



House of Commons
Environment, Food and Rural
Affairs Committee

**Vaccination against
bovine TB**

Second Report of Session 2013–14

Volume II

Additional written evidence

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The Environment, Food and Rural Affairs Committee

The Environment, Food and Rural Affairs Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department for Environment, Food and Rural Affairs and its associated bodies.

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List of additional written evidence

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

Badger Trust	Ev w25
British Veterinary Zoological Society	Ev w42
Brock Vaccination	Ev w35
Dairy UK	Ev w54
Family Farmers Association	Ev w1
Martin Hancox	Ev w8
Humane Society	Ev w20
International Fund For Animal Welfare	Ev w46
Ian Kett	Ev w17
Carla Kidd	Ev w53
Keith Meldrum	Ev w19
National Farmers Union	Ev w51
Network For Animals	Ev w27
DG & GE Purser	Ev w5
Rethink Bovine TB	Ev w39
Philip Robinson	Ev w2
Roslin Institute	Ev w37
Royal Society for the Prevention of Cruelty to Animals	Ev w2
Royal Society for the Protection of Birds	Ev w22
Secret World Wildlife Rescue	Ev w50
Society of Biology	Ev w31
Team Badger	Ev w48
Veterinary Association of Wildlife Management	Ev w29
Wildlife Trusts	Ev w44

Written evidence

Written evidence submitted by the Family Farmers' Association

This association has long been extremely concerned about the effect that bTB has on family farmers—it has been literally devastating on some. We have repeatedly begged Defra to reinstate a policy of seeking out infected badger setts and gassing them, which we believe to be the only way to rid the country of this scourge.

Many people are now advocating vaccination as a solution to bTB. In conversation I am frequently asked “why can’t we just vaccinate badgers (or cows)?” I trust that this investigation will prove that that is, in fact, not a useful road to go down. On the other hand, if it should discover that vaccination will in fact solve the bTB problem in a practical way, so much the better, but it seems to us unlikely.

We do not have any scientific expertise to deploy on the subject. The reason I am writing is to beg you to find some scientists who are *reliable*! The whole long running debate and “study” on how to solve the problem has been characterised by constantly confusing and contradictory statements by people labelled scientists. The badger lobby has been loudly proclaiming as scientific facts a lot of things which farmers with practical knowledge of both the incidence of bTB, and the conduct of the RBC Trials, find very hard to believe. In fact we could go so far as to say a lot of statements were false, though it is hard to tell if this was due to ignorance or if it was deliberate. Jim Paice politely summed up some of the statements in the parliamentary debate as “misinformed”.

Vaccination will not cure TB. What we need to know for sure is whether in fact it will have sufficient effect to make it worthwhile. Also, whether it will need to be done annually, and its cost.

In the case of vaccinating badgers, this would be an absolutely mammoth undertaking if done by injection. It would seem that a great majority of young badgers would have to be vaccinated each year for many years until all the old, infected badgers had died off. If this is to be considered seriously, the cost would have to be estimated. I bear in mind that it is now realised there are many more badgers in existence than previously thought; and many people believe the count may still be too small.

I understand that the National Trust in Devon, and possibly some other organisation, have set to work on vaccinating badgers. It will be essential to take evidence as to exactly how well they have succeeded. I believe I read in the paper that the work had been suspended due to too much rain.

As for an *oral vaccine*, this would seem unlikely. Most immunisation is done by injection, except for polio, and *mycobacterium bovis* is said to be very tricky to deal with. If it could be developed, and proved to be effective, it could be very difficult to administer the right dose to all young badgers.

In the case of vaccinating cows, the main objection, to my mind, is that that would have little effect on the amount of *mycobacterium bovis* circulating freely in the countryside in badgers and infecting other animals. Camelids are said to be very susceptible and much infected. There are reports of many other species now having bTB, including man. This is clearly highly undesirable; it does not take much imagination to envisage a scenario where tuberculous badgers in a garden infect a cat or dog, which passes the disease on to a child. Even very rare cases would hardly be acceptable. I am told there is one, which is being kept quiet.

I hope your committee will be able to investigate all the rumours which are rife about the extent of the spread of bTB to other mammals, and that facts are being kept from the public.

You are probably aware that there are conflicting statements as to the availability of a DIVA test. The exact truth needs discovering, and also whether there would be serious objection to selling vaccinated cattle, either for meat, or for breeding. (I cannot see why there should be—domestic animals are vaccinated against a multitude of diseases these days.)

Is there any hope that you may be able to investigate other possible means of eradicating bTB as an alternative to Defra’s present unsatisfactory and unpopular plan, especially if you find that vaccination will not in fact succeed? We have been extremely concerned that the PCR has not been put to use for this purpose. It is said that it is not entirely reliable in field conditions; others say it has been made so. We do not like the proposal to shoot 70% of badgers, and told Defra this. We believe that even if not entirely accurate, using a PCR to determine which badgers to cull would be much better than “free shooting”. What is more, we believe that, properly presented, such a plan would be mainly acceptable to the public.

Brucellosis Having had personal experience of it 55 years ago, I think you might find it helpful to study what was done towards eradicating brucellosis. This disease was to dairy farmers in the 40s and 50s what TB is now. That is: a constant worry to all, and sometimes seriously devastating when a brucellosis storm hit a dairy herd.

A system of immunisation by injection was instituted, it had to be done to heifers when still young. They were marked, to indicate vaccination, and later tested to find out if they were then immune. In fact one of our heifers, which had been injected, gave a doubtful reaction to the test. She was tested again, same result. She was duly culled, in spite of the fact that she had given birth to a healthy calf. In this case it would seem that

the vaccination had been successful, but the testing was not. This is my recollection of long ago. It will need conformation from some elderly vets..

I hoped brucellosis had been eliminated, as we have never had a case. But vets tell me there is quite a lot of it still. Insofar as there was a fair success from the scheme, that might seem hopeful. *But*, as far as I know, no wild and ubiquitous animal was harbouring the disease, so the case is not at all parallel

I hope some of this is helpful. Above all, I hope you will be able to get to more *truth* about what actions are or are not useful. Even suggest a feasible solution?

January 2013

Written evidence submitted by Philip Robinson

1. I would like to draw the attention of the Committee to a review paper* written by myself and six co-authors from Northern Ireland, the Republic of Ireland, and France on the subject of badger BCG vaccination against tuberculosis.

2. The authorial team consisted of five veterinary epidemiologists, a veterinary immunologist, and an OIE-recognised (World Animal Health Organisation) veterinary expert on wildlife diseases.

3. The paper was published in July 2012 in the peer-reviewed scientific journal *Comparative Immunology, Microbiology and Infectious Diseases*, and may be found at the following web address:

<http://www.sciencedirect.com/science/article/pii/S0147957112000100>

4. The paper reviews both oral and injectable BCG vaccine research in badgers; discusses possible vaccination strategies; and suggests future research which will better enable us to understand the role of badger vaccination in on-going efforts to eradicate bovine TB.

5. We conclude that research into areas such as duration of immunity, the effect of revaccination, whether vaccination reduces *M. bovis* excretion from badgers already infected, and the excretion patterns of vaccinated badgers subsequently infected, would be very valuable not just for policymaking directly, but would also improve the modelling of vaccine deployment strategies. Perhaps most critical of all would be data from field research to determine the effects of badger vaccination on cattle TB incidence.

We trust that the paper may be helpful to your inquiry.

*Robinson, P A, Corner, L A L, Courcier, E A, McNair, J, Artois, M, Menzies, F D, & Abernethy, D A (2012) BCG vaccination against tuberculosis in European badgers (*Meles meles*): A Review. *Comparative Immunology, Microbiology and Infectious Diseases*, **35**, 277–287.

Philip Robinson BVMS DSV MSc MRCVS (and on behalf of my co-authors)

December 2012

Written evidence submitted by the Royal Society for the Prevention of Cruelty to Animals

SUMMARY

The RSPCA believes that vaccination of badgers and cattle can play an important role in eradicating bovine TB in cattle. The bTB vaccine in badgers is safe, reduces the progression and severity of the disease in badgers and, though there has not been any evaluation of the impact of this on the disease in cattle, it is likely to reduce the risk of bovine TB in cattle. Vaccination modelling has shown that the differences between the outcomes of culling or vaccinating badgers are quite modest. Whilst the vaccine is expensive to administer solutions should be possible to reduce this through volunteer programmes; the government should be looking at all options to reduce costs. The DIVA test provides an opportunity to break the deadlock in cattle vaccination. Field trials may not be needed in the UK once permission has been given that this will not impact on the UK's status of being Officially TB free and its ability to export beef and dairy products. A clear timetable is needed from the OIE on authorisation of the DIVA test.

1. The RSPCA is pleased to submit evidence to the enquiry on the timescales and challenges in delivering TB vaccination programmes for badgers and cattle and whether a vaccination programme could be delivered without having a negative effect on UK exports. The RSPCA is a member of Team Badger, the coalition of animal welfare groups working to reduce bovine TB in cattle through humane non-lethal methods and supports vaccination for badgers and cattle as a way to eradicate this disease. The RSPCA rehabilitates badgers through its four wildlife hospitals and works to improve the welfare of dairy cattle through, inter alia, providing standards for assurance schemes such as Freedom Food and its membership of the Cattle Health and Welfare Group, which administers the National Dairy Cow Welfare Strategy and the Red Tractor Dairy Technical Advisory Committee (TAC).

Injectable Badger vaccination

2. Vaccination as a mechanism for the control of infection in populations is widely practised in animals including domestic stock, wildlife and man. An injectable badger vaccine, Badger BCG, has been licensed for use in the United Kingdom since March 2010. It reflected 10 years and £11 million of Defra-funded research and development.ⁱ In 2012 over 2,500 badgers have been vaccinated using the injectable vaccine. Most of these have been in the Intensive Action Area in Wales (over 1,400)ⁱⁱ and the Badger Vaccine Deployment Project area in Gloucestershire (989).ⁱⁱⁱ However, conservation organisations such as the National Trust, the Wildlife Trusts, the RSPB and private individuals have also been vaccinating badgers. This indicates that using an injectable vaccine in wild badgers is feasible and contradicts claims that such vaccination is “impractical”.

3. There is good and accumulating evidence that an injectable bTB vaccine is both safe and provides at least partial protection in badgers. The vaccine has been shown to reduce the severity and progression of bTB in badgers. Vaccinated badgers showed a reduction in lesions and bacterial count compared to nonvaccinated animals.^{iv, v} Recent research has also shown that BCG vaccination in a wild population significantly reduces the risk of TB infection in vaccinated badgers and in unvaccinated cubs. The unvaccinated, susceptible cubs were indirectly protected from disease transmission through a “herd immunity” effect.^{vi} The benefit of herd immunity is that there is no need to vaccinate 100% of susceptible animals in a population to get a protective effect from vaccination but only enough animals to break transmission.^{vii}

4. A significant percentage of those wild badgers that receive an injectable vaccine are likely to become resistant to infection and/or disease and will therefore be epidemiologically less important in the transfer of bTB between badgers and cattle, and between badgers, for a period of time. Although there has been no evaluation of the impact of badger vaccination on the incidence of TB in cattle, repeated vaccination in an area is likely to reduce the level of bTB infection and disease in the local badger population and thus the risk to local cattle from badger-to-cattle transmission.^{viii}

5. The RSPCA believe that providing a badger vaccination programme in targeted hot spot areas can not only have an impact on the disease but can gain support from farmers as an option to culling to fight the disease. Initial indications from one project being run by the National Trust shows a big shift in the views of tenant farmers now that trapping and vaccinating badgers has been shown to be practical.^{ix}

6. Vaccination modelling has shown that the differences between the outcomes of culling or vaccinating badgers are quite modest. Over a 300 km² area, over a ten year period, the difference between strategies appears to be less than one herd breakdown per year.^x

7. The RSPCA was disappointed that one of the early actions of the Government was the axing of five of the six areas chosen for the Badger Vaccine Deployment Project. The estimated savings of this action were about £6 million.^{xi} In comparison, the now postponed badger cull is already estimated to have cost £1 million and may cost over £5 million if it goes ahead.^{xii}

8. Defra estimated that the cost of vaccinating badgers to be around £2,250/km²/year.^{xiii} Given that the effectiveness of the vaccine laid out above, it is important that further work is carried out in how to reduce these costs. The RSPCA is willing to support any practical methods to achieve this such as the use of volunteers in targeted areas.

Oral badger vaccine

9. The use of an oral badger vaccine, deployed in baits could be a cheaper and easier way of vaccinating badgers. Research is being undertaken into aspects such as efficacy, safety, bait development and bait deployment optimisation. In 2008 a best case timeline for badger vaccine development suggested that 2011–12 might have seen an oral field trial perhaps leading to licensing and commercialisation in 2013 and widespread use in 2014.^{xiv} In Ireland there is thought to be a very real prospect of having an effective vaccine for field use in wild badgers before 2014.^{xv}

10. Extrapolation of information from one species to another may not always be appropriate but there are a number of projects in other countries on other species showing that vaccination is regarded internationally as a potentially very important tool in dealing with bovine tuberculosis in wildlife populations.

