? Can it be fatal?
Professor Drew: The studies that have been done—both in observations of field cases and experimental work done by German colleagues—show that in cattle there is some clinical disease. There is a mild fever, which can last about five or six days. In adult cattle, there is a milk drop and there is also diarrhoea. However, the disease is quite transient and the animals do recover both in terms of their health and in terms of their milk yield. In sheep, there have been no clinical signs observed in adults.

Q68 Sheryll Murray: What about deer? Are they affected by Schmallenberg as well?
Professor Drew: Yes, they are. There have been some observations of isolation of the virus from red deer and seroconversion in red deer, fallow deer, sika deer and roe deer.

Q69 Sheryll Murray: Is there any evidence of Schmallenberg affecting species besides ruminants?
Professor Drew: Not in terms of clinical disease, apart from in goats. There has also been seroconversion demonstrated in diverse species such as bison and alpaca even. A part of our work is also monitoring other species for seroconversion as well.

Q70 Richard Drax: What is the impact of Schmallenberg—if I can say that word without stumbling—on non-pregnant adult cattle and sheep? Can it be fatal?
Professor Drew: As I have said, the impact in adult sheep we would regard as minimal, because we have not been able either see any reports of clinical signs from the field; likewise, in experimental infections, there is no apparent clinical disease. Our conclusions from that are that the virus has no observable effect, although the animals do seroconvert. As I have said also, cattle are different. There is a transient illness seen with cattle that will manifest itself both as a slight dip in growth rate, but also, in milking animals, there will be an economic impact in the milk yield as well.

Q71 Richard Drax: Can deer be affected?
Professor Drew: Yes, they can. We assume so. We do not know about the clinical signs in adult deer or whether there is any clinical disease. What we do know is that it is likely that red deer are likely to be more affected than fallow or roe deer. The reason for this is the time of the year when they get pregnant and the fact that fallow deer and roe deer come into season later, over the winter, when the vectors are likely to be very much less. Red deer, however, are much earlier in the season. It is likely that they would be affected more; that is our prediction. This is purely speculation, but we would anticipate that that would be the case.

Q72 Richard Drax: Is there any other evidence at all suggesting that other species besides ruminants are affected by it?
Professor Drew: Where we see a seroconversion, we would anticipate there is always a chance of this, but this is work to be done in the future.

Q73 Mrs Glindon: Are you confident that exposed animals develop immunity and will not suffer any ill effects if exposed to the virus on a subsequent occasion?
Professor Drew: Yes, we do see that animals seroconvert very readily. This means they produce an antibody. We have experimental evidence that animals which undergo this production of antibody are then protected from subsequent infection. This has been shown experimentally and there is also evidence from data coming out of Germany, particularly between the 2011 and 2012 lambing season, that those flocks of sheep that were affected by Schmallenberg in the 2011 season did not have losses in the 2012 season. This is also evidence that animals do seroconvert and are then protected. There is a similar disease that is prevalent in Asia and Australia, which is called Akabane, which is a similar virus. Likewise, there is a similar level of protection afforded by prior exposure to this virus also.

Q74 Mrs Glindon: Do you think that there is evidence that immunity can be passed down?
Professor Drew: We can speculate that. We have not done the experiments to prove that, but we would speculate that the antibody in the milk of the mother would protect the young animal. I would, however, stress that a young sheep, essentially, in terms of its susceptibility to the virus, would be exposed but would probably not show any illness. In a young calf, if it were not protected by a maternal antibody, the most that might happen would be a fever and transient diarrhoea.

Q75 Neil Parish: Last year, we were told there were a few cases of Schmallenberg; that we should not get overly excited about it; it was coming across from the east coast. There were very few actual cattle or sheep in the west country, for instance, which were affected. This year, in early lambing flocks, we have seen quite a lot of infection, and we have seen quite a lot in cattle. It is very important now to know when a vaccine will be available. Are you putting enough resource towards it?
Alick Simmons: The development of vaccines in this case is something for the commercial pharmaceutical companies. We understand that one company has already submitted a dossier for consideration for approval to the Veterinary Medicines Directorate, and there may be more. The reason why I cannot be precise about that is that that is a relationship between the vaccine manufacturers and researchers and the regulator, the Veterinary Medicines Directorate, to which I am not privy. The reason I know about one of them is because it has been mentioned in the press. It is not the role of Defra or other elements of Government to develop a vaccine for this disease.

Q76 Neil Parish: Yes, but with the time it takes to validate it and get it on to the market, are you absolutely certain that it is being validated? It is no

good to wring our hands and say, "This disease will go away." That is what we were doing last year and it has got worse. I accept it is not necessarily Government's responsibility to produce a vaccine, but it is Government and Europe's responsibility to validate one. What is actually happening?

Alick Simmons: As my colleague said when we were talking about TB vaccines a while ago, the process is that the dossier that is submitted by the pharmaceutical company that has developed the vaccine needs to show data to support three tests: quality, safety and efficacy. Provided it can meet those three tests, it will get a licence for when it can be used. The process, as I understand it, is going through. What actual stage it is at is, as I say, commercially confidential and I have no data.

The point it is quite important to emphasise here—and I know it is a quite difficult message to put out—is that the quicker and faster this disease spreads over a larger geographical area, the better it will be, inasmuch that the majority of animals within a given population will be exposed and become immune. Whilst we do not know how long that immunity will last, we know it lasts at least one season and quite possibly may last a number of years. If that is the case then the quicker this spreads through the entire population, subject to geographical constraints, the better, particularly if that spread takes place before animals are pregnant.

The point, as my colleague has just mentioned, regarding animals that are born now out of affected or exposed ewes, young lambs, if they are exposed this summer, before they get pregnant, whilst they are just a matter of weeks old, they will be solidly immune before they go to the ram in the autumn. Therefore, whilst they may well get exposed again, it will not matter because they will be able to fight off the infection.

Q77 Neil Parish: I thought there was now some doubt as to whether immunity is being passed on through the mother to the offspring, those that survive and those that actually get the disease.

Alick Simmons: With ruminants, what you find—I do not think we have the data for this particular disease—is that there is a degree of passive immunity, which is transmitted from the milk to the neonate, the young animal. Provided that is given in the very first few hours of birth, often as little as six hours after birth, circulating antibodies will be passed from the milk, will go into the bloodstream and will protect it for a period of time. Subsequently, when the animal is exposed either through natural infection or artificial stimulation of the immune system through vaccine, as that immunity given by the milk starts to wane, it will be picked up by naturally acquired immunity, which will be more solid.

Q78 Neil Parish: There are flocks that have lost 30% of their lambs. We have quite a lot of dairy herds now that have been quite badly affected, with some heifers never really recovering from the disease. Are you saying that farmers just have to live with it? I am just not convinced that you are taking it seriously enough and encouraging a vaccine to develop, albeit this is not the Government's responsibility. You seem to take it for granted, in saying, "Let this disease go through and all will be well." I am not convinced by this attitude at all.

Alick Simmons: From a policy perspective, we strove from the outset—and I believe we have done this—to understand where the disease was, admittedly not at a herd level but at a wider geographical area, provide as much advice to farmers and private veterinarians as practicable and develop a research portfolio in collaboration with other affected countries in Europe. We have done that.

We provided good, comprehensive information about where the disease has been and we have encouraged farmers, through information we have provided, to seek specific advice in relation to their own flocks and herds to help them address this disease. As I am sure you are all aware, however, against a disease that is transmitted by vectors—that is, by insects, biological transmission of the disease from animal via insect and back to animal—there is little work that can be done in the absence of a vaccine.

Whilst I can understand the frustration that farmers, private veterinarians and this Committee have, it is important to recognise that the process by which a vaccine gets approved is not something on which it is appropriate for someone in my role or a Minster's role to intervene. It is a process that needs to follow a tried, tested and properly legal method, which is open to appropriate scrutiny by the Veterinary Products Committee.

Q79 Neil Parish: I would have more confidence in what you were saying if it was not that last year the whole thing was played down, it was all going to go away and we were told not to worry about it. If the vaccine is available, are you going to do a system like the last Government did with blue tongue, which was to buy up a lot of vaccine to make sure vaccine was available, or are you just going to stay there wringing your hands for a bit longer?

Alick Simmons: I am not aware that any of my team or I, in the number of interviews we did or the articles we published, ever said not to worry about this disease. We have taken it seriously from the outset, and we always said that we expected the affected area to be extended in 2012 and therefore start to show problems at the beginning of this year.

On the point of a vaccine, it is important to draw a distinction between blue tongue and Schmallenberg disease. Blue tongue is a disease that is subject to international and national controls. We are obliged to impose restrictions over affected areas. The economic impact that that was having on farms was primarily because of the restrictions imposed, rather than the disease itself. Therefore, in order to get it out from under that, the previous Government decided to underwrite the purchase of vaccine. There are no plans to underwrite the purchase of vaccine for Schmallenberg disease if and when a vaccine becomes approved.

Q80 Sheryll Murray: Am I to take it, then, that you are going along the lines of Dr Rachael Tarlinton, when she said that it is here to stay because midges

are all over Europe? The virus will settle down to be endemic; when this happens, most of the animals will be infected in their first year of life before they get pregnant. Farmers are going to have to bear the burden of this. Is that what you are saying? Rather than going along the vaccine line, you are expecting farmers to bear the financial burden?
Chair: Professor Drew, we do have more questions on this; please answer briefly.
Professor Drew: In summary, that is the most likely scenario for the simple reason that it is just impossible to control midges across an area the size of Europe. Even if we had some national campaign, it would be quite simple that midges could be blown over. Of course, we cannot control the disease in wild deer. It is likely that your scenario is the correct one.

Q81 Dan Rogerson: On the basis that it is here to stay, do you foresee any trade issues for the United Kingdom as a result of this?
Professor Drew: Yes, there have been a number of countries that have already requested testing for the Schmallenberg virus and antibody to it in the context of trade. This includes animals and trade in semen as well. We have been very active in developing tests and validating them for use with semen. Now we are in a situation where we can provide testing services; these can accompany export samples. We have done this for bovines. We are still working up the sheep semen.

Q82 Dan Rogerson: That is semen and live animals. What about for meat?
Professor Drew: Our assessment is that meat does not constitute a risk.
Dan Rogerson: That is your assessment.
Professor Drew: That is our assessment.

Q83 Dan Rogerson: However, as we have seen in the past, other jurisdictions like to latch onto these things. What should we be doing at the European level, for example, to make sure we have a framework that guarantees that a particular country's industry will not be badly affected?
Professor Drew: That is more a policy question.

Q84 Chair: Before you answer that, if vaccination is explicitly forbidden, is that just for bovine TB? Are we allowed to use the vaccination for Schmallenberg? Would the meat be admitted in circulation?
Alick Simmons: If a vaccine is approved, it will state on the product licence the species for which it could be used and the withdrawal period for meat and milk that is derived from any animals for which the vaccine is given.

Q85 Chair: Mr Rogerson's point is asking what stage we are at with the vaccine now. This is big business in North Yorkshire and other parts of the country as well.
Alick Simmons: Yes, indeed.

Q86 Chair: If we proceed to vaccinate, what reassurance do we have that the meat or the live animal could be exported into the food chain?
Alick Simmons: We need to draw a distinction between the European Union and third countries. The European Union is a highly regulated market, where essentially we reach agreements within the 27 member states. Therefore, any arrangements that would apply would apply to all the other member states. There are no restrictions on the movements of animals in respect of Schmallenberg between member states.
As my colleague was saying, some third countries have imposed restrictions on the movement of live animals out of the UK and some of the other affected countries in Europe to third countries. We are in active negotiation with them. The European Commission has quite rightly concluded, as we have, that we want to try to keep this as low key as possible to ensure that we do not make an industry out of a disease that is of relatively low economic importance, and for which we believe we can provide assurances about any products or live animals that we intend to export between the UK and other countries.

Q87 Chair: I am confused. Earlier, you said it was not of low economic importance; you actually gave the figures and they were quite significant. Now, you are saying you are not expecting it to last very long, but you simply do not know. What reassurance can you give sheep producers who are coming into another season where they might be exposed to this? This is cart and horse again: are we going to proceed to supply the vaccine, even if it is at the farmer's expense? Are we going to negotiate with the European Commission that we are allowed to export the meat into Europe?
Alick Simmons: I do not believe there are ever going to be any restrictions on the meat derived from ruminants between member states in respect of Schmallenberg

Q88 Chair: Are sheep ruminants?
Alick Simmons: Yes.

Q89 Chair: You think it will be all right.
Alick Simmons: I am as confident as I can be. The evidence base will continue to grow, but we know that there are no legitimate reasons for imposing trade restrictions between one country and another in respect of this virus in respect of meat. It is very likely that there are very few, if any, legitimate reasons to impose restrictions on germplasm—that is, embryos and semen—and/or live animals, provided one or two steps are gone through in order to satisfy one or two conditions that might be imposed. However, this is a disease that we believe will, either through vaccination or through natural spread, become less of a problem over time. Already in the areas that have been affected in northern Europe and, to a certain extent, in the south-east of England, the disease is less than it was last year.

Q90 Dan Rogerson: You have covered most of the issues there. I am interested in what is happening at the European level. You said you do not want to escalate it too much so that we inflame the situation and make it more likely that people will latch onto it

as an issue. On the other hand, it has already been present in other EU countries for some time and I understand there is a ban, for example, by the Russian Government. We need to make sure we get this covered and use the collective bargaining of the European Union to make sure that products are not being squeezed out unfairly. Do you think there is enough evidence to allow them to have a robust discussion with other jurisdictions on that?

Alick Simmons: There is enough evidence in respect of meat. There is emerging evidence in respect of semen. We have a little bit of information about the persistence of the virus in semen that my colleague can enlighten you on.

Professor Drew: I would not like to use the word "persistence". At the time there is viremia—in other words, when there is virus circulating in the blood of the animal—there is also virus in the semen of the animal. It seems to be very low. There was a German study that took something like 16 different bulls that had been where there was virus present. They could detect the virus by molecular means. When they inoculated this semen into the skin of an animal, two of six batches were able to be infectious and the animals seroconverted. We do know that there is viable virus in the semen of animals. We must take a precautionary approach, which is simply to test by a very sensitive molecular test to look for the virus. If we do not find the virus, we can be reasonably sure that that semen—

Q91 Dan Rogerson: This would be at the time of infection, when there is an attack, if you like, and that viral level drops?

Professor Drew: Exactly; the virus is only present in the animal for about six days. The animal responds very quickly to it. It is a very transient infection.

Q92 Dan Rogerson: I assume our Government are involved in these discussions to make sure that our meat and animal products can—

Professor Drew: Yes, both in the discussions on my colleague's part but also on the science part, we are collaborating very closely with all our European partners. The EU has given an amount of money to answer a number of very specific scientific questions, which includes the issue of semen. We are working up tests to provide that assurance.

Q93 Barry Gardiner: Mr Simmons, what did your Russian counterpart say to you when you said to him what you told us—namely that the sooner and the faster this virus swept over the farms of Russia, the better it would be for all concerned?

Alick Simmons: Whether the disease transmits to Russia or not, I would not want to predict.

Q94 Barry Gardiner: They are trying to make sure that it does not.

Professor Drew: It has just arrived in Poland.

Alick Simmons: The eastward spread as well as the westerly and northward and southward spread has been very efficient. It is an extremely efficient virus, given the appropriate vector and a sufficient density of livestock. Even if it does spread into Russia by natural means, obviously that would be quite a significant problem for them. However, what I think is very important is, as a third country with whom we trade, we seek to work on the evidence and convince bilaterally. With Russia it does tend to be done bilaterally between the European Commission and the Russian Federal Customs Service and the Customs Union of Belarus, Kazakhstan and Russia.

In general, we reach an agreement between two countries to ensure that we provide evidence-based certification based on the best available evidence. It is for the receiving country and receiving Chief Veterinary Officer to understand that risk and consider whether or not, based on the evidence they we are prepared to give, he is prepared to take that risk, small or whatever else he might assess it to be. The way we do this is by negotiation. We have been very successful in opening up markets to Russia and China based on that over the last two to three years.

Q95 Barry Gardiner: Professor Drew, you described the condition that the animals have, or the loss of condition. Given that this is not a notifiable disease, would you say that it makes sense for a farmer who suspects their cattle have developed Schmallenberg then to get them to abattoir as quickly as possible, because, as day follows day, they will be losing pound for pound, will they not?

Professor Drew: No, I do not agree at all. All the experimental evidence we have had and all the field studies, which have been very carefully monitored by scientists, show that the disease is an acute one and animals recover. In the case of sheep, there are no discernible clinical signs. There are reports, which I have read myself in the lay press, that report more chronic disease and animals that never recover, but I am afraid that I have no scientific evidence that this is due to Schmallenberg.

Q96 Barry Gardiner: Surely, this will depend on the time of year. If you have beef you have raised up, you are getting them ready to go to market and you want to get them off the land this year, this perverse incentive that I talked about would kick in, would it not?

Professor Drew: If you had an animal that had been naive to Schmallenberg its entire adult life and then, just before it was due to go to market, developed diarrhoea and a slight fever, I am not sure that that would actually reduce its meat value significantly.

Alick Simmons: I would emphasise, though, that only clinically healthy animals should be put forward for slaughter for human consumption. Therefore, during the period of time the animal was sick—as my colleague says, that is generally very short—that animal should be given appropriate treatment and only once it recovers should it go forward for slaughter for human consumption.

Q97 Barry Gardiner: You would be confident that no animal currently infected with Schmallenberg—you said it was six days—could actually be presented for slaughter in the UK?

Professor Drew: This is what we would call the acute disease. I do have a certain caution, however, because

of the effects of the virus in the young foetus. We do know that it infects the nervous tissue—the brain and central nervous system—of the animal. We do not know what happens to an animal that might be infected at just about the time it is developing immunity. There is a possibility that you might have a small number of animals that might be infected at that time and not show these gross physical abnormalities that we have all seen. There may, however, still be some residual damage done. We do not know about that, because we would have to make a long-term scientific study. It is planned, but it has not been carried out.

Q98 Barry Gardiner: The European Centre for Disease Prevention and Control suggests that there is a low likelihood of any risk to public health. Can you quantify what that likelihood is?
Professor Drew: There have been three different studies, and the one you cite is just one of them. There have also been other studies done by colleagues in the Netherlands in the context of monitoring veterinarians to do with a completely different disease, but they had the samples. None of these studies have shown any evidence of antibody production as a result of exposure. There certainly must have been plenty of exposure on the part of veterinarians and farmers. There is absolutely no evidence that human beings are infectable with this virus.
Alick Simmons: It is worth pointing out that the Netherlands study did look at farms and farmers on farms which had been quite badly affected

Q99 Barry Gardiner: Sorry, are we talking about normal transmission of the disease from species to species, or are we talking about ingestion?
Alick Simmons: Let us first deal with infection via vectors. It is worth remembering that many of the midges we are dealing with are quite catholic in their tastes.

Q100 Barry Gardiner: I was not worried about the midges; I was worried about eating the meat, rather than the midges.
Alick Simmons: There is no evidence for that. The most likely route of transmission for this disease is by a biting insect. That is the nature of the organism; it lends itself to being transmitted via biting insects, rather than by ingestion.

Q101 Barry Gardiner: There is no compensation to farmers for infection?
Alick Simmons: No.
Chair: Thank you very much indeed. This is a subject to which we will wish to return; but for this afternoon, thank you very much for coming in and accommodating the delay in timing; we are immensely grateful. We will now break into private session, so we end the formal public session.

Tuesday 26 February 2013

Members present:

Miss Anne McIntosh (Chair)

Richard Drax
George Eustice
Mrs Mary Glindon
Neil Parish
Ms Margaret Ritchie

Examination of Witnesses

Witnesses: **Bernard Van Goethem**, Director for Veterinary and International Affairs, DG Health and Consumers, **Francisco Reviriego**, Head of Sector, Disease Control and Identification in Unit SANCO/G2 Animal Health, **Koen Van Dyck**, Head of Unit SANCO/G4 Food, Alert System and Training, and **Jacqueline Minor**, Head of the Commission Representation in London, gave evidence.

Q102 Chair: Good afternoon and welcome to our witnesses. Just for the sake of the record, could you individually introduce yourselves, starting with Mr Van Goethem, just saying who you are and the position you hold, if you would. Or if we start on the right, Mr Reviriego? Espanol? Okay. *Encantada de encontrarte*. If you would like to introduce yourself and give your position, we will move along that way.
Francisco Reviriego: Thank you; it is a pleasure for me. My name is Francisco Reviriego and I work in the Directorate of Mr Van Goethem. I am Head of Disease Control and Identification.
Bernard Van Goethem: My name is Bernard Van Goethem, and I am Director in the Commission in charge of veterinary and international affairs.
Jacqueline Minor: Good afternoon. I am Jacqueline Minor. I am Head of the Commission's Representation Office in London.
Koen Van Dyck: Good afternoon, my name is Koen Van Dyck. I am working in the Directorate of Bernard Van Goethem, and I am the Head of the Food and Feed Hygiene Unit.

Q103 Chair: Thank you. We are immensely grateful to you for being here this afternoon, and we apologise for the delay. Obviously our role is as legislators as well as taking evidence, so we are very grateful to you for your patience. I wonder if we could set the scene at the outset: how many other member states experience bovine tuberculosis to anything like the extent that we have experienced?
Bernard Van Goethem: I wanted to start with that and I have brought with me some maps of Europe with the prevalence of TB in Europe. I think it will be useful for the Members to see a bit and to have an overview of the situation in Europe.
Chair: Do continue.
Bernard Van Goethem: If you see the map of Europe, and I include all the member states, the situation is different between what we call the old member states and the new member states. You can still see that the vast majority of the European Union is on the map in green, which means officially free of tuberculosis, which is the highest status that is defined in the legislation of the European Union.
You have some countries like Spain, Portugal and the south of Italy, and then on the right side Hungary, Romania, Bulgaria and Greece, which have a less high status. Then you have the spot on the island, the southern part of GB, and the island of Ireland, which has the worst status in Europe. It is not the best situation. You see Scotland on the northern part, which has gained the status of officially free of tuberculosis, if I remember, two years ago.
We face a situation here that is without precedent in the European Union. That is why over the last three years we have intensified the help from the European Union to that part of the European Union, to try to eradicate tuberculosis. My personal point of view—and this is my personal point of view—is that during and due to the bovine spongiform encephalopathy (BSE) crisis, things have not been implemented properly: the eradication programme, the obligation that the member states reach the status of officially free of tuberculosis.
There is, of course, an incentive in our legislation to obtain this status, because when you obtain this status you can export bovine animals to the continent in a much easier way. Due to the restrictions that were imposed during the BSE crisis, there was less incentive for the farmers to try to gain this status of officially free of tuberculosis. Over the last four years all the stakeholders, by which I mean the industry in the UK, but also the Government, have tried take a grip—excuse my English, it is not my mother tongue, so I am trying to do my best—together to reinstall and put forward and implement rules that would allow them to slowly gain this status again.
For that purpose, the European Commission has adopted and financially supported the eradication programme, which was presented by the UK for the eradication. I recollect that it is the highest financial contribution that the European Commission has put forward to eradicate disease in the European Union. We have a budget for the eradication of animal disease in general that is around €200 million for all diseases over the entire European Union. We are spending this year, and we have spent last year, €31 million to contribute to the eradication of TB in the UK. Financially speaking that is the programme for us that has, at present, the highest priority to help the farmers, but also to allow them to trade more easily and to gain—

Q104 Chair: Okay. We shall open up to questions, if we may. Thank you. Can I just ask: there is a timeframe for the decision to be taken, which we will come on to. If the UK, for example, adopted a cattle

vaccination programme within the EU legislative framework as it currently is, would we be allowed to export a live animal and for that meat to go into the human food chain in the European Union?
Bernard Van Goethem: First, it is clear that the present legislation prohibits the use of the TB vaccination of animals. It is not foreseen in the legislation, because so far the vaccine does not exist. It is not foreseen in the European Union legislation, but also in the World Organisation for Animal Health (OIE) international legislation. There are no rules established, meaning that animals that would be vaccinated would not be allowed for trade. That is absolutely—

Q105 Chair: For trade? You see, we are in this Catch-22: you wish us to eradicate bovine TV from our herd; we wish to eradicate bovine TV from our herd. You will remember *Catch-22*, the film that was going round in perpetual circles. We are there now. We need your permission to vaccinate, or we could vaccinate cattle that are only destined for the UK market. You would have no problem with that, because there would be no circulation of the meat in the EU trade. Mr Reviriego, do you want to comment?
Bernard Van Goethem: The vaccination of cattle is, as I said, not foreseen in the legislation and therefore is not allowed. Of course, research has to go on; field trials have to be performed. There is the flexibility to foresee in a programme, and that is what the Ministry in the UK is doing at present, reflecting on a programme to see the efficacy of the vaccine, which is claimed to be efficient.

Q106 Chair: You are not saying that we cannot vaccinate; you are saying that we need to set the parameters for the—
Bernard Van Goethem: I say it is prohibited by EU legislation, but the research has to go on.

Q107 Chair: Is the current legislation there to prevent the spread of disease in cattle or is it to prevent any threat of TB passing to humans? What is the purpose of the current legislation?
Bernard Van Goethem: The international rules foresee that, not only from an animal health point of view but also from a public health point of view, to protect also humans from tuberculosis, you have to reach the status of officially free country or region of tuberculosis.

Q108 Chair: Right. How do you think we can reach the officially free status if we do not vaccinate?
Bernard Van Goethem: Research for a vaccine started in UK some years ago; it might—I insist, it might—be a tool to help eradicate tuberculosis. All the other member states, all the countries around the world, have been able so far to eradicate TB; I do not think in one or two years, it takes five to 10 years. We have had the experience now of the new member states which, when they entered the European Union, had the status that was not as good as the rest of the European Union. It took them five to 10 years to reach the level of officially free of tuberculosis, and that was without the use of a vaccine. For us, the vaccine might be a tool that might help to eradicate TB, but there are basic rules, which are and have been implemented all around the world for decades, which allow the eradication of tuberculosis.

Q109 Chair: Is Britain the only country that has given protected status to badgers in the European Union? Is that the case?
Bernard Van Goethem: I do not know. It might be, but badgers also exist on the continent. There are other livestock, wildlife or other species that are also contributing to the spread of TB on the continent that are not badgers. The wildlife is part of the problem, but it is not the only problem, far from that, and that needs to be highlighted. Sorry for my English again.
Chair: You are very welcome. We could continue in French, but I do not think it would be permitted.

Q110 Richard Drax: Certainly not if I was speaking it, sadly. Has the UK Government applied for a derogation to enable it to conduct field trials of the cattle vaccine and Differentiating Infected from Vaccinated Animals (DIVA) test?
Bernard Van Goethem: There has been formal contact at the highest level between the Secretary of State and Commissioner Borg and our previous commissioner, to explain. That was made clear in the letter that the Commissioner signed to Mr Paterson, which I think you have, explaining how the system would work.[1] At present, as far as I know, they are in contact with my staff to prepare a programme, a large-scale field trial, which would be discussed with us to try and see on a large-scale format if this vaccine would work or not, if you are referring to the vaccination.

Q111 Richard Drax: How long do you think all this might take before it has all got the go-ahead? There are talks going on now?
Bernard Van Goethem: Yes, yes. There are reflections going on—

Q112 Richard Drax: When will the talking stop and the action start?
Bernard Van Goethem: There has been a meeting in Cardiff in December of last year, where all that was also discussed between our officials and the officials of the Ministry, to see how to put forward a programme with all the guarantees necessary to avoid those animals being considered any danger for the others.

Q113 Richard Drax: I understand. When do you think it is likely the talking will stop and the action will start?
Bernard Van Goethem: I understand, but it is not in our hands. It is up to the UK Ministry to come forward with a programme. I understood that they are working very intensively on it as we speak. I understand also, from seeing in scientific papers, that field trials are being performed as we speak outside the European Union by a researcher from the UK.

[1] Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/183229/bovinetb-letter-paterson.pdf

Q114 Richard Drax: Would field trials in countries outside the EU be an idea?
Bernard Van Goethem: Any data that would substantiate the efficacy and the efficiency of a vaccine would be taken into account for upholding the vaccine.

Q115 Chair: Could you explain to the Committee about these field trials? Are you familiar with the results of the field trials?
Bernard Van Goethem: The idea was discussed, and now it is to elaborate and to put in place all the barriers, the framework to be able to implement it—

Q116 Richard Drax: There is no action yet, is there?
Bernard Van Goethem: As far as I know, no.
Richard Drax: A lot of talk.

Q117 Chair: Is the purpose of the field trial to establish a vaccine that will differentiate in the animal, between an animal that has been vaccinated and an animal that is infected?
Bernard Van Goethem: That is one of the data which is needed from the field trial, but there are a lot of other data. Is the vaccine efficient?

Q118 Chair: Is it not quite important to proceed with these field trials?
Bernard Van Goethem: As far as I know we do not have data proving that the vaccine is efficient.

Q119 Chair: Are you saying there is no political will?
Bernard Van Goethem: No, not at all; not at all. I am saying that to be able to efficiently start a vaccination campaign—leaving the legislation aside; purely from a scientific point of view—before starting to use a vaccine you have to ensure that the vaccine is efficient.

Q120 Chair: How do you know if you have not used it?
Bernard Van Goethem: Exactly. That is why field trials are ongoing outside the European Union, but those are not the only data that we need from the field trials. You mentioned the DIVA strategy, which is also very important. At present there is nowhere in the world where you could start the vaccination campaign without being able to differentiate the vaccinated animals from the non-vaccinated animals, but you have a lot of other data which are important: is the live vaccine strain that you are injecting in the animal shed by the milk? Is it infectious for humans? There are a lot of data that are needed to ensure that the vaccine is efficient and safe, and then you get the authorisation to use it.
There is another important idea that also came out. The first time it came into the public arena was during the foot and mouth disease (FMD) crisis in 2001, and a bit later in 2007: is the public ready to accept vaccinated meat? We know the debate, which was ongoing at the time in Europe, about allowing vaccinated meat to be put on the market, especially in that case where the agent is not purely an animal disease, like foot and mouth disease in the past, but is also an agent that can constitute a public health risk.

Q121 Chair: Can I just put to you the question I asked a little earlier? Under the current legislation, could a farmer vaccinate his animal in the UK now?
Bernard Van Goethem: No. There is no vaccine approved, so it is prohibited.

Q122 Neil Parish: Good afternoon, Bernard. The Commission has provided a tentative timetable for the use of a cattle vaccine, which is 2023: this is a possibility and a potential end point. In 2010 the UK reported that a vaccine might be available for use by 2015. Why is there such a marked difference between where the UK may be and where the European Commission is on the timescale, or do you not believe there is a vaccine available yet?
Bernard Van Goethem: As you mentioned, 2023 is the end of the process. You have seen the timetable in the letter of the Commissioner; there are various steps that are needed to arrive to something that is at present a hypothesis. The first, important part is the two first years, where, as is mentioned in the annexe of the letter, we need a large-scale trial under EU field conditions to see if the vaccine is efficient. If that is the case—

Q123 Chair: That is wonderful and we would all like to do that, so what is preventing it from going ahead?
Neil Parish: We have not had the trial of it yet.
Bernard Van Goethem: We are awaiting the results of the trial.

Q124 Chair: Why can we not have the field trial now? This is what we cannot understand; why can we not have the field trial now?
Bernard Van Goethem: As I said earlier, the UK is now putting on paper a programme, a large-scale field trial, which would give us and the scientific community the data necessary to evaluate the efficiency and the efficacy of the vaccine.

Q125 Chair: Could you just be clear what the criteria are to permit that trial to go ahead, because the annexe does not say anything particularly. The annexe in the letter from Mr Borg, of 14 January, does not actually specify the criteria.
Bernard Van Goethem: I agree, but in the letter itself, in the fourth paragraph of the second page, you have as an example a list of data, of gaps that need to be filled before vaccination could take place. I can mention the performance of the vaccine and the level and duration of the protection. If your vaccination only protects for one year it is a never-ending story: you have protection from disease or infection, meaning if the animal is vaccinated and then infected maybe it would not develop the disease, but it would still be infected. Those are parameters that could be even worse, because then you have vaccinated animals and you do not see it. A lot of data are needed before the vaccine is put on the market. They are all listed in that letter.

Q126 Neil Parish: Can I press you on the timescale? What is your view currently of the vaccines that are out there? I think it has been reported that they are only 65% accurate, or whatever. Is that your view as the European Commission currently?
Bernard Van Goethem: I have read the same data as you: about 65% protection. I do not know if it is for an annual vaccination, but if you keep in mind that there is a high prevalence of TB in GB, but still it is not 80%—we are talking about 10%. Keeping in mind that there are ways to eradicate TB, like movement control, clear restriction on the farms—all the usual veterinary measures that you apply when there is a disease—and if the vaccine is only efficient for 65%, the efficacy of that vaccine, if it is to be done each year, is residual, if you compare it to all the other measures, which are efficient and which have proven to be efficient over the last decades.
That is why we urge—and that is also mentioned the Commissioner's letter—that all other measures have to be implemented: control and avoiding a lot of movement between farms. That is a very specific point in GB, where there is a lot of movement of cattle, which is an important way to transmit disease. There is much more movement of cattle in the UK—

Q127 Neil Parish: We take that on board. Today we are particularly interested in the vaccine. If—and it is a very big word, "if"—if there was a vaccine that was available, does the political will exist across member states to enable a fast track for the use of the Bacillus Calmette–Guérin (BCG) vaccine?
Bernard Van Goethem: If, if—
Neil Parish: If—I know it is a big word.
Bernard Van Goethem: If you would use the vaccine once on cattle and you would eradicate the disease, of course there would be incentive for everybody to use it. At present it is not the case, but there is a political will. I repeat, there is a clear political will, not only from the Commission, but also from all the other member states, to help the southern part of GB and Ireland as much as we can to eradicate this disease. As I said, it is the most important financial support we give, and we give it with the support of the other member states. What we give to the UK we do not give to other member states, so it is clear that there is a big political will to help eradicate TB in the UK.

