House of Commons

Environment, Food and Rural Affairs Committee

Vaccination against bovine TB: Government Response to the Committee's Second Report of Session 2013–14

Third Special Report of Session 2013–14

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Environment, Food and Rural Affairs Committee

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Third Special Report

The Environment, Food and Rural Affairs Committee reported to the House on *Vaccination against bovine TB* in its Second Report of Session 2013–14, published on 5 June 2013 as HC 258. The Government's response to the Report was received on 5 September 2013.

Government response

Introduction

The Government welcomes the Environment Food and Rural Affairs Committee's helpful report on 'Vaccination against Bovine TB' and its recognition that whilst vaccination of both cattle and badgers are potentially important tools in the overall TB control strategy, they are not enough on their own.

The Coalition Government made clear from the outset that its policy has been to introduce a carefully managed and science-led policy of badger control in areas with high and persistent levels of bovine tuberculosis, as part of a comprehensive package of measures to address this terrible disease. That continues to be the case. The draft Strategy for achieving Officially Bovine TB-Free Status for England ('the draft TB Strategy') launched on 4 July sets out our proposed approach for the future.

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)

The Government is constantly looking for ways to improve communications on its approach to tackling bovine TB to what is a very diverse stakeholder group. In the case of work in support of an application to the Veterinary Medicines Directorate (VMD) for a marketing authorisation (MA) for our candidate cattle vaccine we are, however, constrained by what is a strict regulatory process. Nevertheless, we will reflect on what more we can do to improve communications for the future.

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)

On 4 July 2013, the Government commenced a consultation on its draft TB Strategy, which considers the use of existing tools and progress in developing new ones, including timelines. To aid public understanding, the Government is funding a 'citizen dialogue on bovine TB' project which will support the public consultation on the draft TB Strategy and provide a basis for ongoing dialogue.

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)

Vaccination of cattle against TB is prohibited under EU law and Defra's communications have reflected that formal position. Commissioner Borg's letter of 14 January 2013 starts by referring to that explicit ban and goes on to propose large scale, long lasting field trials to examine the scientific basis of the vaccine and DIVA test.

Field trials may only take place if the Government is successful with an application for an Animal Test Certificate (ATC), which would need to be awarded by the VMD. . We are in discussions with the VMD on the precise details of this, including what scientific data is needed to support our application.

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)

The Government welcomes the Select Committee's comments.

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)

At this stage of the field trial design process it is not possible to provide precise details of how they would operate—for example, the number of herds that will be required and how the field trials will be managed. That will depend, in part, on the terms of the Animal Test Certificate, should we be successful in our application to the VMD. Given the probable scale of the field trials, it is likely that they would need to involve commercial herds.

We are fully seized of the need for additional data to be generated on the public safety aspects of the candidate vaccine, as is the European Commission. Work on this will be completed in time to support our application for an ATC.

The Government will communicate details of the planned field trials, within the necessary constraints of the regulatory processes, both to the Committee and to stakeholders and on an ongoing basis.

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)

The Government notes the Committee's recommendation and agrees that the work towards the ultimate lifting of the legal ban on trade in vaccinated cattle should happen as quickly as possible. Whilst the Government would hope to be able to compress the indicative 10-year timetable set out by the Commission, it should be noted that the requirements set out in Commissioner Borg's letter of 14 January to the Secretary of State are challenging. The initial stage of this process will involve large-scale and long-lasting field trials. These will be complex and expensive trials, and it is important that sufficient time is taken to design and execute them properly so that they provide the necessary data to address the issues raised by the Commission.

The ongoing dialogue between the Government, EU and the OIE is an integral part of the ongoing process and will lay the foundations for later stages of this work.

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

The Government wrote to the European Scrutiny Committee in March 2012 and July 2012 providing updates on progress in developing a proposal for an EU Animal Health Law. On 6 May 2013, the European Commission published its proposal for an EU Animal Health Law to replace around forty basic Directives and Regulations, some adopted as early as 1964. The European Commission's press release is available at http://europa.eu/rapid/press-release_IP-13-400_en.htm. On 22 May 2013, the Government submitted an Explanatory Memorandum (Ref. 9468-13 Proposal for a Regulation of the European Parliament and of the Council on Animal Health) on the proposal to the European Scrutiny Committee. The European Parliament and the Council will consider the proposal and adopt their positions in due course. The European Commission estimates that the proposal will enter into force in 2016, to be followed by a proposed three-year transition period.

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)

The Government agrees and work on the cost-benefit analysis is underway.

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)

The Government welcomes the support of the Committee for the ongoing research programme to develop cattle vaccines against bovine TB and associated diagnostic tests. In addition to the work towards field trials of the BCG vaccine and interferon gamma DIVA test, the government continues to invest in the next generation of vaccines and diagnostic tests.