11. For example, research in Spain has shown that oral vaccination with BCG in captive wild boar is safe with significant levels of protection against challenge with virulent *M.bovis*. A new heat-inactivated *M. bovis* vaccine showed protection and produced immune responses similar to those seen in BCG-vaccinated boar. They have developed delivery systems for bait-containing vaccines and are moving to a field trial.^{xvi xvii}

12. Research into vaccination of brushtail possums has been undertaken in New Zealand and demonstrated that BCG vaccination is protective and can prevent infection. Field trials have provided encouragement that BCG vaccination could be effective in controlling TB in wild possum populations. A lipid-based bait, which protects the vaccine from stomach acids, has been developed for oral delivery of BCG and trials have shown that baits distributed in sachets are readily taken up by possums.¹⁶

Cattle vaccination

13. In 2008, the Defra document “Options for vaccinating cattle against bovine tuberculosis”^{xviii} which the RSPCA fully endorsed, detailed all the issues associated with cattle vaccination. It also looked at a number of scenarios for using the vaccine, ranging from the compulsory vaccination of all cattle, to one where voluntary vaccination was the main method of delivery.

14. After years of vaccine research costing millions of pounds, the attenuated Bacille Calmette-Guerin (BCG) vaccine is deemed to be the most suitable vaccine candidate. Alternative vaccine candidates including adjuvanted proteins, viral vectored and attenuated mycobacteria have so far not been deemed to confer greater protection by themselves, than the BCG vaccine.^{xix} The most promising approach appears to be using a heterologous prime-boost vaccination strategy where combinations of BCG with the elements noted above have proved most successful²¹ in experimental challenge trials.

15. The efficacy of the vaccine was stated to be up to 68% with cattle in small scale field trials in Ethiopia and Mexico. The nature of the protection that the vaccine gives, covers a relatively broad spectrum, ranging from cattle getting no protection to those who are fully protected. The vaccine also has no therapeutic effect with already infected animals. The RSPCA does not believe that 100% effectiveness is needed to eradicate a disease, so this vaccine could still play a major part in reducing or eliminating bTB, especially if combined with a test that would identify infected (differentiated from solely vaccinated) cows.

16. As trials have occurred on Holstein cattle and in New Zealand, which has similar climate conditions to the UK, the RSPCA does not believe there is a need for UK specific trials. However, the UK needs to clarify with the EU if the present results would be sufficient to ensure “TB free status” for the UK. If not, provisions should be made to start such trials once the DIVA test is agreed and VMD approve the vaccine. The recent vaccination workshop organised by the Welsh Assembly Government shows the sort of preparatory work that can be achieved.

17. The efficacy of the vaccine can also be affected by a number of variables found in the field, for example, cattle infected with parasitic helminths have the potential to adversely affect BCG-induced immune responses and coinfection of cattle with liver fluke (*Fasciola hepatica*) and BCG reduced gamma-interferon (IFN-γ) responsiveness.^{xx} Given that liver fluke infection is a particular issue at present in Great Britain, this issue would need careful consideration should the vaccine be introduced.

18. The cost of individual doses of the vaccine have been quoted as high as £20 each,⁶ although the government’s own estimates are lower at around £8.25.⁷ The overall annual cost will be determined by a number of factors, notably, whether it will be compulsory to vaccinate all cattle, including neonates, or whether it will only be a voluntary scheme; will the vaccination policy only target high risk herds or only certain animals in individual herds; who will pay for the vaccine and its delivery; the duration of immunity and hence repeat costs. Any costs would also have to factor in those associated with the DIVA (Differentiating Infected from Vaccinated Animals) test.

The DIVA test

19. Vaccination of cattle is prohibited under Directive 78/52/EEC as there is no test to differentiate between infected and vaccinated cattle, and the EU has a ban on trading any cattle that are not Officially TB free (Directive 64/432/EEC). To solve this either (a) the restriction on trade needs to be removed or (b) a test needs to be developed that does differentiate, and is approved at a UK and global level. This can then lead to a reversal of the ban on use of cattle vaccine. The development of the DIVA test which differentiates vaccinated from infected animals, gives this opportunity. It is vital that this is internationally accepted as soon as possible. Marketing Authorisation for the vaccine has been sought from the Veterinary Medicines Directorate (VMD) since the beginning of 2012 and is expected in early 2013. It is understood that discussions have started with the OIE on getting agreement to accept the DIVA test is; agreement is also required within the EU that developing and using such a test on cattle would not impact on the UK’s status as Officially TB free and on beef and dairy exports. With three authorising bodies all considering different facets of agreement on cattle vaccine it is essential that good communications are kept between all three to ensure that the processes can occur in parallel rather than sequentially and so speed up the authorisation process. Political support for such a position should be sought as soon as possible particularly within the EU-27 where the TB problem could be seen as limited to UK/Ireland.

20. Whilst challenges exist with rapidly authorising and implementing a cattle vaccine, the country is now in its’ best position ever to see such a programme implemented. Any timetable on a cattle vaccine should not be used to defend other perceived disease control methods such as a badger cull. Each should be debated on their own effectiveness in reducing the disease of bovine TB.

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January 2013

Written evidence submitted by DG & GE Purser

We own a 48ha farm in Gloucestershire and have kept beef cattle since the 1980's in a TB "hot-spot". The business has included a commercial beef and calf rearing unit but the herd has never been under TB2 restrictions.

SUMMARY

1. Concern that Defra has distorted the extent of bovine TB infection in England and Wales.
2. BCG cattle vaccine and the Diva test are available.
3. A trial of cattle vaccine should be rolled out in areas with repeated outbreaks of bTB.
4. An earlier Defra report models cattle vaccination policies in great detail.
5. History gives us the example of Brucellosis which was successfully eradicated via a cattle vaccination program.
6. Defra must ensure that the EU prioritises work on the New Single Regulatory Framework for Animal Health.
7. Role of the EU.
8. Conclusions.
9. References/links.

1. Concern that Defra has distorted the extent of bovine TB infection in England and Wales

The object of the exercise when addressing the issue of bovine TB should be to adopt an approach which is not detrimental to the business of cattle farming and which takes account of good public relations. But the

more that Defra has become fixated on the idea of a badger shoot, the more the department appears to have ignored public opinion and distorted the extent of bTB infection in this country.

For example, Defra Minister Owen Paterson recently made a statement in the House of Commons on the badger cull—widely reported in the press—which included the claim that “bovine TB is the most pressing animal health problem facing the UK today” and he described the incidence of bovine TB as an “epidemic”.¹

But Defra’s own statistics simply do not justify these alarmist claims.

According to Defra’s latest figures published on 12th December 2012, the number of cattle slaughtered each year for bTB control has remained *stable for the last ten years* at a figure averaging just half of one percent of the national herd, year on year.² This figure is easily outnumbered by fallen stock and cattle slaughtered annually due to lameness, infertility, mastitis etc.

Defra present their bTB “Key Facts & Figures” for 2011 negatively but we can still see from these figures that 88.5% of herds in England and 76.4% of herds in the hot-spots went about their business completely unaffected by bTB for the whole of that year and most of the remaining herds were only restricted for a short time.³

There are “TB maps” on the Defra website with areas shaded red but they contain far too many red dots to correspond with half a percent of the national herd slaughtered for bTB control annually and there is nothing on the web page to explain what each of the red dots represent. If each dot is a bTB incident then each dot must be removed when the incident is cleared otherwise the map is nothing but a misrepresentation of the true extent of infection.⁴

Clearly it is Defra’s “test and cull” policy which causes the most grief to the cattle industry so it is vital that the incidence of bTB infection is properly presented and that the minority of herds affected are precisely identified in order to ensure that any future plan for control is proportionate.

2. Cattle vaccine and the Diva test are available

Cattle vaccination is the only long-term solution to bovine TB and this approach could be pushed through with the right political will.

Cattle vaccine and the Diva test are available as reported on the Defra website as follows:

- (a) “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)”
- (b) “Our plan is to make an application to the OIE (World Organisation for Animal Health) in summer 2012 for international certification of the [diva] test. Providing the OIE is satisfied with the fitness for purpose of the test, the earliest we could have OIE validation and certification would be the end of 2012”

NB. This page on the Defra website was referred to during the Commons debate on the badger cull on 25th October but the reference to the “diva” test was subsequently removed from the web page on 5th Nov 2012. However, a cached version of the original web page from the Defra web site on 29th Oct 2012 is attached for reference.⁵

3. A trial of cattle vaccine should be rolled out in areas with repeated outbreaks of bTB

Defra need to apply to the EU for a derogation to allow UK field trials of the cattle vaccination and the Diva test to begin.

A trial of BCG cattle vaccine could be rolled out to individual herds which are identified as having repeated outbreaks of bTB along with “ring fence” vaccination of surrounding herds.

In addition, a cattle vaccine trial could be offered as an option to all farmers/keepers with pedigree, single-suckled or dairy herds who currently have to trust to luck to avoid having their breeding and foundation stock wiped out by Defra’s test and cull policy.

None of the vaccines we use for our livestock gives 100% protection but, as it states on the Defra website,⁷ a vaccine against bTB can reduce the prevalence, incidence and spread of TB in the cattle population and also reduce the severity of a herd breakdown, regardless of whether infection is introduced by wildlife or cattle.

The status of vaccinated cattle could be certified by stamping the animal’s individual passport.

4. An earlier Defra report models cattle vaccination policies in great detail

A Defra report entitled “Options for Vaccinating Cattle Against Bovine Tuberculosis” produced in 2008 and endorsed by numerous prominent stakeholders, including the NFU, set about modelling various vaccination programs, including the lead option of compulsory vaccination of high risk herds in annual testing parishes.⁶

The model showed that this option, funded by the govt, would save up to one fifth of the costs of the current “test and cull” policy, as follows:

“The model predicts vaccinating cattle in yearly tested parishes would cost around £170 million to £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 million and £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.” (Para 1.2 “Economic Assessment of Lead Option”).

The report also suggests that certifying vaccinated cattle would save on resources in terms of the Diva test (Para E14, E15). Cattle now have individual cattle passports so these can be stamped to show the animal has been vaccinated.

5. History gives us the example of Brucellosis which was successfully eradicated via a cattle vaccination program

The Defra report “Options for Vaccinating Cattle Against Bovine Tuberculosis”⁶ includes a detailed section on the vaccination policy which led to the successful eradication of Brucellosis (Annex 6.1.1).

This involved a combination of voluntary and mandatory vaccination, in line with the geographical incidence of disease, administered by Defra Local Veterinary Inspectors or Local Veterinary Practices and a herd accreditation scheme was established to monitor disease status.

This system could be adapted for use with bTB. Cattle now have individual cattle passports so these could be stamped to show the animal has been vaccinated saving on resources in terms of the Diva test.

6. Defra must ensure that the EU prioritises work on the New Single Regulatory Framework for Animal Health

Defra say on their website “An opportunity to provide a future legal basis for vaccination of cattle against TB is likely to be created by the proposed new European Animal Health Law, which is currently under consideration by the European Commission”⁷

The EU describes the New Single Regulatory Framework for Animal Health, the so-called EU Animal Health Law, as follows:

“Current legislation does not fully support prevention. It is more reactive than proactive and doesn’t provide real incentives for stakeholders (animal keepers, traders, business operators) to use mechanisms to prevent, on one hand, the introduction of the diseases to their holdings and, on the other hand, their spread to other holdings, regions and countries.”⁸

The AHWBE (Animal Health and Welfare Board for England) were due to publish their review of these EU proposals in 2012 but we have not received a reply to our request for a copy of their conclusions to date.⁹

7. Role of the EU

In a recent statement, the European Commission confirmed that the EU Health Commissioner would advise on the exact process and timing required to implement cattle vaccination in the UK.¹⁰

The Commission also points out in this statement that substantial financial support is provided for the UK bovine TB eradication programme adding “For 2012, EUR 31.2 million were allocated to implement a rapid eradication strategy. There is no EU financial support provided for the culling of badgers.”

8. CONCLUSIONS

- Defra are using the badger shoot as a distraction and obfuscating the facts around the incidence of infection of bovine TB seemingly to avoid addressing the necessary option of cattle vaccination. The generous funding provided by the EU may be acting as an incentive to continue with the current “test and cull” policy.
- The current Defra administration must not sideline the valuable research and information contained in the earlier Defra report entitled “Options for Vaccinating Cattle Against Bovine Tuberculosis”⁶.
- Defra should apply to the EU Health Commissioner for a derogation to allow UK field trials of the cattle vaccination and the Diva test to begin.
- Defra officials must shift their focus away from badger shooting and concentrate on the proposals from the EU for a New Single Regulatory Framework for Animal Health, the so-called EU Animal Health Law, which will pave the way for proactive and preventative cattle vaccination for the benefit of the cattle farming industry long term.