Q128 Neil Parish: I think you have partially answered the next question, and that is what can the UK do to bring the timetable forward, and that is probably have the field trials and make sure that there is a vaccine that works. Is that the case?
Bernard Van Goethem: Yes.
Neil Parish: That is a good short answer. Madam Chairman, thank you.

Q129 Chair: What can the UK do to bring forward the timetable to meet your criteria?
Bernard Van Goethem: As I said, they are working on the programme, which has a lot of implications. You do not design a programme in half an hour. You have to see what you do with the animals. You have to see what you do with the offspring of the animals. You have to see what you do with the meat. You have to control the movement. It is not something you can write on one piece of paper; it will be a heavy programme, which we are helping the UK to draft, and we are waiting to discuss that with them. I can assure you that they are giving the highest priority to that in the veterinary service in the Department for Environment, Food and Rural Affairs (Defra).

Q130 Mrs Glindon: Are you surprised that the UK Government applied for "in principle" marketing authorisation when, in your words, "more studies are required to address food safety concerns"?
Bernard Van Goethem: I did not understand that question, I am sorry.
Mrs Glindon: Do you think the UK Government should not be going for a conditional "in principle" marketing authorisation when there are concerns, as expressed by yourselves, around food safety issues? Do you think we have—I was going to say jumped the gun—you have been pre-empted?
Chair: You talk about the knowledge gaps: are we in the UK getting ahead of ourselves, is what Mrs Glindon is asking, by trying to market before—
Bernard Van Goethem: You need a lot of data before you use a vaccine. It could harm the animal, but it could have a public health impact also. Unless you make a field trial you do not know that. If I take what I said earlier, if you are using a vaccine and you realise only afterwards that when the animal is infected it continues to shed tuberculosis in the milk, it is becoming a real public health risk. Therefore, you need field trials and you need data before you authorise a vaccine, even temporarily.

Q131 Mrs Glindon: You have mentioned some of your concerns earlier, but what are your main concerns, for example, in relation to food safety?
Bernard Van Goethem: As mentioned in the fourth paragraph of the second page of the Commissioner's letter, there are safety issues that need to be addressed before a vaccine can be used. You see possible shedding of the live pathogen by vaccine into animals.

Q132 Chair: We are going to come on to the skin test in a moment, but before we leave the vaccination, I would just like to pin you down, right? It strikes me that you answered in the positive to Mr Parish just now. You answered in the positive. We would like to know, is there anything preventing the UK from conducting field trials now? We would then have the information to answer all your questions, so we are on your side. You want to help us; we want to help you.
Bernard Van Goethem: The UK, as I said, is trying to establish a programme, the field trial, which will be discussed with us, and then they will be able to start if we have ensured that all the safety nets are there to protect spreading of disease or any public health risk.
Chair: Okay, that is progress; that is good.

Q133 Richard Drax: I think what this gentleman is trying to say is the ball is very much in our court.
Bernard Van Goethem: Yes, yes, that is what I was trying to say.
Richard Drax: We have to come up with something and get on with it.

Bernard Van Goethem: Yes. I think this meeting, which was organised in Cardiff in December, which was the meeting with all the stakeholders—I was not there, but Mr Reviriego was there—was the key moment for everybody to realise how important it was to design that programme.

Q134 Chair: I just want to clarify: if you vaccinate the beast, the cow, it will come up as a reactor, right? Jacqueline Minor is nodding. There is a distinct difference and this is quite important for a successful vaccination programme. You have an infected animal, which is clearly infected and will demonstrate all the signs of infection. If you vaccinate the animal then obviously you are putting a little bit of that TB into the animal. What I am trying to be clear is: do we have the scientific knowledge in Europe or anywhere in the world as to how you can distinguish between an animal that reacts to the vaccination, because it has been vaccinated, as opposed to an animal that is infected?
Bernard Van Goethem: For the moment the reply is, no, not at present.

Q135 Chair: Is that also one of the purposes of the field trial?
Bernard Van Goethem: That is also one of the purposes of the field trial, Mr Chair.
Chair: Madam Chair is fine. I do not want to worry colleagues any more than they are already.
Bernard Van Goethem: In the field trial, you take free animals or clearly infected animals, but you also have to take into consideration all the examples I gave about what is happening when you vaccinate. I am not talking about TB, I am talking in general, because we have simply no experience with TB vaccination. Nobody knows what they are talking about. If you vaccinate an animal when he is infected, but when the disease does not yet show, what is happening?

Q136 Chair: Let me take a clean beast: I have a beast in my herd, which I have not, but say I had an animal, which, before we vaccinate shows it is clear of TB. Then you vaccinate and it will show a reaction. I am trying to ask about the purpose of the field trial: are we currently unable to distinguish between a vaccinated animal and an infected animal?
Bernard Van Goethem: Yes, we are not able to at present.

Q137 Chair: Excellent. And that is one of the purposes of the field trials?
Bernard Van Goethem: One of multiple purposes of the field trial.
Chair: We have the letter, and we shall publish it. Thank you.
Bernard Van Goethem: We have published it.

Q138 George Eustice: I want to establish other aspects of the timetable, because the European Commission set out this idea that, of course, it starts with field trials, 2015–16. There are then a number of other stages: 2016–17 is a marketing authorisation procedure; 2017–18 is a debate about veterinary conditions to allow the use of the vaccine; and then finally the practical experience of piloting. Could those be condensed and run in parallel? For instance, I do not see any reason why you could not have a debate about the veterinary conditions under which a vaccine would take place, at precisely the same time that you are going through the marketing authorisation procedure. You could condense some of those things, do all of them, but do them together rather than wait for one stage to be completed before you even begin the next.
Bernard Van Goethem: You can always shrink the timetable, but you have to convince the scientific community and the international community. As I said, it is not only EU legislation; it is also the international legislation, which needs an amendment of the OIE code. That is a quite a lengthy process, which would also give the blessing of the international community to such a programme. If the consequence of something we do in part of the EU is that all our exports will be jeopardised from the entire EU, it would, of course, not be supported by other members of the European Union.

Q139 George Eustice: You do not think it is possible to condense it?
Bernard Van Goethem: It is possible to shrink it, but field trials are field trials.

Q140 George Eustice: What is interesting is it is suggested that the field trials only take about a year, but it is this term "practical experience using the vaccine". That is a full five years; I just wonder whether that could be started earlier and finished much earlier?
Bernard Van Goethem: The first one, which is the most important, is the field trial. One of the purposes of the field trial is to see how the calves of vaccinated animals will react. There are a lot of things: you need to wait for an adult to become pregnant, to have a cow. There are a lot of issues. There are things that take the time that nature requires. The debate between the scientific community and legislation of course could overlap, so it would be possible to shrink a little bit, but not to reduce it by half, that is for sure.

Q141 George Eustice: Could you get it down to, say, five years? Do you think that would be possible if you were to run some of those processes alongside one another?
Chair: Is it open to negotiation?
Bernard Van Goethem: It is not open to negotiation. It was clear in the Commissioner's letter that you have to take it step-by-step: let us first see if vaccination is useful. As Mr Parish said before he left, it might only be useful in only 65% of the cases. That is, as I said earlier, with all the other measures that we know are efficient, that have been applied throughout the world for decades and we know work; 65% in addition to that: the efficiency is residual, marginal.

Q142 George Eustice: If the field trials conclude that it is 95% successful, in that case can we speed up the remaining parts of the timetable?
Bernard Van Goethem: If you find a marvellous vaccine that you inject once, a diseased animal

becomes healthy: fine. Life and biology is sometimes not like that.

Q143 Ms Ritchie: Does the European Commission have any concerns about the accuracy of the current tuberculin skin test, and should the legislation not allow for other tests should more effective ones become available?
Bernard Van Goethem: The efficacy of the tuberculin test to detect non-infected animals is nearly 100%. When the skin test does not react you are nearly sure—

Q144 Chair: Which skin test; both skin tests?
Bernard Van Goethem: The tuberculin test.
Ms Ritchie: We have two skin tests. The primary screening test is a single intradermal comparative cervical tuberculin test. Then there is the second one, the ancillary gamma-interferon diagnostic blood test.
Bernard Van Goethem: The second one you mentioned is not approved at international level; research is ongoing. We have asked the European Food Safety Authority (EFSA) to advise us on the efficiency and efficacy of that skin test, but for the moment it is not approved in the European Union, nor is it recognised at international level. Currently there is only one test that is recognised throughout the world.
With this test, as I said, when the animal does not react you are nearly sure that it is not infected: it is not 100%, I would say it is between 95% and 100% sure that the animal is not infected. The animals that do react are between 50% and 94%, which is called median sensitivity. When the animal is reacting to the intradermic test, you have between 50% and 94% sensitivity of the test. That is why, when it is positive, normally you have to redo a test to see if it is really infected.
Chair: Apparently the second test is used in part of the European Union.
Francisco Reviriego: The gamma-interferon test is allowed to be used now as an ancillary test in conjunction with the normal tuberculin skin test, in order to find more infected animals. It is not a test that is prescribed to be used for trade. We know from the scientific angle that the test works, because EFSA has recently issued a scientific opinion in which the scientists wrote in a clear manner that the test works, but it has not been approved yet in the EU or at international level. We hope that the test can be used soon, but it will still take a while to get it through in Paris, in the World Organisation for Animal Health, and also in Brussels, because we need to change the legislation, and this can only be done by the Council and the European Parliament.

Q145 Chair: Should we not have field trials?
Francisco Reviriego: We already have a good scientific basis for the gamma-interferon test.

Q146 Ms Ritchie: Do you think that there is any possibility that you would want to use or you would want to give legislative effect to other tests in order to make the whole procedure foolproof? I represent a constituency in Northern Ireland where there is a considerable level and quite a lot of TB reactor herds.
Francisco Reviriego: There is nothing that should stop us to move to approve this test.

Q147 Ms Ritchie: That is the second test?
Francisco Reviriego: Yes, the gamma-interferon test; we should.

Q148 Ms Ritchie: What is the timescale for that, if you decide to go down that road?
Francisco Reviriego: As I said, this has to be done in the EU, in the Council and the Parliament, and we are in the middle of the adoption of a new Animal Health Law that will be a legislative framework. Only later on will we review this particular legislation.

Q149 Richard Drax: The movement of cattle has been enhanced in this country earlier this year. Are you satisfied with the new rules and regulations, or could the UK have done more?
Bernard Van Goethem: It is clear in the letter. As I mentioned earlier, in the UK, or in GB at least, there is much more movement of cattle between farms than anywhere else in Europe. There is a habit of moving cattle from one farm to another to sell it to somebody, and all that does largely contribute to spreading tuberculosis. One of the main issues we had, which was presented by the UK in the programme we are approving this year, where we helped with €31 million, is the strengthening of the movement control in farms and between farms in Great Britain.
That is one of the key issues, and we have been reassured at all levels in Defra that stricter movement controls will be applied for the movement of cattle between farms when animals are found positive, before they go to the slaughterhouse, and so on. There are a lot of measures there, which, in my personal point of view, are much more important to implement in the UK than the ideal hypothesis for the future that the vaccine will help.

Q150 Chair: Would you like to share with us what these measures are?
Bernard Van Goethem: They are in the letter.
Chair: We are back to the letter. Right, okay.
Richard Drax: Chairman, we have asked the second question three times already, so I am not going to ask that one again.
Chair: You might have more luck.

Q151 Richard Drax: If a vaccination programme is found that is going to work, you would fast track it as fast as you could, would you not? You would be very supportive of that?
Bernard Van Goethem: Yes.

Q152 Mrs Glindon: What impact will the new European Animal Health Law have on the control and prevention of bovine TB?
Bernard Van Goethem: As Mr Reviriego said earlier, within the Commission we are at the final stage of approving the proposal, which will be transmitted to the European Parliament and the Council. This Animal Health Law will give an overarching

framework on all rules linked to animal health, being for trade of animals, being for eradication of disease, being for animal health rules for products—I mentioned the meat that could be contaminated earlier. It will give an overall framework, which will be then implemented through what we call a delegated or implementing act, which is a new way of building European legislation since Lisbon.

Q153 Chair: At what stage are we consulted? At what stage are national Parliaments consulted?
Bernard Van Goethem: National Parliaments are consulted when the proposal is issued. The head of the organisation knows more about the procedure, but national Parliaments are, indeed, consulted, and can give evidence to the Commission.
Jacqueline Minor: The proposed framework legislation will be available for scrutiny by national Parliaments before it makes its way through the legislative procedure in Europe, so before adoption by the Council of Ministers, including, of course, by the UK Government and by the European Parliament. That is the framework legislation, but, as Bernard said, the framework legislation will then provide for implementing legislation, or secondary legislation.

Q154 Chair: Which instrument is it? A decision, a directive, a regulation?
Jacqueline Minor: The framework will be a proposed regulation.
Bernard Van Goethem: A regulation.
Jacqueline Minor: A regulation, yes.

Q155 Chair: A regulation that is directly applicable?
Jacqueline Minor: Yes.
Bernard Van Goethem: Yes, it is.

Q156 Chair: You are saying, Jacqueline Minor, that it will come to us, or come to the home Government?
Jacqueline Minor: All proposed Commission legislation is sent to national Parliaments now, under the Lisbon Treaty, for consideration. National Parliaments are invited to issue an opinion, which is then taken into consideration by the Commission. In addition, of course, I presume that the work of this Committee will inform the positions adopted by the UK Government in the Council of Ministers as the legislation is discussed and debated. The regulation will have to be approved by a qualified majority of member states.

Q157 Chair: Just remind me, because if it is a directive it can be implemented and transposed into national legislation. If it is a regulation it has to be directly applicable as it is. Therefore a Parliament or a national Government can vote against, but cannot amend. Is it normal to use a regulation as opposed to a directive for this type of legislation? Mr Reviriego is smiling.
Bernard Van Goethem: It will be a framework. All the real substance will be done through an implementing or delegated Act, which are not necessarily regulations. If it is a delegated Act the European Parliament has the right of veto. If it is an implementing Act the UK Government, in the form of the Committee which is taking place in Brussels, will vote with the voting right, which is applicable—

Q158 Chair: It is potentially going to be adopted by comitology?
Bernard Van Goethem: No, no. I said the implementing acts. If I—
Chair: Hang on a minute; you cannot have a regulation that is implemented. I thought it was directly applicable?
Jacqueline Minor: The regulation itself will be adopted as primary legislation: adopted in co-decision by the Council and the Parliament.

Q159 Chair: This will have huge implications for our industry. What consultations have there been with the UK industry to date?
Jacqueline Minor: There have been extensive consultations with all stakeholders—including industry and including British industry—prior to preparing this proposal. There is an impact assessment, which will be published alongside the proposal and which will contain a summary of all the consultations that were carried out and the responses to those consultations. That, again, will be available for consideration and scrutiny by this Committee.
To come back to your earlier question, the framework law will be a regulation of the Council and the Parliament. The framework law will then grant the power to take either implementing measures or delegated measures.

Q160 Chair: Who decides?
Jacqueline Minor: There will be a proposal as to which it should be for different types of rules; that will form part of the proposed regulation, but can be amended by the Council and the Parliament as it goes through the legislative procedure. Once the regulation has been agreed by Council and Parliament, those powers will be exercised to put in place detailed measures on a number of important issues.

Q161 Chair: So if after the primary regulation it is delegated legislation, the European Parliament can block it; if it is implemented, the UK Government can block it in—is this the Committee of Experts? So it is comitology?
Jacqueline Minor: These are the new comitology terms under the Lisbon Treaty.

Q162 Chair: Okay. We signed up to this, did we?
Jacqueline Minor: We did.

Q163 Mrs Glindon: The second half of the question is, will this new law bring an opportunity to amend the directives that prevent the vaccination of cattle against bovine TB? What is the timetable for its agreement?
Bernard Van Goethem: The proposal for the Animal Health Law will replace all the existing legislation linked to animal health, so it will repeal something like 60 different legislative Acts that exist at present. It will also repeal the existing directive, which does not allow the use of vaccination, but it will be replaced, as Jacqueline explained, by a new framework. That framework will need to be

implemented, which will be fed by implemented or delegated Acts.

Chair: We are busy trying to fit in with the current legislation, whereas you are busy trying to amend it.

Bernard Van Goethem: We are trying to review all the legislation and make it easier to work with. The timeframe we have for the Animal Health Law is a presentation to the Parliament and the Council before the summer break. I do not expect with the new procedure established by the Lisbon Treaty that the Council and the Parliament will be able to adopt that in less than two years. It will be huge legislation that afterwards, as we said earlier, needs to be completed by an implemented or delegated Act. We have to work and we have to think within the existing legislation.

Jacqueline Minor: There is an important point, which is that the proposal is likely to make it easier to change the rules on vaccination. Currently they would have to be changed by primary legislation, so it would have to be a proposal for a directive of the Council and the Parliament. Within the framework of the new legislation, once adopted, it would be possible to change the rules on vaccination by a delegated measure, which would be much quicker in principle.

Q164 Chair: That is whether it goes under delegated legislation or implemented legislation. That is what they are telling you. Is that the case?

Bernard Van Goethem: Yes.

Chair: Thank you for that. We shall obviously watch that very closely.

Q165 George Eustice: I want to come back to the reasons why the UK and Ireland are specifically affected by this. The incidence, as your presentation at the start showed, is incredibly high here. You have talked about cattle movements being high and things like that, but are there any other reasons beyond that, because it is still such a huge difference?

Bernard Van Goethem: My personal point of view is that, because of the BSE crisis, there have not been the incentives for the farmers to properly apply the rules. They knew that they would not gain anything in terms of exports if they would be officially free or not, because they were blocked for export by the BSE restrictions. For me, that is one of the major issues, or problems, that arose in the past.

Q166 George Eustice: I do not quite understand. Can you just explain that in a bit more detail? I do not quite understand why that has caused—

Bernard Van Goethem: The BSE restriction had an influence on the—

Jacqueline Minor: I think the point that Bernard is trying to make is that to have TB-free official status grants advantages in terms of facilitating trade, but those advantages would in any case have been denied to British farmers because of BSE measures. The incentive to achieving TB-free status was absent for a long period for the United Kingdom, because they would not have been able to benefit from the usual advantages attached to TB-free status.

Q167 George Eustice: You mentioned that other countries had managed to become TB free by pursuing the types of things you talked about, but did they do that from the same starting point that the UK and Ireland were in, or did they do that from a much lower level of incidence?

Bernard Van Goethem: If I go back into the past, there was also high incidence of TB on the continent as well. If you look at the incidence in the UK, it has grown in 10 years. From where you started 10 years ago—I do not know if it is on the map, but we have other graphics here—you see that the incidence has grown over the last 10 or 15 years. The situation was much better at that time. There has also been the influence of the FMD outbreak where you needed to restock, so there was a lot of movement of animals, perpetual and uninterrupted movement of animals between farms, restocking farms. When your farm is infected, only sending one animal to the slaughterhouse, or sending animals to a specific farm where they will continue to grow before sending to slaughter: you miss the movement control on the farm. That is the key issue.

Q168 George Eustice: Has Ireland been affected by all those same things?

Bernard Van Goethem: The situation in Ireland, on the island I mean, is not as bad, as you see on the map, as it is in the—

Q169 George Eustice: No, but it is still pretty bad, is it not, compared with the rest of Europe?

Bernard Van Goethem: If you look on the second map I have distributed, you have 4.3% for Ireland, whereas you average 11.7% for the UK. Keeping in mind that Scotland is free, the prevalence, especially in the south and west part of GB, is really, really high.

Q170 George Eustice: Can we get from this 10% to 0% by changing movement?

Bernard Van Goethem: Yes, by applying all necessary measures that exist to eradicate TB and get the officially free status, yes, you could get to 0%.

Q171 George Eustice: In your conversations with Defra, do they agree with your analysis on that?

Bernard Van Goethem: Yes, of course. That was repeated in the letter you have, and it was acknowledged by Mr Paterson, who replied a couple of days later, saying—

Chair: We have the letter.

Bernard Van Goethem: We are transparent; always transparent.

Q172 Chair: Thank you very much. I would just like to ask very briefly about Schmallenberg virus in sheep. Do you envisage any trade implications for the European Union of this disease?

Bernard Van Goethem: Schmallenberg is a disease which appeared in the Dutch, German and Belgian area one year ago now; it has spread throughout Europe. It is not a disease that deserves international rules. It has some implications for individual farmers, but not for the Union as a whole. If I look at the incidence of the damage it has caused on a large scale—not for individual farmers; I am talking globally—statistics for the first year show 6% of

sheep herds would be affected in one way or another. That might only consist of one newly-born deformed lamb. It can take the proportion of more lambs in the herd.

Q173 Chair: Are you aware that Russia has imposed a ban on sheep coming from the Netherlands, Belgium and Germany?
Bernard Van Goethem: I could stay for a long time making a list of what Russia has banned from the different member states in relation to live animals, animals for slaughter, meat, seeds. They have a long list of restrictions they have imposed over the last six months or one year on the export of various commodities from the European Union. Let us start with live pigs—

Q174 Chair: Time does not permit, but what steps are you taking to ensure that Schmallenberg does not pose a risk to human health, or are you convinced that it does not?
Bernard Van Goethem: As soon as the disease was notified, first by the Dutch authority and then confirmed by the German, we immediately asked the European Food Safety Authority, the European Medicines Agency here in London and the European Centre for Disease Prevention and Control in Stockholm to see if it would pose a public health risk. The reply was clearly that Schmallenberg does not constitute a public health risk.

Q175 Chair: When might a vaccine be available?
Bernard Van Goethem: Research is ongoing. I think that the European Union has financed a programme of up to €3 million for the research of a vaccine. The companies are working on it. My view is that, if the evolution of Schmallenberg is like that of a similar virus existing somewhere else in the world, you will see a first wave, as we saw on the continent last year, and then there will be a global immunity, which will be throughout the livestock in the European Union, and you will not see any disease any more. Personally, I doubt whether, from an economic point of view, the pharmaceutical industry, if it is not easy to develop a vaccine, will want to conduct a lot of research into a vaccine that might not be used a lot.

Q176 Chair: If there was a vaccine and if the animal was vaccinated, would that be allowed to be freely exported to other member states? You are being inconsistent here: why can you vaccinate a sheep and put that into circulation, but you are saying we cannot vaccinate a cow against TB? You have got to be consistent here, surely?
Bernard Van Goethem: I am consistent; I have always been consistent.

Q177 Chair: Is it because Schmallenberg is in Belgium, Germany and the Netherlands, and because bovine TB is in Britain? Tell me that is not the case?
Bernard Van Goethem: Schmallenberg is throughout Europe. We have never even thought that a disease transmitted by a midge could spread so quickly throughout Europe. It is everywhere. It has been made clear by the World Organisation for Animal Health that this disease did not deserve any rules at an international level. Vaccination can be done; vaccines can be produced by industry, approval can be requested, but there will be no restrictions implemented by European rules or by international rules on Schmallenberg: neither the disease nor the vaccination. Despite that, some third countries have taken unilateral action to ban the import of live animals, or products, or semen, from the European Union to those third countries.
Chair: Thank you very much indeed Mr Van Dyck, Madam Minor, Mr Van Goethem, Señor Reviriego; thank you very much indeed for being with us, being so generous with your time, and being so patient with us for the delay earlier. We are immensely grateful to you. I am sure we will see and hear from you again, I hope, on matters of animal health. We are most grateful to you.

Wednesday 27 February 2013

Members present:

Miss Anne McIntosh (Chair)

Richard Drax
George Eustice
Barry Gardiner
Neil Parish
Ms Margaret Ritchie

Examination of Witnesses

Witnesses: **Jackie Atkinson**, Director of Authorisations, and **Anna-Maria Brady**, Head, Biologicals Team, Veterinary Medicines Directorate, gave evidence.

Q178 Chair: Good afternoon and welcome. Thank you both very much indeed for participating in our inquiry into bovine tuberculosis vaccination. Could I ask each of you to introduce yourselves and give your position for the record?

Jackie Atkinson: I am Jackie Atkinson. I am the Director of Authorisations at the Veterinary Medicines Directorate, which is an executive agency of the Department for Envirionment, Food and Rural Affairs (Defra).

Anna-Maria Brady: I am Anna-Maria Brady and I am Head of the Biologicals Team, which is the group that deals with assessing veterinary vaccine applications.

Q179 Chair: Thank you both very much indeed for participating. Can I just ask a general question about the European Commission's approach to vaccination? Do you think the Commission's approach is consistent regarding the bovine TB cattle vaccine and the potential sheep Schmallenberg virus vaccine?

Jackie Atkinson: That is probably going outside the VMD's remit. Our role is in authorising veterinary medicines. In terms of deployment and whether you declare a disease as one that warrants restrictions on vaccinations or warrants trade constraints, that falls outside the VMD's remit.

Q180 Chair: If it is a notifiable disease, would that help expedite a vaccine?

Jackie Atkinson: In terms of the timescales for dealing with an application for a marketing authorisation, there are a number of factors that affect that. Would it be helpful to set the scene a little bit for marketing authorisations and timescales?

Q181 Chair: I will ask the question in a different way. If you take the Schmallenberg vaccine, for example, what does processing an application for marketing authorisation involve?

Jackie Atkinson: I will take you through the steps. The first thing to say is that Schmallenberg is an emerging disease. The type of application that we are dealing with is called a provisional marketing authorisation. This is a UK-based scheme that is intended to allow the company to apply for this type of provisional marketing authorisation, which would allow them to market the product while they continued to generate all the data they would need for a full marketing authorisation.

As has widely been reported and has now been confirmed in a statement, Merck Sharp & Dohme (MSD) submitted a provisional marketing authorisation application to us at the end of August. The first step in the process at VMD is that we go through a process called validation. It is really quite a simple process: we use checklists to do this, and it means looking at the dossier provided on quality, safety and efficacy, and looking to see that there is information in each of the sections provided. We do not make any judgment at that stage about whether the data is adequate; we are just making sure that everything is there that will allow us to proceed with our assessment.

So we did the validation of the MSD application. There were a few things that were missing—for example references; unless we have the references we cannot do the full assessment, so they had to provide those. Then, by the middle of September, their application passed validation. In terms of the next stage in the process, we do an assessment. We initially assess all the data and we produce an assessment report. In that assessment report we develop a list of questions for the applicant.

We went through that process and sent the questions to the company at the end of November. We then waited for them to compile their responses and put all the information together. We got a response from them at the end of January. To highlight something, during that period of time, a lot of people were asking what VMD were doing. In fact we were waiting. It was very helpful that MSD—because of the interest in this and the problems of some misinformation—allowed us to put out a statement about the timings. This is not something we can usually do because it is commercially confidential.

So we received the responses to the questions at the end of January. We are in the process of assessing those responses now. Can I now talk more generally about the process rather than this specific application?

Q182 Chair: Yes. It would be helpful if you could give the Committee a timeframe that showed whether this was unique, or whether it was fairly typical of how long the process would be to bring an application of marketing authorisation from start to finish.

Jackie Atkinson: In terms of the company bringing forward their application to VMD, they were very quick. The disease was really only recently identified, so they were very quick in bringing forward their application. In part they were able to develop a

vaccine quite quickly because there were a lot of similarities to the blue tongue virus vaccine, so they were able to adapt their technology and respond quickly. The company were very quick in developing a vaccine and pulling the data together. In terms of our processes, we completed our initial assessment about three weeks earlier in the process than we would usually.

Q183 Chair: You have not said how many months.
Jackie Atkinson: It took us 70 days to assess the application from passing validation to reaching our conclusions from the initial assessment and sending questions.

Q184 Chair: Will there have been trials of the vaccine? When it comes to market authorisation, what stage is the vaccine at?
Jackie Atkinson: When the data package was submitted to us, there was supporting data in there. Perhaps Anna-Maria could say a little about the type of data we had at the outset.
Anna-Maria Brady: This was an application for a provisional marketing authorisation. This scheme is there to allow a response to a situation of need. Therefore, the data that would come forward would not be as extensive a data package as one might expect for a full marketing authorisation. There are certain data derogations that are acceptable, given that the product will still be at a stage of incomplete development. It will be very near full development but it will not be at the stage that would normally be acceptable for a marketed vaccine for a full MA package. So in terms of efficacy, one might expect that there would be little or no information on the duration of immunity, because those are longer-term studies. The sort of data package that will be provided is based on laboratory trials, mainly, which can be conducted as proof of principle of the action of the vaccine. There are also unlikely to be field trials for such an application because, again, those are longer-term investigations.

Q185 Chair: I am just a little bit concerned. When it is given marketing authorisation, is it at that stage that the company would proceed to do field trials?
Anna-Maria Brady: We will assess the application in terms of an overall benefit/risk assessment, taking account of all the information that is there. A provisional marketing authorisation is granted for a very limited period of time. There will be conditions put upon it to generate further information by which to upgrade it to a full marketing authorisation.

Q186 Chair: But it will not have been tested on an animal at that stage?
Anna-Maria Brady: Yes, it will have been tested on an animal. It will have met key safety and key efficacy parameters.

Q187 Neil Parish: So this year, have sheep and cattle been given the vaccine to know whether they have then been infected or not? What stage are they at?
Anna-Maria Brady: I do not think we can really go into the details of the data package because that is a commercially confidential issue.

Q188 Chair: We will respect that, but are you able to hazard a guess at a date when the Schmallenberg vaccine might be available?
Jackie Atkinson: I can take you through the next steps in the process and then give you an indication. We have the responses in. They have to go to our Biologicals Committee, which involves people from VMD, other Government departments and also independent experts, if we consider that necessary. That is the step we are at now. We take a decision at that stage about whether we need to go to the Veterinary Products Committee, which is an independent committee, for advice. I would say, with this particular type of vaccine, because it is very similar technology and issues that we have dealt with before, it is unlikely we will go to the Veterinary Products Committee.
The next stage will be sending a final list of questions to the company, and it will depend how long they take to answer those questions as to the timescale for us making a final decision. Whether our decision is positive depends on what they tell us in those answers. I would put it in a more general context and say, with a provisional marketing authorisation application such as this, if the company is responsive, fairly quickly, to dealing with our questions and deals with them appropriately, then 10 months from start to finish is a reasonable timescale. If we think about the period of risk and when we want the vaccination to be used, which will probably be in early autumn—September—whilst I cannot say it will be guaranteed that there is going to be a provisional marketing authorisation at that stage, it could be the case. It depends how the company deals with the questions that we put to them, when we put them to them.
Neil Parish: So it could be this September?
Jackie Atkinson: It could be.

Q189 Chair: But that is for the next stage. That is when it would actually be available for use on animals?
Jackie Atkinson: That would be when we would be able to issue a provisional marketing authorisation. That means that it can be administered and used. The company are required to do further work but it would be used for vaccination.

Q190 Chair: When does the provisional marketing authorisation become a permanent marketing authorisation?
Jackie Atkinson: When we grant the provisional marketing authorisation we tell them exactly what additional data we expect them to generate to get a marketing authorisation. It will depend how long it takes them to do that work to apply to convert it to a full marketing authorisation. There is an example with the blue tongue virus vaccines. They were originally provisional marketing authorisations and in the meantime they have done the work and most are now converted to full marketing authorisations.

Q191 Chair: Is the process and the timescale the same if it is from the public sector, through the Animal Health and Veterinary Laboratories Agency (AHVLA), or from the private sector through a company?
Jackie Atkinson: When we are dealing with an application, the interactions we have with the applicant, the way we approach the assessment, the rigour and robust approach to our assessment is the same whether it is Government or the pharmaceutical industry making the application.

Q192 Ms Ritchie: Do you liaise with potential applicants, such as the AHVLA, before an application is made, in order to ensure that all the relevant information is provided from the outset and the risk of delay is therefore reduced?
Jackie Atkinson: We always encourage applicants, whether they are industry or Government, to come and talk to us in advance. We encourage them to do that as soon as possible because if they come and talk to us just before they submit the application, it is really too late for us to help them get the right data package together. Perhaps my colleague can say a little bit about some of the interactions we had with AHVLA in the lead-up to the cattle Bacillus Calmette–Guérin (BCG) application.
Anna-Maria Brady: Since 2000 we have been involved in meetings with AHVLA and other stakeholders. Between 2000 and 2007 there was a TB Steering Group, which VMD staff took part in, giving regulatory advice. After that we had meetings with AHVLA as the applicant, giving them pre-submission advice both on the badger vaccine and the cattle vaccine. We have had about 25 meetings since, between 2000 and 2011.

Q193 Ms Ritchie: Regarding the BCG cattle vaccine, what further information did you request from AHVLA in November 2012, and why was it not provided at the outset?
Anna-Maria Brady: Actually, we requested the information in June 2012 and they responded in November 2012.

Q194 Ms Ritchie: Can you provide us with an assessment of why they were four to five months in providing that information?
Anna-Maria Brady: In terms of the normal timescale, it is up to the applicant to take the necessary time to answer the questions. We would normally anticipate that six months is a reasonable timescale to respond to questions and they responded within that timeframe.