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)

The Government acknowledges that there are gaps in our knowledge about the performance of badger vaccination on the level of disease in a badger population when deployed across wider areas, and the impact of badger vaccination on TB breakdowns in cattle herds. Mathematical modelling has been used to predict the possible outcome but investigating both of these questions in the field would require expensive, large-scale field trials.

Data on the use of the injectable badger vaccine in the field by other organisations, including the Welsh Government and various NGOs, is being collected. Over time, the growing database of badger numbers and locations has the potential to be used to assess the effects of badger vaccination on TB in cattle herds. Potential protocols for doing this are under discussion by Defra officials and researchers from AHVLA and Imperial College.

Badger vaccination must form part of any strategy to eradicate bovine TB, though badger vaccines cannot cure diseased badgers. These diseased animals will continue to infect cattle herds.

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)

As the Committee acknowledges, the Badger Vaccination Deployment Project (BVDP) was not designed as a scientific trial to test the effectiveness of the vaccine or the impact of its deployment on the incidence of TB in cattle. Rather, the BVDP is in place so the Government can learn practical lessons from deploying the vaccine in the field and to provide a platform for training lay vaccinators. Those objectives are being met through operations at the single project area in Gloucestershire. The other five BVDPs would only have served to replicate those data.

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)

The Government is supportive of vaccination. For example, it continues to support the BVDP and has set up the Badger Vaccination Fund to provide successful applicants with up to 50 per cent towards the first year costs of vaccination. The Government is keen to work with others to coordinate vaccination activities and to encourage vaccination through training and start-up grants. It also represents an important part of the draft Strategy referred to above, in the edge areas in particular.

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)

We acknowledge that the relative importance of cattle and badger transmission is a key evidence gap, but this is extremely difficult to address experimentally and likely to differ in different epidemiological situations. Mathematical modelling suggests that half of all new bovine TB cattle herd breakdowns in the high-risk area may be caused by badgers, while majority of breakdowns in the low risk area can be traced back to the translocation of infected cattle. Even within these areas, however, the relative risk of transmission from cattle and badgers is likely to vary on a finer scale. The recently published draft TB strategy acknowledges the need to address this through a more local approach to the epidemiology of disease. This improved, more localised epidemiology has already been introduced in the low risk area and the draft TB strategy proposes rolling this out to the high risk and edge of high risk areas.

In addition to the ongoing research work to develop and implement effective badger exclusion measures, the Government is funding the development of an on-farm assessment tool to provide a measure of risk of likely presence of badgers in farm buildings. To understand more about the interactions between cattle and badgers, we are also funding a project led by the Zoological Society of London to quantify the number of direct and

indirect interactions between cattle and badgers at pasture compared with when cattle are in housing. The results of these studies will inform where biosecurity measures to separate badgers and cattle can be most usefully deployed.

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)

We agree with the Committee that this is an evidence gap. Using field studies to investigate the proportion of animals that need to be vaccinated to achieve herd immunity would be a large, complex and expensive undertaking and would require suitably sensitive badger diagnostic tests which are not currently available. We have therefore sought to investigate this using mathematical modelling.

The proportion of the badger population that needs to be fully immunized to ultimately eradicate bovine TB has been estimated at ~40%. (Delahay et al 2013), but as BCG does not give lifelong immunity a larger proportion of the population would need to be vaccinated. Even if this level of immunisation could be achieved, it would still take decades of continuous vaccination to eradicate bovine TB in a badger population.

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)

The Government acknowledges the enthusiasm among voluntary organisations for deploying badger vaccine. 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 however. 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. The Government, therefore, remains to be convinced of the merits of setting up the sort of advisory service recommended by the Committee but will discuss this with interested NGOs.

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)

Defra is funding a number of research projects that seek to develop existing and novel tools to detect TB infected badgers and their setts. AHVLA Weybridge hosted a workshop in April 2013 to consider the stage of development of these tools and their potential future applications.

A PCR-based test to detect *Mycobacterium bovis* in badger faeces has been developed by Warwick University under a Defra funded research project. This test could reliably detect 95% of samples where bacteria have been artificially added to the sample being tested. However the performance of the test on these artificial samples does not mean that it will work on samples collected from the field.

The test is currently being assessed (as part of a second Defra-funded research project) for its accuracy at reliably detecting TB in samples from naturally infected wild badgers and their latrines, the results of which are due later this year.

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)

To date, there has been very limited interest in this training course from farmers. Farmers who want to vaccinate badgers and are members of a Voluntary and Community Sector (VCS) organisation like a Wildlife Trust can apply to train as lay vaccinators and receive the current grant, however. They will, of course, benefit indirectly from the subsidy in cases where they are willing to allow VCS organisations to vaccinate badgers on their holding.