9. REFERENCES/LINKS

¹ <http://www.defra.gov.uk/news/2012/10/23/badger-cull/>

² page 6

³ <http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/>, Key Facts & Figures

⁴ <http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/about-bovine-tb/>

⁵ Defra cattle vaccination Google cache 29 Oct 12.mht (NB This is a cached version of the original web page from the Defra web site on 29th Oct 2012 and is an mhtml file which opens as a web page).

⁶ http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/vaccine_cattle.pdf

⁷ <http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/vaccination/cattle-vaccination/>

⁸ http://ec.europa.eu/governance/impact/planned_ia/docs/45_sanco_animal_health_law_en.pdf

⁹ <http://www.defra.gov.uk/ahwbe/files/ahwbe-forwardplan2012.pdf> , page 2, Action Plan

¹⁰ http://ec.europa.eu/unitedkingdom/press/press_releases/2012/pr1245_en.htm

January 2013

Written evidence submitted by Martin Hancox

A. CATTLE

1. VACCINATION. TB is like “Consumption or phthisis” in man, entirely a (broncho-) PNEUMONIA, acquired via droplet infection (think swine flu !) by prolonged contact with other cattle over-wintering in enclosed barns/yards, or in milking parlours; exactly like other Pneumonias especially of calves, be they viral :-IBR, PI3, RSN, BVD; bacterial: Pasteurella, Mannheimia, Haemophilus; or Mycoplasma..the pleuropneumonias. Vaccination of calves at birth with rearing isolated from main herd is commonsense. The VLA trials abroad of BCG show up to 75 % effectiveness, and the DIVA test distinguishing vaccinated from infected cattle has been available a decade:- depressing that an application to the EU for approved use not made long ago.. already clear EU would regard such favourably (G.Watson MEP pers.com.) procrastination just like “ novel” IFN testing; or FMD pen-side test 2001; Why not get on with it !?

2. CHRONIC HERDS/ANERGY. These are the pivotal problem underlying recalcitrant local hotspots:— 3 elderly cows non-reactor to skin tests ie. “anergic” caused 18 herd breakdowns or 10 % of breakdowns in the West Penwith (Lands end) study (20), so not surprising even this problem area went clear in 1985, with depopulation of a few key chronic herds (maps 2, 5, 6).

Gopal’s restocking study in northeast England found c. a third of breakdowns came from one Cheshire herd. With some 2000 herds currently been under restriction 10–16 years its disgracefully incompetent of DEFRA not to be tackling the matter urgently with different tests .. depopulation of very large herds, an uneconomic last resort. The active spreader anergic culprits could be found within DAYS using either and Antibody test or PCR:- Ireland routinely use the Enfer Chemiluminescent Multiplex ELISA ; the OIE have recently approved the IDEXX M .bovis Ab test. Cows with advanced TB may shed 38 Million bacilli/day in 30 lbs of faeces (6a), so PCR on faecal swabs would provide a rapid resolution.

B. BADGERS

“New Science “Shock .. BADGERS INNOCENT .. ANY CULL/VACCINE HENCE UTTERLY POINTLESS (WHY shoot the messenger , miner’s canary to cattle problem).

Rather depressing that the 25th October debate whilst very well-intentioned, was badly misinformed, both on Perturbation and vaccines, Irish already well advanced on an ORAL badger one; the three year Kilkenny field trial of a badger one just ended, but 500 or so badgers in 755 sq.km. (1/1 1/2 sq.km.) vaccinated wont have made any difference to cattle TB (10, 5 Dec. 2012 first results in Plosone e 50807 online).

ABSOLUTE KEYSTONE/CORNERSTONE TO WHOLE GREAT BADGERS AND TB DEBATE:- Gallagher in Zuckerman 1980 p.86, 94 ... Cattle “Open lesion” INFECTIOUS cases; only 21 in 1000 reactors, 2 % SO ““In the context of the total bovine population, the number of cattle excreting bovine tubercle bacilli appears of no consequence in the maintenance of tuberculosis in badgers, and of very little consequence in its maintenance in cattle “.

THUS, Having RULED OUT cattle, the self-maintaining reservoir must be badgers, and transmission one way badger to cow SEE Transmission box figure, inner cycle; Cattle crisis ironically shows exact opposite is the truth Outer cycle.

Section 1.- Five main reasons why badgers are not the problem!:- A to E

1. Cattle is 100% from other cows Lesions almost entirely in lungs and pulmonary lymph nodes (bronchials and mediastinals; Liebana; 6 a,b; 8, 15, 16, 19). Prolonged contact needed, one school study required 130 hours of shared classes to achieve transmission. Badgers popping into a barn for a drink and snack of cattle nuts wont "cut it"; besides, most badger barn visitations in summer when cattle out at pasture anyway! Afraid 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; rest disinfected by UV in sunlight within three days, so a cow most unlikely to ingest the minimum dose of c. 1 million bacilli, ie. 3 cc of fresh urine .. amusing anyway, that special pleading of conversion of ingested bacilli to aerosol by eructation ie. burping of rumen gases is also implausible(8). Francis (6) was very clear, cattle do not usually catch TB from contaminated pasture, unless via un-composted/bio-degraded manure/slurry spread direct ; indeed dont catch TB until they enter the cowshed when first calving . Slurry risk, Maddock/Schellner, in 8,20.

NB. a huge difference from respiratory TB which CAN be via a single bacillus direct to thin walled alveoli. Ironically all this was clearly understood from a classic study a century ago:-Svensson 1904 , 13 calves caught airborne TB in a barn, separated by 6 metres from the main TB herd, five reacted by six month, other eight after one year .Contrast, badgers in a very artificial close confined yard experiment, DID give calves TB:-But, four exposed under one month didnt get TB, the other five reacted after six month (16).

2. Cattle ARE major self-maintaing "HIDDEN" RESERVOIR OF TB (see cases "below "c" =Sea, Confirmed level in Two pyramids" figure). Badgers are merely a spillover host, like dirty feeding pigs, wild boar, and locally commonest deer ; Sika Purbecks, Scotland; Red Exmoor; Roe Glos, Wilts even 1 Hants recently ;Fallow Chilterns, Hereford; 1 Muntjac Glos., and TB dies out when not topped up from cattle . SEE Section 2 (3) below:- Cattle pose a risk to badgers.

3. Cattle Crisis is NOT mostly due to badgers since Despite UNBelievably, according to farmers/vets cattle-to-cattle spread is UNimportant.. it is simply an explosion amongst cattle (Surely they must realise this in bad herd breakdowns with 1/2 to 3/4 herd affected ! ?); It was just about plausible that at the low point Map 2, with 100 breakdowns/a, and similar numbers of TB badgers ; badgers might be the hidden self-sustaining reservoir ; BUT SINCE spread way beyond the supposed tiny badger TB hotspots in the southwest (maps 2 to 3-4) .. badgers are not moving outwards by 10 km a year, 99 % die in their natal clan territory.

4. Cattle controls alone have eradicated Cattle TB, WITHOUT ANY CULLS .Indeed, cattle TB shrank so fast to tiny southwest hotspots, hard to believe there werent some TB badgers left behind, but they did not cause delayed breakdowns. Cattle controls alone even suggested by ISG (p. 5, 147-9, 175). Penwith as noted above, the Isle of Wight/Anglesey/see maps 1-3. Wales almost went clear by the late 1980, tiny Dyfed hotspot; Scotland went clear with no wildlife culls although TB known in 1 badger, a few sika, roe, red deer. Ulster had a textbook scheme, got down to just 174 reactors in 1971, then prematurely went to three yearly testing so TB shot back up ..cattle TB halved since intensive testing post-FMD, badgers regarded as spillover host and not culled (17). Switzerland also clear, although the first wild badgers/and foxes with TB found there in 1950s, spillover from last cattle via eating roe deer carrion , found also in chamois. TB badgers now found where cattle TB not solved in Spain, Italy.

Amusingly, the "first" TB badgers were in fact 1938 London Zoo, one at Whipsnade 1950s, maybe from Sika herd outbreak, Ireland didnt find any until 1985 since they didnt look. Cattle to badger spillover quite efficient, so TB badgers from 27 GB counties, Leics next ?; and all 32 Irish counties.... MAFF data only 4608 with TB, in 42,130 badgers sampled 1972-96 (RTAs +culls) ; some 90 % from seven southwest problem counties.

5. GB had a textbook CATTLE TB ERADICATION SCHEME ...(6b, 14, 17, 18,20) . As shown in The Two Pyramids figure & accompanying Reactor graph with corresponding Maps. The pathogenesis progression of TB (left pyramid) shows a steady rise in number and size of LUNG lesions, hence infectIOUSNESS. Annual skin tests find cases before they reach the more infectious stage with "Visible Lesions"... gamma interferon IFN finds early cases , but a late TB antibody test is essential for skin non-reactors

Tests are simply missing a huge "hidden reservoir "of cattle TB:- Around a third of cows go temporarily non-reactor at calving (immune system damped down since calf is 1/2 "foreign" protein) (1; immuno-suppression may also involve BVD, fluke ,recent Liverpool study &, AFBINI , Wilesmith); so Skin test is 80 % accurate, at best, but about a third of repeat tests are non-reactor too (65%); and so around a third of bad breakdowns WILL give repeat breakdowns within 14 months ISG p. 239. A.Conlan, Cambridge, recently suggested 20-50% of herds may have repeat breakdowns within two years (8). So there has always been a huge "hidden Reservoir" amongst cattle:right pyramid .

As clearly noted by Blood 1989; "There are as yet no reliable tests to detect the poorly sensitized animals in the EARLY AND LATE STAGES of the disease which are the USUAL CAUSE OF RECRUDESCENCE in herds that have been classified as free of the disease" SO, the Other MAJOR HIDDEN reservoir has been the unconfirmed cases with no gross visible lesions and too few bacilli to be detected. ALSO, minority of cattle may take four—seven years to progress to reactor status .. including IR or INCONCLUSIVE REACTORS .. SO TB "appears" SEEMingly out of nowhere "(8) . The Critical importance of UNCONFIRMEDS/IRs/ ANERGIC CHRONIC HERDS, discussed in Section 2 c below.

The eradication scheme had three main phases ..

1. starting in 1935, the aim was to remove clinically sick older cows with tubercular cough, emaciation, and often udder TB bacilli in milk smears, .. 24,000 cases in 1938, none left by early 1960s ;sadly, the crisis now so bad, some udder TB cases now reappearing, pose a major risk via bulk milk to batches of calves... and to man via few greentop milk producers;
2. voluntary testing with increased bonus for Attested milk/beef; and
3. having “thinned out” the problem, compulsory Area Eradication with whole country recruited by 1960 (14).

Sadly, then at the low point with “first TB “badger in 1971, it was assumed, badgers not cattle were the hidden reservoir..

The Cattle TB Crisis took off from mid 1980s, see reactor graph .. and had many contributing factors ..

- too few cattle tested only two million/a 1988–94, contrast all nine million in 1960;
- switch to longer four year testing 1993;
- drop from 240, 000 herds 1960 to 90,000 now .. and herd size 1970 of up to 50 cows .. now 150 normal, 300 or 1000 not unusual ...the bigger the herd the more missed/test (8).. hence also herds subdivided with rented grazings so far more chance contiguous spread (Ulster study, suggested 30 % breakdowns due bought in stock, up to 70% contiguous ,McIlroy BUT Ulster odd in having small herds much subdivided (17); and
- also southwest cattle population doubled 1964–74 Pout, with intensification of dairying which is most at risk of developing chronic status.

Tragically TWO VERY SIMPLE errors allowed the crisis to RE-emerge: -a failure to eradicate TB from chronic herds at the heart of annual testing hotspots (Map 2) ; then a failure to ensure TB did not spread back into cleared areas eg by pre & post-movement testing. Annual test foci have traditionally had a parish wide two year test ring fence (see 3c, annex E) and current TBEG 2 parish wide firewall .. but TB simply spreads into this ring, builds up into bad breakdowns , and is totally irrelevant in containing outwards spread. Bringing two, three, four year areas back into annual testing is merely catch-up on spread; hopefully the new EU inspired 19 Oct. scheme from 2013 with 10 new counties may “get ahead” of the spread. Sadly southern Ireland made exactly the same mistake, after the 1965 low (Watchorn), so TB spread from high density southwest dairying hotspot counties, back to northern areas with new hotspot herd clusters (17).The four year intensive ERAD scheme produced more than the usual 30,000 reactors, but estimated actually 60,000 reactors “out there” awaiting identification (17).