Q195 Ms Ritchie: Defra announced that the assessment process for BCG cattle vaccine may take up to a year. When do you expect to conclude your work?
Anna-Maria Brady: We are in the final stages of our work. My colleague has already referred to the Veterinary Products Committee and the application has been considered by that committee recently. We are dealing with the final questions from that committee to be sent to the applicant.

Q196 Ms Ritchie: Can you provide an estimated timescale in relation to that?
Anna-Maria Brady: Again, that is going to be up to the applicant, in terms of how they respond to the final questions.

Q197 Ms Ritchie: Will you be pursuing the applicant in that respect?
Anna-Maria Brady: We do pursue applicants. We have to take the practicalities into account around the questions we have asked. We do, in our own organisation, have timescales that we consider acceptable for responding, and we will pursue in those times.

Q198 Neil Parish: In 2010, Defra said they aimed to have a vaccine and differentiating infected from vaccinated animals (DIVA) test licensed by 2012 but they could not be used in the field before 2015 due to the need to change EU legislation. Did the Government consult you on the indicative timetable for the availability of the vaccine and how you update the timescale of the whole thing?
Anna-Maria Brady: I am not entirely sure that that question is within our remit to answer. That is really for the applicant to address in terms of the timescale they have put on the development of the product.

Q199 Neil Parish: You are the licensing authority, are you, or what?
Anna-Maria Brady: Yes.

Q200 Neil Parish: Let me rephrase the question then. Are you able to license a vaccine for use in this country if it is not allowed to be used in the EU?
Jackie Atkinson: The situation at the moment is that European legislation and also UK national legislation says that where there is a prohibition on use, we cannot issue marketing authorisation, nor are we able to issue a provisional marketing authorisation. We have known that, and Defra has known that, so we have always worked on the principle that our assessment will be giving an in-principle decision; we would not actually be able to take it all the way through to the issue stage. My understanding was that the goal was to have VMD's assessment of the data to be able to then talk to the Commission, with that robust assessment of quality, safety and efficacy to take to the Commission as a basis to take forward a discussion in terms of changing the legislation. The recent Commission letter has changed things around from what was expected in terms of the process. The output from the Veterinary Products Committee will be a list of questions. We are going to break the list down to the questions that we would need to issue an in-principle provisional marketing authorisation and the extra data we would expect to see for a full marketing authorisation, and we also plan to include a list of questions that will explain what would be required to get an animal test certificate. To explain, to conduct field trials in the UK it is necessary to have an animal test certificate. We think it will be helpful to set out exactly what will be required in order to proceed with that.

Q201 Neil Parish: When Defra came up with the original idea in 2010, when they said they aimed to have a test licence by 2012, did they get that information from yourselves? Where did this information come from, for them to make the statement?
Jackie Atkinson: Through these regular meetings there will be discussions on usual timescales and what might be reasonable timescales from start to finish in terms of reaching a decision on a particular authorisation. That was only around in-principle decisions, not actually being able to use the vaccine itself.
Anna-Maria Brady: I would point out that we did not actually receive the application until 2012. So in terms of timescale before 2012, that is in the applicant's hands.

Q202 Neil Parish: Defra are now saying that the use of the vaccine is many years away. Where has this change of tack or change of thought come from? Is that an unfair question?
Jackie Atkinson: I think there may be others who are better placed to answer that question than VMD.

Q203 Neil Parish: Would you like to add anything, Ms Brady?
Anna-Maria Brady: I have to say that the development of the vaccine is a complex process.

Q204 Neil Parish: In fairness, it was still a complex process back in 2010. Why is it more complex than it was, or why did they come to that conclusion then?
Anna-Maria Brady: That question has to be directed to the applicant.

Q205 Chair: We are coming on to Europe now, but we learnt yesterday that the Commission is looking at amending animal health legislation and bringing out a framework regulation. Would you, as a licensing authority, be consulted on such proposals as to how they will impact on yourselves and animal health in this country?
Jackie Atkinson: We certainly would not lead on animal health law.

Q206 Chair: No, but would you be consulted?
Jackie Atkinson: Colleagues in Defra would highlight to us specific aspects that could be relevant. So we would have input to that process.
Chair: That is helpful, thank you.

Q207 Barry Gardiner: Are you surprised at the Health Commissioner's request for more studies to address food safety concerns with the BCG cattle vaccine? How would that affect your work?
Jackie Atkinson: In terms of our assessment, we identified issues around consumer safety, relating to both meat and milk. Those questions were put to the applicant. We have seen those responses and formed a view on them. The Veterinary Products Committee has largely supported those views.

Q208 Barry Gardiner: What are the views? Do you want to set them out for the Committee?
Jackie Atkinson: In terms of further information being required, our views are fairly well aligned with the Commission views on where additional data is required. So, from our point of view, further information and assurances on human safety are required.

Q209 Barry Gardiner: How does it affect your work? Have you taken that into account so that it does not affect your work? Or do the Commissioner's requests here impact on you at all?
Jackie Atkinson: The Commission letter is very recent, so we had already formed our views on where the deficiencies were in the data, put them to the company and were already part way through assessing responses when they arose. We read them with interest but they did not change our own views.

Q210 Neil Parish: In their tentative timetable, the European Commission have earmarked 2016–17 for the cattle vaccine to undergo a marketing authorisation procedure. From what we learnt yesterday, it might be further away than that. Why does it take so long and how does that fit in with the work you are trying to do? Also, the Commission seems to want the test to take place outside the EU rather than inside.
Jackie Atkinson: The Commission's timetable in terms of applying for a marketing authorisation envisages the field trials being conducted first. They give an estimate of how long it would take to do those studies. The duration of your study will depend on what you want to prove. A study could take five years but you could design a study for one or two years instead. The Commission timetable was only indicative in that sense.

Q211 Neil Parish: You would not know, with respect, how long the vaccine would work if you did the test over only one or two years. You would not know whether you had to inject each year or what, would you, if you did it only over one or two years?
Jackie Atkinson: In terms of getting a full picture, with a longer study, you may get a longer duration of immunity. Are they not usually proven in the laboratory?
Anna-Maria Brady: It would be a mixture. The field trials that are being alluded to in the discussions that have come forward are extensive field trials that will not just be investigating things like duration of immunity. They will be looking at many aspects in the field that have not been examined yet, because we have only seen laboratory data, effectively.

Q212 Neil Parish: Are you proactive with the EU Commission or not over this issue? Or is it not your role to be proactive?
Jackie Atkinson: On the particular aspect of changing the legislation and deployment of vaccination, that is not an aspect we liaise with the Commission on.
Chair: I think we are moving onto that now, if we may.

Q213 Barry Gardiner: Defra said that they would need advice from the Commission, suggesting that

validation of the DIVA test by the World Organisation for Animal Health (OIE) and an opinion on cattle vaccination from the European Food Safety Authority might be prerequisites for any Commission proposal that would provide a legal basis for cattle vaccination. How might you be involved in the UK efforts to change EU policy regarding a BCG cattle vaccine?

Anna-Maria Brady: Would it be useful if I set the scene on the DIVA aspects that we have seen?

Barry Gardiner: Please, yes.

Chair: I think we understand, but you might just spell out what the DIVA test is. People might think that we are the divas, being the politicians.

Anna-Maria Brady: Basically, the DIVA approach is to differentiate a vaccinated animal from an infected animal. This is a key necessity for a vaccine being used where there is surveillance for a disease and, in the case of cattle tuberculosis, it is a statutory surveillance scheme. So the ability to differentiate an infected from a vaccinated animal is a key need. In terms of this vaccine, they have incorporated that approach within the vaccine because the strain of the vaccine differs slightly from the wild-type infection organism. It is possible to exploit that difference in tests to differentiate.

Part of our remit in examining a vaccine that comes forward with a claim for the DIVA approach is to ensure that any claims that are made around a DIVA approach are scientifically valid; if it is based on the structure of the vaccine strain organism, that that is scientifically valid; and that any test needed for use in the field is a valid test. That is our remit and we have seen that information and made an assessment of it as it stands.

Q214 Barry Gardiner: For example, would you be involved in discussions with the European Food Safety Authority?

Anna-Maria Brady: We would not be directly involved in those discussions, no. This is a national application and therefore we are assessing it on a national basis. Because there is statutory legislation in the UK and Europe underpinning cattle tuberculosis surveillance, that involves the European scenario but that is not within our own remit.

Q215 Barry Gardiner: What do you think the key obstacles to changing EU policy on a BCG vaccine are?

Anna-Maria Brady: I do not think that is for me to comment upon. It is not within the remit of VMD.

Q216 Barry Gardiner: Let me ask you a slightly different question then. If you heard the evidence from yesterday, it was suggested that this is a problem of cattle movements and improved biosecurity, and the vaccine, in their eyes, does not seem to be the nub of this. Do you ever feel that you are labouring in the vineyard in vain?

Anna-Maria Brady: Again, that is not for me to say. As a regulator, my role is to assess applications we receive. We decide whether they are valid or not. If it is a valid application, it arrives in my team, and our role is to assess it against the legislation.

Barry Gardiner: Beautifully deflected.

Q217 Chair: I referred earlier to the animal health framework regulation. We were told by Mr Van Goethem that he thought this would make the application for a vaccine, and for the changing of the law at the European level, easier. Would you have a view about that? No? All right.

Q218 George Eustice: I will bring it back to technical veterinary things. I want to pick up on what Neil was saying earlier because it is relevant to this. You said that you effectively concurred with the EU that there were gaps in the knowledge about the current BCG vaccine. Do you concur about the timescale needed to research those gaps? Is it a decade that we need to research those? Based on your experience looking at other vaccines, such as Schmallenberg where we can do it in 10 months rather than 10 years, could we fill those gaps in, say, two years?

Jackie Atkinson: The point is that the only bit we could comment on is the next stage, which is the identified need for a field trial. I have to say that I took a different message from the Commission yesterday. I actually thought that, by referring to the Commission letter, their expectation is for field trials in the EU. I know they mentioned maybe using studies outside the EU but I think they were really thinking of those as supportive studies. At this stage we can only look to the next step, which will be a field trial in the UK with an Animal Test Certificate. It comes back to the issue of how long that will take. It depends what people want to prove in that study. It is all around the design of that study. That will dictate the length of that study and the subsequent steps. The Commission really need to see that robust evidence. My view is that what they are looking for is that concrete evidence before them, which says, "Yes, this is a safe and effective vaccine". Until they have that, the argument is rather theoretical for them.

Q219 Chair: May I put it another way? The Commission clearly said yesterday that they want to have field trials first then marketing authorisation. What you just told us, in relation to Schmallenberg virus, was that you do it the other way. How are we ever going to get around this circular argument? Does what the Commission is saying invalidate the work you have already done?

Jackie Atkinson: The big difference is that with Schmallenberg there are no restrictions on vaccination. That means that we can issue a provisional marketing authorisation, so people can continue to generate field trial information in the UK while the product is used. The difference with the cattle BCG is this prohibition, which means that, even if we reach the point where we say that we are very happy to issue a provisional marketing authorisation, the law prevents us.

Q220 George Eustice: Where does that come from, though, that prohibition?

Chair: Is it from the Commission?

Jackie Atkinson: The prohibition is in the European legislation.

George Eustice: Why does it not prohibit the Schmallenberg one if there is no more evidence—

Q221 Chair: I put this to you, as I put it to the Commission yesterday. Schmallenberg exists in just about every European country. It started in France and the Benelux countries. For the moment it is primarily the UK and Ireland that have high incidence of bovine TB. Do you see any correlation in the way they are approaching vaccination here?
Anna-Maria Brady: I think you have to take the wider context. Cattle tuberculosis is a zoonotic disease; it can be transmitted to humans. That is partly why there is statutory surveillance.

Q222 Chair: But we do not know about Schmallenberg virus, do we? Is it not a little premature to draw that conclusion?
Anna-Maria Brady: Possibly, but we know what we know. We do not know about Schmallenberg, as you say. It is an emerging disease and the historical scientific context around it is still to be explored, in terms of the longer-term effects. We do know a lot about tuberculosis. That is why there are such strict provisions around tuberculosis. The vaccine we are looking at is a live vaccine for use against a zoonotic disease that has statutory surveillance. The requirements around that vaccine are much greater than around a disease such as Schmallenberg, which is not notifiable and there are no legal restrictions around it.

Q223 Chair: Could you just respond a little more fully to Mr Gardiner's question about the Commission seeming to think that bovine TB was all down to cattle movements?
Anna-Maria Brady: I do not think that is within our remit to comment on, and I would not have the personal knowledge to comment on it.

Q224 George Eustice: I want to come back to the point I raised earlier, because this is a key point. Leaving aside what the European Commission think, you agree with them on what the gaps in the knowledge are, but given that you know what the gaps in the knowledge are, are you not in a position to judge how long a field trial should take? Do you know what type of field trials are necessary to fill those gaps?
Anna-Maria Brady: We know what the gaps are.

Q225 George Eustice: What sort of work is needed to fill those gaps?
Anna-Maria Brady: We are a regulatory authority that assesses the data and the gaps. It is for the applicant to make the decision about how they address those gaps because they have to put the financial resources into addressing those gaps. While we are happy to indicate the knowledge that we need to see, we cannot actually do more than that.

Q226 George Eustice: I understand that, but having seen lots of other vaccines going through, surely you must, just by your experience, have a sense that this is probably a year or two years, rather than 50 years—just a ballpark idea. Is it 10 years? Are the Commission right that it is a decade of work?
Jackie Atkinson: It does come back to the issue of what they want to prove in the study.
George Eustice: You know what they need to prove.
Jackie Atkinson: If they want to prove something simple, and a short duration of immunity, then there will be a shorter study. If they want to demonstrate that it is going to prevent transmission and ultimately allow eradication, taking account of all the different control approaches that we might have in the UK and all the different elements, such as DIVA, it is a much longer study.

Q227 George Eustice: Is the longer study what you want?
Jackie Atkinson: No, I have no views on whether it should be a short or long study. I am entirely neutral on that.

Q228 George Eustice: What are you trying to prove? Are you trying to prove that it is durable or are you trying to prove that it is not a public health—
Anna-Maria Brady: We do not try to prove anything; that is for the applicant to prove.

Q229 Chair: You will be familiar with the letter from Commissioner Borg of 14 January to the Secretary of State, Owen Paterson, on the bovine tuberculosis eradication programme 2013 and the conditions that were set out therein. Would you say that these are reasonable conditions, or are they just pushing the deadline further and further away about when a vaccine might be available, particularly in the annexe where they set down the conditions and talk about "practical experience on the use of the vaccine and DIVA test under the new rules"? Does it seem reasonable to you that it can be met within a five-year timeframe?
Jackie Atkinson: As to the first step requiring EU field trials and whether that is reasonable, yes, we agree that is reasonable and necessary. Is it reasonable in terms of saying 2015–16 may be the duration but then, equally, they talk about two to five years? I am sorry, but it comes back to the question of what you are trying to prove in that period of time. That will affect the length of study. I agree there is a need for field studies, but—

Q230 Chair: I presume that we are trying to prove that the vaccine is efficient?
Jackie Atkinson: When we receive an application, the applicant tells us what they want to put on the labels. For a vaccine it might say, "This will prevent disease". Then they will have to design a study to demonstrate prevention. Equally, they may say it would be enough, and I am not suggesting it is in this case, to have a claim to reduce a particular clinical sign, linked to a particular disease, and then they will design a study to prove that point. It does come back to what they want to prove. If it is ultimately linked to eradication, they want to prove prevention, I would anticipate. That is something that is harder to prove.
Anna-Maria Brady: We also need to bear in mind in this particular case that they have to address the DIVA

aspects in the field as well. So the field trial or field trials will need to look at various aspects of the claims around the vaccine. They will not just be the claims around efficacy per se; they will also be around the DIVA aspects. That is liable to be quite a complex trial.

Q231 Chair: Is it provable?
Anna-Maria Brady: I cannot say.

Q232 Neil Parish: What discussions do you have with your equivalent bodies in other member states about vaccines? On TB vaccine, are you talking to the Republic of Ireland, as they have a particular interest on this? On Schmallenberg, surely there must be work being done all across Europe, because of the amount of Schmallenberg disease across Europe. Do you have any contact with the appropriate bodies in other member states?
Jackie Atkinson: We certainly have a European network where we talk on a regular basis to our counterparts on issues. Taking the Schmallenberg example, it is possible for European applications to go forward, in which case there would be a co-ordinated assessment. Until that happens, there will not be those types of discussions in the context of an application. The scheme that we are operating is entirely a national scheme, so we would not be liaising with them in terms of our assessment and the output from that. Informally, though, we have quite a good network and we would usually get some intelligence and feedback if others are dealing with a similar type of application under a national scheme. I would say, in terms of Schmallenberg, at this stage we are not getting any sense from others that they are doing something similar, but I cannot guarantee that they are not.

Q233 Neil Parish: With Schmallenberg I think they have had it for nearly three years in parts of Europe. Are you surprised that we are now coming forward with a vaccine and it has not come forward from other member states in Europe?
Jackie Atkinson: I do think there is a benefit in the UK legislation because we have provisional marketing authorisations, which is a national scheme. We know that other countries look to us and like that model. In fact, the Commission is revising veterinary medicines legislation and looking at some of the lessons to be learned from that. The parallel is bluetongue virus vaccine. The UK was the first country to have a provisional marketing authorisation to allow the use of the vaccine. When it went through the European procedure, it took considerably longer—some 12 to 18 months later.

Q234 Neil Parish: On the TB vaccine, what is the Republic of Ireland doing? Are they doing work on a vaccine? What is happening there, do you know?
Jackie Atkinson: The application we have is only a national application. It is a national marketing authorisation application. The system is such that it is not possible to put marketing authorisation applications into more than one country without there being a co-ordinated assessment, so we know there cannot be an application in Ireland from the AHVLA because the law would require us to have a joined-up approach to our assessment. It is only a UK marketing authorisation application at this stage.

Q235 Chair: A company wishing to introduce the vaccine and market it across 20-however-many member states would have to go through a similar exercise in every member state. What would the cost be?
Jackie Atkinson: There is quite a complex landscape of different procedures. In the scenario where a vaccine is first authorised only in the UK, and then the company wants to place it in other markets, there is something called a mutual recognition procedure. Other countries look at our assessment report and are asked to recognise our decision. There are also other procedures. One is called a centralised procedure where a single application and all countries work together on a single decision. Then there is something that sits somewhere between the two, where everyone works from the outset together in a co-ordinated way. The cattle BCG and Schmallenberg are UK-only applications at this stage.
Chair: Thank you; that is very helpful.

Q236 Richard Drax: Is that what a limited marketing authorisation is?
Jackie Atkinson: At the top level, there are exceptional marketing authorisations. There are two types of provisional marketing authorisation; one is a stepping stone to a full marketing authorisation. Then you have a limited marketing authorisation, which is the other arm. A limited marketing authorisation is, again, a UK scheme, and the idea is that there are some markets for certain species and disease combinations where a company or Government are never going to go away and do all those studies, because it is unrealistic or impractical. A limited marketing authorisation is recognising that you have a product where the benefits outweigh the risks but people are not being forced to go away and do more studies to convert it to a full authorisation. The badger BCG is a limited marketing authorisation.

Q237 Richard Drax: Presumably, from what you have just said, it is unlikely to go on to receive full marketing authorisation unless it is such a success that everyone wants a piece of it or it gets exported elsewhere, or what?
Jackie Atkinson: Yes, it will be for the holders of the authorisation to decide whether they want it as a full marketing authorisation and whether there is a benefit in doing the additional work required to obtain a full marketing authorisation. From our point of view and from the VMD's point of view, a limited marketing authorisation means that there is an annual reassessment. In that, we look at two things: whether a new product has come along with a full marketing authorisation in the meantime—which is unlikely in this scenario—and what type of side effects have been reported to us from use of the vaccine in the field. That would look at: have there been any problems in badgers as a result of the vaccine and have there been any problems in people as a result of the vaccine? We look at that information and, if that is all okay, it

continues until the next annual reassessment, which we trigger.

Q238 Chair: Is there a normal lifespan for the marketing authorisation, if it is a full marketing authorisation?
Jackie Atkinson: A full marketing authorisation is initially issued for a five-year period, after which it is renewed. Beyond that there are no further renewals unless there are concerns. For a limited marketing authorisation, while we can set a renewal period, we do not have to because we have this annual process, and in the case of the badger authorisation there is no renewal date set for that, so it will just be subject to this annual process.
Chair: May I thank you on behalf of the Committee? You have been extremely helpful and patient with us. Thank you very much for participating and being so generous with your time. We are very grateful. Thank you very much indeed.

Examination of Witnesses

Witnesses: **Carl Padgett**, Past President, British Veterinary Association, and **Neil Blake**, Chairperson for the British Cattle Veterinary Association's Government/Agencies Liaison Working Group, gave evidence.

Q239 Chair: May I welcome you both most warmly? Could I ask you, for the record, just to introduce yourselves and give your positions?
Carl Padgett: I am Carl Padgett, past President of the British Veterinary Association and veterinary practitioner.
Neil Blake: I am Neil Blake, Chairperson of the BCVA Government/Agencies Liaison Working Group, and a farm animal veterinary practitioner in north Devon.
Chair: We are very grateful to you for participating in our inquiry. Before we proceed to questions, we have a little bit of housekeeping. I should state that I was your guest at dinner last night, just so it does not look like we are too cosy.
Neil Parish: I am an associate or an honorary member of the BVA, so I had better declare that.

Q240 Chair: You will have heard the previous speakers and probably followed some of the discussions yesterday. What would you say was the normal timeframe, in your experience, for a vaccine to reach the marketing stage?
Carl Padgett: That is a difficult question to answer for practitioners who are not directly involved with vaccine development. Often we do not know of many vaccines until they get to the near-market point and some of the marketing activity starts occurring from those manufacturers. Also, vaccines vary and diseases vary so there is no stock answer. In general, a rule of thumb I have always had is that bacteria are much larger, bigger, more complex organisms than viruses, and so making a vaccine to find the protective elements of bacteria is a lot harder. That is a general rule of thumb I have used.

Q241 Chair: Do you believe that the European Union has been completely consistent in its approach to vaccines, if you look at the Schmallenberg virus and the bovine TB for cattle vaccine?
Carl Padgett: From the activity I have seen, I have no reason to believe they are being inconsistent.

Q242 Chair: Something you say in your written evidence is that vaccination can play an important role in eradicating TB. However, a policy of vaccination should take place alongside other control measures. Would you just like to elaborate on that a little bit?
Carl Padgett: As with many other diseases, vaccination itself is rarely the pure answer. We have to adopt as many of the relevant control mechanisms as possible in the disease mix that is happening in whatever species are actually harbouring the infection. So vaccination is certainly one tool; it is available and we should learn how best to deploy it, to use it to its best effect. However, it is very rare that that would be the only answer in any disease I am aware of. Other measures need to be employed.
Neil Blake: I would add to that in terms of a similar disease, paratuberculosis in cattle, where you have a vaccine that is potentially available but you would use all other control measures to address the presence of infection before you go down the route of vaccination. It would be an aid to control; it would not be something you rely on. Generally speaking at the moment, with paratuberculosis, you would use a vaccine for damage limitation, rather than as something from which you would expect to achieve control and eradication from a herd.

Q243 Chair: How accurate do you think the current tuberculosis skin test is?
Carl Padgett: We can go from the studies that Defra have the figures for. If we look at sensitivity, spotting those animals that are affected, there is a range of 60% to 80%. The more you undertake the tests—on lots more animals, on a full herd, for example—the sensitivity goes up because the more it is repeated, the more chance there is of finding the infected animal, so sensitivity increases. It is highly specific so you do not get many false positives with that particular diagnostic test.

Q244 Chair: The Commission said yesterday that, in their view, they thought it was 99% effective. You are saying 80% effective.
Carl Padgett: Specificity is 99.9% or greater. That means that, if you took 100 negative animals, 99 of them would come back as truly negative and one false positive might occur, to agree with a 99% figure.

Q245 Chair: Can the result be affected by another disease in the animal or the fact that the animal was pregnant? Would that have an implication for the skin test?

Carl Padgett: A number of infections have been looked at. There is certainly speculation about the role of bovine viral diarrhoea (BVD, which alters the immune status of the herd involved. So, are we getting the same reaction to the skin test when it is effectively an immune reaction that we are testing for? There is some work from the University of Liverpool recently that indicated the role of liver fluke in reducing the sensitivity of the test.

Q246 Chair: Do you think that non-reactive cattle are a source of transmission of TB?
Carl Padgett: With the characteristics of the test we have at the moment, it is highly likely that some herds have infected animals left at the end of the testing procedure, yes. Indeed, some work from Cambridge at the moment is looking at that. They published something saying along of the lines of one in four or five cleared herds may still have infected animals in them.

Q247 Chair: Do you think the skin test should be used in conjunction with other tests, such as the ancillary gamma interferon diagnostic test?
Carl Padgett: I think we have to try to deploy it as best we can within the armoury of other diagnostic tests, yes. One thing we need to remember about the skin test is that it has served worldwide, although in slightly different patterns and protocols for use, as a very good diagnostic and eradication tool. If we look at low-instance areas of the country at the moment, it serves well there in the eradication of infection and the little foci of infection that appear. So it is a very good test that can actually eradicate the disease when we are dealing with the infection in focused elements of individual herds.

Q248 Barry Gardiner: It must be an awful thing to have to tell a farmer that one of their herd has reacted as positive. It can really devastate that farmer's livelihood, can it not?
Neil Blake: Yes, it can. It is a difficult conversation to have every time it happens. Unfortunately, in the last 10 years or so, it is happening with increasing regularity. Yes, it is always a difficult conversation and I suspect Farm Crisis Network, for example, are a lot busier nowadays than they used to be.

Q249 Barry Gardiner: That means that the pressure placed on vets not to report, particularly where the results are borderline, is a real pressure. It is a human pressure.
Neil Blake: With every disease on a farm you are working with farmers to try to alleviate the problems associated with that disease. TB is a statutorily controlled programme. You apply the test diligently and we are required to notify where we discover disease. That is what we endeavour to do. So, irrespective of the difficult conversations we have to have, we are pretty well trained in terms of delivering that bad news.

Q250 Barry Gardiner: You will be aware of the practice on Anglesey last year where they were suspended from testing pending the completion of retraining of the staff, because the audit of their testing had shown that they were not being as rigorous as they ought to have been.
Carl Padgett: I am not aware of the specifics of the case as such, but I understand the generality. Yes, quality assurance of TB testing is a major issue and we have to have measures and procedures in place that ensure the test is being undertaken to the best of the veterinary surgeon's ability to give the best results. We have a population of veterinary surgeons who are no different from any other human beings. Some people unfortunately, as with any system, may cut the odd corner or two, or feel that they have the most expeditious route of delivering the test. We therefore have to have an independent quality control mechanism, developed more robustly and delivered to ensure that veterinary surgeons are testing to the best of their ability. My own belief is that most of them are.

Q251 Barry Gardiner: This is a very sensitive area, and I am trying to ask these questions sensitively because I respect the job that these guys have to do and it is a tough one. Wales has adopted an auditing programme. Should we have an audit of tests in England to ensure there is not an underreporting of TB reactors by vets?
Carl Padgett: We should have an auditing system in place, and indeed we are involved with helping AHVLA develop one that makes sure testing is done properly, rather than for the avoidance of underreporting.

Q252 Ms Ritchie: In your written evidence you state that you do not support the policy of trapping and testing badgers adopted by Northern Ireland. Why is that?
Carl Padgett: We do not support that policy in England and Wales at the moment, rather than not supporting it in Northern Ireland. In England and Wales, the modelling work that was undertaken for the Welsh Assembly Government actually showed that that was one of the worst options. That was largely because the diagnostics for badger-side testing have a low sensitivity of about 50%. So arguably, in simple terms, for every two infected badgers that are trapped and tested, one will be vaccinated and released and one will be culled and removed. So we still have the disturbance in the badger population from that proportion that has been culled. That can create perturbation. What you have actually done is release infected badgers back into that perturbed population. Potentially you could make the perturbation effect worse than removing badgers on a pure culling exercise alone; that is what the modelling showed. The potential difference in Northern Ireland is that the badger population is very different, so actually the modelling might come out with different sums. At the end of the day, it is a modelling exercise.

Q253 Ms Ritchie: I also understand that we are awaiting progress reports from the Department of Agriculture and Rural Development in Northern Ireland. Have you received any such reports as yet?

Carl Padgett: Not as yet, but I was talking with the Chief Veterinary Officer of Northern Ireland just the other week, when I was across in Belfast, loosely about that work. It is still ongoing, as far as I am aware.

Q254 Ms Ritchie: Do you have any idea when it is expected?
Carl Padgett: No.

Q255 Chair: Could I just put to you the number of tests carried out in 2001 and the number of tests carried out in 2011? In 2001 the total number of tests on herds was over 13,000. In 2011 that went up to 76,000. The total number of tests on cattle in 2001 was over 1 million. In 2011, the number of total tests on cattle was over 7 million. You may not be able to answer this, but why do you think there was suddenly a great increase in testing?
Carl Padgett: There are two aspects to that. One is the actual spread of the disease and infection. The infected area is getting bigger so that naturally leads us to move more animals from four-yearly testing to annual testing as infection is found. That means many more tests are undertaken.
The other aspect is that the risk-analysis procedures for actually classifying the herd testing intervals have expanded the annual area somewhat. That is to try to cover some of the concerns the Commission had that maybe we were not testing robustly across a wide enough area often enough, that we had too many four-year testing areas butting up to annual areas. However, the decision made in this country was that it did seem a peculiar thing to do and it would be best for us to make the decision anyway to expand annual testing. That, therefore, has increased the number of tests being done, not just because the disease has spread but purely because a surveillance programme has been rolled out.

Q256 Chair: It has led to a significant number of slaughters. There were 6,000-plus cattle slaughtered in 2001. More than 34,000 cattle were slaughtered in 2011. That will be a direct correlation with what you have suggested.
Carl Padgett: Yes, it would. There is an element of seeming to chase the infection outwards when we apply the Commission directive in terms of eradication to the letter. When we find an infection we move to the next farm along and find it again. So we are following that leading edge. Indeed, one of the focuses at the moment is to try to take a bit of a variation from the traditional way of rolling out surveillance testing, and try to jump in front of that edge.

Q257 Chair: Returning to what you said about the fact that any vaccination should be used alongside other control measures, can you think of any country that has eradicated bovine TB that has not addressed the reservoir in the wildlife?
Carl Padgett: If there has been a significant reservoir in the wildlife that has been maintaining the infection and the risk to cattle—so unlike the spill-over hosts, where the infection will still spill out from the cattle population into another population, but it has no real epidemiological significance back to cattle; it is self-limiting and sorts itself out in that population—countries that have those infections have not necessarily addressed that wildlife host. Where you have a wildlife host that is a maintenance host, and infection is crossing backwards and forwards between the two and it is a significant reservoir, I am not aware of any country that has eradicated the infection without addressing that reservoir.
Chair: That is very helpful, thank you.

Q258 Neil Parish: Good afternoon. In your written evidence you cast doubt on the effectiveness of a badger vaccination policy in areas where TB in badgers is endemic, because the vaccine does not cure an infected badger and it still carries on spreading disease. How do we actually know where these areas are? Do we do testing of the badgers? Do we do enough? Do we know where the real infected areas of badgers are?
Neil Blake: Within AHVLA, certainly with the case of new breakdowns, there is an effort to try to identify the source of the breakdown. It is easier in terms of different spoligotypes, different strains of TB, which are isolated and they can maybe home in and determine whether it is to do with translocation movement of cattle. In terms of the endemic parts of the UK, that is more difficult to determine but the analysis that has come out of recent work associated with the randomised badger culling trial indicates that about half the breakdowns in those areas are attributable to infection from wildlife. Certainly what we see on the ground would support that. It is difficult to get absolute corroborative evidence to state that as a fact but it is certainly what we see on the ground.

Q259 Neil Parish: I take it that the badger carries bovine TB, so therefore, if a cow gets TB, you cannot necessarily tell whether that cow got the TB infection from another cow or whether it got it from a badger. Is there any way of telling that or not?
Neil Blake: Not at that stage, no.

Q260 Neil Parish: If you get a lot of breakdowns in a given area do you then test the badgers? Does Defra test the badgers? Does anybody test the badgers?
Neil Blake: Not that I am aware of. There has been work where you would collect data from road traffic accidents. There is the work associated with the RBCT that was looking at the prevalence of infections in badgers. On an ongoing basis at the moment, my understanding is that it is not widely undertaken.

Q261 Neil Parish: If farmers find infected badgers on their land or badgers that have died and are very emaciated and are likely to have died from TB, are they able to take them anywhere to get them tested?
Neil Blake: There is a system where they can report that. I am not aware of what proportion of those might then get investigated further. That is probably a question for AHVLA, rather than us in the field.

Q262 George Eustice: Before we leave badgers, obviously one of the practicalities is just in trapping

and injecting them, which is itself quite a practical task. There has been previous talk about having some kind of oral vaccine. Is that realistic? Given that we seem to be in never-never land in terms of a vaccine for cattle, is that something that could be done?