Unless and until there is evidence of strong demand for training from farmers, the Government does not believe that providing a general subsidy to train farmers as lay vaccinators—which would need be notified as an agricultural state aid—would provide good value for money.

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)

There have been vacant places on the lay vaccinator training courses each year so far. The Government does not believe, therefore, that there is yet a case for increasing the number of training places. If and when that situation changes we will re-consider this recommendation.

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)

This is covered by the Government's response to recommendation 10.

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)

This is covered by the Government's response to recommendation 15.

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)

The draft TB Strategy sets out the Government view on the part which injectable badger vaccine may play in combating the risk of bovine TB in the various TB risk areas in England. We will continue to offer to work with other organisations to ensure that their collective efforts yield maximum benefits.

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)

We welcome the Committee's endorsement of our commitment to continue to invest significantly in the development of an affordable oral vaccine for badgers, currently anticipated to be just under £4 million over the next three years. It is highlighted as high priority research in both the TB Evidence Plan and draft TB strategy.

AHVLA have recently expanded their research capacity and work is underway to investigate the relative effectiveness of different doses of BCG. We are also working in collaboration with research groups in Ireland, New Zealand, Spain and France.

The development of a suitable formulation for an oral vaccine is challenging, especially in the absence of knowledge of exactly where BCG is taken up in the body of the badger. So, in parallel to the vaccine efficacy studies, AHVLA are engaging in research to look at this, in collaboration with research groups in France and the Netherlands.

Research by its nature takes time and as such we cannot say with any certainty when—or even if—a vaccine product suitable for licensing will be available.

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)

In parallel to the research described above (see response to recommendation 22), we are also funding research to optimise bait deployment. This research seeks to design a cost-effective vaccine deployment strategy that would also minimise uptake by non-target species.

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)

We agree with the Committee on the importance of managing expectations about what an oral vaccine—should we be able to develop one—will be able to achieve.

There is no panacea for bovine TB control, and no one solution to the problem. Achieving officially TB free status for our cattle herd will need a combination of tools that address all routes of transmission. In this context and when used alongside other measures, an affordable oral vaccine is a potentially valuable tool, but we need to bear in mind that BCG vaccination has no known effect in animals that are already infected, and offers variable levels of protection to those that are not.

Given that oral vaccine is unlikely to be more efficacious than the injectable vaccine, it will need to be significantly more efficient to manufacture and deploy than the injectable vaccine if it is to provide a more cost-effective option.

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)

Basic details of Defra funded research and development is available online (http://randd.defra.gov.uk/). As the Committee will appreciate, the length of time required by to develop an oral vaccine and indeed if a cost-effective vaccine can be developed at all, is currently unknown. Scientific research is by its nature is an iterative process, where the nature of the results is not necessarily known, and the follow-on work must be planned and adapted based on the results obtained.

However, in the spirit if trying to inform public expectations we have provided our most optimistic deployment estimate in the draft TB Strategy launched on 4 July.

It is not possible to publish the results of all the experiments that underway due to intellectual property issues and the potential to compromise the licensing process for the eventual product. We are however in discussion with both manufacturers involved and the VMD about what would be acceptable, with a view to making more information publicly available.

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)

Whilst the gamma interferon test is more sensitive than the skin test, the relatively poor specificity of the test means that its use as the primary TB test would be hugely expensive for Government and for farmers. We would see longer lasting TB restrictions and more reactor animals slaughtered. The Government is, however, reviewing its potential increased use in breakdown situations where it could be beneficial in speeding up the clearing of infection and in reducing potential residual infection (see also our response to recommendation 27).

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)

AHVLA has conducted initial tests on four alternative suppliers of gamma interferon testing kits. None of the alternatives offered a significant improvement in performance but additional analysis of potential financial savings is being carried out.

In addition to this, AHVLA has introduced amended guidelines for usage of the equipment used to transport blood samples for gamma interferon testing, particularly in cold weather. Improving the sampling and transport of blood samples should provide quicker results and reduce costs through the avoidance of the need for re-sampling.

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)

The option of enhancing the role of local vet businesses has been included in the draft TB Strategy. It is also reflected in proposals which AHVLA is developing for enhanced training of Official Veterinarians. That should equip local vets to provide well-founded advice to their farmer clients, integrating TB prevention with the herd health plan and

providing advice to help mitigate the impact of a breakdown. A Defra-funded pilot ran in the South West in 2011 with mixed results and we have taken that experience into account.

There may be scope for private vets to undertake some case management tasks currently delivered by AHVLA but this requires further consideration to avoid conflicts of interest and inconsistencies.