There were four major jumps in the reactor graph:

1. BSE/Mad Cows peaked 1993, 36,000 cattle to be replaced, so spread especially by unconfirmeds to areas TB-free 20 plus years, Exmoor, Hereford,Thornbury, Jim Paice pers.com.,noted;- by 1999, over 50% of breakdowns were in areas TB-free 10 years (cattle or badgers !); Avon 15 out of 25 breakdowns , Cornwall 103 out of 139, Devon 54 out of 90; and “frontier” counties even worse Shropshire four out of five, Derby six out of six & Staffs 29 out of 30 .. by 2004 DEFRA noted 6,000 reactors in this new D/S hotspot (3c). TB in badgers absent until spread inwards by cattle eg. Derby, Powys.
2. FOOT & MOUTH, 2001, a disaster, since lack of testing allowed TB to build up in herds untested two years +, hence bad breakdowns of six plus reactors went from 23 % 2000, to 42 % 2002, back down to 17 % 2005.. herds doubled 2000 to 2002, but reactors trebled England or fourfold Wales. Such bad breakdowns also seen at fringes in peaks 3/4 below.
3. the 2005 peak or 30,000 was simply due to the previous autumn package with zero tolerance of overdue tests (26,000 start 2002); and bringing new hotspot parishes back to annual tests.
4. the 40,000 peak 2008 nearly as bad as 1940s!; was again due to recruiting two, three, four year parishes back to annual tests, and Wales entire national herd survey: -hence they doubled from 2006 6,000 reactors, to 2008 12,000. Additionally, use of IFN tests more widespread, and pre-movement testing brought in (also post-movement in Scotland).

NB ... CATTLE TB OUT OF CONTROL .. IN Fact, since the perfectly logical cattle peak 2008, TB has consistently been dropping ever since .. first 1/2 2012, down 2% on 2011.

Section 2:- *A critical reappraisal of these issues exposes a multitude of anomalies and persistent “false facts”*

DARWIN’S BULLDOG; THE GREAT T.H.HUXLEY “THE GREAT TRAGEDY OF SCIENCE IS THE SLAYING OF A BEAUTIFUL HYPOTHESIS BY AN UGLY FACT”.

DARWIN himself, Descent of Man; “False facts are highly injurious to the progress of science and often endure long”.

Scientific revolutions come about when a “critical mass “of “anomalies” force a gestalt shift/reversal in the accepted wisdom paradigm . AND as regards the current CATTLE TB CRISIS, clearly, policies based on

current understanding of TB in badgers and cattle have failed spectacularly, prompting a comprehensive re-think. In fact, a whole generation of farmers and vets have grown up being told badgers are the main problem, so have no understanding of the completely wrong assumptions underpinning the debate, as to the basics of how TB works in cattle.

GB had a textbook Area Eradication scheme, which shrank cattle TB from nationwide to tiny southwest hotspots; SEE Reactor graph and Maps 1–2. HENCE, HAVING RULED OUT CATTLE as the persistent TB reservoir, the rationale behind badger culling or vaccination is that badgers are THE major hidden self-maintaining reservoir of TB, and cause of cattle herd breakdowns, so the TB transmission is one way:- badger to badger to cow, inner cycle in Transmission box Figure... computer simulation models explicitly assume this (21).

Unfortunately, it is crystal clear that the exact opposite is the case, Outer cycle in Figure, CATTLE have been the self-maintaining source of TB to other cattle and badgers all along : a 180 degree U-turn in perception needed.

The four key “FALSE FACTS” Behind all this are very simple misunderstandings A TO D:

- A. Only “OPEN Visible “ lesion cattle are infectious ; Zuckerman p. 86, 94 ; Dunnet para 60 .Simply wrong .. M’Fadyean knew 1888 that non-visibly lesioned cases infectious (16); Cattle lesions “Open” throughout, unlike man, so “if reactors with even slight lesions left in herd, spread more or less rapid ” (6, also 1) ; ”infectious at any stage of the disease “ (20) SEE left hand Pyramid figure; and facts re-discovered by McIlroy/Neil:-c. 20 % of “ NVL” reactors sputum positive, ..infectious before they become reactors, or develop visible lesions (15, 19). In fact, more intensive postmortems, with serial lung sections show microscopic lesions, and some 70–80 % of these NVL so-called UNConfirmed cases DO have M. bovis (Dunnet para 32, Wilesmith). The late stages of eradication in Australia put great emphasis on the NGSP or national granuloma submissions programme to nail these cases (17).
- B. FALSE POSITIVE reactor cattle . A little knowledge is a very dangerous thing! .. early on in the eradication scheme, it was noted up to 14 % of “reactors” were infected with avian TB, which is why GB & Ireland got derogation to use the comparative skin test . False positives also from Johnes vaccination, human or skin TB (24).Tragically it has been assumed for decades that so-called unconfirmed cases, APPARENTLY with no visible lesions at gross abattoir inspection, and too few bacilli to be detected were false positive. BUT They DO HAVE TB, the specificity of skin test is 99.99 % so only one in 1,000 truly false positive, the other 999 DO HAVE TB. SEE Tale of two pyramids Figure, these UNCONFIRMED reactors/herds c. two in three cases, are a HUGE “Hidden Reservoir” .. since foot & mouth, out of 305,000 reactors, c 180, 000 UNconfirmeds (Contrast very few TB badgers in ISG study, in para 4 below). Large number of breakdowns with 1 IR Inconclusive reactor also TB + (3c).

After peak of Mad Cow disease/BSE IN 1993, 36,000 cases .. restocking with untested cattle .. simply allowed spread into areas TB-free for 20–50 years, start of “new problem areas:-Thornbury, Exmoor, Hereford/Worcs, Derby-Staffs (a new French spoligotype).. some 85 % of breakdowns were unconfirmed SEE maps Krebs p. 156.Tragically this was also the start of Welsh recrudescence, nearly eradicated by late 1980s, but then Dyfed pocket expanded eastwards, to meet westerly spread from Forest Dean/Gwent/Hereford , meeting then into Powys .. the 700 breakdowns 1972–96 although “mostly due to badgers “according to MAFF, cannot have been, a mere 46 TB badgers out of 2363 sampled, two relic cases left in Glamorgan 1971 as it went clear, NONE in Powys, until TB reintroduced in cattle!

Depressing that UNconfirmeds have been ignored for so long ... the scatter of unknown/unconfirmed cases back during the low point in the 1970s, ALL miraculously became “Due to Brock” at midnight, 31st Dec. 1978 see MAPS 5 & 6. VERY Belatedly, DEFRA have accepted EC Directive 64/432 advice, need two clear tests like confirmed breakdowns to derestrict; and incidentally remove IR Inconclusive reactors at 1st retest. CRITICALLY Important, but largely overlooked TBEG Group AT LAST recognise importance UNconfirmeds (22).

CHRONIC HERDS .. DUE TO SKIN TEST NON-REACTORS ie “ANERGIC” CATTLE. Sadly, it has been widely ignored, but at the heart of intractable hotspot areas have been the small numbers of anergic cows causing chronic herd infection, and the “engine” driving the scatter of new breakdowns in persistent pockets of high density dairying (Maps 1 , 2.. 5,6,7).

Steeple Leaze supposedly a proof case that badger culls work was a cluster of 6 herds, 1973–4 up to five tests/a, removed 244 reactors , a third VL, clearing the problem, gassing badgers After that totally meaningless!

- C. BADGER TB RESPIRATORY:- advanced TB is mostly in the lungs and kidneys, so it has been assumed that spread amongst badgers has been 82 % respiratory, 18% bite wounding...simply wrong; same study showed 70 % STARTS in lymph nodes below mouth, submandibulars, entry via palatine tonsils, just as in dirty feeding pigs/humans from unpasteurised milk “scrofula” (6) and the lung lesions are secondary spread (2, same from superb autopsy studies by O’Boyle in ERAD Reports in Ireland, surprisingly the RBCT autopsies found NO submandibulars, maybe confused with submaxillaries ISG p.77)). A thigh inoculation in badgers, or in neck/tail in cows ends up in lungs

.. but doesnt show actual transmission route ! Wild boar too get “scrofula” TB from cattle, Spain, Germany, etc but NIL evidence they can pass it back to cows either.

Rather ironically Chris Cheeseman was surprised that even when a sputum positive “hoocher” badger was present, there was little spread within the clan, despite sleeping in close four—five badger huddles in underground nest chambers.(wrong type of aerosol, or hoocher banished to annex sett ?)..models of badger TB lack actual data on route or rate of transmission amongst badgers (21), and no-one seems to have noticed but a hoocher sow swallowing sputum will be weaning cubs by regurgitation with a soup of half digested earthworms with TB flavouring so will be the perfect route for “pseudo-vertical” transmission thought to be important (2, 21). Another amusing red herring, compares fossorial badgers with miners prone to lung immunocompromisatiion and silicosis.

D. THE GREAT PERTURBATION MYTHOPOESIS.

DODGY DOSSIERS, as a basis for policy .. there were no WMD aimed at London within 45 minutes, and the whole Perturbation/Edge effect is a last Hurrah or Jewel in the Crown myth in the long past -its- sell- by Great Badger TB Debate :- Alice in Wonderland/virtual reality “science”.

The last major review of badger/cattle TB by Krebs, re-discovered “a link”; BUT he very clearly warned “IT IS NOT KNOWN IF, HOW, OR TO WHAT EXTENT BADGERS MIGHT GIVE COWS TB (12). SAD, hence that the Randomised Badger Culling Trial and Independent Scientific Goup, (three of whom were part of Krebs); chose to again ASSUME Three things (as previous reviews, 5, 26):

- that badgers DO give cows TB (EVEN though they were uncertain as to actual transmission ISG p. 121, 173).. it must be from badgers somehow since allegedly not from cows;
- they are a major reservoir, maybe causing up to 60 % of breakdowns (drop by B in Graph.. or up to 76 % ISG p.114–8). The claim that X % “Was due to badgers” is actually based on the flimsy evidence that the breakdowns were supposedly not due to cattle, but in fact the rises/falls in trial areas ARE are simply a measure of the effectiveness of cattle controls and spillover cow to badger SEE Section C below.
- AND so the ISG chose to INTERPRET the increases/decreases OR detrimental/beneficial effects AS DUE TO culls , SO CULLS MIGHT work or make things worse via a mythical perturbation effect...badger researchers, had long concluded that the failure of 35 years of culls to solve the problem, (because the problem was cows all along) was due to TB badgers immigrating INTO vacuum cull areas , eg Woodchester see 2.b. ..BUT, Clearly immigrants didnt get TB until later herd breakdown spillover !!! It is bizarre logic, that badgers immigrating INTO cull area should cause rise in 2 km wide OUTSIDE ring ..see graph from Consultation. NB. The Irish E.Offaly/Four Areas trials did not find outside perturbations !!

Unfortunately the ISG don’t really understand their own data ..AS REGARDS CRUCIALLY ; A TO D:

- A. far TOO FEW TB badgers to account for the rises/falls in cattle TB just 311 reactive, 1204 proactive with TB ie. 1515 among 11,000 badgers culled, or 1/7 sq.km., under 15/100 sq.km. in nearly half the proactive culls .. and A MERE 166 so-called”superexcretors” (p.77) which might have been a risk to other badgers or cattle.
- B. REACTIVE CULLS NIL IMPACT:- As I explained previously to EFRA COMMITTEE (9), the statistically non-significant 23 % rise in reactive areas happened Before the cull p.109, so daft to say it was due to the cull, it was imported cattle with different DNA Spoligotype to the resident badgers (Report SE 3108), and 1 year after culls ended no difference to no-cull areas, 356 vs 358 accumulated breakdowns p. 249.

PROACTIVE CULLS HAD NIL IMPACT on UNCONFIRMED breakdowns ISG p.96, 101.

Both the Godfray and King reports noted (3 a) the “biological implausibility “of cull effects so rapidly, after catching TB (FROM other cows or badgers?) it probably takes 12–18 mnths for cases to become reactors, have their next annual test .. so cull to effect within a couple of months improbable in either reactive or proactive culls. The START supposed rise in outside areas (SEE GRAPH) A, was merely part of national trends, with nearly as big a jump by C in 2008 see main reactor graph, when TB peaked at 40,000 reactors. Their own data (IJID 2007) showed a rise beyond the 2 km badger movement ring; also hidden in the excruciatingly complex statistics .. the first 1/2 km of the outside ring had a DROP, since the boundary defined on badger territory, encompassed “inside” herds. p.99.

Lies, damned lies and statistics !.. puzzling why ISG give both Vetnet and own database results on cattle effects .. supposed to be SAME herd breakdowns, but differ by 10–20 % ie. the usual alleged cull effect arisen by chance in statistics. Also, Perturbation non-statistical upswing disappeared after 18 mnths, ie. cattle controls took effect... in consultation graph.... and by D the outside/inside effects almost back to ZERO.

The ISG were also absurdly puzzled by finding “NO CLEAR EXPLANATION FOR THE REAPPEARANCE OF BENEFICIAL CULL EFFECTS!”, after 2nd peak .. AND , in fact cattle controls gave a bigger reduction in outside vs inside cull areas from A to B 70 vs 49 %; C to E , ie. five years after end culls Aug.2011, of 42 vs 4 %.