Carl Padgett: It is very realistic from the work that is ongoing. I do not know enough of the detail, again, because it is being developed in studies that are similar to the studies for the injectable vaccine. We have had oral vaccines for other diseases but again I go back to the difficulties of bacterial infections. There are challenges with making sure that we can deliver a BCG vaccine in a proper bait that will make sure the correct target animals eat that bait and it is not going out to other species and with whether it is safe for other species. There are other challenges there for an oral vaccine but if they could be met, certainly it would be a much more practical answer.

Q263 George Eustice: Are they easier to meet than a cattle vaccine, in your view?

Carl Padgett: I would not like to say. The challenges are immense on both sides.

Q264 George Eustice: I want to talk about the biosecurity and movement restrictions. The clear message we had from the EU Commission representatives yesterday was very much that the real problem we have here in the UK is that, since bovine spongiform encephalopathy (BSE), there has been less incentive for farmers to take proper care of hygiene issues. Also that, after foot and mouth, the restocking led to large-scale movements of cattle, which was responsible, they said, and the culture we have of moving cattle around to large markets and that kind of thing was the real problem. You said earlier that you cannot deal with this problem just with a vaccine, which I understand. Is it possible to deal with it without a vaccine, just by sorting out these movement restrictions that the Commission said were the real cause?

Carl Padgett: I do not think it is. In the outputs of the Commission and their various visitations over the years, I have yet to be wholly convinced that the Commission fully understands some of the challenges we are up against in this country and in Ireland too, with the picture of TB that we have. I do not buy the BSE story and the foot and mouth story. If we take BSE, there was still an incentive domestically to remain free of TB, to ensure that trading was able to occur and not be locked up. So there is still an incentive there, regardless of the international element of the trade that was stopped at that time. It may be true that resources from AHVLA, Defra—the Ministry of Agriculture, Fisheries and Food at that time—were focused on getting rid of BSE. So maybe a little eye off the ball may have occurred, but not to the extent where we have allowed TB to stretch forever in front of us.

If we take foot and mouth, where testing did pause for a little while, while we were trying to concentrate our resources on getting rid of that disease in 2001, infection was transported with restocking, up to Cumbria for example. But the testing processes put in place immediately after those outbreaks had been found eradicated that infection in those translocated environments. So the testing process works when we have cattle-only breakdowns. What we have in a significant part of this country is a mixed reservoir of infection, with not only cattle but wildlife, which is providing an extra dynamic that testing alone in cattle is struggling to cover.

Q265 George Eustice: So their suggestion that other European countries solved this problem by following certain approaches to movement restrictions does not apply to the same extent, or is there anything further we ought to be doing on that?

Carl Padgett: We can always look at movement restrictions. We have to be as proportionate as possible. We could put in sufficient movement restrictions to kill the industry. What would that do for us in terms of having a future cattle industry if we just stopped all cattle movement tomorrow? It certainly would not stop all TB transmission tomorrow because we would still have the wildlife element coming in from outside. We can go all the way down that scale. We have to be proportionate. Whenever we identify an area of risk or behaviours that are risky, we need to try to challenge those behaviours and try to stop those movements that are occurring that are most risky. I will let Neil pick up on risk-based trading possibilities in a second. We do have to look at movements but, again, it is not the whole story.

Neil Blake: I was just trying to remember my thoughts on that as it was coming up. There are several aspects to your question. One is the reminder that, in the absence of wildlife reservoir infection, in the parts of the UK where we do not have that, we are able to get rid of TB with existing diagnostics. As far as disease translocation is concerned—the movement of disease with the movement of cattle—ever since 2006 we have enhanced the cattle controls. Pre-movement testing is there as an additional safeguard against that risk. It is not 100%, of course it is not, but it is an additional safeguard against translocating disease from one part of the country to another, so there is a lot of tightening on the cattle controls that have been put in place in the last six or seven years. Not all of those have been popular but most of them you cannot argue with from a disease perspective.

Alongside that, with risk-based trading disease transmission, TB is not unique in that regard. With all endemic disease there is merit in trying to reduce the risk of transmitting that disease from one herd to another via the movement of cattle. I would not view TB in isolation. I do not think we should ever view TB in isolation in that regard. To an extent, routine surveillance is probably better for TB than for some of the other diseases that are out there, because we do have pre-movement testing as a prerequisite for moving cattle from endemic areas.

Q266 George Eustice: Are you satisfied with the speed at which the AHVLA turn around test results? Does the Government have sufficiently robust data management to monitor the spread of the disease?

Neil Blake: Do you meant in terms of the general statistics or the specific breakdowns?
George Eustice: Basically, the data management system, so they know where problems are and where they have originated.
Neil Blake: From a practitioner's perspective, there are problems with the flow of information and co-ordination of the programme. That is a belief that I have and I think it is a belief that is shared by many. We could improve. The passage of information could be improved on the current state of play. A lot of frustration for a lot of us is that we do not have consistent linking between AHVLA, ourselves on the ground and the farmer. It still is really quite a fragmented process. You do get some information in terms of the confirmation of disease on an individual farm. There is obviously a time lag. It is fairly straightforward if they find visible lesions, and there is a time lag in trying to culture that bacteria. On the bigger picture regionally and nationally, I would say there is room for improvement in terms of that passage of information and the ability to involve all in the process of TB control.

Q267 George Eustice: You mean by just making it much more available about which farms are infected?
Neil Blake: I think in greater involvement of local practitioners who have a real handle of what is going on on the ground. Wales is probably the best example of what could potentially evolve. They have much better and much more efficient use of local vets on the ground, in terms of biosecurity advice, not just in endemic areas but also in TB-free areas. You are trying to get in ahead of the problem again. You are trying to offer advice that reduces the risk of disease spreading and also advice to try to limit the damage of ongoing transmission of disease on the farm. For both of those elements there are, in my mind, very positive movements in Wales where they are looking to explore and make greater use of the vets on the ground.

Q268 Chair: I should know the answer to this but is the six-day rule part of the control restrictions for this or for BSE and foot and mouth? I mean the six-day rule that, if you take cattle through a red market, you either have to send them to slaughter or you take them home and you cannot move anything for six days.
Carl Padgett: It is effectively in place for hyperinfectious conditions such as foot and mouth. So it comes from the foot and mouth controls.

Q269 Chair: I know my farmers would like to see it lifted but do you think it is necessary that we keep it?
Carl Padgett: I think, with hindsight, if we had another outbreak of foot and mouth as explosive as the last one in 2001, and we had only just got rid of the six-day rule, we would rue the day we got rid of the six-day rule.

Q270 Chair: Could we not suspend it and then re-impose it?
Carl Padgett: I would answer that by asking how we would suspend it because we do not know when that incursion is going to happen.

Chair: I will let you loose on my farmers.

Q271 Ms Ritchie: Are some breeds of cattle more susceptible to bovine TB than others? If so, might this be down to habitat or genetics?
Carl Padgett: That is a very complex area and I am not a geneticist who has studied that in depth. There have been suggestions that dairy cattle breeds, for example, may be more susceptible, or lines within dairy cattle. When you look at all the different management practices in farms it is quite hard to tease it out and to actually apply any benefits from that across a whole industry to improve some degree of genetic resistance; I am not sure how practical that would be. So yes, academically, it looks like there is an indicator that there is some genetic resistance, but how practical it would be to utilise I am not sure.

Q272 Ms Ritchie: Have you seen any particular research in this area? I know you say you are not a geneticist but have you seen research and an evidence base that would suggest either direction?
Carl Padgett: I have been made aware of one output from the Roslin Institute, which suggested somewhere along the lines of 18% heritability in dairy cattle.

Q273 Neil Parish: I want to talk about other animals, especially alpacas, llama, outdoor pigs, deer and sheep. Should we be taking these breeds more seriously and what measures should we put in place? As far as I am aware, certainly for alpacas and llamas, you do not actually have to notify where you have moved those animals to. There is nothing really laid down. What is your view on these other animals? Have they potential to spread the disease? We have quite a number of alpacas and llamas in the West Country.
Carl Padgett: Do you want to pick that up directly with your West Country experience?
Neil Blake: There are concerns. We have made representation before about ensuring that some of those issues are addressed. However, the caveat is that, to date, in terms of the potential for the spill-over hosts Carl was alluding to earlier, they are susceptible to infection and acquire infection, but they are not thought to be significant to the ongoing transmission. So yes, they are significant where they occur but are they significant in the general spread of TB? The data to date suggests that they are not of great significance in that regard.
Yes, I think there needs to be consistency in the application of the rules and regulations that pertain to bovine TB control but we still have to get things in perspective. By far the greatest risk is cattle and wildlife. It is sensible to focus most of our efforts and resources where the greatest risk is thought to be.

Q274 Neil Parish: You talked about wildlife; what about deer?
Neil Blake: They are locally significant rather than significant in the widespread area. We would recognise in parts of north Devon that there are local pockets where we might feel that they are of greater significance than others. Generally it is thought that levels of contact between deer and cattle are likely to

be far lower than between badgers and cattle, so the potential for transmission between the species is lower. It would be way down the list behind badger and cattle interaction as a risk factor.

Q275 Neil Parish: Therefore you are saying that while some of the deer may well have TB, they are much less likely to infect cattle?
Neil Blake: That appears to be the case, but locally it can be significant. That is my understanding.

Q276 Neil Parish: I have one final question on alpacas and llamas. You have quite a lot of alpacas and llamas where they might take the male and transport them across the country. Are you still not worried that we do not really know where these animals are?
Neil Blake: I certainly did not say I was not worried about the movements. There are aspects of what goes on that need to be tightened up. There is the potential with translocation of undetected infection; of course there is. Knowing where these animals are going and having better information in that regard is going to be a help.
Carl Padgett: In an ideal, non-resource-constrained world, I would love to have all species with similar compulsory arrangements as there are for cattle. But is that the best bang for our buck when we are in the situation we are in at the moment? I am not sure, given the risk scenarios Neil has just outlined. That does not mean that there should not be some responsibility taken for understanding the movements of these animals and recording them, so that we know where we are and are minimising the risk. If we do not even achieve that bit, what are we saying to the farmers who are being subject to controls and have breakdowns on their farms? Those farmers feel there is a level of inconsistency. It is not a level playing field. When they have that pocket of infection next door to them, it is a real risk situation for them, so they feel that the playing field is exceptionally unlevel. We have to deal with the argument about credibility in the system as well, and try to ensure that those species are dealt with appropriately but without diverting such significant resource that we are taking our eye off the main ball.
Neil Blake: We have personal experience with several outbreaks in camelid populations. It is a frustration and a concern but, again, I come back to the point I made earlier on about TB. It is not the only disease out there. It is better to offer biosecurity advice to any livestock keeper ahead of movements than for those movements to occur prior to that advice being given.

Q277 Neil Parish: Is it unreasonable to ask those with camelids to run a database, which can actually show the movements of those animals, albeit on a voluntary basis? Is that not possible or a good idea?
Carl Padgett: I think that is reasonable. I am not very closely in touch with the camelid world but I was of the belief that the camelid industry was looking at voluntarily trying to come together to do that kind of thing and take their responsibility on board.

Q278 Barry Gardiner: Trained members of the public are allowed to vaccinate badgers. Am I right in thinking that they are not allowed to vaccinate cattle? If not, why not?
Carl Padgett: The answer at the moment is because no one is allowed to vaccinate cattle, of course. If we take the general principle, I am not sure it is absolutely correct. The actual process of vaccinating an animal is a simple technical process. What we do not yet understand about vaccination of cattle is what other administrative record-keeping-type certification issues may follow to ensure trade can continue to occur. It may well be that, at the end of all the debates on how best to deploy the vaccine as and when it becomes available, certification at the end of the process might have to say, "I vaccinated that animal by a veterinary surgeon" as the requirement for trade as a health statement. Then it would be the vets.
Barry Gardiner: Like horse passports.
Carl Padgett: Possibly, yes.
Barry Gardiner: They have not done a terribly good job, have they?

Q279 Chair: To be fair, I am assuming that every bovine that goes from the farm to market is passported currently and that passport goes with it.
Carl Padgett: It has a passport, yes.

Q280 Chair: So one certification procedure would be that you would mark it on that passport. Just to help the Committee, is there any one organisation that administers the passports for cattle? Which is that organisation?
Carl Padgett: It is basically the BCMS—the British Cattle Movement Service.

Q281 Chair: So the position with horses is different?
Carl Padgett: Very different.

Q282 Chair: How many do they have?
Carl Padgett: I think the last number was up towards 100. I would not swear to that but it is lots.

Q283 Chair: If the DIVA test was being employed, would you suggest that cattle would have to be tested every time they are moved, or would it be marked on their passport and that would be sufficient? I am just pursuing this idea of certification. If the DIVA test eventually is recognised, would it be a one-off test or would it have to be tested every time the cattle was moved?
Carl Padgett: My understanding of the principle is that the testing procedures that are currently in place would still apply in vaccinated animals. The DIVA test would be used to differentiate those that actually react to that skin test to make sure that it was a natural infection and not a vaccinated infection, so it would be applied to those animals that were the ones causing concern. That is my understanding at the moment.
Neil Blake: Yes, that would sum it up pretty neatly. If we are moving into the realms of the DIVA test, the big caveat to it all at the moment is what we do not know; there is a lot more work that needs to be done to demonstrate the sensitivity and specificity of these tests, both the vaccine itself and the DIVA test. A

worst-case scenario, for example, is if you skin test a positive animal that is a genuine reactor, which tests negative to the skin test. The things to overcome are: what is the status of that animal? In the worst-case scenario you have cleared an animal that is still a reactor. There is a lot more work still to be done.
Touching on what was said earlier, the complex nature of this bacteria and the complex nature of the diagnostics challenge should not be underestimated. One of the points we have been trying to get across is the need to manage expectations.

Q284 Chair: We are coming on to that. Do you have any indication at all of what the cost of the vaccine and the DIVA test might be?
Carl Padgett: No.

Q285 Chair: Is there a risk that it might be prohibitive for farmers and it could just be too expensive?
Neil Blake: It would come down. This comes back to the efficacy and confidence in a vaccine or a programme. With any vaccine I would be advising my client on a cost/benefit basis, and crucially on my confidence in the efficacy of that vaccine. All those questions and all those facts would come into play. When you look at the cost of delivering a programme or adding vaccination or DIVA testing into it, you have to look at the potential benefits. How effective is it going to be? Will it be associated with, in conjunction with other measures, a reduction in TB? There is bound to be a cost associated with any additional measure. We have to be shrewd about trying to look beyond the initial cost and see, all the time, the potential benefits of what we are trying to do. Ultimately, the best way to save money with TB is through reducing the disease.

Q286 Richard Drax: Has Defra done enough to explain to the public the process involved in developing the cattle vaccine and the chances of the vaccine and the DIVA test successfully controlling that disease?
Carl Padgett: We are back to managing expectations again. In my own contact with the Department, I think the work that has been done there has always been pretty realistic about the true practicality of delivering a vaccine and managing those expectations. With the greatest respect to all the Members here, it is an easy thing for a politician making statements—I am looking at Ministerial or Secretary of State level over the years—to take vaccine as an answer that is a good news story and lock onto it like a favourite sweet in a sweet shop. I understand that; it is human nature, at the end of the day. That actually creates an expectation that is not always deliverable. I understand how that has happened and I would not necessarily blame anyone for it. We are where we are because everybody wants that panacea. We have a wider issue of educating even the public at large about exactly what the limitations of vaccination across the board are: what are the pros and cons of vaccination? Everybody thinks that as soon as you have a vaccine, that is the end of the story, for whatever disease it is that we are talking about. It is not always the case. That element of public education could be managed better.

Q287 Richard Drax: Is bovine TB "the most pressing animal health problem facing the UK today"? That is a quote taken from Mr Paterson, in effect. He thinks it is. Would you agree that it is the most pressing animal health problem in the UK today?
Carl Padgett: I would personally, certainly in the cattle industry, but I would say across the agriculture industry, yes.

Q288 Ms Ritchie: Are there any lessons that can be learnt from the response to brucellosis?
Carl Padgett: What do you mean by "the response to brucellosis"? Could you just expand please?
Ms Ritchie: The Family Farmers' Association caution that "no wild and ubiquitous animal was harbouring the disease, so the case is not at all parallel". Several people who submitted written evidence to us mentioned the successful vaccination campaign against brucellosis back in the 1940s and 1950s. The disease, according to the Family Farmers' Association, was "to dairy farmers in the 40s and 50s what TB is now". Have any lessons been learnt?
Carl Padgett: I will pick up half of that and let Neil pick up the other half. In the first half I will deal with the technicalities. There are a lot of lessons that could be learned from the technical issues of delivering a vaccination programme on a nationwide basis to try to eradicate the disease: what you have to roll out, how you have to put your resources in place, and so on. So we could learn from that. Neil will answer with respect to the disease itself.
Neil Blake: I was not in practice when the brucellosis eradication programme was taking place but it is clear to me that the diseases are very different beasts. TB is a very much more complex issue to address. I agree with Carl: you could learn some lessons from the delivery mechanism of a programme like that but in terms of what it is going to achieve, that is a completely separate issue.

Q289 Neil Parish: Could I also raise a point? I think brucellosis was very much cow-to-cow and animal-to-animal. There were no other vectors, as far as I am aware.
Neil Blake: Exactly.

Q290 Chair: But it was zoonotic, so it could transfer to humans.
Neil Blake: As is, potentially, bovine TB.

Q291 Chair: How did we eventually eradicate it?
Carl Padgett: By vaccination in this country.

Q292 Chair: So not restricting movements?
Carl Padgett: And restricting movements where infections were in place. Indeed, work in Northern Ireland recently has got to the point of achieving eradication there of the small foci of infection that were there. Again, it was based on surveillance, reporting of infection, testing and removal of animals.
Neil Blake: You have to caution against suggesting that the way to go is exactly mirrored by brucellosis.

As you say, it is a completely different entity. We have a much more complex disease picture in which wildlife is a significant part of the problem. You cannot make direct parallels with the control programme for brucellosis. Yes, you can look at the way vaccination was delivered, but those are the mechanics of delivering a programme, rather than looking at it as if it is going to achieve the desired goal.

Chair: That is helpful; thank you very much indeed.

Q293 Neil Parish: What is your perception of the incidence of Schmallenberg virus so far this year, and what advice do you give to farmers who suspect they may have animals infected with the disease?

Carl Padgett: I trust my learned colleague who is dealing with it on a daily basis at the moment.

Neil Blake: We have had quite a lot of experience of this over the last six or seven months. We know that the virus was very prevalent and very active in July and August, through the summer months. We saw significant problems in several early lambing flocks around that time, which have subsequently experienced problems with deformed lambs at lambing time around about Christmas. On the cattle side of things, again, we have experienced some. The effects have been variable but in some situations it has been very significant. Early on it was with the dairy herds, in particular, where milk production was hit, and now, interestingly, as you would expect given the expected passage of disease, we are seeing deformed calves coming through in the last one to two weeks. On the ground, yes, we saw it as very active back in the summer and we are seeing the effects of that. It varies in terms of the effects by herd; we get some herds where we find little effect and others where we are finding quite serious impacts.

Q294 Neil Parish: On some flocks of sheep, especially early on, some farmers were losing up to 30% of lambs and more, so it has had a devastating impact. We did have evidence from Defra vets who said that the sooner everything has it, the sooner they would have immunity. I thought that was slightly heartless, to be blunt. Also, should we be more proactive on vaccine and actually try to stamp it out in that way, rather than just letting it spread everywhere?

Neil Blake: My view on vaccination is a little bit like that on BCG. We want to have confidence that it is effective and is going to do the job we want it to do. Yes, I think there is real merit in having a vaccine available. There is certainly information on the high-value flocks that they would have loved to have had a vaccine prior to the rams going in back in the summer. They will use it next season if it is available. The experience we have had locally is that there will be a proportion of farmers out there who will seize the vaccine if it is available.

Q295 Chair: Would you give us an indication of what you think the economic impact is? It was actually the deputy chief vet who said to just let it waft over and that it is not doing any harm.

Neil Blake: At the moment a lot more work needs to be done. The official statistics are the ones that go through AHVLA from the submissions. So early on, when they were mapping the spread of infection, there was a subsidised route, where you were submitting samples and there was no cost direct to the farmer. That has changed subsequently, so the discussion is had at a farm level as to whether we investigate what we suspect to be Schmallenberg virus (SBV) or not; we all know that the statistics are not a reflection of the true prevalence out there. There is a risk in terms of all the processes ongoing at the moment. In my mind, there is a risk of reducing or dismantling the veterinary infrastructure and surveillance infrastructure that is out there. We need to have a robust system in place and we need to do more work with SBV to assess the true impact. My instinct is that it has been very significant in certain farms, which have taken a big hit, but I could not put an economic figure on it.

Q296 Barry Gardiner: So you would not agree with Nigel Gibbens that it is a low-impact disease?

Neil Blake: Our experience on the ground is that there have been variable effects. In some herds we have detected SBV antibodies, so we know that those cattle or sheep have been exposed to it and it appears to be an incidental finding. In others, there is no doubt in our minds that it has had quite a significant effect.

Q297 Barry Gardiner: Can you talk about the impact on non-pregnant adult cattle and sheep?

Neil Blake: With sheep, our experience on the ground is that the effect on the adults was not hugely significant, but it is different in the dairy herds, for example, where we have seen quite significant production loss associated with acute infection when it has been passing through the herds. We are talking, probably, about four litres of production. We have a couple of cases locally where we reckon it was probably four to eight litres a cow down whilst the infection has been ripping through the herd. That is a real hit that can easily put farmers into economic difficulty.

Q298 Barry Gardiner: Some farmers have said that they believe they have lost cattle through Schmallenberg. Do you have any evidence that it can be fatal?

Neil Blake: This comes back to surveillance ability and the funding available to properly look at the effects of the virus. We have had situations where, in a few cases, herds have lost adult cows during the course of the passage of SBV infection through the herd. I am careful how I word that and I am saying, "during the course of". We do not know because there may have been other factors at play in those herds. It may be that SBV was the final straw that put extra pressure on those cows. We do not have the definitive answers to that but we have had situations where we know SBV was active at the time they got the production loss, and they lost cows at the same time. There are not many but we have had a few.

Q299 Chair: Do you accept the argument about immunity: that if the animal gets the virus in the first

year of life and then gets pregnant, it can build up an immunity? Do you agree with that?

Carl Padgett: We have seen the statements of Professor Drew noting how animals react to being infected by viruses in the same family, so one would hope that immunity is good, but the proof does not seem to be there at the moment. I want to pick up the point that was mentioned before that maybe what we need to do is have the virus go right through the country and, Bob's your uncle, we now have naturally immune flock and herd status. That is not how endemic diseases—because that is what it would have effectively become by then—tend to work in reality. They tend to ebb and flow, so you will go through a period where there is a high level of natural immunity, then that will wane and we will get another disease picture. So it does tend to go in a sine-wave-type fashion.

Q300 Chair: So do you foresee a need for a vaccine for Schmallenberg?

Carl Padgett: Absolutely.

Neil Blake: Yes.

Q301 Chair: How do you recommend it should be deployed in order to achieve the most cost-effective impact, given what you were saying earlier, Mr Blake?

Neil Blake: Those are discussions that you are probably going to end up having on a farm-by-farm basis. I cannot see that it is ever going to be a compulsory vaccination programme. I am not sure in my own mind that there is merit in that anyway. I certainly think that it would be one of those, like other endemic diseases that are present in the UK, where we will have those discussions and will advise accordingly. There is certainly merit in it, there is certainly value in it, there is certainly need for it and hopefully it will be available for the next season. It is down to the licensing and regulatory authorities whether that vaccine becomes available in time.

Q302 Chair: Should the farmers have to bear the cost?

Carl Padgett: If it is going to be an endemic disease, which it looks like it is going to be, I would struggle, given the spread over the whole of Europe, to contemplate eradicating it with the midge being the vector. With most other endemic diseases, farmers, I am afraid, bear the cost and make the choices as to what control measures they are going to put in place. So unless one had a compulsory vaccination programme nationwide, which I simply cannot see being proportionate to this infection, I suspect farmers will have to bear the cost.

Interestingly though, with this discussion of low impact, there is of course the danger that the market is talked down, and so investment in vaccination does not occur. That is what I am particularly scared of. This is high impact for individual farmers that have that high impact. It may be relatively low impact industry-wide or have impacts in ways we do not yet fully understand, so we have to be careful that we do not demonise the virus and make everyone scared of it, and blame it for absolutely everything, but we also need to proportionally make sure that, when Schmallenberg is involved, we identify it properly to stimulate true investment in vaccine production.

Q303 Neil Parish: In the 1980s, I had enzootic abortion. Some ewes became immune but it was only when we started to use a vaccine that we really stamped it out. They are not exactly the same diseases but do you see some similarities there?

Chair: I will take that as a no.

Neil Blake: I think you treat each disease on its merits and you have to fully understand the pathogenesis, the transmission, the modes of transmission and how best to counter that transmission. A crucial difference between enzootic and Schmallenberg is that Schmallenberg is vector-borne, and enzootic is transmitted from sheep to sheep. They are not directly comparable.

Q304 Chair: If there is conflicting evidence about whether it is going to be endemic or whether it is going to waft over, what is the best approach to take at this time to the Schmallenberg virus? Is it that we should proceed with the vaccine?

Carl Padgett: I think we should be proceeding with the vaccine. I would like to see further surveillance being encouraged, so that we understand as much as possible of the infection and the disease picture that it causes. We simply do not understand that sufficiently at the moment. There is no real incentive for farmers to submit samples at the moment. Why should they pay for tests for an infection that they cannot do anything about controlling at this moment in time?

Neil Blake: There is one word of caution on this as well. If we are going to gather more information, it has to be industry-led and work in partnership. We also have to be careful when we gather more information that it is as accurate as we can make it. One of the concerns, and this happened to a degree back in the bluetongue days, is that everything gets blamed on the new kid on the block; so when Schmallenberg crops up, everything gets blamed on Schmallenberg, which is clearly not the case. Again, it highlights the need to have joined-up thinking and a flow of information; we have a lot of information through the area we cover. We are not collating that information at the moment to get the best picture of what is happening out there. We can look at other countries but field conditions and livestock densities vary throughout Europe. Our part of the world is a very livestock-dense area, so the question is: is the effect of the virus the same here as it is elsewhere? We do not know because we are in the relatively early stages in terms of the passage of the virus through the country. It has really hit this year; it barely hit last year.

Q305 Chair: Are you concerned at all about liver fluke in sheep in the UK?

Neil Blake: Yes, I am hugely concerned about liver fluke, the increasing prevalence and the increasing significance of it. It is something that we have observed, this year in particular, where, as an example, farmers in our part of the world would treat a lot of flocks and herds for liver fluke at the end of a

season if they felt the need. This season they probably had to go through two treatment cycles to be confident they have kept it under control. It is more akin to the situation in Ireland, for example, where they would be treating regularly through the season. The succession of wet years and the warm climate is not helping us in that regard. Historically we have usually had cold winters where the fluke would become dormant, so you get two or three months in the year with no active infection. We are seeing active liver fluke now on the wrong side of Christmas, in January. We have not seen that in our part of the world until probably this year.

Q306 Chair: You mentioned, Mr Padgett, that you thought it would be difficult to introduce compulsory vaccination across Europe or even here. If farmers were to be compensated for the loss of stock due to Schmallenberg, might that encourage them to notify?

Carl Padgett: I am sure it would. Compensation mechanisms always incentivise some form of involvement. Again we go back to the issue of proportionate measures for this particular infection. Whether that is proportionate or not is something about which I would have to be persuaded.

Chair: On behalf of the Committee, I thank you, Mr Padgett and Mr Blake, for being so generous with your time and contributing to our inquiry. I am sure we will meet again very soon. Thank you very much indeed.

Wednesday 6 March 2013

Members present:

Miss Anne McIntosh (Chair)

George Eustice
Barry Gardiner
Mrs Mary Glindon
Iain McKenzie
Sheryll Murray
Neil Parish
Dan Rogerson

Examination of Witnesses

Witnesses: **Professor Glyn Hewinson**, Chief Scientist, and **Simon Hall**, Veterinary Director, Animal Health and Veterinary Laboratories Agency, gave evidence.

Q307 Chair: Good afternoon, gentlemen, and welcome. Thank you very much for being here today and contributing to our inquiry into bovine tuberculosis vaccination. Would you like to introduce yourselves, starting with Professor Hewinson, and giving your names and positions for the record?
Professor Hewinson: I am Professor Glyn Hewinson, and I am the Chief Scientist at the Animal Health and Veterinary Laboratories Agency.
Simon Hall: I am Simon Hall, Veterinary Director of that same agency.
Chair: Thank you. I think we met at dinner last week.
Simon Hall: We did, yes.

Q308 Chair: We are very grateful to you for being here. I will start off by asking: is there a particular reason why the UK seems to have the highest concentration of bovine TB in Europe?
Professor Hewinson: There are probably many reasons that may have conspired to create the situation. You probably know that we got TB fairly under control into the 1970s, and since the 1990s we have seen exponential growth in TB. There are a number of things that have happened during those times. One is the protection of badgers; another is the changing of the tuberculin we used to control TB. Thirdly, the genetics of the herd has also changed. Another is the size of the herds, which makes diagnostic tests and identification of all infections greater, along with the movement of herds and the whole farming situation. There are many different circumstances that may have conspired to increase the level of TB. This is a real evidence gap, but teasing out the things that have produced this situation is quite difficult. One of the real evidence gaps is how much TB is given from cattle to badgers, how much TB is given from badgers to badgers, how much TB is given from badgers to cattle, and how much TB is given from cattle to cattle. Without being able to quantify that, it is very difficult to tease out exactly what the reasons are.

Q309 Chair: Which organisation will be best placed to plug the evidence gap in that regard?
Professor Hewinson: There are many organisations that would need to come together. Firstly, clearly the Food and Environment Research Agency (Fera) have played a leading role in understanding TB in badgers. AHVLA have now brought together the animal health side, which was part of the control, and the science and diagnostic parts, so we have much of the cattle side of the evidence. It is pulling it all together that is crucial.

Q310 Chair: I am particularly interested in knowing if we are the only European Union country that gave protected status to badgers in the 1970s.
Professor Hewinson: I am not sure of that. We would have to check that.

Q311 Chair: We have a map here from the Department for Environment, Food and Rural Affairs (Defra) website, which shows that in 1986 there really was not much density of bovine TB in the herd. By 2009 there was this massive concentration in the west and south-west. Have you done any research into that, Professor Hewinson, that would help our understanding?
Professor Hewinson: Well, I can try to help with it. One of the things that we introduced was doing molecular typing of strains of TB that you get from cattle, and indeed badgers, which we can talk about later. Although that map shows, as you see, the spread of TB across the country and it gets blacker and blacker, there are two things that are happening; it is not just one epidemic. What the molecular typing has shown is that you have one progenitor strain—one parent strain, if you like—that has spread across the country, but that it is throwing off daughter strains in different areas of the country. Although your map there looks as though it is just *M. bovis*, in fact, in different parts of the country there are different strains of TB causing that spread. So, in fact, you have geographical localisation of different strains of *M. bovis* that have arisen from one bacterium. So it started off as one bacterium, and then we call it "clonal expansion"; TB is expanding in those small geographic areas. Therefore, local epidemics are happening.
Part of what might have been happening is, as TB decreased, the testing regimes became less frequent, and the areas in which you tested were at the parish level. I think what happened for a while was that we were revealing an infection that was already there, rather than showing that there was an explosive infection in real time. One of the responses to that is that we have a very large area that has now gone on annual testing to try to get ahead of the epidemic rather than behind the epidemic. Part of the modelling, when you look at the molecular typing, is suggesting

that the strains in badgers and cows are the same. Clearly there has been a bottlenecking of the TB, probably spread from cows into badgers, and it is now being spread out again, but then you have a complex situation where you have got badger to badger, badger to cow, and cow to cow spread in high prevalence areas, and quantifying that is difficult. So I cannot give you a definitive reason for why that spread has happened, but I can tell you that they are local epidemics. The other thing you should know is that the British Isles has its own strain of bovine TB, a clonal complex that is different from the European strain.

Q312 Chair: Other colleagues will want to come in on this point, but I will just ask this. Obviously we have got a very large back-stop industry, so in those areas like North Yorkshire that are currently free of bovine TB, should we be worried that a similar epidemic might reach us?

Professor Hewinson: At the moment, I think the evidence suggests that, in low prevalence areas, the tests, slaughter and tracing that go on seem to control the disease, which is one of the reasons why Scotland has become officially TB-free, and why, even after the introduction of infected cattle into areas after restocking following foot and mouth, TB has been brought under control by the current tests in low prevalence areas. Of course, the tests may behave differently in a high prevalence area to a low prevalence area. That is consistent with the maintenance of a plateau from the 1970s to the late 1980s. In low prevalence areas you seem to be able to control TB, and in high prevalence areas that is more of a challenge. The question is: has TB got into wildlife in those areas, and will it take a long time to spill back into cattle? The answer is: I do not know, but I think that the evidence from Scotland and, as I say, from these other areas, shows that at least at the moment those low prevalence areas seem to be maintaining their low prevalence. Part of the reason is that when we find an infection we throw everything at it; we throw a gamma interferon test and a skin test to try to stop the disease from getting into wildlife.

Q313 Chair: When a badger is run over and left at the side of the road in areas like North Yorkshire, should we be testing those for TB?