C. CATTLE POSE A RISK TO BADGERS :-Sadly, they almost realised that badger TB is merely a spillover from cattle as shown by TB prevalence levels in first cull badgers re. previous years cattle reactors (25 , 2009, updates 2005):

TRIPLET REACTORS	A	B	C	D	E	F	G	H	I	J	TOTALS
INITIAL	57	70	62	187	34	14	23	36	152	215	852
BADGERS	8	13	4	102	29	13	29	12	82	65	357
TB+											
CLANS	7	7	4	44	17	7	13	8	29	32	168
TB +											
BADGER	1.1	1.0	1.0	2.2	1.3	1.1	1.7	1.0	2.0	1.6	1.7
+CLAN											

THUS D I J were recruited into the trial, and brought onto intensive annual testing AFTER the 2002 foot & mouth upsurge, hence had the most reactors, the most TB badgers, most clans affected and higher numbers/clan .. the ISG noted the doubling in badger TB prevalence, including RTAs, ie not culled or cull-perturbed ...and that this suggested that cattle pose a risk to badgers pp. 73–8, 84, and 243 Proc.National Academy ScienceBUT CHOSE to interpret the rises in reactive/outside proactive areas AS DUE to Perturbation. Ironically, the West Cornwall, triplet F ..Lands End, which supposedly had the “Hardest Boundary” stopping the “migrating badger” edge effect ie the sea, was merely the triplet which had been the longest on intensive annual testing Maps 5, 6, 7.

BADGERS DO NOT present a self-maintaining reservoir of TB. The Map 2 solid “badger parishes” hotspot is very misleading... within this TB in badger clans is actually in incredibly small micro-pockets as shown by the clean ring culls, spillover at the epicentre of the cattle breakdown/s; And the WOODCHESTER study 9 sq.km. found over 14 years, to 1994, in 868 badgers, only 188 with TB, 51 infectious, a mere 17 superexcretors, (21); so not surprising there was little evidence of spread within/between clans, NOR any herd breakdowns from this “endemic” source, (2, 4, and Krebs p.48). Badger computer simulation models lack data on transmission route/rates (21).

Prevalence in badgers was not related to density (Krebs p.46 Cornwall, lowest density highest prevalence), and no minimum threshold clan size to sustain TB:- AN amusing red herring trying to tie TB to density .. with the silly idea of fertility control TO STOP TB ! Prevalence is simply via but spillover cow to badger as in ISG data in above Table, 168 clans; and combining the N.Woodchester/N.Nibley data 16 out of 20 clans had only one—two TB badgers .. but bad breakdowns could spillover to the whole clan Cornwall eight of eight; Jacks Mirey clan, from four contiguous inner ring farms 1986–7, 93 reactors (4, 23, 25). And badger TB dies out when not topped up from cattle .. Woodchester (4), GB Krebs p.62, ULSTER recent DARDNI RTA survey, Four areas study (ISG , PNAS P.243 & Report to Mary Coghlan). Indeed some badgers may even self-heal!! (7). The Woodchester recolonisation study in fact showed immigrant or new cubs didnt have TB until 1988–9 breakdown a decade after the cull (2 b).

BADGER CULLS WORK! ? Unfortunately the other studies supposedly proving culls work reveal an extraordinary Cognitive Dissonance in Seeing what they Wanted to Believe:

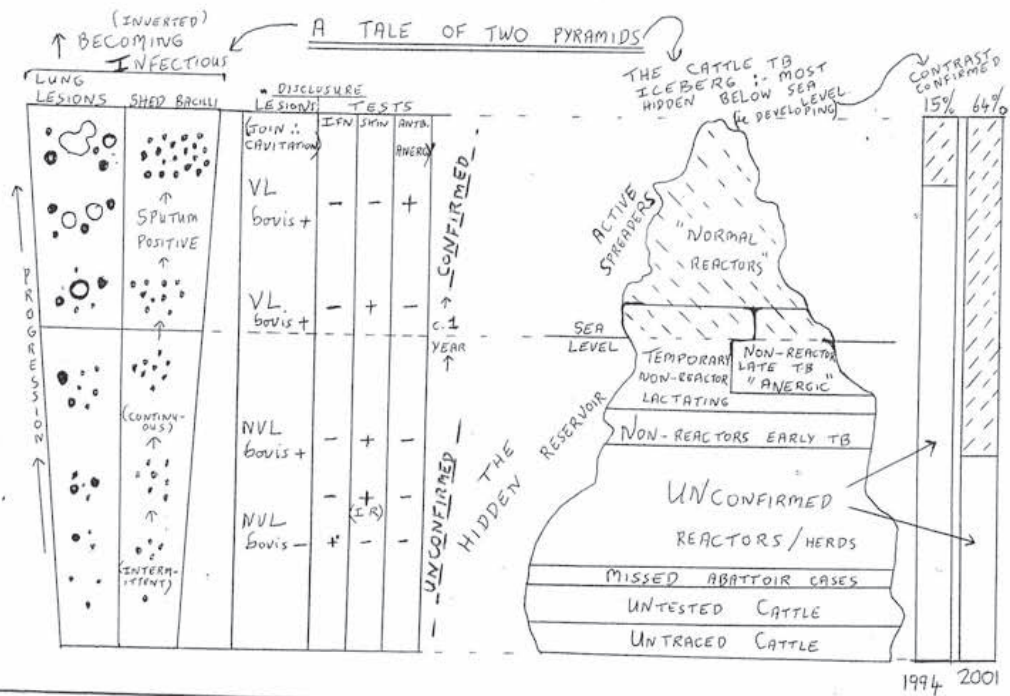
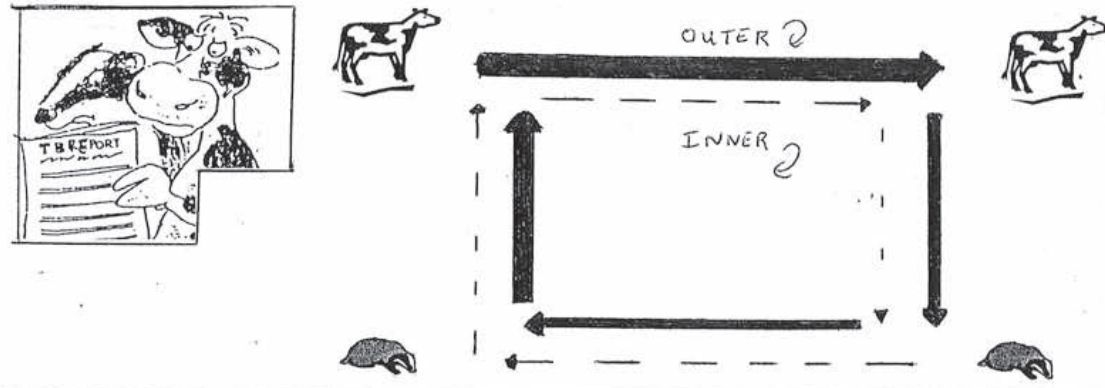
- Hartland went clear by cattle controls, went to two year testing so flare up cattle, cleared by intensive synchronised testing, gassing badgers After that meaningless see Maps 5 ,6 (20). Steeple Leaze was simply a cluster of chronic herds cured by maximum testing, gassing irrelevant, as also Thornbury;
- Although the reductions in cattle TB were assumed to be due to the cull, rather than effective cattle controls, there were incredibly few badgers involved as re. Thornbury (7, Krebs Avon p.46)/East Offaly 141 badgers from 600 sq.km./Four Areas trial, supposedly cull effects of 51–76 %; but a mere 286 TB badgers from 960 sq.km. ..Cork 115, Donegal 37, Kilkenny 59, Monaghan 75 ..NB biggest “DROP” in Donegal was IN FACT a flare up in contiguous outside reference herds so DIFFERENCE of 97 % not a drop inside “due to cull”!/the RBCT 1515 TB badgers from 1900 sq.km. not causal either (see 9 b, c ; ISG p.79, 114–8) The Staffs, Sussex culls were inconclusive as well.

D ..HENCE .. the proposed cull , balancing these supposed beneficial/detrimental effects ; as explained in Consultation Document (3a, Annex B, para. 20), MIGHT prevent some 12–16 % of breakdowns , OR in practical terms :-a mere 46 out of 292 expected breakdowns AFTER nine years in a 150 sq km area ..spectacularly irrelevant given c 7000 breakdowns/a.; and the problem area now 1/2 of GB Map 4 .. The Consultation, and FERA models, suggest A BADGER VACCINE would do half as well, and the 2 km ring vaccine firewall which supposedly would avoid the mythical perturbation effect , would be politely tiptoed beyond by cattle moves so is crass nonsense (21). Prof. McInerney part of Dunnet & ISG stated culls in 1986/7 would have very dubious impact, and be wildly uneconomic BUT “ANY Cull decision a POLITICAL ONE!” .. SAME WARNING Recently.

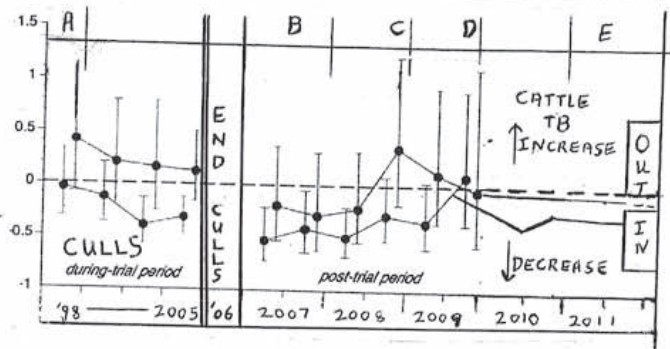
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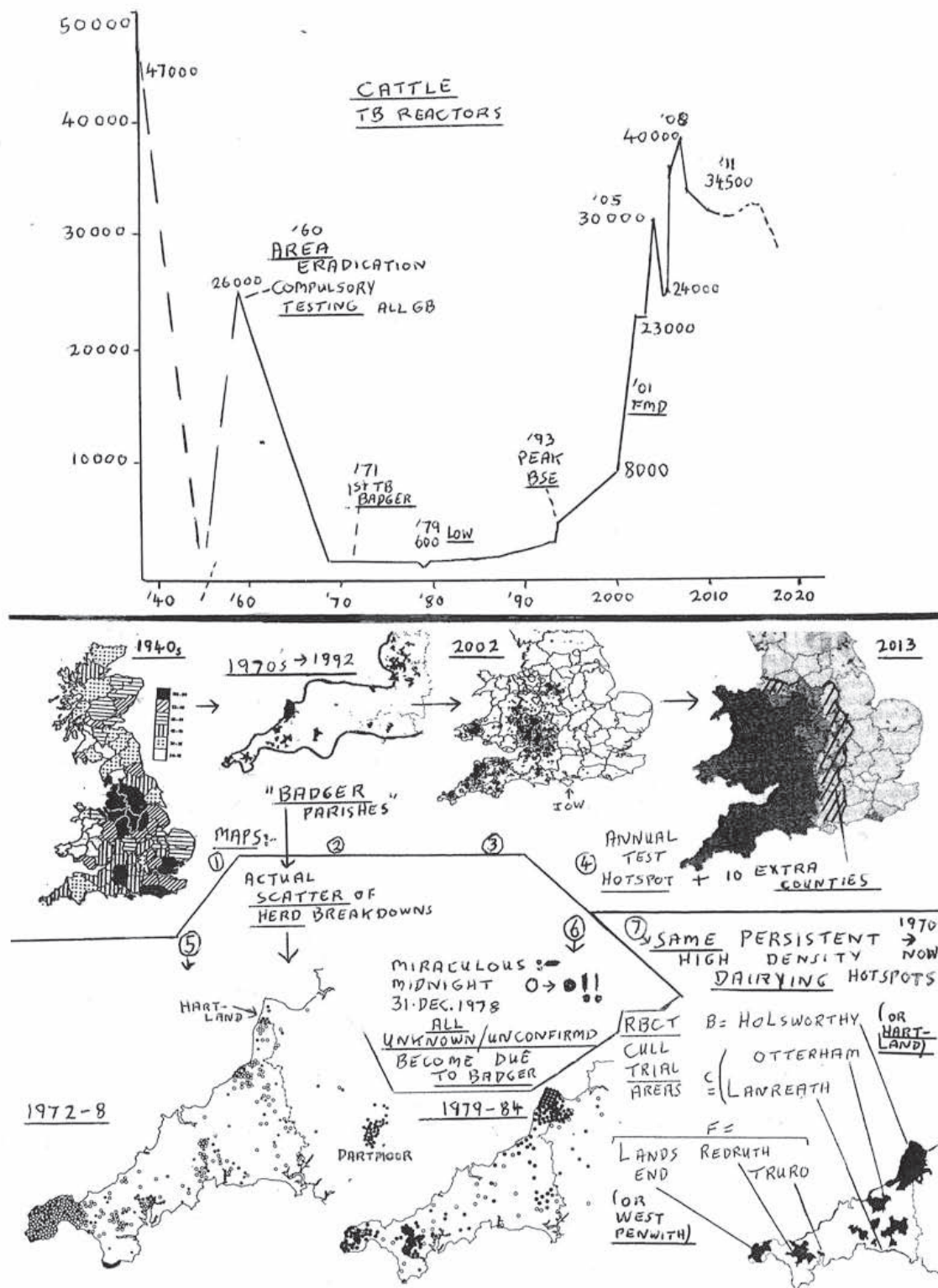
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January 2013



CONSULTATION SUMMARY
RBCT
CULL = BASIS
PROPOSED 2
PILOT CULLS





Written evidence submitted by Ian Kett

My name is Ian Kett. My wife and I farm 75 acres on the Quantock Hills in Somerset, grazing traditional cattle (English Longhorns) and sheep in an extensive system designed to favour conservation of wildlife and landscape. We have kept longhorn cattle for over 20 years. In January 2012 we suffered a severe bovine tuberculosis (bTB) breakdown along with all of our neighbouring farms. We lost 75% of our breeding cows, a junior bull and our stock bull.