Professor Hewinson: When they looked at the road traffic accident badgers in the past, before the Randomised Badger Culling Trial, the information, because there were so few badgers, was not that informative about the prevalence of TB in badgers in those areas. I think that is an evidence gap. I have to say, from my perspective, we do not know whether TB is in badgers in areas where there is no cattle TB, and some of the work in Ireland suggests that there is TB in badgers in both high prevalence and low prevalence areas; it is just the level of TB in those badgers that is the difference.

Q314 Chair: Did I understand you to say that the tuberculin has changed over the years?

Professor Hewinson: From the 1960s until 1975, they used a tuberculin that was made from human tuberculosis—*Mycobacterium tuberculosis*, the same tuberculin that was used for skin testing humans. In 1975, they introduced a tuberculin made from *Mycobacterium bovis*, the organism that causes TB in cattle, as a way of improving specificity. This was a strain that was isolated from a cow in the UK and then grown on glycerol. Usually bovis does not grow on glycerol, but they grew it on glycerol and it created mutations in the AN5 strain, which meant that it could grow very quickly, and so you could produce enough *M. bovis* to make a tuberculin. That has been adopted across Europe using this AN5 strain.

Q315 Chair: I have had family members who caught TB from cows' milk 30 or 40 years ago. Are we confident that the present strain of TB cannot pass into humans?

Professor Hewinson: Do you mean *Mycobacterium bovis*?

Chair: Yes.

Professor Hewinson: We have been looking at *Mycobacterium bovis* in humans. Most of the strains that we have seen—and we work closely with the Health Protection Agency on this—are due to reactivation of TB from older people, and, interestingly, the strain profile is slightly different to the profile we see now. The strains we saw in humans are closer to the European-type strains. However, we have seen some recent outbreaks; there have been at least two documented. There you saw human-to-human transmission, but there were immunosuppressed individuals involved in that. It is rare, but it can happen. Simon, did you want to say anything?

Simon Hall: I will just make the simple point that yes, bovine TB can infect people. That is why, on the whole, milk is pasteurised, and why, where there is a dairy herd with a TB problem, they do not have the option of selling unpasteurised milk in England. Fresh meat can also potentially lead to infection, but, again, that is one of the purposes of the meat inspection service that is run by the Food Standards Agency, so that beyond a certain point meat from an infected animal cannot be put into the human food chain. It is their responsibility, and they have carried out risk assessments to satisfy themselves that this is satisfactory.

Q316 Dan Rogerson: Coming back to the characteristics of the pockets of disease that you were talking about, and the different localised types, one thing that we hear from people who perhaps do not look at this in this detail is that, "It is all about cattle. It is cattle-to-cattle transfer. It is going on across the country." What do you think the situation you have described says to the argument that it is not about the wildlife at all?

Professor Hewinson: I think it says that both cattle-to-cattle and badger-to-cattle infection is going on. The evidence is clear that that is the case. I would say that the model you probably saw was bottlenecking of TB into a stable population, because if it was all cattle movement you would see mixing of strains. You have a geographical localisation, but, on top of that, most movement of cattle is local, so it is actually very

difficult to tease out whether it is badger to cow or cow to cow, or how much is due to either vector. However, the evidence is fairly clear that badgers do contribute to bovine TB, as do cattle.

Q317 Neil Parish: Can I ask you a loaded question? Basically, if you test all the cattle, you clean the cattle, because you take out the infected animals; is it logical then to put those clean cattle back into a field where they can be infected by badgers carrying the disease?
Professor Hewinson: If the prevalence in badgers is high enough to spill back into cattle then, yes, you would get spillback. The difficulty is quantitating the level of infection—
Neil Parish: And how infectious these badgers are.
Professor Hewinson:—and how infectious it is. Yes, it would depend. Clearly, other countries have cleared up TB through depopulation of cattle and then restocking, without a wildlife risk.

Q318 George Eustice: Some of the evidence we have had around the tuberculin test—the skin test that we have at the moment—has raised doubts about its reliability. What is your assessment of how reliable it is?
Professor Hewinson: There are clear figures on how well it performs, in terms of the sensitivity and the specificity of the test, and those are average figures. I do not want to obfuscate, but actually the answer is, "It depends". I will give you some examples.

Q319 George Eustice: First of all, what are those figures? What is the range?
Professor Hewinson: At an individual level, again, the sensitivity of the test will vary depending on the prevalence of infection. The specificity of the test will be fixed. The specificity of the comparative skin test is about 99.9%; so less than one in every 1,000 might give you a false positive.
Simon Hall: I will just give Glyn a little rest. What we have been discussing in the last couple of minutes are individual animal figures. If you take a typical figure for sensitivity of the test of 80%, that says in theory that you miss one in five infected animals, which sounds really quite bad, but practical experience is that this test is fit for purpose to eradicate TB in places like Scotland, for example. Why is that? It is to do with the strategies with which you deploy the test; when you start using at a herd level rather than an individual animal level it becomes much more effective. For example, where you test a herd of cattle and find one positive animal, yes, you kill and destroy that animal, but you put the whole herd under restriction. You retest the herd with the test usually recalibrated to make it more sensitive, and, by using these types of strategies, you can make very effective use of the test, where, if you just look at the simple individual animal sensitivity figure, it may not appear to be very good.

Q320 George Eustice: Is there no case for using the gamma interferon test alongside it?
Professor Hewinson: Yes, in fact we do. Perhaps I should tell you what happens during an infection. When you have an infection of TB, it has evolved along with its host, so it has very clever ways of avoiding immune responses. For most infections, usually you have an explosive infection, and you have a lot of antibody response, so most diagnostic tests are based on antibody responses. TB has evolved to go inside the host's own immune cells, the macrophages, and hide from antibodies. It grows slowly, so you have a much slower response to infection. Hiding in a macrophage means that the body has to induce a different type of response, called the cellular response, and the first wave of responses that you see are the gamma interferon responses. They are the first signs that there is an infection, so they identify infection early, and are the most sensitive.

Q321 George Eustice: What circumstances is that used in?
Professor Hewinson: The way we use the gamma interferon test at the moment is in areas where there is no TB—so where cows that are infected with TB have moved into TB-free areas. We identify an infection, and we then throw both tests at it. The skin test picks up the fact that there is an infection, and then we use the gamma interferon test, because the gamma interferon test added to the skin test gives an increased sensitivity and pulls out animals that are at an earlier stage of infection. What you are trying to do is to mop up infection quickly before it gets into the wildlife population.

Q322 George Eustice: Coming back to what you were saying, about how the whole herd response is what makes a skin test acceptable, what if it is only a couple of cattle that have got it, when they are skin tested, and those both slip under the radar? That means you have got infected cattle potentially still moving around the national herd.
Simon Hall: That can happen.
Professor Hewinson: That does happen.

Q323 George Eustice: Is the skin test a much more expensive test? Is it too expensive to use as the default test?
Professor Hewinson: In EU legislation, it is not the recognised frontline test. I think you were talking to the Commission about other tests last week. There has just been an EFSA opinion on the gamma interferon test, looking at whether the gamma could be used as a frontline test, and the findings of that are that they have similar sensitivities and specificities, but they would like to see how it operates in the context of mixed infections.
Simon Hall: I will just fill that in. In very round figures, the standard tuberculin skin test done by the vet on farm is about £3 a head. For the gamma interferon test, the lab cost is about £30, and it requires special conditions for transport of the samples to the lab, so that is a cost. If you remember, for the tuberculin test, the specificity is extremely good. There are only about one in 1,000 false positives, whereas with the gamma interferon test you get a few more false positives, and if you slaughter those and pay compensation for them, the overall cost of using that test as a widespread first line screening test really would mount up very considerably.

Q324 George Eustice: Finally on this point, have you done any modelling to look at the impact of larger herd size, and whether the element of unreliability causes a particular problem with larger herds?
Professor Hewinson: With larger herds you are less likely to identify all infected animals. There is modelling that we can send to the Committee.

Q325 George Eustice: But it is still your position that it does not matter because you have got a whole herd?
Simon Hall: Well, it works both ways. If you have a large herd of cattle and there is a proportion of infected animals, you have got a better chance of identifying the herd as a whole as being infected. So actually, if you have got a small herd, the statistics say that the herd-level infection is easier to miss. However, when you have got a very large herd of cattle, yes, picking out the individual infected animals is harder, but we recognise that, and that is why we use the second-line test, which is the more sensitive interpretation of the skin test, and/or the gamma interferon blood test, in order to address that problem.
Professor Hewinson: I think the take-home message is that two tests are better than one at identifying all infected animals, but that comes at a cost, so you might need to do a cost-benefit analysis on how to use the best combination of those two tests in a given epidemiological situation.

Q326 Chair: Were you surprised that the European Food Safety Authority (EFSA) opinion was not favourable to the gamma interferon test?
Professor Hewinson: I thought they were favourable to it. I thought they are now considering it as a frontline test.

Q327 Chair: So they will. Would you normally use both tests in all circumstances?
Professor Hewinson: No.

Q328 Chair: Only in the circumstances that you described?
Professor Hewinson: My own feeling is that one approach does not fit all situations, and you actually have to have a much better understanding of the infection process, of what is going on in that herd at the local level, to really make the decisions on how you use your tests most effectively.

Q329 Neil Parish: When gamma interferon first came in it was going to be the magic test, and it then turned out that it threw up a lot of false positives. I think you almost played down the number of false positives. Have you got any numbers on that?
Simon Hall: It is Glyn's expertise, but what the farmer may perceive as a false positive and what truly is in the biological sense may be different.
Professor Hewinson: Shall I step in here? When you do a specificity trial, to see how specific the trial is, in negative animals, you find that the specificity of the gamma interferon test is about 97%. If you used it as a complete screening test in negative areas, that would be three animals in a hundred that you would identify as a false positive, in areas where there was no TB. If you go into a herd where you know there is already TB, the likelihood of a positive response being a positive response is much higher, because you know there is infection in that herd, and you need to clear it out.
There is another misconception about the gamma interferon test, which led to this idea of there being a lot of false positives. As I was saying, the first response you see in infection is a gamma interferon response. As the disease progresses, you then start seeing a skin test response, and much later you might see an antibody response. That is linked to the progression of the disease. Your earliest infection is detected by a gamma interferon response, when you have no lesions and very few bugs, and where you cannot find any sign of infection. That does not mean the infection is not there; it just means that you are identifying animals at that very early stage, before they have developed disease and become infectious. For me, the ideal test would be to identify animals that have no visible lesions, because that means they are less likely to have transmitted disease. By the time they have developed lesions, they are more likely to have spread disease.

Q330 Neil Parish: It's a bit late when you slaughter them, they have not got the lesions and they have not got the disease. They are dead.
Professor Hewinson: In a herd where you know there is TB, it is most likely that that positive response is due to infection.

Q331 Neil Parish: I want to take you on to the BCG vaccine and how effective it is. There have been some small tests done in Mexico and Ethiopia. It has been found to be only 56–68% effective. With the BCG vaccine in cattle, do factors such as the presence of other diseases impact also on its efficacy?
Professor Hewinson: On the efficacy of the vaccine, or on the efficacy of the diagnostic test?
Neil Parish: This is a vaccine.
Professor Hewinson: On the efficacy of the vaccine?
Neil Parish: Yes.
Professor Hewinson: I think this plays to the next steps in vaccine development in that, as you say, these are very small research studies. They give you some indication of the fact that not all animals are protected, but some are protected from infection. The reason, as the Commission outlined in its letters, that you need to do large-scale trials is to take into account the facts that you may be trying to protect different breeds, different populations exposed to different diseases. It is only when you get to that field study stage that you start to observe those effects. It is difficult to do. You cannot do that in the laboratory. It requires large-scale field trials.

Q332 Neil Parish: Is it possible to achieve herd immunity? This is if you are using the vaccine. What percentage of cattle would need to be vaccinated, how often, and how long would the programme need to last? It is only a simple question.
Professor Hewinson: We come back to the question of how much TB is spread from cattle to cattle, how much is coming from cattle to badgers, and how much

badger to badger, and the performance characteristics of the vaccine under UK conditions. So the answer is that we do not know. Those are unknown parameters.

Q333 Neil Parish: How big a field trial would we need to be able to try to sort that out? Some people say that the vaccine is the magic bullet, but is it or is it not?
Professor Hewinson: The answer is that it is not a magic bullet; it is just another tool. Coming back to your question, the first thing you can do is model what might happen. If you model what a vaccine does in cattle, you can make up whatever efficacy you want when you are doing a model. When you model what happens during vaccination with cattle, at the beginning you do see quite a dramatic decrease of TB over a few years. However, you come to a plateau, and that plateau depends on the contribution of badger-to-cattle infections. If it was all cattle to cattle you might conceivably get herd immunity and, in fact, in the old days, where they used some BCG vaccination strategies on the continent, they found that you could probably eradicate TB from a herd. It took about eight years to do so.

Q334 Neil Parish: Provided the disease was just in the cattle and not in the wildlife.
Professor Hewinson: Exactly. Your plateau will be determined by the efficacy of the vaccine. So the more efficacious the vaccine, the lower the plateau. The more badger-to-cow contribution there is, the less likely it is that you will get herd immunity, as you talk about it, and you will not get eradication.

Q335 Neil Parish: So if—and it is a big if—we had a vaccine that we could use now, in your view, we would still have to do some control of the disease in wildlife, either by culling, vaccination or whatever, in order to get to an immunity situation.
Professor Hewinson: In order to eradicate, yes, because you will get spillover from the wildlife host. Of course, that depends also on the contribution of cow-to-badger infection, and badger-to-cow infection.

Q336 Neil Parish: Is there any evidence that vaccinated cattle might contribute to the spread of disease, for example, by shedding TB bacteria? Say for instance it was only a 50% take, is there a problem with those that have had a vaccination that has not worked?
Professor Hewinson: Yes, we do see that some animals are not protected at all. About 10% of animals seem to be refractory to vaccination, and we are trying to look at why that might be at the moment. The point that you do not have a perfect vaccine is the reason that you need a test that differentiates between vaccinated animals and infected animals—
Neil Parish: Which we have not got.
Professor Hewinson:—so that you can remove the infected animals.
Neil Parish: Have we got that test?
Chair: We are coming on to that.

Q337 Neil Parish: Sorry, I will not take you there, but I have just one final point. If you have vaccinated an animal and it has not given it immunity from TB, could that vaccinated animal then be shedding TB bacteria?
Professor Hewinson: If it becomes infected, just like a non-vaccinated animal, it will—

Q338 Neil Parish: But the vaccine itself will not create that, because it is dead, is it? Is the disease dead?
Professor Hewinson: Do you mean, will the vaccine be shed?

Q339 Neil Parish: If you have vaccinated an animal and the vaccine has not worked, is it possible that instead of actually stopping the animal from having TB, for want of a better way of putting it, it gives it TB and it sheds it?
Professor Hewinson: No, it would not give the animal TB. Do you mean, would the vaccine revert to virulence and become virulent?
Neil Parish: Yes, that is right.
Professor Hewinson: All I can say about BCG is that it has been used in 8 billion people and more children than any other vaccine, and they have not seen a reversion to virulence in humans. That is part of the reason you would look at BCG, because of its safety record. You still have to do some formal safety studies.
Neil Parish: Have you any idea of cost, if the vaccine was available?
Chair: I think we will come on to that.
Neil Parish: Do we come on to that? All right, I will leave it there. Thank you.

Q340 Chair: Professor Hewinson, it appeared to be a caveat to the questions that Mr Parish has just put that we do not have the information as to how TB is spread from cattle to cattle, from cattle to badger. Is that quite an important caveat?
Professor Hewinson: When you are trying to model how useful a vaccine would be, ideally you would want to quantify how much TB is coming from badgers to cattle, how much TB has been spread cow to cow, and how much is being spread from badger to badger, because that would then help you to answer those questions about whether you would be able to achieve herd immunity.

Q341 Chair: We are not there yet.
Professor Hewinson: No, we have not quantified that.

Q342 Chair: When might we be in a position to quantify?
Professor Hewinson: It is a very difficult thing to quantify. I know that there are some published results now that suggest approximately 50% of TB might come from badgers to cows.
Chair: 50%?
Professor Hewinson: But the confidence intervals are very wide.

Q343 Sheryll Murray: Could I just turn to licensing? When will you respond to the Veterinary Medicines Directorate's further questions regarding

the application for "in principle" marketing authorisation of the cattle vaccine?
Professor Hewinson: As soon as we have got the letter, we will start replying to their questions and putting the response together.

Q344 Sheryll Murray: I understood that they have asked further questions, and are currently waiting for your response.
Professor Hewinson: No, we put in our responses, and they have now had a meeting, I think last week, with the Veterinary Products Committee. I think that, on the basis of that meeting, they will be sending out a letter to us, to highlight what further work might be required.

Q345 Dan Rogerson: Are you surprised at the EU Health Commissioner's request for more studies to address food safety concerns over the cattle vaccine? What action are you taking to deal with that?
Professor Hewinson: A lot of those issues are dealt with through the Veterinary Medicines Directorate, so we are waiting to see.
Dan Rogerson: We're back to this question.
Professor Hewinson: We come back to that question. We are waiting to see what other studies might be required. What happens for all vaccines is that you look at the safety data that is generated in the laboratory, which is then submitted to the VMD for an Animal Test Certificate, or a Provisional Marketing Authorisation, which of course we cannot have because of the illegality of vaccination at the moment. You then do the second phase. In this case, for the Animal Test Certificate, you would do field trials to see whether the safety aspects that had been generated in the laboratory were consistent in the field. You would do what is called 'pharmacovigilance'; you would look at what happens in the field under all these uncontrolled circumstances, to see whether the safety profiles that you had seen experimentally were realised in the field. You do need field trials to create a safety portfolio. It is not a surprise; in fact, when we did the badger vaccination we had to do a field trial that was about the safety of the vaccine in the field.

Q346 Dan Rogerson: But the question was specifically about food safety. Obviously the issue with badgers is slightly less; we have had a few interesting ingredients in food recently, but I am not aware of badgers being on the menu at the moment. I have one constituent who has been on television who does eat them but that is another matter. With regard to food safety concerns in particular, the process that you are describing is the standard process that we would go through. Is there anything that the Commission has asked for over and above that standard process that surprised you?
Professor Hewinson: The Commission have not asked for any detail. You have seen what they have asked for in that letter. What they want is reassurance that it would be safe.

Q347 Dan Rogerson: They want lots of cover. The Commission have also said that marketing authorisation cannot happen until field trials have been completed, which is what you are saying. How would future field trials impact on the "in principle" application that you have already submitted?
Professor Hewinson: I guess the "in principle" application was in fact to tease out what data would be required from the VMD for licensing. You will see that the letter also says that we would need a marketing authorisation eventually. One of the reasons behind putting in the "in principle" application was to identify what data sets we would need to create in order to get a marketing authorisation. It is, if you like, a dummy-run to getting a marketing authorisation.

Q348 Dan Rogerson: Just to finish off on this line of questioning, we have a triangle going on between the Commission, the Directorate and yourselves, of feeling your way towards approval of something. For those people who are very interested in what is going on, and in what we are saying here, there is a danger that this could look like something that could drag on forever. What is the way for all the legs of that tripod to get to a stable base where we can move forward? Or is it going to be a buck passed between all three?
Professor Hewinson: I do feel very sympathetic, but we are in uncharted territory in some ways because of the anti-tuberculosis legislation, so it means that you cannot follow the pathway that you would normally follow to get a vaccine licensed. It does require much larger and more extensive field trials to reassure our European colleagues of all the things that the Commissioner lays out in his letter. Did you want to say anything, Simon?
Simon Hall: Just to simplify, it is obviously very important, if any vaccine is going to be used in a food-producing animal, that it is safe from a public health perspective and that it is not going to do any disproportionate harm to the individual animal. Our own VMD and the Commission have the same concerns, and we will all want to be reassured of that before any deployment was carried out. Next, a series of field trials are required to gather additional information in order to build on that safety case, to understand the efficacy of the vaccine and to understand the sort of strategies that you might use to deploy it. Helpfully, what the Commission have effectively said is that there is no fundamental barrier in European law to that occurring, because it is clear in the directive about eradication programmes that you cannot use BCG and tuberculosis vaccines as part of an eradication programme. That could be side-stepped; it is implicit in the trade and food safety legislation. However, as a field trial under the close control of the competent authorities—that is us—there is a way in which it can be used, and enter into a cycle of learning by doing. Then you ultimately arrive at an end point, which might be 10 years away, where everybody, including the Commission, other member states and ourselves, has sufficient confidence in the characteristics of the vaccine that it could become a normal thing to use, and that live, vaccinated animals could be traded freely within the EU. However, you can do a lot along the way to that.

Q349 Chair: What the Commission officials did actually say to us was that they are coming up with a new EU animal health regulation, which they explained would expedite the adoption of a TB vaccine for cattle. Do you share that optimism?
Simon Hall: Yes. The EU legislation can be constructed as people see fit, but before worrying too much about that, there is a legitimate concern that in deploying such a vaccine, we must not do anything that results in TB spreading more widely within the UK and into TB-free regions and member states. There is the fundamental science and the strategies for applying this vaccine, which are a bigger hurdle to get over. Yes, it would be good if the legislative process was slightly slicker, but I do not think that is the primary consideration.

Q350 George Eustice: I want to probe that a bit, because it seems that one of the really frustrating things in this is that it feels like we have a vaccine that is almost ready to go, but it is the bureaucratic process that is slowing things down. You said that the legislative process could be slicker. If you were just to remove it and pretend there was no such thing as EU law for a while, but you were serious about taking the threat to food safety seriously, how quickly could you agree to use a vaccine? How quickly could you do all the relevant testing needed? Is it a decade? Do we actually need a decade, or is it more like four or five years, assuming a common-sense world?
Professor Hewinson: With other vaccines, you can get vaccines into the field quite quickly. So you just have to generate the level of assurance through your field trials and, as Simon says, you are learning as you go along.

Q351 George Eustice: On this particular vaccine, roughly how long do you think that is? Is it roughly 10 years, or is it roughly three years, if you pretend that there is no such thing as EU marketing or authorisation, or anything else you have to jump through?
Professor Hewinson: It is hard to comment, because we do not yet know all the things that we would need our field trials to show. At the moment, we are still awaiting feedback from the VMD. From the tone of the letter from the Commission, I think they will be substantial field trials, and will need to last for a number of years.

Q352 George Eustice: I will turn to the Differentiating Infected from Vaccinated Animals (DIVA) test. We talked about the tuberculin skin test. Another important thing here is that you have a DIVA test that can distinguish the virulent TB from the vaccine. How accurate do you think that test is at the moment?
Professor Hewinson: You can create your sensitivity data on *M. bovis* infected animals, so you can look at the animals that are already infected with *M. bovis*, and you can see how well the test performs on those. You can look at uninfected animals and see how well the test performs on those, and that gives you sensitivity and specificity in unvaccinated populations. You need field trials, because unfortunately the number of animals that you have to perform these tests on in vaccinated populations is large. We have not been able to do field trials. I can tell you what the sensitivity and specificity of the test is on limited populations in unvaccinated animals. What the field trial will need to do is give the data in vaccinated animals. Sorry, have I been clear enough?

Q353 George Eustice: Well, some of the evidence we have had has said that the DIVA test has been around for 10 years. I suppose the question is: if this has been around for 10 years, why has it not been possible to do all the box ticking, the field trials and everything necessary to clear these hurdles sooner?
Professor Hewinson: Although we have got a more sensitive DIVA test, the DIVA tests are available for humans. Bacillus Calmette-Guérin (BCG) vaccinated humans already have DIVA tests, which are very similar to what we use in cows. The DIVA test has been in development, and we have looked at the performance characteristics.

Q354 Chair: For cattle?
Professor Hewinson: In cattle, but not in vaccinated cattle, and of course you need to get the vaccine to a stage where you can do field trials. We needed to do the safety studies and some of the experimental efficacy studies, and to put the dossier together to give to the Veterinary Medicines Directorate (VMD), in order to be allowed to do the field trials in vaccinated animals, which would then generate the performance characteristics of that test in a vaccinated population.

Q355 George Eustice: Is it the information you give them that will determine the scale of field trials required, for both this and the vaccine? I pressed them on the same point, and they said, "Well, we can't really say how long a field trial will be, because it'll depend on what we are told about how much evidence we need." There is a sort of vicious circle, where no one is willing to say, "The gaps in the knowledge are X, therefore it will take Y number of years to fill that gap." I know it is difficult.
Professor Hewinson: I know you want a date. It is difficult, because there will be feedback from the VMD that might highlight experiments we need to do before we can do a field trial. We will then look at designing those field trials to create the data that is robust enough, firstly, to go through the process for World Organisation for Animal Health (OIE) validation, because I think the Commission said that we had to go through the OIE. There is a set and prescribed data requirement.

Q356 George Eustice: There was no way we could have applied to the OIE prior to this date, given that this has been around?
Professor Hewinson: No, because the very first thing that you have to do in an application to the OIE is to say how you will use that test. Until you know how you will use that test, you cannot validate against that test. Then you need a population of animals that you will do that test on to generate the data in order to validate it. Without the field trials, you cannot create the data.

Q357 George Eustice: Has there been no similar challenge in the last 20 or 30 years, where a vaccine has been developed from scratch, authorised and used in a particular timescale, where you can say that "It took X number of years for that. Therefore it should be something similar to this"? What would you compare it to? Is it bluetongue, or something like that?
Professor Hewinson: This comes back to what I was saying at the beginning about TB having co-evolved with the hosts. It uses strategies to subvert the immune response that is responsible for protection in most vaccines. Most vaccines that have been successful are antibody based, and there are very good and well-tried technologies to create vaccines that require antibodies. You have a compound that makes the immune response better, called an adjuvant, and the safety data on that adjuvant has been created over years. Then you can either get an inactivated virus or the part of the virus that you know gives you protection.
That is how bluetongue works. For many vaccines where we know what the basis of protection is, we can create vaccines quite quickly. With TB, you are on the cutting edge of human knowledge, in terms of development of human TB vaccines or bovine vaccines, because of the way it lives within the macrophage. There are very few vaccines that have been produced that stimulate the T-cell part of the immune response. Many vaccines have been produced against diseases where it is easy to produce a vaccine, but you are now into a situation with human immunodeficiency virus (HIV), malaria and TB where you need a different arm of the immune response, so you are right at that cutting edge. It is a much more difficult task that we are facing than with something like bluetongue.

Q358 Neil Parish: The European Commission told us that they are waiting for the UK Government to submit plans for conducting field trials for the vaccine and the DIVA test. Have you had any confirmation from the Commission that field trials can take place in the UK, despite the EU ban on vaccinated cattle?
Simon Hall: The letter appears to say that, doesn't it?
Professor Hewinson: The letter would say that. There are a number of levels; we have to wait for the feedback from the VMD in order to get an Animal Test Certificate, so we might need to generate some more data to get the Animal Test Certificate, which would allow field trials. We are then looking at what field trials might look like in terms of the data we need to generate; it might be safety data, DIVA test data or vaccine efficacy data. It is slightly too early to answer that question. The thinking processes have started, but we are not quite sure what the output should be yet.

Q359 Neil Parish: All right. We do go round in circles on this one; I can understand partly why. If a field trial takes place in this country, and if those animals are dairy cows, I imagine you can carry on using the milk. Can you? If they are beef cattle, there is no way that those cattle could then go into the food chain as the law stands. They certainly could not be exported. Going back to foot and mouth in the Netherlands, they vaccinated a whole load of cattle, and then they had to slaughter them afterwards. They did not have the disease, but because the vaccine was not recognised under IOE rules they were all slaughtered. I think we have to get to grips with where we are going with this.
Chair: I think it was a question, not a statement.
Neil Parish: No, it is important, Madam Chairman, because what are we going to do with these vaccinated animals once we have vaccinated them?
Simon Hall: As this is an unprecedented situation, and because EU law is not actually explicit in all these respects, this is a matter for negotiation between the UK authorities, Defra and the European Commission, to arrive at a plan that will meet everybody's legitimate concerns—and there are some. First of all, Glyn has explained why the BCG is not really quite the same as the bluetongue vaccine. This is a disease with public health implications and international trade implications. Because of the characteristics of the disease and the vaccine, there is a legitimate concern that if you go into a herd of cattle with the wrong strategy, you may not build up herd immunity and eradicate the disease. You may conceal the disease and allow it to spread within the herd, which then presents a risk to the wider community. What will we have to do? What is the thinking of the Commission? You look at analogies; for TB control purposes, you pasteurise the milk. Is that sufficient for milk from cattle in a vaccine trial? Well, it is a good point to argue, but it will need to be backed up with scientific data.

Q360 Neil Parish: You not do even know whether you could use the milk.
Simon Hall: Well, today, no.

Q361 Neil Parish: Sorry to keep on about this, but if I was the farmer, why on earth would I enter into a trial to have my cattle vaccinated, when firstly, I would not be sure whether I could sell my milk, and secondly, I do not know what the hell I am going to do with the cattle when I have vaccinated them? It is a no-brainer. Until you can actually tell us what you are going to do with these cattle, this is why we are going round in circles over the vaccine. It is no good saying this vaccine is a marvellous thing if we cannot even test it.
Professor Hewinson: I agree with you that before you embark on field trials you need to know exactly what you would do with the milk and the meat, and that would be part of the considerations.

Q362 Neil Parish: At the moment you do not know?
Simon Hall: No.

Q363 Neil Parish: It is not only EU, is it? It is IOE as well. You cannot even just blame the EU for this one. It is international trade rules as well, isn't it? I am asking you.
Simon Hall: It is in the legitimate interests of our Veterinary Medicines Directorate that we do not use a vaccine in food producing animals where there is any consequent risk to public health, so these international organisations are not being in any way difficult.

Q364 Neil Parish: No, but they are the ones who lay down the legislation as to whether you can trade meat across borders.
Simon Hall: Yes.
Neil Parish: I think you will find if they did not accept the vaccine, you would not be able to trade that meat across borders. Is that your view as well?
Professor Hewinson: At the moment I do not know.

Q365 Chair: If Mr Parish wants to pursue this, the question is: will the Commission allow us to vaccinate if there is a ban on milk and meat products going to other parts of the EU?
Professor Hewinson: Part of the discussion would come out of the data that the VMD would look at in terms of the safety that has been generated, along with the Commission.

Q366 Neil Parish: But I think you accept my point that farmers are not going to rush out to offer their cattle for vaccination if they do not know whether they can sell the milk or the meat. I think you would probably accept that, would you?
Simon Hall: Yes.
Professor Hewinson: Yes.

Q367 Chair: Will it be for you to decide, or will it be for the Commission to decide how long the field trials will last?
Professor Hewinson: It will not be me.

Q368 Chair: Would it be for the UK authorities?
Professor Hewinson: It would be for the UK to come up with the designs of the field trials.

Q369 Chair: Are you able to say at the moment how long you think the field trials should last?
Professor Hewinson: No, I am not.

Q370 Chair: Is it dependent on this wonderful letter from Commissioner Borg?
Professor Hewinson: It will depend on what data we need to generate.

Q371 Chair: You see, this is what we are getting a little bit frustrated about. When are we going to know what data we need to comply with?
Professor Hewinson: I would hope fairly soon.

Q372 Chair: Within five years; 10 years; our lifetime?
Professor Hewinson: When will we know the data?
Chair: Yes. Fairly soon? Three months; three years?
Professor Hewinson: I would hope that the letters that we get from the VMD will give us a view on safety. The OIE has some very prescriptive numbers that you need to generate to validate your diagnostic test, and then I think the efficacy would be something that you would want to discuss, or that we would design and then show to the Commissioner, on what level of certainty the performance of the efficacy studies gave them.

Q373 Chair: Can I ask you again? How long do you think the field trials will have to last? We do not know.
Professor Hewinson: Not at this time.

Q374 Neil Parish: Do you know whether the Government has sought volunteers to volunteer their cattle for this idea of having a field trial? I cannot see people queuing up.
Chair: I think we will cross that bridge when we get the data.
Professor Hewinson: Yes, to get to the design you need to sort out the issues of milk and meat.

Q375 Mrs Glindon: What estimate do you have of the cost of the vaccine and DIVA test?
Professor Hewinson: Again, that will depend on the scale of use of it, but at the moment, based on the fact that the dose you use is 10 times lower than the badger vaccine, I think the price at the going rate would be about £5 or £6 per dose. However, that will depend on how much vaccine you would use. I think the DIVA test would be a similar price to the gamma interferon test, which is about £25.

Q376 Mrs Glindon: So in total it would be quite a considerable cost.
Professor Hewinson: I do not know if that is considerable, but that is what it would cost. However, there could be scales of efficiency.

Q377 Mrs Glindon: It has been estimated that 50% of the vaccinated cattle population will test positive to the tuberculin test at every routine annual test, and so DIVA testing would be necessary if it was introduced on stream.
Professor Hewinson: What we see from BCG vaccination is that the sensitisation to the skin test falls off such that, at about nine months, there are only about 10% of animals that are positive. Again, this comes to how you would use the test, how you might align testing and vaccination, and the logistics of how you might use a vaccine, but that might mean that you would only use the DIVA test on the positive animals. That is one way that you might use it—I am not saying it has been decided yet—but that would mean that you would be using the DIVA test on maybe 10% of animals.

Q378 Mrs Glindon: Trained members of the public are permitted to vaccinate badgers. Could the same policy apply to the vaccination of cattle, or must the cattle vaccine be administered by a vet?
Simon Hall: In principle, farmers, who are, on the whole, skilled professionals, are allowed to vaccinate their own animals. It is foreseeable that one of the conditions that the Commission might put on in the early stages of the trial is that they want, probably, official vets to carry out the vaccination to make sure that the vaccinated animals are being correctly identified. Other than that, what you say is true.

Q379 Mrs Glindon: Practically, if the animal was identified, there would be no barrier to a trained person who was not a vet administering?
Simon Hall: The competence to administer a vaccine is well within a trained farmer. The level of assurance that we would have to give, quite reasonably, that

vaccinated animals had been correctly identified and were properly controlled, if there were restrictions on how they could be traded, would almost certainly require official supervision, if not officials doing the vaccine, during the controlled stages of the field trail.

Q380 Chair: Could I just ask: is there going to be an administration charge as well as the vaccine and the DIVA test?
Simon Hall: There would certainly be an administrative cost, yes, which somebody would have to pay.

Q381 Iain McKenzie: On that administrative cost, I take it that is a cost for the vet? I take it these animals will have an individual passport as such, a veterinary passport, so the vet will add this to their passport. If the vaccination were administered by a trained farmer or others, would they still be able to add this to the veterinary passport for each animal?
Simon Hall: We are getting into the realms of speculation, because these are details that would need to be sorted out, but actually the cattle traceability system now relies far more on computerised data than it does on paper passports. Paper passports are really just a back-up. In some way, vaccinated animals would have to be officially recorded as such, so that, in particular if we were not at liberty to export them alive to other countries, we could provide those guarantees.

Q382 Chair: It has not prevented horses being—
Simon Hall: If I could just digress a little bit, the Commission blamed BSE for some things, but what BSE has actually given us is a very rigorous system of individual identification and traceability in cattle, with a centralised database, which actually has been extremely valuable in implementing TB controls and would be well suited to regulation of a statutory vaccination scheme.

Q383 Iain McKenzie: Let us take it a step further and look at other vaccines. Are any of you gentlemen aware of any work being done to find vaccines that are more effective and do not interfere with the skin test?
Professor Hewinson: That is research that is ongoing. The ideal would be to have a vaccine that did not desensitise the animal to the skin test, so then you could carry on using the skin test and that would overcome the need for a DIVA test. There is some work ongoing. There are some proofs of principle that there are vaccines that do not desensitise to the skin test, but at the moment none of them have proven as effective as BCG on their own. There is ongoing work, but this is long term; this is not a short fix. Certainly what you pick up from the Commission is that, if you could carry on using the skin test, that would help give that level of assurance, as long as the vaccine did not suppress the skin test response.

Q384 Iain McKenzie: Looking at the other direction, would you say there are breeds of cattle that are possibly more susceptible to bovine TB than others and, if there are, might there be a genetic solution for the future?
Professor Hewinson: Often it is quite difficult to tease apart what is due to a breed and what is due to the management of those animals, in terms of how resistant they are, versus whether your management system is pushing infection. The studies that have been more convincing are, one, a study that showed if you put zebus and Holstein-Friesians and mixed breeds together in a situation where they are all exposed to the same force of infection, zebu animals—these are the African and Indian animals that have the hump on the back—were about twice as resistant to infection or were half as likely to get TB as the Holstein-Friesians. Again, that could be because the Holstein-Friesians may be under more stress and producing more milk, etc. There have been some studies now genetically in the UK and in Ireland that are trying to look at defining heritability of resistance to infection. There is a paper that has come out recently that suggests there is 18% heritability—whether it is resistance to infection or response to the skin test is a key question.

Q385 Iain McKenzie: It is not necessarily straightforward to look at an area of the country and say, "A low infection rate: that equals that particular breed of cattle"? There are complexities involved in it?
Professor Hewinson: It is the complexity. What you would need really to do is to put the different breeds all together under the same force of infection, and see if some were more resistant than others. They are trying to look at certain bulls that have sired, by artificial insemination, and whether there is any association with different lines and resistance to infection within herds, but it is not clear whether that is true resistance or whether it is a response to the skin test that you are testing. It would be wonderful to select for animals that were resistant to TB and did not lose any of their other traits. That would be fabulous. If, on the other hand, you were selecting for animals that did not respond to the skin test, you might have a different problem on your hands. There is more work to be done yet, but it might be possible. There is no one single gene that has been found that gives you resistance; it is a combination of genes.

Q386 Dan Rogerson: Back to badgers, what benefits would an oral vaccine for badgers bring?
Professor Hewinson: As opposed to an injectable vaccine?
Dan Rogerson: Vaccination for badgers, full stop. Inevitably, I would think, an oral one is going to be preferable to trying to manhandle badgers. I will take that as read.
Professor Hewinson: It is obvious. Again, this comes back to the question of how much TB is going from badgers to cows, how much is badger to badger and so on. To quantify the advantage is difficult, but I think the lessons are that, if you do nothing about your wildlife reservoirs, when you model disease, then you will get spillback into cattle. The two control tools you have in wildlife are either culling or vaccination. If you model what happens with vaccination of cows and badgers, if you do both, you will reduce TB

further than just using cattle vaccines alone, because you are creating immunity within that population.

Q387 Dan Rogerson: How much further? Significantly further?
Professor Hewinson: Significantly further. Then, theoretically, could you get herd immunity? I do not know; the logistics are very difficult. However, the modelling suggests that this would take many, many years to achieve, so vaccination would not be a quick fix especially as, when you are vaccinating badgers, you are leaving infected animals, so the vaccine does not cure pre-existing infection. The time it takes for a vaccine to start having an effect in a wildlife population is dependent on the infected badgers dying off and then the remaining population getting more protection. Any vaccination strategy focusing on badgers would need to be, I would say, quite wide-scale and long-term.

Q388 Dan Rogerson: What progress has been made towards developing one?
Professor Hewinson: Oral vaccines?
Dan Rogerson: Yes.
Professor Hewinson: Progress is being made. There are a number of formulations that are under investigation. I would say that none of them are ready for use yet. Oral vaccination, I think, has its own challenges: one, that you have to protect the BCG; and two, you have to reproduce it. There are technical challenges to immunising the animal itself reproducibly. There are technical challenges in delivering the vaccine. The efficacy of a vaccination campaign with oral vaccination is not just how well it works in the individual.
Dan Rogerson: You have to get it into the badger.
Professor Hewinson: It is how much population coverage you can get. There are two challenges to get the right deployment strategy with the right bait and the right oral vaccine. Oral vaccination is harder to control the dose to get to the right place to give you protection.

Q389 Dan Rogerson: Accepting these technical challenges, the question was: how much progress are we making?
Professor Hewinson: There are some lead candidates that have given proof of principle that oral vaccination can give you similar protection to injectable vaccination. There are proof-of-principle studies.

Q390 Dan Rogerson: That is the technical side. The other challenge is getting it in the right forum for badgers.
Professor Hewinson: There are still technical challenges to getting uptake to the different populations. Cubs seem to be slightly easier, in terms of the formulations that we have at the moment, than adult uptake.

Q391 Dan Rogerson: The follow-on question is that, in the Republic of Ireland, they are making some progress; they are trialling something now. Are they further ahead than us and, if so, why?
Professor Hewinson: Actually it is a partnership. We are working together with the Republic of Ireland. We have been doing some of the experimental studies. They are doing a field trial that will give proof of principle that oral vaccination in the field might be possible, and this is linked in with New Zealand, because the formulations that have been used have been developed for possums in New Zealand. It is divvying up the work, working together collaboratively, to try to generate enough data to give proof of principle and to create data that might go into a licensing document.
The trial that is going on in the Republic of Ireland is not a trial of how the vaccine would be finally used, so it is not being incorporated in a bait and being up taken up as bait. They are trapping the badgers, anaesthetising them and then injecting the formulation down, so that they swallow the BCG in a formulation. Although it will give you proof of principle of how the vaccine in that formulation might work, it does not give you—

Q392 Neil Parish: You still have to trap them.
Professor Hewinson: You have to trap them, yes. It is not telling you how effective it will be in a bait. I would say that there is progress, but it is not something that is—

Q393 Dan Rogerson: It is our progress too is what you are saying.
Professor Hewinson: These things are so different. These things take a lot of time. One of the other differences is that every TB experiment takes a year, because the disease progresses so slowly. If you have variation in one experiment, that takes you back a year. We have a very strong network of collaborators, both on the human TB vaccine side, to see if there are any advances that we can apply to badger or cattle vaccination, but also a network of people who work on *M. bovis* vaccination, so that, with the scarce resources around the world to do this sort of work, we are trying to optimise the information that we can all generate in a synergistic way.

Q394 Neil Parish: I want to ask a question about public expectation regarding vaccine and DIVA tests. To use your own words, Professor Hewinson, either badger or cattle vaccine is not a quick fix.
Professor Hewinson: It is not.

Q395 Neil Parish: Yet, in part of the public out there, there is an aspiration that it is a quick fix. What can Defra do to manage people's expectations more on this matter?
Professor Hewinson: You can ask Defra. I think there might be something in public engagement around what is known and what is not known, and the challenges that are ahead.

Q396 Neil Parish: There is no doubt, Madam Chairman, that the more evidence we take on vaccination, one way or the other, one, the more confused we become and, two, the longer time it seems to be in the process. I do not think that the length of time it is going to take to develop these

vaccines has got out to the public. Can Defra not actually be putting more on its websites or whatever? Surely there is something Defra can do.

Chair: It is something we might wish to ask the Minister. Do you have a view?

Professor Hewinson: My view, and I have been doing some of this, is to engage with the press to try to communicate some of these issues. I have been saying it is not a silver bullet—you need to use all the different tools and emphasise some of the complexities around vaccine development.

Q397 Neil Parish: There is also the timescale, this is the point. What we are getting in evidence is that, however we do it, it is going to take some years, probably 10 years, and I just do not think that is coming out. Very few people seem to be aware of this.

Professor Hewinson: I would say the only tool you have around vaccination in the immediate term is the injectable vaccine for badgers. That is licensed and available. The challenge is how you would utilise that most effectively.

Q398 Neil Parish: For cattle, there is none.

Professor Hewinson: For cattle, there is no vaccine at the moment. As Simon says, there is an issue of rolling out and learning as you go, but it is not available yet, no. The only thing that is available is an injectable badger vaccine.

Q399 Chair: Could I just move on to the rationalisation of the veterinary laboratories, Mr Hall? We did discuss it briefly when we met last week. You will be aware of the view that the Committee took, when we took evidence on this in early 2012, particularly of the impact it would have on rural areas. Will you share with the Committee the rationale behind the closure of the vet labs, rather than just saving money?

Simon Hall: When we talk about vet labs, these are the laboratory-testing people standing at benches, working with test tubes and the like to diagnose and investigate disease, carried out in what were then approximately 14 regional laboratories spread around England and Wales, and one in Scotland. Very simply, the level of work that was available for them to do had dropped dramatically and, in particular, large-scale testing and the surveillance and testing campaigns that had gone on for decades—for example, brucellosis testing in the 1970s and 1980s, moving on to BSE and then scrapie testing—had all come to an end and had not been replaced. Fundamentally, we had over-capacity. We had skilled people and expensive facilities with not enough work to do. Even though the workload had dropped dramatically, in fact the costs to us, and eventually the taxpayer, were going up.

First of all, we as an agency have a responsibility to deliver efficient and cost-effective public services, so that has to be a consideration. Also, if skilled people do not have enough work to do, they are unable to maintain their expertise. Also, in the way in which we work, which is quality-assured and where there is a heavy input on health and safety, the overhead cost of each team of people is considerable. That was the essence of the business case for rationalising the laboratory testing done out in the regions from 14 down into six locations, where we can have good-sized teams of staff, which are fully occupied, doing a good range of work, maintaining their expertise and being effectively managed.

Q400 Chair: It is just that Newcastle does not strike me as being a centre of livestock production. Presumably one of the reasons that these veterinary laboratories had grown up was that they were close to where the livestock were. The Committee would just like to know if you have now proceeded to a further consultation with a view to further closures, and completely closing those such as in Thirsk, in my own constituency, where you have already taken some of the scientists out. That has coincided with the rise of Schmallenberg and possibly liver fluke as well. We just wondered if you would like to comment on whether you think the labs now have the resources to cope with such an incident. One issue is a rapid response and a rapid test to limit the economic impact on that community. Clearly, the longer distances the samples have to travel do not necessarily lend themselves to that.

Simon Hall: There are quite a lot of different diseases out there. A lot of the testing that is done is fairly routine. There is no great rush and, in fact, it is commonplace for samples to be transported either by courier or even first-class post between laboratories. It is normal that vets would submit samples to investigate their clients' problems by post or courier. In fact, in amongst our network when there were 14 laboratories for the laboratory testing, it was set up so that certain ones specialised in certain tests. Something that was perhaps hand-delivered to the laboratory in Thirsk would then be couriered overnight to somewhere else where the test was actually done.

In the specific case of Schmallenberg, because it is new and the tests are, to some extent, under development, they are all actually done at the central laboratory in Weybridge, not in the regional laboratories. For diseases where a rapid response is important, for example, foot and mouth disease, that again is already centralised where the expertise is, so Pirbright or Weybridge, and there are rapid mechanisms, including, if necessary, aircraft, to get the samples to the single expert lab. That is laboratory testing.

I would also note that, for many of these tests, there is a commercial market. For example, for Schmallenberg, vets and farmers have the choice of private sector labs, which will provide them with a service and that is fine. That is part of the service.

The consultation, which was out a few months ago and finished on 15 February, was not about that. It was about our disease surveillance network customarily built on a network of, in fact, those same facilities, where there are expert vets there to investigate disease outbreaks or disease events, and with a post-mortem facility for dealing with carcasses as part of that investigation. That is what that latest consultation has been about. It closed on 15 February. We had a lot of responses; we are analysing them. The

principles that were given to us by the independent advisory group chaired by Professor Dirk Pfeiffer again pointed towards concentrating the work in fewer locations, where we can maintain the expertise better. We can maintain and develop the expertise better, and make better use of expensive staff and facilities, by keeping them fully occupied.

Q401 Chair: I am pleased you mentioned that, because my understanding is that Thirsk does most post-mortems for many miles around. Are you saying that now they are going to be couriered or lifted by aircraft to be tested, when they would actually have been tested on the doorstep, as they have been at the moment? Was this all part of the master plan in September 2011, but that was just the first round and this was always planned as the second round of closures?
Simon Hall: To a reasonable approximation, these are different activities.

Q402 Chair: Those are weasel words, "a reasonable approximation".
Simon Hall: Okay, I will say the big picture and then the approximation. Samples—blood samples, faeces samples, milk samples—that need some scientific test done on them to detect disease, for example, are commonly couriered around the country, sent by post and even sent abroad if that is what is necessary to do the test. That is a perfectly satisfactory way of organising that.

Q403 Chair: Excuse me a moment, but is that deemed to be cost-effective?
Simon Hall: Yes.

Q404 Chair: It is better to post it or courier it from Thirsk to Amsterdam than it is to do the original test in Thirsk?
Simon Hall: On the whole, yes, though not Amsterdam but one of our remaining locations, for example in Bury St Edmunds. In the nature of modern laboratory testing, there are economies of scale. You have expensive machines and expensive people. If you can keep them fully occupied, it is much more efficient and easier to quality-control.

Q405 Chair: Do they produce many sheep in Suffolk?
Simon Hall: Sheep in Suffolk?
Chair: Yes.
Simon Hall: Yes.

Q406 Chair: As many as in North Yorkshire?
Simon Hall: I do not know, but possibly not. If I can move on to the second part, the thing that we have consulted on recently is not that; it is about having teams of vets with post-mortem facilities at their disposal to investigate disease and other incidents on farm. That does generate some of the samples that require testing and that is where the overlap is, but not all of them. A lot come in by post anyway. Sorry; I will stop there.

Q407 Neil Parish: I know we got the answers on Schmallenberg, but if you have a suspected case of Schmallenberg on a farm, how long does it take to get it tested? Secondly, are you aware of how far away a vaccine for Schmallenberg is?
Simon Hall: Schmallenberg is not a regulated disease, so it is between a farmer and their private vet. They may well not even notice that they have had the infection, because often it can pass through a flock unnoticed. It is up to them now to decide what level of investigation to carry out.

Q408 Neil Parish: If they wanted to have it tested, how quickly could it be done?
Simon Hall: First-class post into our lab network ends up in Weybridge. I am not sure what the turnaround time is but, if you are doing serology, you are not looking at the acute situation; you are really looking at historic infection. It is not a result you are going to take immediate action on, so the timing is not critical, unlike some things like foot and mouth disease, where you need it virtually instantaneously. On the vaccine, I think you heard from VMD what they know about it and I do not have any better information than that. Unusually, information has been released to the press that there is at least one candidate vaccine under consideration by VMD. Normally this would be regarded as commercially confidential, but information has been released.

Q409 Chair: There is potentially a loss of expertise, presumably, with these vets and post-mortem examinations being lost from areas like North Yorkshire, like Thirsk, where, obviously, Stan Done is internationally renowned for his expertise as a leading veterinary scientist. Are you not the least bit worried that this expertise is going to be lost?
Simon Hall: The point that was brought to our attention by the independent advisory group is, if we want vets with expertise, for example in pathology, pig disease, whatever, for the future, the up-and-coming vets have to have a case load; they have to be able to work with colleagues. That is one good non-financial reason to concentrate this activity in fewer, busier centres. In fact, the objective of sustaining the expertise that we need to carry out surveillance on behalf of Government is one of the main motivators behind the proposal that we consulted on.

Q410 Chair: If you are a vet and you want to work with sheep, I do not suppose you would think of going to Weybridge as the obvious place to go.
Simon Hall: Well, no.

Q411 Dan Rogerson: Something that is raised from time to time—and I represent an area that has a high incidence of TB—is concern about other species, pets for example. We have talked about the health issues around TB and how it passes along the various vectors and so on. Is this something that you are doing any work on currently; whether it is, for example, transferring increasingly into cats?
Professor Hewinson: It is statutory to report TB in different species so, yes, we do report strain type and

culture, especially to our Health Protection Agency colleagues, if there is TB in cats or other domestic species where there might be a health risk.

Q412 Dan Rogerson: Is this something where there is a fairly flat-line number of incidences that are reported to you or is this something that is on the increase?

Professor Hewinson: I would have to get back to you on that, I am afraid. I do not know.

Q413 Dan Rogerson: I would be interested to hear anything you have on that one or any other species that are in contact with people.

Professor Hewinson: We do publish the species.

Q414 Chair: Will you provide, perhaps, not a longer paper but a short note?

Professor Hewinson: We will send you a graph or something like that.

Chair: Thank you. Professor Hewinson and Mr Hall, I thank you very warmly on behalf of the whole Committee for being with us. I am sure we will have an opportunity to meet again in the future. Thank you very much indeed for participating.

Tuesday 19 March 2013

Members present:

Miss Anne McIntosh (Chair)

George Eustice	Sheryll Murray
Barry Gardiner	Neil Parish
Iain McKenzie	Ms Margaret Ritchie

Examination of Witnesses

Witnesses: **Mr David Heath MP**, Minister of State for Agriculture and Food, **Professor Ian Boyd**, Chief Scientific Adviser, and **Nigel Gibbens**, Chief Veterinary Officer, Defra, and **Professor Glyn Hewinson**, Chief Scientist, Animal Health and Veterinary Laboratories Agency, gave evidence.

Q415 Chair: Minister, welcome. Good afternoon and may I thank you and your team very much indeed for being with us and participating in our inquiry into bovine tuberculosis vaccination? You may just like to introduce your team for the record, if you would.

Mr Heath: Certainly. I am accompanied by: Professor Hewinson, who I think has already given evidence to your Committee on this subject; Professor Ian Boyd, our Chief Scientific Adviser within the Department; and Nigel Gibbens, the Chief Veterinary Officer.

Q416 Chair: I shall start by looking at the timetable and the expectation in the public's mind as to when vaccination might be available. It was believed and the Department for Environment, Food and Rural Affairs (Defra) indicated that its aim was to have both the Bacillus Calmette–Guérin (BCG) and the Differentiating Infected from Vaccinated Animals (DIVA) test licensed by 2012. Obviously there has been quite a degree of slippage in that. Now we have been told that "they could not be used in the field before 2015". On what basis was the 2015 date selected?

Mr Heath: I shall start and I am sure my colleagues will want to add more details. As you will know, Miss McIntosh, we had a valuable discussion recently with Commissioner Borg in setting out the possible timetable for a legalisation process for both the vaccine and the DIVA test.

Chair: We will come on to that.

Mr Heath: Sorry; you do not want me to go on to that yet?

Chair: If you could, set the scene.

Mr Heath: I was simply saying Commissioner Borg then wrote to us to say that his view, and I think it was a realistic view, was that we were talking about an approximately 10-year process for everything to happen. Within that, there are obviously benchmarks, some of which are the field testing of the vaccination and the various regulatory processes that then follow. What we are talking about, in the first instance—what I understand your question to be about—is when we might be able to be testing the BCG vaccine and the DIVA test in field conditions. Is that right? Have I understood correctly?

Q417 Chair: It is just that now we are looking at a date of possibly 2023 for a vaccine actually being implemented. The expectation of the public for the use and implementation of a vaccine seems to be wildly out of kilter with what they were led to believe by the Government.

Mr Heath: I think we have always said that this would be a very long process. There is a big difference between having a viable vaccine, which we have at the moment up to a point, and the process of making that legally available within this country, under EU law. Perhaps Professor Hewinson would like to say a few words about the expectation in terms of the timing of the trials that we envisage.

Chair: That would be most helpful. Professor Hewinson, welcome back.

Professor Hewinson: Picking up on that, the letter refers to the 10-year time point as when you might be able to incorporate vaccination as a use across trading partners in Europe. 2015 was envisaged for when you might use the vaccine under field conditions, which is in line with the letter from Commissioner Borg in terms of rolling out the vaccine to start vaccinating in the field, but those would be field trials.

Q418 Chair: Perhaps I am not being very clear. The Committee would just like to understand how you reached the 2015 date.

Mr Heath: I am sorry, Miss McIntosh, if we are not being clear. We have been asked now to produce a model for how we will carry out field trials. We need to discuss that with the EU authorities. We need to satisfy them that what we have in place is satisfactory, as far as they are concerned. We also have to deal with area selection; we have to have people who are prepared to take part in such trials; and there will be bio-security and other implications for the area that is selected. We would like that to happen at the earliest possible opportunity. It is not a question of not having the vaccine, because we are dealing with the BCG vaccine, as you know, which is already available. It is a question of being able to demonstrate that in UK conditions.

I am not trying to be either vague or difficult in not giving you a precise answer; I am saying we will do that as quickly as we can. It is realistic to say that 2015 would be about the time that we would have field trials actually happening. If we can bring it forward from that, the Department will be delighted, but we are also realistic that there are a lot of rivers to cross along the way.

Q419 Chair: Without putting words in your mouth, it was an underestimate of the time that the process would take?

Mr Heath: No; as I say, if we are talking about field trials, we are talking about the same date, although I would love it to be earlier than that. I do not think we have ever said that there would be a time when we would have a vaccine that we could freely use in this country, which would be legal under EU regulation, within anything like that timescale. We have always said it would be a very long process, and what Commissioner Borg has said in his letter is to confirm exactly that point.

Q420 Barry Gardiner: Sorry, Minister; I just want to clear up a confusion here, because in the Defra document, *Bovine Tuberculosis: the Government's approach to tackling the disease and consultation on a badger control policy*, which was published in 2010 by the Department, you stated, "Due to the need to change EU legislation, which is a lengthy process, we anticipate that a cattle vaccine and a DIVA test could not be used in the field before 2015." That was the date that was set then. Were you intending that to mean for field trials, although you did not say that, or was it, as the implication was, that by 2015 you would actually be able to use it?

Mr Heath: Mr Gardiner, as you know, I was not in my present post in 2010, so I cannot speak for what was in the minds of the people who wrote that then, but I am interpreting it in the context of what I know to be the case now.

Nigel Gibbens: Producing a vaccine that can be deployed is a difficult thing to do, as you all know. Even though BCG has been around for a long time, with cattle and deploying in the field, you have the challenge of being able to distinguish between vaccinated and infected animals. You will have heard this before. In parallel with being able to do the work to show that BCG can be at least effective enough to start looking at it as a candidate vaccine, you also have to produce a test—that is novel work done by Glyn and his team—to be able to differentiate one from the other. This all takes time. During the time we have been looking at producing vaccines, we have been doing research and development, and these dates are aspirational. That is why they say, "We do not expect it before" date whatever. What we have now is a much clearer set of conditions that the Commission has set out, which gives us another timetable to work to.

Q421 Neil Parish: This is one of the problems: there is too much aspiration out there and not enough facts. There is no doubt that we have taken a lot of evidence in this Committee about vaccine and the availability of vaccine. I think I am right in saying that the efficacy of the vaccine is only between 58% and 65%. It is being tested in Ethiopia and Mexico so far. Dare I challenge that they may not be the best countries to test it in? Now we are saying that the public is expecting this vaccine to be this great silver bullet to cure the problems we have with TB. How can Defra manage public perception of this much better because, at the moment, they are inclined to think it is just around the corner? Dare I say that some people are perhaps putting that prophesy out there, but it is not? As a Government and as Defra, we need to be absolutely clear that a vaccine is at least to 2023 away, even if we could actually use it across Britain and across Europe then.

Mr Heath: Mr Parish, that has been exactly the point of view that we have been expressing in the debate in the House of Commons and elsewhere, saying that it really is nonsense to suggest that we could do this tomorrow, if only we were not so stupid and obstinate as to refuse to do it. Nothing would delight me more than to have an effective vaccine as part of the array of tools that we can use for bovine TB, and at the earliest opportunity, but the fact remains that we have this conundrum that we have, up until now, not even been able to test it in UK conditions. As you say, we have tested it in countries that arguably are not desperately similar, in terms of their environment, to our own.

We would dearly love to be able to demonstrate effectiveness or otherwise in UK conditions. That is why we made the approach to Commissioner Borg to see what the process would be from now, given that we now have a diagnostic test. We need to demonstrate that both the vaccine and the diagnostic test are effective and then go through the various regulatory and legal hurdles in order to allow them to be used in UK conditions. That is inevitably going to be a long process, which is why we have to develop a strategy that includes all the possible methods we have to bear down on bovine TB, rather than relying on a single one.

I should also say, as you raised it, that because of the level of efficacy of the vaccine, we will always be in a position where, even when we are able to deploy it, we will want to be using a variety of means in order to seek to eradicate bovine TB. It will not be the silver bullet that finally removes the infection from this country.

Q422 Neil Parish: I very much appreciate your answer, but how can we actually get that much more out in the public arena? I should perhaps have checked what is on Defra's website, because I am pretty certain that lots of people think that this cattle vaccine is only a year or two away and will cure all of our problems, when we do need actually to deal with infected wildlife as well as infected cattle. It has to be absolutely clear to the public. We have to be honest with the public exactly where and on what timescale this vaccine will or will not be available.

Professor Boyd: That is absolutely correct. We are approaching this in a structured way by producing a TB eradication strategy, which should be published by June. We expect that to show all the methods that are available for eradication, when they are going to come on line and what their contribution is going to be to the ultimate eradication of TB. That has to be expressed in very plain language and it has to be expressed very clearly, so that the public can see exactly where vaccines and other methods fit into the pattern of implementation of a TB eradication strategy.

Q423 Ms Ritchie: Minister, what is the outcome of the review by the Veterinary Products Committee of the application for the cattle vaccine?
Mr Heath: I think Professor Hewinson is better placed to answer that, so I shall ask him to do so, if I may.
Professor Hewinson: We have received some feedback from the Veterinary Medicines Directorate as a result of the meeting with the Veterinary Products Committee, and it has been very helpful to outline a route to field trial. The clear route outlined is that one needs to get an animal trial certificate, and they have outlined a number of further experimental data that would be required in order to achieve an animal trial certificate. Those are along the lines of what we described the last time I came in front of the Committee: looking at whether BCG is excreted in the milk of lactating animals—further assurance on that—looking at how long the BCG persists at the site of injection and whether there is any dissemination of the BCG into tissues, so that there is assurance of the meat and milk products; and the final area is looking at whether there is any reversion to virulence of the BCG vaccine.

Q424 Ms Ritchie: Does the Veterinary Medicines Directorate require further information before it will issue an animal test certificate, other than what you have already told us?
Professor Hewinson: We are meeting with them tomorrow to discuss the experiments around how we might approach that. The Veterinary Medicines Directorate cannot tell us exactly what they should do, but they can advise which areas we need to create the data from, and then we would submit that data for further review.

Q425 Ms Ritchie: Through the Chair, would you be able to come back to us in writing, on foot of your meeting tomorrow, with any further advice that you may have been given or any further guidance?
Professor Hewinson: I am sure we could do that.

Q426 Ms Ritchie: On what date do you expect to see full marketing authorisation?
Professor Hewinson: The other part of the advice that we are given is that they would not be allowed to give us full marketing authorisation until EU legislation is changed, because there is anti-tuberculosis legislation.

Q427 Chair: Minister, are you surprised at the cumbersome procedure to gain marketing authorisation?
Mr Heath: We have always been very conscious of the fact that this is a very cumbersome process. I am very glad that we are now getting it properly under way, and the Commissioner was actually very helpful to us. I felt that his letter was a very positive response to our need. Nothing about European Union legal process ever surprises me, in terms of its cumbersome nature. I knew it was going to be a long, hard process, and we have to jump an awful lot of hurdles along the way.

Q428 Chair: I know we are going to come on to talk about European Commission procedures, but we heard in evidence that the Commission is reviewing animal health regulations and coming up with a novel EU regulation.
Mr Heath: What we hope they will do is to provide the legal basis for eventually lifting the ban, which is not clear at the moment. We have been pressing very hard to influence the Commission's thinking on this to make sure that what emerges is a clear legal basis on which, eventually, once we have satisfied all of the requirements that we need to along the way, they will be able to lift the ban.

Q429 Chair: Is the Republic of Ireland in a similar position?
Mr Heath: We work very closely with the Republic of Ireland on this, because obviously they have a similar situation, as, up to a point, does France.

Q430 Neil Parish: If field trials take place as the law stands at the moment, what is the status of meat and milk from those cattle that are injected with a vaccine? Can it be used?
Mr Heath: This is one of the things we need to satisfy the European Commission on because, frankly, we need to have an outlet for that meat and milk, assuming it is safe, which is viable in order to help fund the trials. It would be a rather unacceptable offer to any participating farmers: "Please take part in this test. By the way, you won't be able to sell anything for the next few years."

Q431 Barry Gardiner: Minister, I understand that you were not in position in 2010 when the report I referred to earlier was produced, but between the four of you, you represent the corporate memory of the Department back to that time. I wonder if you could tell us, given what you said about the need to change EU legislation in this regard by 2015, what was the first action and proposal that you made to the EU, after that statement in 2010, to try to break that EU logjam, as it were, or to broach the issue?
Mr Heath: Can I be clear? I am afraid we are not a desperately good corporate memory, in that I think all of us—
Barry Gardiner: I am sure you have been briefed.
Mr Heath: With the possible exception of Professor Hewinson, we have been put in post since, which is why I am not in a position to put myself entirely in the mindset of—

Q432 Barry Gardiner: If you cannot, could you write to us setting that out?
Mr Heath: Can I answer your question? There are stages that we have to go through first. It is no good going to the Commission asking for a proposal for field trials until we have not only the vaccine that we have shown to be viable within its limits, but also the diagnostic test, the DIVA test, which we also need to have shown is viable. It is only when all those factors are in place that we could make a sensible approach. Our judgment earlier this year, or late last year, was that all those factors were now in place and we were able to make an approach to the Commissioner, which

is exactly what we did. The Secretary of State and I had a very valuable and positive meeting with Commissioner Borg, and the outcome is as you know.

Q433 Barry Gardiner: Really what you are saying is that it is only since, effectively, the end of last year and the beginning of this that you feel that you have been in a position to make that approach.
Mr Heath: That is right.

Q434 Barry Gardiner: Thank you. That does rather suggest that a 2015 timeline for this to be used in the field was never a realistic option, given that you had a better handle on how long it would take to go to the VMD and the AHVLA and get this preliminary stage under your belt.
Mr Heath: That depends on your interpretation of what was written in 2010. If you interpret that as being a vaccine that was freely available for use across the UK, then I think it was an optimistic assessment. If, on the other hand, you interpret it as being used in the field in the sense that we will be, I hope, using it in the field in 2015, it is exactly accurate.

Q435 Barry Gardiner: It says "used in the field", not "used in the field trials". Let us move on and go from where we are now, which is the letter from Commissioner Borg to the Secretary of State. The Commission has said to us that it is waiting for the UK Government to submit plans for the conducting of those field trials for the vaccine and the DIVA test. Have you had confirmation from the Commission that field trials can take place in the UK, despite the EU ban on vaccination?
Mr Heath: We are in the process of discussion. Mr Gibbens has been talking to his counterparts in the European Commission, so perhaps I could ask him to answer that question, in the first instance.
Nigel Gibbens: You have seen that the letter sets out a number of tests. Quite a cluster of them around safety will be dealt with in the process of the VMD application that is now in place. Although, because of the law, they cannot issue a full authorisation, they will not issue any authorisation at all until we have dealt with a cluster of safety issues. Then you are looking at the performance.