I worked as a veterinary surgeon in large animal general practice for 38 years and my wife was a Defra Veterinary Officer in Devon from 1987 to 2007. We therefore approach the problem of bTB as scientists through our veterinary experience, as conservationists who have maintained badgers on our property and as farmers who have sustained heavy irreplaceable losses to pedigree breeding stock as a result of the disease reaching our premises.

The following is an unbiased appraisal of the facts pertaining to the control of bTB in the UK, as far as I am able to ascertain.

OVERVIEW

bTB has been the subject of control measures in this country since the 1950s. By 1984 the disease had been reduced to just 84 outbreaks nationwide, with around 400 animals culled. This had risen to over 30,000 reactor animals culled by 2005. From 1988 to 1997 the effect of badger protection legislation has allowed the population of badgers to rise by 77%. It is reasonable to assume that with this continued rate of increase, the population now exceeds 800,000 animals. This creates population pressures including fighting and forced migration due to feeding and territorial limitations, which in turn can affect the spread of badger transmitted disease.

During this period we have seen the number of badger setts on our land increase from nil in 1990 to four now.

Aside from the disease issues serious damage to infrastructure and wildlife has resulted. A national survey in 1997 estimated the cost of badger damage to be £25.7 million per annum, which included damage to roads, canals, parks, gardens, hedgerows and agricultural land. In addition feeding pressures have dramatically increased predation on ground nesting birds, bumble bees, hedgehogs, grass snakes, frogs and toads.

Hungry badgers have been forced into farm buildings in their search for food, thus increasing contact with domestic animals, in particular cattle through contamination of feed by badger urine. In 1995 the Chief Veterinary Officer concluded from an analysis of field outbreaks that 90% were attributable to badgers.

VACCINATION

It will be apparent from the above that the badger problem is not primarily about bTB but rather it is one of overpopulation. Without addressing the latter there will be no solution to the former. Were it to be successful, vaccination would allow the badger population to rise further thus exacerbating the environmental damage. As an alpha predator the badger has no natural enemies in the UK.

BCG is the only vaccine at present available in the UK for the control of tuberculosis. BCG is only 70% effective in Man and of unknown efficacy in cattle and badgers. Two doses have been shown to give protection to badgers as assessed by blood testing but *not* by assessment of clinical disease. There is no data to show a benefit from a single dose.

The presence of massive challenge to even the most effective vaccine will overcome vaccine derived immunity. Animals grazing grassland contaminated by diseased badger urine are exposed to millions of bacteria. This urine contamination is particular to the pathology of the disease in badgers, which suffer a fulminating form of the disease with urinary excretion a major feature. (Gallagher and Clifton-Hadley, 2000) In cattle, by contrast, bTB is chronic and walled off in tubercles or thick walled abscesses from which there is no bacterial excretion. These are most often in the lymph nodes. When in the chest lymph nodes or in the lungs these tubercles may discharge into the respiratory passages and create a low risk of infection to other cattle in a group by inhalation. There is thus some, but a relatively insignificant, risk of cattle to cattle transmission. This is borne out by the majority of outbreaks in housed cattle affecting small numbers of animals. By contrast, where feedstuff contamination is heavy, large numbers of cattle may be affected at the same time. When susceptible animals are removed from the source of infection, no further cases occur. This has been our experience in our 2012 outbreak where infected latrine sites on autumn grazing were involved. In addition a diseased badger was identified on our neighbour's farm where there was a concurrent bTB outbreak. Unfortunately the badger carcass was not submitted for laboratory testing.

In order to achieve control of any disease in a population by vaccination, at least 70% must be vaccinated. Vaccination of badgers will cause perturbation as a result of trapping and injection. Serious welfare issues may result from repeated trapping and handling of badgers. Repeat doses of BCG can cause acute reactions and even death in man and possibly therefore in animals. Vaccination in cattle is not realistic as there is no benefit from the use of BCG. At the moment there is no test in cattle to differentiate reliably between natural and vaccination antibodies, raising issues of difficulties for future testing and international trade. The test that would be used is known as the DIVA test. The cost of using a DIVA test may be prohibitive to an already

struggling industry (estimated at £26 per test) and may need to be repeated annually following routine tuberculin testing of cattle.

Eradication of any disease by vaccination depends on a highly immunogenic vaccine such as smallpox vaccine, from which a single dose confers lifelong immunity. There are no candidates for such a vaccine against bTB at present. BCG is unpredictable in the level of immunity it confers both in man and experimental animals. Experimental trials with BCG have been shown not to prevent infection or shedding of *Mycobacterium* by infected animals. It does seem to mitigate the effect of the disease, thus increasing the survival time of potential carriers and secretors. (Chambers et al. 2011).

Much of the pressure to vaccinate badgers and cattle is driven by political expedience. Eric Morley in the last Labour government was said to have told the Independent Scientific Group at the outset that a badger cull was politically unacceptable. It beggars belief that a government minister will put the loss of electoral support before the national interest.

There has been a sustained campaign of misinformation and cherry picking of scientific data by the Badger Groups and the RSPCA in support of their own ends. The RSPCA in particular was censured by the Advertising Standards Agency in 2006 and the Charity Commission in 2007 for publishing misleading information about the transmission of bTB.

THE WAY FORWARD

The gold standard solution would be the use of a single dose oral vaccine in badgers combined with badger population reduction to 1980 levels. The disease in bovines would be eradicated by continuing testing on an annual basis using the comparative intradermal test.

Since such a vaccine is not even on the horizon at the moment, the culling option for badgers is the only efficient management tool available. From the standpoint of public acceptability identification of infected setts and then subsequent eradication may offer a way forward (PCR testing). However this does not address the overall problem of a rising badger population.

Opposition to culling has been mounted mainly by referring to the Randomised Badger Cull Trial (RBCT) headed by Professor Krebs. This work has largely been discredited by independent observers owing to the lack of any peer review, and the conclusion that was drawn took no account of the poor cull rates achieved and the effect of significant disruption by animal rights groups. Almost 2000 incidents of trap destruction and release of trapped animals occurred during the trial period but no account was taken of this in estimating the reasons for badger perturbation and increase in disease outside the cull areas.

A substantial body of information exists in the literature confirming positive effects of culling badgers on the rates of bTB in cattle prior to the Krebs Trial. Professor Krebs dismissed these results as having no controls yet failed totally to take account of the incidence of disease in the areas surrounding the trial sites where disease levels in cattle remained the same as before the trials started. This effectively provided adequate control data.

The table below summarises the results of UK and Irish culling trials from 1975 to 2005:

	<i>Area (sq. km.)</i>	<i>Culling</i>	<i>Herd outbreaks</i>
Thornbury	104	100%	clear 10 years
Steeple Leaze	12	100%	clear 7 years
Hartland Point	64	>80%	80–90% reduction 10 yrs.
East Offaly	>38	>80%	88% reduction 7 yrs.
Four Counties	100x4	>80%	60–80% reduction
RBCT (Krebs)	00x10	30–70%	19–23% inside area 22–29% outside area

The admitted difficulties associated with an effective cull policy as opposed to vaccination might be addressed as follows:

1. Remove the excessive protection of the Badger Act, thus rendering animal rights protesters unable to target individuals.
2. Enforce punitive measures against those convicted of badger baiting, including large fines, imprisonment and euthanasia of dogs used for baiting.
3. Allow humane destruction of badgers by landowners subject to a closed spring breeding season.
4. Limit cull methods to carbon monoxide or carbon dioxide administered in daytime when badgers will be asleep underground. If not killed the animals will emerge undamaged as the gas disperses harmlessly.
5. Shooting of individual badgers at dusk with silenced rifles remains an efficient tool in competent hands.
6. Monitor sett health using PCR testing—a technique that at present needs refining.

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January 2013

Written evidence submitted by Keith Meldrum

1. I am writing to the Committee as someone who, as Chief Veterinary Officer in MAFF between 1988 and 1997, had a significant involvement with tuberculosis in both cattle and badgers and spent a great deal of time trying to identify the most appropriate means to address the issue and obtain meaningful results. I now write as a very interested and concerned outside observer and to describe some of the work that was initiated whilst I was in MAFF, including research into badger tuberculosis vaccines, and some of the struggles that we faced.

2. One struggle was to achieve general acceptance that there was any connection between tuberculosis in badgers and tuberculosis in cattle. Some powerful lobbying groups could not be persuaded that there was any such connection although it does now appear that most have been persuaded.

3. Another struggle was to persuade others in MAFF that there was a need to amend the national cattle tuberculin testing programme to address the fact that the incidence of the disease was markedly different in different areas. Understandably there was a reluctance to spend even more money on tuberculin testing unless there was a very clear need to do so. Money was tight even in those days.

4. A great deal was done to intensify the tuberculin testing programme in affected areas, to support the badger observational and sampling programme in Woodchester Park, to improve the epidemiological investigations into cattle breakdowns, to introduce better bio-security on farms, to develop improved diagnostic tests in cattle and badgers and to put in place a programme for the development of a badger tuberculosis vaccine. In fact a research programme was initiated in 1993—and as the Committee will be aware this was expanded in 1998 to cover cattle following the publication of the Krebs report. In addition, and where a herd breakdown could not be attributed to purchased cattle or contact with an adjacent herd, the possibility of a badger source was considered. In the first place a survey of badger activity on the farm was instigated. Evidence gathered was considered by a sub group of the Consultative Panel on Badgers and Tuberculosis and they would decide whether the evidence supported a badger removal operation on the farm. During the time that I was CVO over 1,600 badger removal operations were carried out and over 13,000 badgers were put down and examined postmortem of which 23% showed evidence of tuberculosis. This policy was discontinued in 1998 after publication of the Krebs Report.

5. I have not kept my files from the time but the CVO's published report for 1993 explains that a review of the current status and future trends of the vaccination of animals against tuberculosis was undertaken. The study concluded that vaccination, particularly of badgers, was feasible although it would require significant and long term research resources. We knew that it would be a very difficult task to develop a new vaccine since other researchers had been trying for years and had failed, and so it has proved to be. The Committee will be aware that the only vaccine that is being taken forward at this time is BCG that was first used in humans some one hundred years ago. From the recent Defra papers that I have seen the BCG vaccine has comparatively limited value in protecting cattle against tuberculosis and that is why I hope that research into vaccines for use in both cattle and badgers will continue to be funded in the hope that a second generation vaccine will be developed that will afford cattle a higher level of protection than is obtained from BCG.

6. A review of the action taken by MAFF and Defra will demonstrate just how much time, energy and money has been directed at the tuberculosis problem over the years. I was never in any doubt from the evidence put to me that it was not unreasonable for badger numbers to be reduced, in a humane manner, in areas with a high incidence of disease in both cattle and badgers not only to reduce the risk of the disease spreading between cattle and badgers and vice versa but also to combat the very serious disease in the badgers themselves—something that is often forgotten.

7. I am quite clear that during my time as CVO real attempts were made by MAFF to do more and more to address the issue of tuberculosis in cattle and even in those days we were trying to use “every tool in the toolbox” whilst accepting that there were no easy solutions. I had the feeling at that time that farmers should do more for themselves and that we in Government also had to do more. I was concerned then and am concerned now that farmers should not bring any cattle onto their premises unless they can assure themselves that they are free of tuberculosis. This was extremely important in those herds where there had been partial or total depopulation- for whatever reason. This brought veterinary surgeons in practice into the equation since they were and still are in a unique position to advise their clients on what they should do to reduce the risk both of disease introduction and disease spread. Only too often cattle farmers in high incidence areas are forced to accept that they have got to live with the disease- and that to my mind is a totally unacceptable option.

8. A great deal has been said in recent days about the use of a vaccine in cattle assuming that this is not too far off and some have said that negotiations within the EU to amend the rules to permit vaccination would be

a comparatively simple matter. I wish that were the case. Our cattle industry has been hit so hard and so often in recent years that we must get this one absolutely right. Not only did they have to deal with the effects of bovine spongiform encephalopathy but also with foot and mouth disease and tuberculosis in their cattle must, for some, be the last straw. To this should be added that the UK cattle industry was constrained from importing valuable genetic material from the USA for very many years because of the perceived risk from bluetongue- a risk that we subsequently found to be seriously overstated. I remain concerned that our export markets may be damaged if the “wrong vaccination policy” were to be introduced and absorbed into the EU trade rules making it even more difficult for our elite breeders to retain their trading foothold in the EU. At the moment all our animals are eligible to enter intra-community trade if they meet the standard laid down in Council Directive 64/432 but it will be very difficult for those animals to attract a market if they have been vaccinated and their passports annotated. It is therefore imperative that our negotiators must ensure that any change to our trade rules does not disadvantage the UK. Members of EFRACOM will be aware that amending trade rules to be agreed by both the Council of Ministers and the European Parliament can be a long and complex procedure and the outcome can never be predetermined. I conclude on this point that our negotiators in Brussels will have an uphill struggle to obtain amendments to the legislation that may be needed without putting our cattle industry at a distinct trading disadvantage.