Q436 Barry Gardiner: Would you like to outline those safety issues for the Committee?
Nigel Gibbens: Glyn mentioned this earlier. This is whether the BCG will be excreted in milk, for how long it will be present in the meat of the animal at the injection site or elsewhere, and what are the issues in relation to the food chain. That does require some more work, and the VMD wants to make sure they get it right. It is important to recognise that we are not doing this just for a UK audience; we have to persuade the EU audience, so we have to get it right. That addresses a lot of the issues.
In parallel, we need to plan what field trials will look like. The Commission has made it very clear in their letter that they want really quite extensive trials before they will consider that we have gathered enough evidence to go forward and make any changes at EU level. Similarly, we have the rest of the world to look at, which will also look at it in the same way. There is a bit of an interaction here. You mentioned earlier that we need to make sure that we have confidence around safety, such that meat and milk can be marketed, so that we can plan trials using, essentially, our commercial herd, in a way that is affordable. We now have to do that work in parallel, and we will be in dialogue with the Commission about it.

Q437 Barry Gardiner: There is, at the bottom of the first page of Commissioner Borg's letter, an interesting paragraph that suggests there may be another precondition. He says, "In the past four years the Commission has allocated considerable funds to support the UK bTB programmes…We therefore expect significant improvements in the epidemiological situation in 2013 that show efficient use of Union funds. This is absolutely necessary in view of a further renewal of the EU financial support to this programme." Are you in a position to tell the Committee whether that significant improvement in the epidemiological situation this year actually obtains?
Mr Heath: I can give a political answer to that, rather than a scientific answer.
Barry Gardiner: I think the Commission will probably want a scientific one.
Nigel Gibbens: I will follow up with a technical one.
Mr Heath: I believe the intention of the Commissioner there was to remind us that we have signed up to a variety of actions in this country, which we have set out as part of our bTB eradication plan. Any backsliding from that would be taken as being a dereliction of duty on our part, and the EU would take that into account. It was really reminding us that, not only do we have to take forward the work that we are doing on vaccine, but we also have to take into account the work that we have done in tightening up our bio-security and animal movement areas, and, indeed, the proposals for testing our badger cull proposals, which were all part of the package that we have agreed with the EU.
Nigel Gibbens: The technical answer is very similar. Because we have an eradication plan with the EU, we set out our proposals and they have sought a strengthening of the measures across the board. Dealing with wildlife is one component, but cattle measures are an important component too and, in the last year, we have made some very significant changes. We have changed the proportion of the country on annual testing, so we are looking harder for the disease. We have increased the restrictions on farmers, so they now find it harder to move animals. They are looking to us to tighten the rules around pre-movement testing, where that makes disease control sense, and it does. We will be looking to take that forward.
That will all strengthen our TB control measures. The phrase "the epidemiological situation improving"—we know and they know that that will take a long time, but they want to see us delivering on a comprehensive package of control measures that justifies the spending of EU money. We have to show that we maintain that. We also need to monitor what

is happening and strengthen, where necessary, and they will look for that reassurance every single year.

Q438 Barry Gardiner: That is very interesting, because what you have said, Mr Gibbens, is what they are looking for is outputs, not outcomes, yet what Commissioner Borg's letter suggests is that they are looking for outcomes, not outputs.
Mr Heath: Can I say that, quite apart from the letter, we discussed this point in the meeting with Commissioner Borg, and he made it very plain that he expected us to deliver what we had committed to doing under the proposals that we had previously agreed with the EU. That is exactly what he said in the letter, but he underlined that point. He said, basically, and I'm paraphrasing, "Don't expect us to play ball with you if you promise and don't deliver."

Q439 Barry Gardiner: I am sure that that would inevitably be the case. I am pleased to have your reassurance that there is nothing further that has been demanded in terms of outputs. Can I just check with you? Point 5 in the annex to the letter—this is the timetable now right the way through to 2023 as the end point with the EU—says, if all the above is done, "Possible EU rules on vaccinated animals and herds to enter intra-Union trade". Then it puts in this other phrase "in parallel with amendments of international standards (OIE Terrestrial Code and Diagnostic Manual) [2023]". I just want clarity here that, once we have got to that point, having done everything that goes before in Commissioner Borg's letter, and we get to 2023, we have not overlooked the "in parallel with amendments of international standards". What are the international standards and what are the amendments to them that will have to be brought in to make sure that 2023 is genuinely an end point and not a new departure point?
Mr Heath: Can I say I think it would be a tragedy if it was a new departure point? I entirely agree with you, Mr Gardiner, that we need to look at that. What this is saying is that the outcome, in legal terms, has to be consistent with what we hope to achieve in practical terms. That will involve the Commission looking at changes in EU law. They will have to take into account any other parallel factors that come into play. Of course we understand that, but I do not think we have had drawn to our attention any particular instances that we can expect, within a 10-year period, other than the commitment that he made to try to provide the legal clearance which we have asked for.

Q440 Barry Gardiner: Minister, do you not think it is rather essential that you now write back to Commissioner Borg to ensure that when in 2023 we get to the point where we have possible EU rules on vaccinated animals entering into intra-Union trade, we have clarity on what the additional amendments to the international standards might be, how long it might take to get those international standards amended and who the appropriate authorities are that would have to sign them off?
Nigel Gibbens: What the EU is referring to is the OIE, the World Organisation for Animal Health. It is a standard-setting body. It sets out both guidelines for member countries to follow in securing safe trade in animals and their products, and guidelines on the tests that they should use. Clearly that is very relevant when you are talking about trade in live animals vaccinated for TB against a background in which the vaccine has not previously been used. Those international guidelines will need to be looked at in parallel, and we are already in discussion with the OIE about what they expect. That is part of the work that will have to be done, and we will need to take those two things forward in parallel. This is exactly what the Commission is flagging up.
Mr Heath: It is a constant dialogue.

Q441 Barry Gardiner: Thank you. Mr Gibbens, you are absolutely confident that, when we get to 2023 and we have fulfilled all the other obligations that the EU requires of us, we will not then have a further hurdle to jump? That will have already been negotiated in parallel?
Nigel Gibbens: We are looking to do two things at the same time. The World Organisation for Animal Health is a body that has its own governance. It has a general session that meets every year that signs off changes so, to land this, you have to encourage the Organisation to put forward the changes and then get all the member countries to sign up to those changes in that general session.

Q442 Barry Gardiner: How many member countries are there?
Nigel Gibbens: 175 or thereabouts.

Q443 Barry Gardiner: How long does it normally take for those 175 countries to agree a new set of standards?
Nigel Gibbens: The OIE is quite swift in terms of international standard-setting bodies so, given a good scientific underpinning, it can be done in one year. It is often done in two—one year for the committee to get a good understanding of the proposals, and then another year to go through. Sometimes it takes longer if they are contentious, but it is not out of line with the way the EU operates, or this timetable, but we will have to work on it. I cannot offer you a guarantee now that that process will not have some difficulty.

Q444 Barry Gardiner: Would it be that the OIE needs to see it, having negotiated all the hurdles within the EU, before they are prepared to consider a change in their own rules? Is that likely?
Nigel Gibbens: I will stay with this because I go to the EU often. They do not work on the basis of what the EU does. They are an independent body that existed a long time before the EU and they operate independently. What they will want to see, though, is very much the same scientific evidence, and they, of course, will be reassured by the work that we do to persuade, first, the Veterinary Medicines Directorate, and subsequently the EU and its bodies, of the scientific underpinning of a cattle vaccine and the test that goes with it. The job to be done, and we have already started, is to carry those two things forward in parallel.

Q445 Chair: Could I just ask, are we expecting legislation then? There is the EU regulation, we think, on animal health, which will be directly applicable if it is a regulation, so there would not be a long implementation process in this country. Are we assuming that this is going to be dealt with under that EU regulation, or is it going to be dealt with under separate EU regulation?

Mr Heath: I do not think we are absolutely clear about that process, if I am honest with you. That is one of the things we are talking to the Commission about. They have set out where they think the end point is. Once we have established the scientific credentials, we need to continue to discuss the legislative process with them, because we are not at that point yet. I would be loth to give you an absolute answer that turned out to be incorrect, Miss McIntosh, but we will be guided by their view of what is required.

Q446 Chair: It might be helpful just to have a note of what your current understanding is, because there appear to be two parallel processes going on. One is the current process that you have outlined here today and in earlier sessions, and the other is this other process, which is throwing everything up in the air and coming down with a new European animal health regulation.

Nigel Gibbens: Can I just try to clarify again? What Mr Gardiner was alerting us to was this point in the letter about the OIE. The OIE is an international standard-setting body. It is not a legislator as such, but it sets standards. It does it by adopting those standards at a plenary session that happens once a year in May. That is the thing that has to be achieved. The reference to both the standard and the manual is one says what the rules for trade are, what tests you might expect of your cattle, and the other is the manual that says what the approved tests you can use are, where we would want our DIVA test to appear. We have to do both those things, but it is a standard-setting process, so it is simply the adoption of a standard by that body. There is no further legislative process separate to that.

Q447 Barry Gardiner: My point to you, Mr Gibbens, and to you, Minister, is that I suspect it is unlikely that, until you are at the point where you can persuade the Commission that it is now time for a change in the EU rules, you will be able to persuade the OIE that it is time for them to change their standards. Therefore, it could well be that there is an extended period here.

I have a final question in relation to this, again with specific reference to the Commissioner's letter: he has talked about there still being many knowledge gaps and fundamental scientific information that is not yet available. On page 2 of his letter, he says that "Future studies should also address food safety concerns," and then "human health concerns." Here he puts in brackets, "BCG is the only vaccine available for humans and its use in cattle may lead to the selection of BCG-resistant strains of bTB that may affect also humans." Now, I am no epidemiologist, so forgive me if I misinterpret this, but please put me right. My understanding of what he is saying there is that one would need to have epidemiological studies that show that there is no such effect and transmission to bTB-resistant strains that could eventually cross into human pathology. How are you structuring a test to show that and how many years would it take to successfully show that no such transference could take or is taking place?

Mr Heath: My lay view is that BCG has been in constant use for a very long time now, in dealing with TB, and resistant strains have not yet appeared, up to the efficacy of the vaccine.

Q448 Barry Gardiner: They are alluding to a specific possibility that they are concerned about and that they expect us to be able to plug the knowledge gap about.

Mr Heath: Mr Gardiner, I understand exactly the point you are making. As I say, I am simply giving a lay view. In terms of establishing that to the satisfaction of the regulatory authorities, I don't know whether Professor Hewinson would like to comment.

Professor Hewinson: It is a conceptual concern. To show that experimentally would be extremely difficult. Obviously, one would need to discuss the design of such a trial with them, but you would first look for changes in *M. bovis* during your vaccine field trials. You would collect the strains of *M. bovis*, during those field trials, to see if there had been any consistent changes in the organism.

Chair: I imagine it is fairly academic, because TB is rife in many countries in North Africa. It potentially could be introduced through human—

Barry Gardiner: It may be academic, Chair, but it is a precondition that the Commissioner has put in place in this letter. Therefore, I think Professor Hewinson is absolutely right in talking about the need to speak to them about precisely what would constitute such a trial and how one might go about constructing it and proving it to the satisfaction of the Commission. Again, we do not want to be in a position where we think we have done enough, but then they say, "But we told you back in 2013 that we expected this and you have not done it."

Q449 Chair: Can we have an answer and then we will move on?

Professor Hewinson: I think that is right; this is part of the dialogue that you would have to develop in terms of design.

Nigel Gibbens: I think Professor Hewinson is right. The Commission has raised all the concerns it considers should be addressed. One way of addressing a concern that is quite speculative—this one—is to look at all the factors that might lead to the risk it says we should address, and consider what needs to be done to have reassurance, so to carry out a risk assessment. The strong parallel is between the use of BCG targeting human tuberculosis for many, many years, with BCG having not changed in its efficacy. Your starting point in that discussion should be there, and I believe that is where we should start and then we should consider whether we need to build on that evidence.

Q450 Neil Parish: Going back to meat trading, are there any vaccinated beef or milk products being traded across the world at all at present?
Nigel Gibbens: We believe that vaccination has been used in New Zealand without any restrictions on the use of milk or meat.
Professor Hewinson: In one area of New Zealand, I think they are orally vaccinating their cattle and those animals are, I believe, going into the food chain.

Q451 Chair: Could I just seek clarification, because I am still not clear? Mr Gibbens, you said that the IOE just sets the standards and how the tests are to be done, but presumably they have to be given legislative effect. The report that we have seen from the Northern Ireland Assembly's sister committee to this one clearly says that there is legislative change to be pursued. The Committee would like to know what the legislative change is and how long you think it might be, so that we do not have a piece of string that we cannot define.
Nigel Gibbens: There is specific EU legislation that requires to be changed.
Chair: That is what I am asking.
Nigel Gibbens: That is the legislative change we need to pursue. The OIE, in its job, sets standards; it does not set international regulations that must be complied with by countries. Countries then choose whether or not to follow those standards. Of course, they would be very wise to. It creates an expectation. What happens between OIE standards and EU law is those standards underpin a lot of our requirements. That makes us, as the EU, in line with the international standard and, therefore, not likely to get challenged under the World Trade Organization (WTO). That is what the standards are for. Once they are adopted, there is no more legislative change to make, other than those legislations that you hold domestically or at EU level.

Q452 Chair: First of all, could you identify which EU legislation needs to be changed, and is it different from the EU regulation that is currently being discussed on animal health?
Nigel Gibbens: The EU regulation is the opportunity to enable a change. The two specific pieces of legislation are one on disease control, which says that vaccination of cattle cannot be used, and another on trading cattle, which requires the standard TB skin test to be applied. Both of those, in effect, would have to be amended, and where we are now is the framework of law is changing, giving us probably more opportunity than we would otherwise have to secure those changes.

Q453 Chair: Is that within the frame of 2023?
Nigel Gibbens: Yes, and that is what the Commission is saying with the timetable it has set out for us.

Q454 Chair: Is that independent of the EU regulation that we heard about on animal health?
Nigel Gibbens: No; these things are linked. The change to the framework of EU law is the new EU animal health law. We have yet to see a draft, but we have been working to make sure that draft contains an enabling measure to allow us to use cattle vaccines. We expect to see that draft this spring/early summer, and then it will enter the normal EU process of negotiation which is likely to take two to three years. It will not be quick, but it is still within the timescale that we are looking at.

Q455 Chair: If I am correct and that is an EU regulation, then it has to be directly applied as it leaves Brussels, so it is absolutely essential we have our arguments put and supported by other member states. Is your reading of the situation that the other member states are going to support us at that point?
Mr Heath: I think that is very difficult to judge at the moment. We are obviously making our concerns known to other member states. A key to this is having the support of the Commission. Without that, we certainly are not going to get to where we want to be. Even then, I can give no guarantee that the other member states that are not in the same situation as the United Kingdom and Ireland particularly are, in this respect, are going to want to accommodate us. We can create the atmosphere, I hope, over the next few years, as we do our field trials, as we report on them, as we suggest that we are making real progress on this, in order to make that a reality. It would be very foolish for any Minister to assume that other member states will support anything that we say in the context of the European Union without a lot of hard work going on, in the background and over the next few years, to make it a reality.

Q456 Chair: Will it be a ministerial decision in the Council of Ministers or will it be experts meeting in comitology and committee?
Mr Heath: I think it will be both. Will it not?
Nigel Gibbens: It will be both. The enabling regulation will be Ministers in the Council of Europe and the European Parliament in parallel. You are familiar with this but, because it is enabling legislation, any further changes will be by comitology. Comitology does not mean it is just experts; it still has reference to Council and Parliament.
Chair: That is very helpful. We got there. Thank you very much indeed.

Q457 Sheryll Murray: Can I turn to testing cattle? Minister, given the greater sensitivity of the gamma test, why is it not used alongside the skin test in areas where TB is prevalent, such as the south-west?
Mr Heath: I am not dodging the question; I am simply going to pass it to the Chief Veterinary Officer, because he is better placed to answer it than I am.
Nigel Gibbens: The gamma test is more sensitive than the skin test. Therefore, it does offer you some advantages. It has the disadvantage that it gives you a higher number of animals that do not really have TB and that you end up taking off the farm. Our policy on using that test is to use it where we have reason more aggressively to seek to remove infection. For that reason, it is used in the low-risk area, where we are seeking to eliminate disease and keep it eliminated, and in those herds in the high-risk area where there is a particular problem and we are seeking to move on from repeatedly using the skin test and,

hopefully, clear a herd. There is an element here of the cost effectiveness of the use of the test, so we are using it sparingly, but we are targeting it to where it will have most effect.

Mr Heath: I think there is an argument for using it more. Again, I speak as a layman rather than a specialist, but I think that there may be a case, and I would certainly like the Department to look at this again to see whether there is better scope for using it, particularly in areas with high incidence.

Q458 Sheryll Murray: Could you tell me what steps the Government are taking to improve the performance and reduce the cost of the gamma interferon test?

Mr Heath: Do we have particular research programmes in that area?

Professor Hewinson: Do you mean the gamma interferon test itself or the DIVA test that is based on gamma interferon?

Sheryll Murray: Gamma interferon.

Professor Hewinson: At the moment, I do not think we have much of a research programme that is looking at improving the gamma interferon test, based on tuberculin testing. The companies that make the gamma interferon test are always looking at trying to improve the format and reduce the cost. The focus of the research is really on improving the gamma interferon test as a DIVA test, as opposed to the normal gamma interferon test.

Q459 Chair: We are coming on to vaccination of badgers, but could I just ask a general question? The incidence in the cattle herd in the UK has gone up significantly over the last 10–12 years. The incidence in Northern Ireland and possibly other parts of Ireland as well seems to have gone down. To what might we attribute that fact, Mr Gibbens?

Nigel Gibbens: Sorry; could you just clarify the incidence?

Q460 Chair: Yes. If I am correct, the figures show that the incidence of bovine TB in the UK—well, English herds especially, or British herds—between 1986 and 2009, has gone up hugely. The level and incidence rates in Northern Ireland and possibly also other parts of Ireland as well seem to have gone in the opposite direction; they have gone down. Is there any particular reason for this, any context?

Nigel Gibbens: We have experienced an escalation in our epidemic at least partly to do with the challenges that we faced in 2001. There was a step change in the epidemic in 2001. Northern Ireland does face a similar challenge to ours and its approach to wildlife has not yet changed. We are in the same place as Northern Ireland with wildlife. The difference on the island of Ireland is in Southern Ireland, where they are culling badgers and where they are seeing a greater reduction in the incidence of TB.

Q461 Chair: 2001 was the year of foot and mouth. Is there a direct correlation? Professor Boyd, you are nodding as well. Was there a direct correlation, Mr Gibbens?

Nigel Gibbens: 2001 caused a hiatus in our TB testing. It meant that we were not able to pursue the control measures that we constantly pursue in the way that we had done before, and it disrupted the movement of cattle, in that a lot of farmers needed to restock their herds. With the benefit of hindsight, looking back, you can see that that seems to have seeded more TB, more widely than it had been before. That increased the level of TB in our cattle.

Chair: That's helpful. Thank you very much indeed.

Q462 George Eustice: Given that we had a very long discussion earlier about how difficult it is to get through the licensing process to get a cattle vaccine, I want to turn to the possibility of vaccinating badgers. You have made available a fund, initially of £250,000 a year, for that. In your written evidence, you told us that it was only going to be used in the two pilot cull areas. Could you explain why you are only doing it in the pilot cull areas?

Mr Heath: Sorry, injectable vaccine?

George Eustice: Yes, a vaccine for badgers.

Mr Heath: It is actually being used in a wider area than that and we are co-operating with a lot of other bodies that are interested in pursuing the option of badger vaccination. Badger vaccination is part of the toolbox that we have. It is, again, not wholly efficacious, as you will be aware. It is not an easy route and, certainly, as you will also be aware, we are looking very hard at whether there is an alternative of an oral vaccine available for badgers, which might make for easier administration and cheaper administration, frankly. Nevertheless, it is part of the armoury we have available. Nigel, the details on where exactly it is being used at the moment—do you have a mental map of the country?

Nigel Gibbens: I do not have a mental map.

Q463 George Eustice: The written evidence we have here says "Defra has made available up to £250,000 per year in the form of a grant scheme, use of which in the current financial year has so far been limited to support for vaccination of badgers in the two badger cull pilot areas and to subsidise the lay vaccinator training."

Mr Heath: That is actually a very key part, Mr Eustice, if I may say. We are making the training places available, which allow for lay vaccination elsewhere.

George Eustice: In terms of actually spending the money on the vaccine itself—

Mr Heath: It is not our view that it is the most effective use of that resource at the moment.

Nigel Gibbens: The badger vaccine deployment project does pursue learning about how badger vaccine can be effectively used by injection, and that is going ahead in Gloucestershire, I believe; then there is a variety of places where badger vaccine is being used. It is being used by the Wildlife Trust in some areas. We are supportive of a range of places where it is being used. We are building knowledge about how you can effectively vaccinate using an injectable vaccine; learning more about how effective it is is much more challenging.

Q464 George Eustice: How far away is an oral vaccine, in your view?
Mr Heath: Professor Hewinson is the one who can answer that, but unfortunately it is not making quite as quick progress as I had hoped a little while ago. Mr Hewinson.
Professor Hewinson: I think I gave evidence to you about the progress last time.
George Eustice: Yes, you did. It is already on the record.
Professor Hewinson: We have not made much more progress since last week.
Mr Heath: I wish we had.

Q465 Ms Ritchie: First of all, to go back to the Northern Ireland Assembly, I represent a constituency in Northern Ireland and the Northern Ireland Assembly has made several proposals. Really, it is a mixture of culling and vaccination. I was wondering whether you had formed, Minister, any view or any assessment of that. That is a view that has been, shall we say, adopted by the Dairy Board (UK), which has an interest in Northern Ireland. They suggested that to me only last week.
Mr Heath: On what is happening in Northern Ireland, we certainly are taking a very close interest in what they are doing. I do not think they would claim that it is an eradication package. They are testing the various hypotheses in the field and we can certainly learn from what they are doing. As I say, I do not want to overstate the case, nor do I want to be critical of what they are doing, because actually it is extremely useful to our sum total of knowledge. Nevertheless, I do not think that they see what they are producing as a package that will significantly bear down on or even eradicate—certainly not eradicate—bovine TB in Northern Ireland.

Q466 Ms Ritchie: As a supplementary to that, Minister, are you or your officials talking to the devolved Minister in Northern Ireland or her officials about their ideas, their proposals and their outworking?
Mr Heath: Yes, we are, but I will pass over to my colleagues who do the talking.
Nigel Gibbens: Yes, we are, but the Minister has covered this very well. They are pursuing quite a novel approach. Wales looked at it from a Welsh point of view, and we work with them as well. There is at least a monthly liaison meeting. They could not show a benefit. The island of Ireland could be different. We understand why it is being pursued in Ireland, and we are interested to see the results. Yes, we do; we are in constant dialogue.

Q467 Chair: Could I just ask why you are limiting support for vaccinating badgers to the cull areas?
Mr Heath: As I say, we do not believe that this is the most effective or certainly cost-effective tool that we have available at the moment. We are very happy to look very carefully at work that is being done with the injectable vaccine. The equation, I suspect, would change if we had an oral vaccine. Certainly the injectable vaccine, for all its limitations, is a useful part of what we have available and it may play a bigger part in the future, if we find the right circumstances to use it. It may be the case that there will be areas where it is the most effective way of dealing with the wildlife reservoir of infection, so I do not rule out expanding the programme in places, but our judgment at the moment is that it will be most effective in the areas where we are using it now. At the same time, we want to provide support, both in kind and in other ways, to those people who want to trial its use elsewhere and we will look very carefully at the results.

Q468 Chair: In different regions, are you checking the prevalence and the level of TB in the badger populations, in areas where it is currently not endemic?
Mr Heath: We are constantly trying to assess where the infection is. I proffer this as not necessarily where we are yet, but we need to look again at whether we do post-mortem testing of casualty badgers to have a better picture. I personally would like to see that. I want our officials to look very carefully at the cost effectiveness of that as a proposal, before I commit to doing so. I want to know what is going on, both in the cattle population, but also in terms of the wildlife population as well.

Q469 Chair: Would you publish the findings?
Mr Heath: I see no reason why we should not.
Nigel Gibbens: That covers it very well. On where the vaccine is used, we are quite keen to encourage work with any groups to deploy vaccine where we can foresee a benefit. This might be on the edges of culled areas, where you are looking to protect those badgers on the edge, or it might be at the edge of the highly infected area, where you can deduce that there is a threshold between badgers that are infected and badgers that are free. We would very much like to keep the free badgers free. There are lots of places where you might usefully deploy vaccine, if you can do it cost effectively.

Q470 Iain McKenzie: Minister, a number of NGOs now have trained vaccinators. How is the Government co-ordinating their efforts?
Mr Heath: They are not Government officials; therefore, it is not really our responsibility to co-ordinate them, but we are very happy to talk to them and learn from them about what they are doing, where they are doing it and the results. It is rather the other way round: they are co-ordinating themselves and we are learning from their experience, and offering as much support as we can.

Q471 Iain McKenzie: What is Defra doing to address the concerns that access to the badger grant scheme is not straightforward and that financial support was not provided for many months?
Mr Heath: I am not sure that that is a real, genuine criticism. Of course, I listen to what people say. Certainly as far as our lay vaccinator courses are concerned, which is the biggest contribution that we make, those continue to be freely available and there are vacancies. I do not think it is a reasonable criticism to say that we are not doing enough.

Q472 Iain McKenzie: Why do you exempt farmers and make them ineligible for the grants to train vaccinators?
Mr Heath: I do not have an answer to that, because I was not part of the design of the scheme. I do not know if my colleagues do. I do not want to give you a false answer. I am sorry; we will write to you on that because, as I say, I am afraid I simply do not know the answer to that.

Q473 Chair: To return for a moment to cattle field trials, how long do you imagine that the field trials will last—what sort of period of time?
Nigel Gibbens: We are designing the trials now, and that process will determine how long we have to run the trials for. I am not dodging your question: we will have to design trials that meet our needs and the expectations of the EU. They will be large and long trials, so we must be talking about years, not months, but we are pre-empting the work we are doing to design the trials at the moment.

Q474 Chair: Are you envisaging it might be difficult, the fact that you are going to agree the legislation before the field trials are completed? Will it pose a problem that the legislation—you have just given us the timeline of the next two to three years—may be agreed before you have conducted the field trials?
Nigel Gibbens: No, it will not happen that way round.
Mr Heath: We may get as far as the enabling legislation, but that simply provides a legal basis for going further. I do not think there are any circumstances in which we would persuade the Commission to proceed with specific legislation, until we could satisfy them that we had met their requirements.
Chair: Thank you. I am very grateful.

Q475 Barry Gardiner: Professor Boyd, just very quickly, Defra's written evidence states that there is currently no direct evidence that vaccination of badgers will result in reduced transmission of TB to cattle. You have said that you have an expectation, but that there is no written evidence for that at the moment. Defra prides itself on proceeding on the basis of, I think the phrase is, "best available science". Is that right? Can you just clarify what you are saying here? Is this proceeding on the best available science, insofar as you are conducting an experiment or insofar as there is scientific evidence that says that this is the right way to go?
Professor Boyd: In terms of vaccination, are you talking about?
Barry Gardiner: Vaccination and cull, if you like, yes.
Professor Boyd: There are a number of lines of evidence that support various different types of actions. The main line of evidence that Defra uses is the Randomised Badger Culling Trials (RBCTs), which they have spent about £50 million on running, which were cull-based trials. Now, if we wanted to have the equivalent for vaccination, we would need to go through an equivalent type of design and we are not in a position to do that. We are into a very different situation with vaccination to try to understand what its efficacy might be. That is about learning on the job, as it were. It is adaptive management of the process. That tends to produce rather messy results, where it is really very difficult to interpret the outcome. In contrast to that, we have a lot less messy results with respect to culling. That is one reason why Defra is looking at the culling, because it is much more evidence-based than a vaccination procedure.

Q476 Barry Gardiner: We are trying not to get into the culling as a principle here, at the moment. I do not want to go down that rabbit hole, or badger sett. What I do want to do, though, is to ask you, very clearly, why it was then, given you have just confirmed to me that Defra tries to operate on the basis of best available science, that when the 127 Marine Conservation Zones were up for consideration, you changed the criteria for that consultation and consideration from "best available science" to, I think the words were, "robust science" and "best science"; and indeed why you excluded any information pertaining to them that was over 12 years of age.
Mr Heath: You have a team who are here on animal health.
Barry Gardiner: I am talking to the chief scientist who was responsible for the criteria change.
Mr Heath: Professor Boyd may be able to answer that. I don't know.
Professor Boyd: I am willing to take that on. With respect to Marine Conservation Zones, we have been very clear about the criteria that are being used to develop the evidence base for the decisions that are being made about which zones should be put forward for conservation.

Q477 Barry Gardiner: Sorry; you have changed the criteria. You have changed those criteria from the "best available science" to "best science". You have excluded evidence that is over 12 years of age. Also you have changed the ecological network definitions by which you are going to judge whether there is a coherent ecological network.
Professor Boyd: With respect, I think you are splitting hairs with respect to the semantics. "Best available science" and "best science" are, in my view, the same things.

Q478 Barry Gardiner: Why did you change it then?
Professor Boyd: I cannot answer that but, as far as I am concerned, they are the same things.
Barry Gardiner: The consultation changed from "best available science".
Professor Boyd: They are the same things. With respect to the question about 12 years, I cannot answer that specifically, but I can give you a general response to that about why I think that might be the case. It is that the marine environment, in particular, is a highly dynamic system and information that is old is likely not to be very relevant. I can provide you with a written response on that, if you wish.
Barry Gardiner: I would be very grateful.
Mr Heath: Miss McIntosh, just to return for a moment to badgers, I think I might just add two things

about the vaccination of badgers, the first of which is, of course, the self-evident point that vaccinating an infected animal does no good at all. They are still infected. You cannot cure a badger by vaccination. The other thing to stress is that I would very much like us to have a more effective way of identifying infected badgers, just as I would like us to have the best possible mechanism for identifying infected cattle. I would much prefer to be targeting our efforts on infected badgers, rather than having to take a wider-spectrum approach. I am hoping that those who are working in this area will eventually be able to provide us with options that are better suited to identifying infected animals.

Q479 Sheryll Murray: Could I come back, Professor Boyd, to the comparison we have just heard between the sites for the badger situation and Marine Conservation Zones? Clearly Marine Conservation Zones are being introduced for a completely different reason and they are looking at an ecosystem-based form of conservation. We are not looking at eradicating any disease through the implementation of Marine Conservation Zones. Am I correct there?
Professor Boyd: Absolutely. Marine Conservation Zones are a totally different subject from the management of badgers.
Sheryll Murray: You should not really make that comparison. It is misleading.
Professor Boyd: They are completely different. There is no read-across whatsoever, as far as I am concerned.
Barry Gardiner: Except in the quality of science that you would wish to apply.
Professor Boyd: One could read that across pretty much all activities within Defra and Government.
Barry Gardiner: You should be able to.
Professor Hewinson: I just come back to the issue of trying to collect data in order to give some evidence base, which is difficult for the effect of vaccinating badgers on TB and cattle. How do you try to collect that data? It also refers to another question about what we are doing to try to co-ordinate efforts. As part of the training process, when a vaccination area is chosen, there is a common database in which to upload the locations of where badgers are vaccinated, so that we can look, over time, at whether there has been an effect on cattle TB. This is the adaptive response. It is not as clean and as good as a trial based on RBCT, but I would put the case that, if there are going to be voluntary vaccinations, they should be co-ordinated, so that we can at least try to get some data as to the effect of vaccinating badgers on cattle herds.

Q480 Chair: Moving to the Schmallenberg virus, Minister, are you aware of the scale of the Schmallenberg virus now, and have you been able to do an assessment of the impact of the virus on the livestock industry this year, not just in sheep but in cattle as well, and what the financial implications will be for the industry and for each individual farmer?
Mr Heath: I am very aware of the prevalence of Schmallenberg. It has now been identified in every county in England, which is obviously of concern. I am very aware of the impact on individual farmers of the consequences of infection with the disease, both in terms of sheep flocks and cattle herds. We sometimes forget the cattle herds, simply because the impact was first seen in flocks.
What is more difficult, I think, is to put that into the context of overall disease patterns, overall losses on farms and the definitions of levels of impact, because the EU recognises this as being a low-impact disease. Now, I think that it is quite difficult. Someone who is on a farm facing a considerable number of malformations or stillbirths in their flocks will say, "Well, it is not very low impact for me." Nevertheless, in purely quantitative terms, in purely epidemiological terms, that is true. In terms of its economic impact, it has not had a huge impact across the country. For individuals, it has had a very significant impact.
The good news as far as Schmallenberg is concerned, or at least what we hope is the good news, is that we do believe that there is a degree of immunity following infection, which may persist for some time. It may be that they were infected last year; it is manifesting itself this year, in terms of the births, but that has actually conferred a much higher level of resistance for future years. Therefore, we may actually see very much less impact in the future on flocks and herds. I certainly hope that is the case.

Q481 Chair: Could you just share with us what proof you have of this immunity?
Mr Heath: It is largely from European comparisons, where Schmallenberg has hit first, but I think the Chief Veterinary Officer would be a better person to answer that question.
Nigel Gibbens: Schmallenberg is a newly found virus, so our expectations of immunity are based on what we know of its near relatives in that virus's family and they do seem to produce a strong immunity. It is reasonable to expect that it would last at least a year. The other evidence we have is that we are now in the second year. We looked quite hard to see where the disease affected England last year, and it was all across the South and the East, up towards the Midlands. We have seen a lower impact on those herds and flocks this year and, in the last summer, it spread to the rest of the country and we see a higher impact in those herds and flocks, which tends to support the fact that you have immunity coming from last year to this year, and we are seeing disease in herds that were not previously affected.

Q482 Chair: The incidence in cattle seems to be a lot higher and farmers are specifically asking about immunity. If they lose a calf this year, what is the position with the cow next year? Presumably you do not have that information.
Nigel Gibbens: The expectation for cattle is the same as for sheep so, if a herd is exposed to Schmallenberg, the adult animals that only show a transient disease—what happens with Schmallenberg, as you have heard before, if we are talking about cattle, is if a cow gets infected at the right stage of pregnancy, the major impact is yielding a deformed offspring. That process, it is reasonable to expect, will give you an immune cow for the coming year. For cattle as for sheep, we should expect previously exposed herds to be

protected in coming years, but it is a new disease, so we are still pursuing the research on that.
In terms of the number of cattle affected, we are hearing those reports too. Schmallenberg has definitely spread throughout the country. We looked for it; we found it. The experience from Europe is that, when it passes over a geographic territory, the number of herds and flocks exposed is really very high indeed so, when farmers are looking, they find that their animals have produced antibodies to Schmallenberg. In terms of their losses, whether they have not had a calf when they expected one or whether they have had calf losses, as opposed to a deformed calf from which we can potentially find the virus, there could be many causes. This has been a particularly hard year for farmers. It is not my job to tell farmers how their businesses are going, but it has been particularly hard and it has put pressure on nutrition, which has an impact on the likely success of the whole herd and other diseases that might affect cattle.

Q483 Chair: Effectively, you do not know whether they will be immune or not.
Nigel Gibbens: We cannot give an absolute guarantee, but it is likely.

Q484 Chair: What should a farmer do if he has a case of Schmallenberg in either sheep or cattle?
Nigel Gibbens: When a farmer sees the impact of Schmallenberg through deformed newborns, whether they are sheep or cattle, that is the impact of disease that was introduced to that herd or flock several months earlier. At the time that they see disease, there is nothing that they can do. They have a duty of care when they are lambing or calving to make sure that they look after the welfare, because these deformed animals are hard to calve, so that is very hard for them. Having done that, they are looking towards the coming year and then, with their vet, they ought to consider the exposure of their herd. We will, I am sure, come on to the production of a vaccine by commercial companies in due course but, if there is a vaccine available, a farmer will need to make a decision as to whether it is worth using that vaccine. If his herd has already been exposed, they may not want to do that.
Mr Heath: Can I just add one more thing in terms of information for farmers? I had a meeting with interested parties, including representatives of the farmers' unions. Following that meeting, it was clear that we needed to give as good information as possible to farmers. We have produced a leaflet, which has been made available since. I think it was on every seat at the National Farmers Union conference recently, and the Committee, if it has not seen it already, might like to look at what was produced.

Q485 Chair: Is it available on your website?
Mr Heath: Yes, it is, but we can make the leaflet available to the Committee, Miss McIntosh, so that you know what advice we are giving to farmers.

Q486 Chair: I was specifically asked by a farmer what advice you are giving. Is this the right time to be closing veterinary laboratories, like those in Thirsk, Truro and others, in rural areas where we really could be doing with them to do post-mortem checks, such as the chief vet has just advised?
Mr Heath: We have to make sure that we have viable laboratory services across the country, capable of reacting to whatever situation we face. I am satisfied that we do have that with the measures that we are taking. It is not easy, I have to say, to make sure that we have a system that is adequate to the task, but I believe we have done so. The AHVLA and others make sure that we have the competence, which you would expect, as a Committee, the Government to have. I am sorry to keep on deferring to Nigel, but he is the Chief Veterinary Officer and it is relevant to his area.

Q487 Chair: It would be helpful. Where are farmers in the south-west and farmers in North Yorkshire meant to take the dead lambs and dead calves to be checked?
Mr Heath: Perhaps you can explain what we actually do.
Nigel Gibbens: We need to have an effective surveillance system that gives us both geographic and species coverage. Of course the network of laboratories is relevant to that, but actually what is most important is, as you said, the ability of farmers to submit to laboratories, wherever they are. We are currently looking at the outcome of the consultation on what we do on surveillance next, but it is very important to realise that the thing that Government can do that isn't increasingly being provided by private labs or private vets is the top-level investigation that deals with the unknown disease, the thing we have not seen before—something like Schmallenberg—or allows us to respond very quickly to the emergency diseases, like foot and mouth disease. We need to concentrate on that.
To do that, the historic shape of service that we have had, which is essentially a subsidised diagnostic service, is not now delivering the cover that we need and we need to look at what we should do to make that better. That is what the consultation is all about and that is why we might have to face some tough choices about how we make this better.
Chair: I just leave you with the thought that moving it from North Yorkshire to Newcastle does not seem an obvious choice.

Q488 Neil Parish: I shall move on to vaccines but, before I do, can I echo the Minister's words? To individuals, this disease is a terrible thing. Not only does it seem to be killing cows and lambs, but there have been cases, certainly in south Devon and elsewhere, where quite a number of adult cattle have been affected as well as sheep, so it has a major impact. I do not know whether you would like to comment on that before I just move into vaccine.
Nigel Gibbens: We are familiar with the clinical signs in adult cattle. They are transient but, if it hits a dairy herd and spreads through a dairy herd, then—
Neil Parish: Cattle are being lost through it.
Nigel Gibbens: Cattle are being lost? We would be very interested to see those cattle because, across

Europe and the experience we had last year, we were not seeing adult mortalities. With this disease, that would be extremely surprising. With the farmer, with their vet, we should be looking to make sure that what has happened is being properly attributed to Schmallenberg, because I suspect it would not be. As I alluded to before, we are here to do the further investigation that helps to unpick those unusual things.

Mr Heath: Mr Parish, can I make this point? I know you will know this but just for the record, a key factor here in terms of the effect on a particular flock or herd is synchronicity of tupping, that they go to the ram at the same time, as they do in order to produce Easter lambs. If the midge happens at exactly the wrong time, then you will have high levels of infection in a single flock. If the midge arrives a week or so earlier, then you have immunity and it is good news.

Q489 Neil Parish: I want to pursue the vaccine now. How far away is the vaccine? What are the economics of it? Will farmers use it? Will you advise farmers to use it? What is the situation?

Mr Heath: It is very difficult to answer that question, because there are commercial judgments involved and it is not for us to second-guess the commercial view of the pharmaceuticals. We know, because they have let it be known, that a vaccine is in the process of development. I think we are at the point of it being before the VMD.

Nigel Gibbens: It is with the Veterinary Medicines Directorate and it is quite advanced in the process, but it is not finished yet.

Mr Heath: We are quite close to it.

Q490 Neil Parish: What is the timescale then?

Nigel Gibbens: It is the VMD's process and they have just taken further evidence. We hope that what the companies have come up with will satisfy their needs as to safety. There are no guarantees, but we are very hopeful we will see it before the next breeding season.

Mr Heath: Our problem is that the VMD, quite rightly, is very jealous of its independence and its process and would certainly not like to be leaned on by the Department for Environment, Food and Rural Affairs.

Q491 Neil Parish: I can understand that. Is there an argument for identifying a stock that would have been exposed to the disease, and is therefore likely to be immune to infection, to see whether the immunity does last for a length of time or not? Surely that is an argument. If an animal gets it and then is immune for the rest of its life, or most of its life, then there is probably not the same argument to use a vaccine. If it is not, or it is only for a year or so, then there is an argument, so are you doing any tests on that?

Nigel Gibbens: One of the things we did very early on—this is a good example of collaboration across Europe—is, with the European Commission, come up with a suite of research strands looking at all the key things that we needed to know. Length of immunity is one of them. I do not think that is being pursued in this country, but it is being pursued in the EU, so we will get that information.

Q492 Neil Parish: Do you not think it would be a good idea to pursue it here?

Nigel Gibbens: The point was that we would each play a role and we would use what research money we had to best effect. We do not need to duplicate what is being done elsewhere.

Q493 Neil Parish: I understand that but, present company excluded—I have to be quite blunt with you—we have had evidence before this Committee before where Schmallenberg was more or less, "Oh, well, it's not going to be much of a problem. The sooner it runs through the whole of our sheep flock and cattle, the better, and then it will be all over." Certainly, the experience of individual farmers in Devon and elsewhere is pretty excruciating at the moment. I would like to see Defra taking a slightly more—dare I say it—sympathetic view on this than some of the evidence that we have had before this Committee, both last year and this, where it was almost dismissed as an irrelevance. I take it that is not your view.

Mr Heath: If I can answer that, Mr Parish, I hope I have already impressed upon you that I certainly do not see it as an irrelevance.

Neil Parish: I am not targeting your good self or the previous Minister. It is evidence that came here from a scientific background that I was not happy with.

Mr Heath: I understand that. It does not stop me hoping that exactly the circumstances you suggest are right: that it does, across the country, confer an immunity, which means that the levels of infection and certainly the levels of manifestation, next year, are much lower; and we will not then have it return before a period of time. We were discussing this earlier, in terms of what the patterns in epidemiology are. It would be typical of a disease of this kind if there was a periodicity to it. Perversely, of course, that might be a disincentive to the producers of the vaccine, thinking, "Well, is there any point in us going into commercial production of something that might only be used once now and then not for a dozen years or more?" Who knows? We do take it very seriously and I certainly am very well aware of the consequences.

Q494 Neil Parish: Going back to the previous question, we do need this evidence as to whether they are going to have long-term immunity.

Mr Heath: There is no reason to suppose that sheep and cows in this country will behave in a different way, in epidemiological terms, to those on the near continent, in very similar conditions. If we can benefit from the research that is being done now, there really is very little point in duplicating it.

Q495 Neil Parish: I can understand that, but can we actually help them with their research then? I really think it needs to be taken a little more seriously than it has been in the past.

Mr Heath: We have commissioned some work with the Pirbright Institute to look at the way that the disease actually operates, the way the midges spread the disease, so there is an area of expertise, which we are using our resources on. It is not what you are

describing, in terms of the conferred immunity; it is a different area, but I think it is complementary and means that, at the end of the day, we have a much better picture.

Q496 Chair: It would be very helpful if you could possibly drop us a line on that, Minister.
Mr Heath: Yes, of course. I would be very happy to.

Q497 Chair: A couple of quick questions, if I may: just going back to the BCG vaccine, given the incidence in camelids, would the cattle BCG vaccine be applicable to camelids?
Mr Heath: I do not know the answer to that. Nigel, do you know the answer to camelids? I do not think we have had incidence in camelids, have we?
Nigel Gibbens: I do not think we have done any work on BCG in camelids, but I am going to pass it to my research colleague here.
Mr Heath: Sorry, BCG. I thought you were asking for Schmallenberg. I do apologise. I was still thinking Schmallenberg.
Professor Hewinson: Again, it is to do with the regulatory hoops that you would have to jump through. Just because you can get a licence for one species, you still have to go through the same types of regulatory studies in terms of safety and efficacy in another. You cannot take BCG for badgers and use that evidence to say that it would work in camelids. Equally, you cannot take the data from cattle and say you would do it in camelids. You would actually have to go through the safety and efficacy studies in camelids.
Mr Heath: Having given you completely the wrong answer a moment ago, can I say I am watching very carefully the situation with camelids? I am very much aware of it and I constantly ask the Department for their views on whether we should be taking any further actions in terms of camelids.

Q498 Chair: It was just a point of information: from the date of the skin test, how quickly are TB reactors removed from the farm? Would you have a timescale, Mr Gibbens?
Nigel Gibbens: There is a target that the Animal Health and Veterinary Laboratories Agency works to of uplifting within 10 days. They pretty regularly hit that or beat that target. There is a requirement on the farmer to isolate positive animals, so that they cease to be a risk to the herd. The reality is, of course, the day before the test was read, they were in with the rest of the herd. You do what you can to prevent spread of disease.
Chair: Thank you. You have all been immensely patient and very generous with your time. Can I thank you all very much indeed for participating in our inquiry? We are very grateful.

Written evidence

Written evidence submitted by BVA—BCVA

1. The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom and has over 13,000 members. Its primary aim is to protect and promote the interests of the veterinary profession in this country, and it therefore takes a keen interest in all issues affecting the veterinary profession, be they animal health, animal welfare, public health, regulatory issues or employment concerns.

2. The British Cattle Veterinary Association (BCVA) is a specialist cattle division of the British Veterinary Association comprising 1,250 members of which approximately 950 are practising veterinary surgeons working with cattle in farm animal veterinary practice.

3. BVA and BCVA welcome the opportunity to provide evidence to the Committee on bovine TB vaccination.

4. In the longer term vaccination can and should play an important role in any bTB eradication policy, alongside other disease control measures. However, it is important to understand the current limitations of vaccination, in particular its availability, practical application, true efficacy and legal status. In this context, there is a real need to manage the expectations of the general public as to the potential role of vaccination in bTB eradication.

5. *We do not believe that at the current time vaccination on its own can sufficiently prevent the spread of the disease or eradicate infection from the UK.*

Injectable Badger Vaccine

6. An injectable BCG[1] badger vaccine is currently available and has been deployed in an attempt to manage the disease in wildlife. While there is evidence that the BCG vaccination in badgers confers some protection against infection and reduces the progression and severity of the disease in those that become infected, it is not fully protective and does not prevent the bacteria shedding in infected animals. It also has no impact on those animals that are already infected prior to vaccination, and therefore its use in endemic areas, where the prevalence of TB in badgers is high, is likely to be of limited benefit.

7. There is no existing data to prove that badger vaccination has an impact on incidence of bTB in cattle, and more scientific evidence to demonstrate the efficacy of BCG under field conditions, measured by noting reduction in bTB incidence, is necessary.

8. Vaccinating badgers using an injectable vaccine is resource-intensive, as badgers have to be trapped so that the vaccine can be administered by trained individuals. The process also has to be repeated annually, adding to the cost. As a result, the long-term affordability of an injectable vaccination programme is questionable. Further assessments of the costs of an injectable vaccination programme are being undertaken in Wales and by FERA in Gloucestershire in the single area Badger Vaccine Deployment Programme. These assessments will hopefully provide a clearer picture on the long-term viability of such a programme.

9. The Department for Agriculture and Rural Development in Northern Ireland has adopted a policy of trapping, testing and then culling or vaccinating and releasing badgers depending upon the results of the test, and are modelling this approach for the particular circumstances in Northern Ireland. Modelling work undertaken for the Welsh Assembly did not support this as the most effective strategy in Wales, with culling or vaccination alone being more favourable. The poor sensitivity of the available trap side tests was thought to make the release of infected badgers into a disturbed population a probability, resulting in the probability of an increased perturbation effect compared to culling alone, worsening the situation in cattle herds. We do not support a trap/test/cull/vaccinate- release policy based on this modelling work, but will await the outcomes of the Northern Irish project with interest should it be found that local conditions could be sufficiently different to support such a policy there.

Oral Badger TB Vaccine

10. There is currently no oral vaccine available for bTB in badgers and our representations to Government have called for more research and development to be conducted. We therefore welcomed the Government's commitment to further invest in this area.

11. It is hoped that an oral vaccine would be easier and cheaper to administer than an injectable vaccine as trapping would no longer be required. However, there are a number of challenges in the development of an oral vaccine which would need to be addressed before the vaccine could be licensed and deployed in the field. These include:

(a) Identifying a palatable carrier substance for the vaccine which the target species will eat but which will not be taken by non-target species.

[1] A scoping study undertaken by a sub-committee of the ISG identified clearly that the only candidate for practical development for a vaccine in cattle and badgers is BCG. BCG was licensed for use in badgers in March 2010.

(b) Combating the problem of acid degradation in the stomach of the target species.

(c) Identifying the correct dose of the vaccine, as animals may not eat all of the carrier substance.

(d) Ensuring that as many members of the target species as possible are reached (particularly cubs) and in sufficient numbers.

12. There have been a number of oral vaccine trials in recent years and of particular interest are the trials currently underway in Ireland. In addition, work taking place in New Zealand looking at an oral vaccine for possums may provide some direction.

Cattle TB Vaccine, DIVA Test and the Impact of Vaccination on Cattle and Cattle Product Exports

13. At present, EU legislation does not allow the use of vaccination against bTB in cattle as part of an eradication programme. Any vaccine would therefore require amendments to be made to EU legislation. Furthermore, any acceptance within the EU for the use of such a vaccine in an approved TB eradication programme is likely to be subject to the ability to differentiate vaccinated from infected cattle using a DIVA test.

14. Similar conditions apply in the context of international trade. EU legislation, with respect to the trade of healthy animals and their products, is based upon the conditions of the World Organisation for Animal Health (OIE), the intergovernmental organisation responsible for improving animal health worldwide. For the EU to adopt changes to bTB controls, the OIE conditions will also require adaptation to ensure third-country trade.

15. These legislative hurdles are not insurmountable, but the time and effort required to drive such fundamental changes on a worldwide stage with only limited international support from bTB free countries should not be underestimated.

16. Work is ongoing on the potential licensing and deployment of BCG vaccination in cattle. We understand that the VMD will soon be reporting on a dossier that has been submitted for licensing a product 'in principle' and this will give an idea of the requirements for further field work needed in this country. Once licensed, a vaccination programme (specifying which animals should be vaccinated, requirements for boosters etc) will have to be designed and farmers encouraged to use it. Determining the efficacy of the vaccine under UK field conditions will be an important factor when evaluating the cost/benefit of such a programme.

17. There are high expectations of cattle vaccination; however as noted above in relation to badgers, the BCG vaccine is not wholly protective against infection, but reduces the progression and severity of the disease in those animals that become infected. Vaccination must therefore be accompanied by a DIVA test to differentiate those animals which react positively to the bTB test (the 'skin test') due to natural infection rather than being sensitised by vaccination. Although a DIVA test is available, as with the vaccine itself, it has not been tried and tested in UK field conditions.

18. It is important that an appropriate vaccine be developed and made available as quickly as possible. However, this is inherently a lengthy process and again, public expectations must be managed better such that the challenges of developing effective and easily deployable TB vaccines (for use in cattle or badgers) and the limitations of the current vaccine candidates are fully understood and accurately conveyed. It would be useful for a best/worst case timeline scenario to be drawn up and published to reflect all these issues and give a better understanding to all stakeholders of the challenges that lie ahead.

Summary

19. As stated above, vaccination can play an important role in eradicating TB. However, a policy of vaccination should take place alongside other control measures. Whilst the slaughter of cattle found to be infected with TB has been an essential part of the strategy to control the disease in cattle for many years, targeted, managed and humane badger culling is also necessary in carefully selected areas where badgers are regarded as a significant contributor to the persistent presence of bTB. In addition, risk-based biosecurity, surveillance and Farm Health Planning at a national, regional and farm level is essential for the control, prevention and eventual eradication of bTB. A holistic approach to TB control is needed, and we should learn from the control principles employed to tackle other similar diseases such as Johne's.

January 2013

Written evidence submitted by the Department for Environment, Food and Rural Affairs (Defra)

Introduction

1. The Government welcomes the Committee's inquiry, which is an opportunity to ensure that there is better understanding of the importance attached to the ongoing but technically complex work to develop and make available vaccines for tackling the problem of bovine tuberculosis (TB).

2. Bovine TB is the biggest threat to the livestock industry in England. The disease has a significant financial and emotional impact on farmers and the current control regime costs the taxpayer around £100 million a year. At present, bovine TB is still not under control and there is no single measure that would, on its own, change the situation dramatically. That is why the Government has a comprehensive, balanced and evidence-based package of measures designed to bear down on the disease in the worst affected areas and prevent its further spread. Badger vaccination by injection is one of the measures already available. We are working hard to develop and make available an oral badger vaccine and a cattle vaccine as soon as practicable.

Benefits and Limitations of Vaccination

3. At present, the only available vaccine for tackling TB—including in the human population—is Bacille Calmette–Guérin, or BCG. BCG does not guarantee full protection and vaccinated humans and animals can still be infected and develop disease. Laboratory studies have, however, demonstrated that vaccinating badgers and cattle with BCG can reduce the progression, severity and excretion of bovine TB, thereby reducing the risk of infection and transmission of the disease.

4. The ultimate aim of a sustained bovine TB vaccination campaign would be to ensure a large enough proportion of the vaccinated animals is protected such that transmission of disease is reduced and disease cannot be sustained. This would take time to achieve, however—if indeed it is possible, given the limited effectiveness of BCG vaccination in preventing infection and the lack of scientific evidence that the vaccine will benefit animals that are already infected.

5. Despite the limitations, making effective use of the currently available injectable badger vaccine and developing effective cattle and oral badger vaccines are high priorities for Ministers. Successive Governments have invested more than £43 million on vaccine research and development since 1994. Research is ongoing and by the end of this spending review period the Coalition Government will have spent a further £15 million.

Badger Vaccination

Effects of badger vaccination

6. In wild badgers, a four-year safety field-study demonstrated that BCG vaccination in a naturally infected population resulted in a statistically significant 73.8% reduction in the incidence of positive results to a badger antibody blood test for TB. Although not a true efficacy figure, this is consistent with a protective effect of vaccination as antibody production is positively correlated with the extent and severity of TB infection. Further analysis of the study data identified an indirect protective effect in unvaccinated cubs (but not adults) in vaccinated social groups such that the risk of unvaccinated badger cubs testing positive to TB decreased significantly as the proportion of vaccinated individuals in their social group increased. When more than a third of their social group had been vaccinated, the risk to unvaccinated cubs was reduced by 79%.

7. Benefits from vaccination of badgers would be expected to accrue incrementally during a vaccination campaign, as the number immunised increases and infected badgers die off naturally. There is no empirical evidence on the optimal length of time of a badger vaccination programme. Benefits will start to accrue from the onset of immunity and current opinion suggests that most individuals already infected with bovine TB will die off within five years.

8. While we would expect vaccination of badgers with BCG to result in reduced transmission of TB to cattle, we currently have no direct experimental evidence on this. Computer modelling has indicated that sustained badger vaccination campaigns could be beneficial in lowering TB incidence in cattle but its precise contribution is unknown. To be able to quantify this contribution it is likely we would need to carry out a large-scale field trial (on a comparable scale to the Randomised Badger Culling Trial) the results of which would take many years to collect.

9. Defra is working with Fera, the Animal Health and Veterinary Laboratories Agency (AHVLA) and external experts to investigate potential methods that will allow assessment of the impacts of BadgerBCG deployment on cattle TB incidence.

Use of injectable badger vaccine

10. More than 10 years of Defra research effort culminated in March 2010 in the licensing of an injectable badger vaccine (*BadgerBCG*). The vaccine has a Limited Marketing Authorisation from the Veterinary Medicines Directorate (VMD)—which means it is subject to renewal after five years—and is currently available for use by vets and trained lay vaccinators under prescription from a veterinary surgeon. There are currently 137 lay vaccinators from 34 different organisations, all of whom have completed training carried out by the

Food and Environment Research Agency (Fera), as part of Defra's Badger Vaccine Deployment Project (BVDP—see below).

11. There are three main ways in which BadgerBCG is currently being deployed:

- Government agency deployment (by way of the BVDP in England and in the Intensive Action Area in Wales);
- use by voluntary and community sector organisations (most notably by a number of Wildlife Trusts and the National Trust); and
- use by commercial contractors.

12. In England, the aims of the four year Defra-funded BVDP in Gloucestershire are to build confidence in the principle and practicalities of vaccination, develop practical know-how for vaccinating badgers and provide the capacity to train lay badger vaccinators.

Table

THE NUMBER OF PREMISES, AREA AND NUMBER OF BADGERS VACCINATED AS PART OF THE BVDP

Year	*Number of premises vaccinated*	*Area of land trapped and vaccinated (km^2)*	*Number of badgers vaccinated*
2010	93	90	541
2011	86	84	628
2012	115	95	998[1]

Table Note:
[1]The increase in the number of badgers vaccinated in 2012 is largely a result of recruiting additional land with high badger density.

Practicality of BadgerBCG

13. Injecting badgers with BadgerBCG requires that they are cage trapped. In practice, it is inevitable that not all badgers in an area will be trapped and vaccinated. There is also the problem that, depending on the size of the area being vaccinated, badgers from neighbouring unvaccinated areas may act as a constant source of infection.

14. Manpower is the biggest single cost. Estimates for badger vaccination can vary widely according to factors such as ease of access to setts, terrain, weather, time of year and experience of personnel. The cost will also depend on factors such as the size of area being vaccinated, density of badgers, frequency of vaccination, and model of deployment. Defra cost-benefit analysis work has estimated cage trapping and vaccination at around £2,500/km. Results emerging from the BVDP are in line with this figure and our current best estimate for the deployment of injectable Badger BCG is £2,000–£4,000/km^2.

15. While we are starting to see voluntary groups working in partnership with farmers to vaccinate badgers, the prospect of vaccination being carried out over a significant proportion of the endemic area in England remains remote. Social research, carried out as part of the BVDP, suggests that there is little interest from landowners and farmers partly because of the costs involved and partly because of the limited confidence many have in the ability of badger vaccination to reduce the incidence of TB in cattle.

Developing an oral badger vaccine

16. A badger vaccine which could be administered orally through baits would be more practical to use in the field and may, potentially, be cheaper than the currently available injectable vaccine, depending on the dose and number of baits that need to be deployed per badger to ensure adequate uptake.

17. Defra has been funding research into the development of oral vaccine candidates since 2005. Further scientific evidence is, however, needed before we can take a candidate vaccine forward to licensing. Linked to this is the need for a deployment strategy for vaccine bait which will maximise uptake among the target badger population and, as far as possible, minimise consumption by other wildlife species or cattle.

18. Until the results of the necessary, ongoing further research are known we cannot be certain of the timescale within which an effective and affordable oral badger vaccine may be available. As of now, no product is ready for licensing. In moving towards a licensable vaccine a key challenge will be to identify from a number of different formulations those which are likely to be most effective, practicable and affordable to deploy. This may rely on scientific breakthroughs and require further research and development work.

Potential contribution of badger vaccination to bovine TB eradication in England

19. There is no evidence that vaccination can disrupt badgers' social group organisation and, therefore, this method of controlling bovine TB in badgers does not have the potential risks arising from perturbation

associated with culling. Ineffective delivery of vaccination is also unlikely to make the disease situation worse. On the other hand, the problems with vaccination of badgers include: the lack of empirical evidence that it can contribute significantly to reducing TB in cattle; the high cost of deploying it; and its estimated effect on the weight of TB infection in badger populations, compared to controlled culling of badgers, over a given timeframe.

20. That is why the Government's view is that badger vaccination on its own is not a sufficient response to the problem of bovine TB in badgers or cattle. As part of an eradication programme that includes badger culling, vaccination of badgers could, however, help reduce the potential negative effects of culling due to "perturbation"—for example, by using vaccination as a buffer at the edge of control areas, or on land within control areas where no culling is taking place (where no other physical buffers or barriers are available).

21. Badger vaccination may also form part of an "exit strategy" from culling—vaccinating remaining badgers with the aim of establishing herd immunity in previously culled areas, for example. Or it could be used to reduce spread to new areas by vaccinating at the edge of high cattle TB incidence areas. To encourage the use of badger vaccination, Defra has made available up to £250,000 per year in the form of a grant scheme, use of which in the current financial year has so far been limited to support for vaccination of badgers in the two badger cull pilot areas and to subsidise the lay vaccinator training and certification costs for voluntary and community sector organisations.

Cattle Vaccination

Developing a cattle vaccine

22. Following extensive research and development work carried out by AHVLA since 1999, an application for "in principle" approval of a marketing authorisation (which is required to place a veterinary medicinal product on the market) for a BCG cattle vaccine was submitted to the Veterinary Medicines Directorate (VMD) for assessment in January 2012. VMD began its assessment procedures in March 2012, following validation of the application. Further information requested by VMD was provided in November 2012. Indications are that the assessment process (which includes external, independent scientific advice) will be completed in the first half of 2013, in line with normal timelines for such applications. In practice, however, VMD will only be able to grant a full marketing authorisation when EU legislation allows vaccination of cattle against TB.

23. The efficacy of BCG vaccination of cattle has been tested in experimentally infected animals, with a mean level of protection (measured as a reduction in visible pathology scores) of 70%. As in badgers and other species, BCG vaccination provides cattle with a spectrum of protection:

- some cattle will be fully protected;
- some will benefit from reduced disease; and
- some will get no protection from vaccination.

24. Because of the EU prohibition on use of BCG vaccine in cattle, it is extremely difficult to collect robust scientific evidence on the performance of the vaccine in cattle in a natural transmission setting. AHVLA has, however, conducted a study in Ethiopia which involved vaccinating calves when between one and 15 days old before they were introduced into a herd containing a large proportion of bovine TB infected cattle. Although a relatively small study, vaccination of calves with BCG in this study provided significant protection against strenuous TB challenge by natural transmission. Overall, the protective efficacy of BCG was between 56% and 68% (depending on the parameters selected).

25. In terms of practical deployment of the vaccine, research results provide evidence that calves as well as older cattle can be protected by BCG vaccination to equal levels. They also suggest that annual revaccination would be desirable. The research results are still under assessment by VMD.

EU prohibition on use of BCG vaccine in cattle

26. EU legislation requires that cattle traded in the EU come only from herds with Officially Tuberculosis Free (OTF) status. This status is determined through use of the Single Intradermal Comparative Cervical Tuberculin Test (SICCT—commonly known as the tuberculin skin test) on each animal in the herd. OTF status must be suspended if animals give a positive reaction to this test.

27. BCG vaccination of cattle can interfere with the tuberculin skin test by sensitising the animal to the test, such that a vaccinated animal might produce a positive reaction regardless of its TB infection status. Mainly for that reason, current EU legislation does not allow the use of cattle vaccination against bovine TB. The European Commission has stated that if a candidate vaccine succeeds in showing scientifically sufficient protection, and no interference with diagnostic tests, it might be used as an additional tool to accelerate TB eradication under certain circumstances. But for this to be allowed, EU and international animal health rules would need to be substantially amended.

Road map for introduction of a cattle vaccine and DIVA test

28. A crucial element of the current work on cattle vaccination—because it is, in effect, a pre-requisite for the lifting of the EU ban on use of the BCG vaccine—is to validate a so called DIVA test. This is an ancillary diagnostic test developed by AHVLA that can differentiate infected from vaccinated animals, the prime candidate for which is based on the interferon-gamma bovine TB blood test. Advice from the European Commission suggests that validation of the DIVA test by the OIE (the World Organisation for Animal Health) and an opinion on cattle vaccination from the European Food Safety Authority will be pre-requisites for any Commission proposal which would provide a legal base for cattle vaccination.

29. International opinion on the approach to validation of the DIVA test has already been canvassed from three international laboratories with expertise in bovine TB. A potential weakness is that the scientific evidence we have on its performance is limited to the results of experimental studies. No EU-generated field trial data currently exists. Work on how such field trial data might be collected—ideally from field trials conducted in the UK—is currently in progress.

30. The Government is continuing to work with the European Commission to develop a road map for introduction of cattle vaccination and the accompanying DIVA test. This is happening at both Ministerial and official level, with goodwill on both sides. We envisage that key domestic stakeholders will have an important part to play in the process in and we will involve them in taking the work forward.

Risks of use of cattle vaccination in contravention of EU law

31. Vaccinating cattle in the UK against TB without a Marketing Authorisation for the vaccine would run the risk that trade in live cattle with other member states could be banned. It is possible that the European Commission would also consider the need for restrictions on cattle products, including meat and dairy products. Any restrictions on EU trade would also put at risk exports to third countries, with some importing authorities likely to follow the EU's lead (including those where markets have been opened up, or restored, relatively recently). While the export market for live cattle is relatively small (valued at £496,000 in 2011), the value of beef and dairy exports is much greater and has been steadily growing in recent years. Beef exports reached almost £490 million in 2011 and dairy grew close to £1.2 billion. It is estimated that the recent lifting of the Russian ban on British beef and lamb could be worth £80 million over the next three years.

Potential contribution of cattle vaccination to bovine TB eradication in England

32. Vaccination of cattle against bovine TB, used in conjunction with existing TB control measures, could have benefits in reducing the prevalence, incidence and spread of TB in the cattle population and could also reduce the severity of a herd breakdown regardless of whether infection is introduced by wildlife or cattle. Early modelling work suggests, however, that while there remains a constant reservoir of badger infection cattle vaccination would not on its own eliminate bovine TB from the national herd.

33. Nevertheless, Defra is currently funding the development of two further mathematical models to look specifically at cattle vaccination within a herd and optimum ways to deploy a cattle vaccine. Defra and AHVLA officials also played leading parts in an international workshop of cattle vaccine scientists held in Cardiff in December 2012, which was designed to advance current thinking on the role that a cattle vaccine should play in TB eradication. One of the next steps is a policy workshop to address the difficult legal and operational barriers on the path to deploying a vaccine and associated DIVA in the UK.

Conclusion

34. Vaccination of both badgers and cattle, while not solutions to the huge problem of bovine TB in England, are potentially important components of what is necessarily a comprehensive, multi-faceted eradication programme. The barriers to wider use of the currently available injectable badger vaccine and deployment of a cattle vaccine and oral badger vaccine are sizeable and will take time to overcome. In the meantime, it is important that other means are used to bear down on the disease.

January 2013