9. As a very interested observer I do hope that Defra will continue to use every means at its disposal to address tuberculosis in cattle and badgers, to include improved bio-security, reasonable movement controls, enhanced testing of cattle together with vaccination and control of badgers in high risk areas. It follows to my mind, that farmers who are in a high risk area or have suffered from repeated outbreaks of tuberculosis in their cattle should be at liberty to make use of any authorised cattle tuberculosis vaccine, if they wish to do so. They would be well advised to consult with their own veterinary surgeon before doing so to ensure that they are fully aware of all the pros and cons. They need to be aware that the BCG vaccine, on its own, would not eradicate the disease from their cattle and that the other measures in the “tool box” must also be deployed and applied with immense vigour.

10. I remain at the disposal of the Committee to answer any questions that may arise from this letter.

K C Meldrum CB, BVM&S, MRCVS, DVSM, Hon FRSPH

January 2013

Written evidence submitted by the Humane Society

1. This submission represents the views of Humane Society International/UK (HSI UK) on the subject of vaccination of badgers and cattle against bovine tuberculosis.

2. BACKGROUND

Bovine tuberculosis, caused by infection with *Mycobacterium bovis*, is a notifiable disease of cattle. All UK cattle herds are subjected to compulsory testing, with animals which test positive for infection subject to compulsory slaughter and infected herds subject to movement restrictions. According to DEFRA figures,ⁱ 11.5% of cattle herds in England were under movement restriction during 2011, and 27,145 positive tested cattle had been slaughtered in 2012 to the end of September. The total cost to the public purse of the bovine tuberculosis control policy over the past 10 years is estimated at £500 million.

3. As well as infecting cattle, bovine tuberculosis is known to infect various other species, including badgers. Badger populations are thought to constitute a wildlife reservoir of *Mycobacterium bovis*.

4. In December 2011 the government published its Policy on Bovine TB and Badger Control in England,ⁱⁱ in which it described plans to license the culling of badgers in order to reduce populations by at least 70% for a period of four years in two pilot zones each of at least 150km², and subsequently in up to 40 additional bovine TB affected areas. If fully rolled out, Natural England estimates that this could result in the killing of up to 130,000 badgers, and the reduction of England's badger population by a third.ⁱⁱⁱ Based on the results of the Randomised Badger Culling Trial,^{iv} the government estimates that this could reduce the incidence of TB in cattle herds by an average of 12–16% within the culling zones nine years after culling commences.

5. Vaccination as a mechanism for the control of infection in populations is widely practised in domestic animals, wildlife and human populations.

6. BADGER VACCINATION

In March 2012 the Welsh Assembly Government, using the same scientific evidence, rejected badger culling and opted instead for a badger vaccination programme^v in the west Wales Intensive Action Area using the injectable BCG badger vaccine which was licensed in 2010. By the end of the first vaccination “season” more than 1400 badgers were reported to have been vaccinated.^{vi}

7. A number of groups and private individuals have also been vaccinating badgers in parts of England. The largest such project is the Badger Vaccine Deployment Project area in Gloucestershire operated by the Food and Environment Research Agency,^{vii} which reported to have vaccinated 998 badgers during 2012. Indeed this

is the last remaining project from 6, following the closure of five similar projects made early in the term of the current government as a cost-saving measure.

8. While it is as yet too early to measure any impact of badger vaccination on the incidence and prevalence of bovine TB in cattle in Wales, the Welsh experience, and the experience of groups in England where badger vaccines have been deployed, have shown that large scale vaccination of badgers is possible.

9. The results of the Randomised Badger Culling Trial showed that reactive badger culling increased, rather than reduced, the incidence of TB in cattle; and that while proactive culling reduced TB incidence in cattle in culled areas, this beneficial effect on cattle breakdowns was offset by an increased incidence of the disease in surrounding un-culled areas. The Independent Scientific Group responsible for the evaluation of the data concluded that this effect resulted from culling-induced changes in badger ecology and behaviour known as the perturbation effect.

10. A recent scientific field study conducted using free-living badgers over four years by Carter et al and published in the scientific journal PlosOne^{viii} concluded that vaccination with BCG not only resulted in a direct protective effect on individual vaccinated badgers reducing by 76% the risk of free-living vaccinated badgers testing positive for progressive infection; but also in an indirect protective effect on unvaccinated badger cubs, with the risk of positive tests in unvaccinated cubs being reduced by 79% when more than a third of the adults in their social group had been vaccinated.

11. Vaccination of badgers using the current injectable vaccine therefore markedly reduces the prevalence and progression of infection in vaccinated badgers and their unvaccinated cubs, as well as eliminating the risks to cattle from badger perturbation that results from badger culling. Badger vaccination is therefore likely to prove a more effective long-term strategy for reducing the incidence and prevalence of bovine TB in badgers, and therefore for reducing the risk of transmission of bovine TB from badgers to cattle, than is culling.

12. The government should therefore adopt badger vaccination as a more effective long-term strategy to controlling bovine TB in badger populations than culling. Greater investment in the development of orally administered vaccines which could be fed to badgers in food bait should be given a high priority by government, since this will greatly facilitate the widespread use of vaccines with which to protect badgers from bovine TB and reduce the need for badgers to be trapped, and the associated costs. Research into orally-administered TB vaccines designed for use in wildlife has already shown promise in terms of controlling the spread of disease in Spanish wild boar,^{ix} and in brush-tail possums in New Zealand. In the meantime, government should encourage innovative programmes, including volunteer projects, to increase the deployment of injectable badger vaccines in areas of high risk for bovine TB.

13. CATTLE VACCINATION

While badger vaccines offer a more palatable and effective method of reducing the prevalence of bovine TB in badger populations, the main source of bovine TB in cattle remains other cows. Therefore safe, humane and effective methods of reducing the risk of transmission of bovine TB between cattle must be sought as a matter of urgency. The elimination of the disease in cattle will depend on the development and use of effective vaccines and sensitive, specific diagnostic tests that allow differentiation between vaccinated and infected animals.

14. These developments were recommended in the Krebs Report of 1997.

15. The BCG vaccine has reportedly shown a 56–68% protective efficacy in neonatally vaccinated calves,^{xi} in small-scale trials conducted in Ethiopia. Larger-scale trials are needed to determine the impact that such levels of efficacy would have at a herd or population level. However, while the development of cattle vaccines with greater levels of efficacy and longevity should be a priority, there is every reason to suppose that the carefully planned, widespread use of the current BCG vaccine in cattle would significantly reduce the risk of transmission between cattle, and therefore the incidence and prevalence of infection in the national herd.

16. Vaccination of cattle against TB is currently prohibited by EU Directive 78/52/EEC, because the use of the BCG vaccine can interfere with the tuberculin skin test, which is recognised as the primary diagnostic test for TB in cattle. Vaccination with BCG produces a reaction to the tuberculin skin tests which subsides after approx. one year in >90% of vaccinated cattle according to DEFRA,^{xii} following which the vaccinated animal will test negative.

17. In January 2012, the Animal Health Veterinary Laboratories Agency (AHVLA) submitted a dossier to the Veterinary Medicines Directorate (VMD)^{xiii} for approval in principal of a Marketing Authorisation for the BCG-based cattle vaccine. According to the DEFRA website feedback was expected from the VMD “within a year”.

18. The AHVLA has developed a test for Differentiating Infected from Vaccinated Animals (DIVA test) which identifies a reaction to specific *Mycobacterium bovis* antigens not present in the BCG vaccine.^{xiv} A positive test therefore indicates an infected animal; uninfected vaccinated animals should test negative.

19. In order to get EU acceptance the DIVA test will need to be accredited by the OIE (The World Organisation for Animal Health), this will also facilitate the trade in products from vaccinated cattle outside the EU.

20. There is a validation process to which the DIVA test must be subjected before an OIE application can be submitted. Once the application is submitted the approval process takes around four—five months.

21. The government should be doing all it can to ensure that the necessary permissions are obtained in order to allow for the DIVA test to be field-tested, and the validation process with OIE expedited. In parallel, the government should be working with its EU partners to ensure that the use of the BCG vaccine, alongside the DIVA test, will enable products from vaccinated, disease-free animals to be traded within the EU.

22. PUBLIC ACCEPTANCE

Vaccination programmes, for both cattle and badgers, will undoubtedly meet with far greater levels of public approval and acceptance than badger culling.

23. Instead of investing large amounts of public and private money in a controversial and unpopular badger culling policy, which will at best result in a marginal reduction in the incidence of bovine TB in cattle over the long term, government should instead focus its investment in biosecurity measures designed to reduce the risk of TB spreading among cattle and between cattle and badgers, and in the development of practical, safe and efficacious vaccination protocols for both cattle and badgers and the political environment which makes their use acceptable.

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^{xii} http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/vaccine_cattle.pdf

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^{xiv} Whelan A O, Clifford D, Upadhyay B, Breadon E L, McNair J, Hewinson G R, Vordermeier H M 2010. Development of a skin test for bovine tuberculosis for differentiating infected from vaccinated animals. *J Clin. Micro.* 48, 3716–3181.

January 2013

Written evidence submitted by the RSPB

SUMMARY

The postponement of the pilot badger culls is an opportunity to reconsider the use of the Injectable badger vaccine in combating bovine TB.

Badger vaccination has strong public support and is a tool that is available now. Recent research suggests that badger vaccination could play a role in bearing down on bovine TB.

The Government needs to set out the most effective strategic role for badger vaccination and actively promote and encourage its use.

Government should clarify its aims for the health of badgers and badger populations.

The Government should set out a clear programme of action for the development, licensing and deployment of cattle vaccination.

INTRODUCTION

1.1 The RSPB is Europe's largest wildlife charity with over one million members, with more than 920,000 of them living in England. The Society manages one of the largest conservation estates in the UK, covering more than 55,000 hectares in England.

1.2 Livestock grazing is an important component of the RSPB's land management with about 8,600 cattle on our nature reserves in England.

1.3 The RSPB's vision is for sustainable systems of farming that produce adequate supplies of safe, healthy food; protect the natural resources of soil, air and water that farming depends on; help to protect and enhance wildlife and habitats; provide jobs in rural areas and contribute to a diverse rural economy.

1.4 The RSPB is sympathetic to concerns within the farming community over the economic and social impacts of bovine TB. Bovine TB is an important disease that needs to be addressed. It is also clear that the disease reservoir in wildlife is contributing, at least in part, to the problem. We recognise the costs to the industry from this disease but also to the taxpayer through the testing regime and compensation. There is considerable public interest in this issue and this must be properly taken into account in determining future policy.

1.5 We welcome the opportunity to comment on the role of vaccination in addressing bovine TB. We believe that the postponement of the proposed pilot badger culls should be used as an opportunity to properly re-examine the potential role of vaccination, including specifically the use of the injectable badger vaccine.

THE ROLE OF VACCINATION IN BOVINE TB CONTROL

2.1 The coalition Government is committed to pursuing pilot culls of badgers as its key measure to address the bovine TB reservoir in wildlife.¹ When considering the killing of native wildlife the Government should consider, very carefully, whether there are other satisfactory solutions as part of its commitments under the Bern Convention.

2.2 The Government's 2011 policy statement concluded "we do not consider that either onfarm biosecurity or injectable vaccination of badgers alone are sufficiently satisfactory alternatives to culling".² In view of new information on the benefits of badger vaccination and the deepening questions over the practicality of culling we believe that the Government should reconsider the role of badger vaccination *and* enhanced biosecurity in the control of bovine TB.

USING EVERY TOOL IN THE TOOL BOX

3.1 We are concerned that the Government has been unduly negative about the potential role of badger vaccination in contrast to an apparent eagerness to pursue a badger cull. Minister of State David Heath MP has described the use of the injectable badger vaccine as "not realistic".³ It is not clear whether he was referring to cost or practicality. However, impressive progress in 2012 by the Government's own agency, FERA, in vaccinating 998 badgers over the 100km² Stroud badger vaccine deployment project area,⁴ the vaccination of over 100 badgers on the National Trust's Killerton Estate⁵ in Devon and the Welsh Assembly Government's progress in vaccinating 1400 badgers⁶ in the first year of Intensive Action Area programme in Pembrokeshire does not suggest that vaccinating badgers on a significant scale is impractical.

3.2 It is not the case that "an injectable vaccine requires injecting every badger every year".⁷ A vaccine only needs to be administered to enough of the population to encourage herd immunity. It is encouraging that recently published results of research into badger vaccination⁸ showed that the risk of non-vaccinated badger cubs testing positive for TB was reduced by almost 80% when more than a third of badgers in their group had been vaccinated. This is an indirect positive impact of vaccination that the researchers put down to a herd immunity effect.

¹ Badger cull to proceed. Defra press release 23 October 2012. <http://www.defra.gov.uk/news/2012/10/23/badger-cull/>

² The Government's policy on bovine TB and badger control in England. Defra December 2011. <http://www.defra.gov.uk/publications/files/pb13691-bovinetb-policy-statement.pdf>

³ Farmers Guardian 25 September 2012 <http://www.farmersguardian.com/home/livestock/new-farming-minister-insists-badger-cullwill-go-ahead/49932.article>

⁴ <http://www.fera.defra.gov.uk/wildlife/ecologyManagement/bvdp/index.cfm>

⁵ In evidence to Northern Ireland Assembly Review into Bovine Tuberculosis <http://www.niassembly.gov.uk/Assembly-Business/Committees/Agriculture-and-Rural-Development/Reports/Review-into-Bovine-Tuberculosis/>

⁶ WAG press release 28 November 2012 <http://wales.gov.uk/newsroom/environmentandcountryside/2012/121128badgervaccination/?lang=en>

⁷ Secretary of State, Owen Paterson MP, 23 October 2012, Hansard Col 843

⁸ Carter SP, Chambers MA, Rushton SP, Shirley MDF, Schuchert P, et al. (2012) BCG Vaccination Reduces Risk of Tuberculosis Infection in Vaccinated Badgers and Unvaccinated Badger Cubs. PLoS ONE 7(12): e49833. doi:10.1371/journal.pone.0049833

3.3 We do not suggest that the injectable badger vaccine is a “silver bullet” or that it will be cost effective for use across the entire area affected by bovine TB, but the same applies to culling. However, we do believe that the Government should give urgent consideration to how badger vaccination could be targeted and co-ordinated to have maximum effect. The Government has stated repeatedly that it will “use every tool in the box to bear down on bovine TB”⁹ To date, the Government appears to have left the injectable badger vaccine in the tool box largely unused.

3.4 The badger vaccine has been available for use since 2010 but five of the six planned badger vaccine deployment projects were cancelled by the incoming coalition Government. Although initially established to test the deployment of vaccination and the training of lay vaccinators, if these projects had been continued we would, by the end of 2013, have six centres where four years of vaccination would have had a chance to bear down on bovine TB. We believe this represents a missed opportunity as well as giving a very negative message about the value of vaccination.

ENCOURAGING VACCINATION

4.1 We consider that the role of badger vaccination alongside culling has been underplayed and inadequately promoted. Modelling work on badger control strategies¹⁰ suggested that culling would be more effective in reducing bTB cattle outbreaks if it was combined with vaccination in the peripheral ring. However, the approach adopted for the two pilot culls leaves badger vaccination as an optional component. We welcome the provision by Government of a fund of £250,000 to assist with vaccination in and adjacent to the pilot projects but we are surprised at the apparent lack of promotion of this particular component of the toolbox.

4.2 The RSPB owns and manages a small woodland nature reserve, Highnam Woods, which we believe* is adjacent to the West Gloucestershire pilot badger cull area. (*Due to the secrecy surrounding the exact boundaries of the pilot culls it has proved difficult to determine precisely how far this land is from the edge of the pilot cull but it appears likely that the reserve is within 2 km of the pilot cull). At no stage during the development of the pilot cull were we approached by either the Government or the company organising the cull and encouraged to vaccinate the badgers on our land.

4.3 The research on badger culling shows that it increases the risk of cattle TB outbreaks in areas around the cull zone due to perturbation. The RSPB believes that the most effective contribution we could make to mitigating this risk to neighbouring farmers and the most positive step we can take for the health of badgers at Highnam Woods nature reserve is to vaccinate the badgers on this nature reserve. We therefore initiated a badger vaccination programme at this site in the autumn of 2012 and this will be continued in 2013. This small project is the current extent of our direct involvement in badger vaccination. We do not own or manage land within or adjacent to the proposed West Somerset Pilot Cull area. However, the RSPB would consider further contribution to badger vaccination were any of our other land holdings part of a co-ordinated vaccination programme.

CLARIFYING STRATEGY AND POLICY

5.1 We believe that the Government has failed to reflect or tap into the high level of public support for vaccination. 92% of the responses to the Government’s 2010 consultation on bovine TB and a badger control policy¹¹ supported badger vaccination whereas 68% of responses were opposed to culling. Public opposition to badger culling has probably grown since 2010. In addition, it is clear that a significant number of leading scientists do not support the Government’s culling proposals.¹² We therefore believe that the Government should rethink its strategy and in particular the role that vaccination could play in addressing bovine TB.

5.2 Badger vaccination has several advantages over culling. It is unlikely to be subject to public opposition/disruption. It does not result in perturbation of the badger population and therefore does not risk making bovine TB worse. Vaccination does not need to be undertaken in a highly synchronised way. We believe this latter point is a significant issue. The pilot culls were postponed when it was apparent that there were not enough trained marksmen to carry out the culls in the allotted six week period. We remain concerned that six weeks is a significantly longer period than was used in most of the scientific trials and we do not believe that this culling period is supported by the available science. Even a six week window can be significantly affected by unsuitable weather. In contrast, a team of trained vaccinators could work systematically across an area during the spring, summer and autumn.

5.3 Senior Government politicians have repeatedly suggested that policy is aimed at delivering healthy badgers as well as healthy cattle.¹³ We believe that the Government should be asked to clarify its objectives in relation to badgers and explain the science behind its current policy. We would agree that it should be an aim of policy to ensure that badgers and badger populations are healthy. We would however question whether there is any scientific evidence that culling, as currently proposed by Government, will improve badger health.

⁹ e.g. Minister of State, David Heath MP during Backbench debate 25 October 2012, Hansard Col. 1177.

¹⁰ Comparing badger (Mele meles) control Strategies for reducing bovine bTB in cattle in England. FERA November 2010.

¹¹ <http://archive.defra.gov.uk/corporate/consult/tb-control-measures/bovinetb-summary-responses-110719.pdf>

¹² <http://www.guardian.co.uk/theobserver/2012/oct/14/letters-observer?newsfeed=true>

¹³ Eg “We want to see healthy wildlife—healthy badgers in this case—living alongside healthy cattle”. Secretary of State Owen Paterson MP, Hansard 23 October 2012, Col 847

The evidence from the Randomised Badger Control Trials showed that the prevalence of bovine TB in the remaining badger population increased following culling. We believe that consideration should be given to the relative effectiveness of culling or vaccination in delivering healthy badgers.

5.4 We believe that consideration needs to be given to the role of vaccination in relation to the pilot culls, particularly if the Government's policy is to improve badger health. The current proposals are for culling in the pilot areas to last for four years. During and at the end of this period badgers from the surrounding areas will colonise these culling zones. If these culls are pursued how will it be ensured that those badgers that re-colonise are TB free, unless through co-ordinated vaccination?

CATTLE VACCINATION

6.1 We have focused our response on badger vaccination as this is the vaccination tool that is currently available. Eradicating bovine TB in cattle (and in badgers) is unlikely to be achievable unless and until a cattle vaccine and a DIVA test is developed and cleared for use.

The government should set out a clear timetable of action for achieving this.

January 2013

Written evidence submitted by the Badger Trust

SUMMARY

- Six members of the Badger Trust have been trained as lay vaccinators since June 2011;
- Badger Trust has surveyed 17 sites where land-owners have expressed an interest in vaccinating badgers against Bovine Tuberculosis. Six sites were part of the 2011 programme, a further 11 became involved in 2012 due to an increased general awareness of badger vaccination over the 12 month period;
- Using volunteers, Badger Trust has been able to vaccinate 97 badgers and only passed on the cost of the vaccine used to the land-owners;
- This vaccination programme has made more people (both land-owners and conservation-group members) aware that an effective vaccine is available;
- It has shown that volunteers are willing to assist in the vaccination process in order to keep the costs experienced by land-owners to a minimum;
- In addition, it has shown that a range of land-owners (Wildlife Trusts, small-holders, private landowners and farmers) are interested in this method to minimise the (already small) risk of Bovine Tuberculosis being transmitted from badgers, if the cost to them is kept low;
- Finally, like many other programmes undertaken by other organisations, it has shown that badgers can be trapped and effectively vaccinated against Bovine Tuberculosis.

1. Over the last 18 months Badger Trust has been investigating the practicality of vaccinating badgers against Bovine Tuberculosis (TB). Following the announcement by the Food and Environment Research Agency (FERA) that an effective vaccine was available, and that members of the public (without veterinary qualifications) could be trained to become "lay vaccinators", Badger Trust enrolled volunteers on FERA courses throughout 2011 and 2012.

2. The aim of Badger Trust members becoming vaccinators was not to enable the Trust to vaccinate all badgers against TB. Rather, the certification of members as vaccinators meant that Badger Trust could investigate the actual costs and practicalities of vaccination for itself. In addition, it enabled Badger Trust to make people aware that a viable vaccine was available and assess the willingness of land-owners and volunteers to take part in a vaccination programme.

3. A vital step in initiating the programme was finding land-owners who were willing to let Badger Trust members onto their land to survey, trap and vaccinate badgers. In order to do this, trusting and professional relationships had to be forged between Badger Trust and land-owners. In addition, the cost of implementing the programme had to be realistic and attractive to the land-owner. To this end, Badger Trust agreed not to pass on the costs of the training and programme start-up to landowners. Instead, the Trust agreed to just charge for the price of the vaccine used (*eg* a set-fee per badger vaccinated).

4. During the initial stages of the programme, the National Farmers Union (NFU) was approached to undertake a "joint-venture" of sorts. Badger Trust agreed to provide all the man-power and equipment for vaccination if the NFU could advertise the Trust's services to its members and provide contact details for farmers who were interested in the programme. This working relationship resulted in a joint Press Release advertising the vaccination programme. It should be noted that, during these initial stages, Badger Trust purposefully approached farmers instead of reserve-owning conservation bodies. The Trust wanted to see if it could assist farmers, form a better relationship between the farming and conservation communities and not be accused of only supporting conservation charities. Badger Trust wholly appreciates that Bovine TB is having

a serious impact on the farming community and so wanted to physically do all it could to assist them “on the ground”.

5. In 2011, Badger Trust was able to get five members through the FERA course, purchase all the relevant equipment and obtain the appropriate certificates of competence in under a four month period. This shows that a vaccination programme can be established in a very short period of time. Throughout this preparation phase, surveys of six sites (three provided by the NFU) were undertaken using local volunteers.

6. Once the location of a willing land-owner was confirmed, the local Badger Group was contacted by the programme co-ordinator. The point of using local volunteers was to keep personnel costs as low as possible (the volunteers were rarely reimbursed for travel expenses), local volunteers know the land well and, sometimes, knew the land-owner involved in the programme. This latter point significantly helped when it came to building trusting relationships with the land-owners.

7. It should be noted that the local Badger Groups were always willing to help and that a significant number of volunteers could be raised to assist with the vaccination programme. All were willing to help with the site survey, placement of cage-traps, pre-baiting (imperative to our programme) and collection of traps. Badger Trust only approached members of Badger Groups. However, now that many of the Wildlife Trusts (Gloucestershire, Warwickshire, Shropshire etc.) are vaccinating badgers on their land, and making their members aware, there could be a larger “pool” of volunteers to call on for any future (large-scale) vaccination initiative.

8. As mentioned, everyone involved in the vaccination programme was a volunteer (including the vaccinators). Therefore, the vaccination schedule had to fit with employment and other commitments. This occasionally meant that vaccinators could not be on site for all the activities

(such as pre-baiting). However, it can be worked successfully by having the vaccinators present on a weekend when the traps are placed on site (locked open), teaching local volunteers to pre-bait and submit their findings on a daily basis (via email) to the vaccinator(s), the vaccinator returning to site on the following Friday evening (the 7th night of pre-baiting) to set the traps live and then vaccinate on a Saturday and Sunday morning. Traps are then removed immediately on a Sunday to reduce any disturbance (and the amount of visits required) to the farmers/site/farming operations.

9. This schedule was agreed with the land-owner before any works took place and Badger Trust always found that, as long as constant contact was maintained with the land-owner, they were happy with the works being undertaken. Land-owners often assisted with survey information, prebaiting and cage trap placement. They also came out during the actual vaccination to talk through the process more, see the badgers in cages and watch the vaccine being administered.

10. Throughout the last two vaccination seasons all the volunteers have acted extremely conscientiously and Badger Trust has passed all its FERA audits. This shows that, just because a programme uses volunteers, it does not make it any less professional. Indeed many Badger Group volunteers are professional ecologists and some work in the farming industry.

11. The vaccination programme has attracted the attention of the media and this has enabled Badger Trust to make more people aware that vaccination is available. The programme has been discussed on BBC Radio 4, Countryfile, BBC “Inside Out” and in publications such as BBC Wildlife magazine, the Mammal Society Newsletter, Wildlife Trust Newsletters and numerous regional and national newspapers. This shows that there is an immense interest in badger vaccination. The general public are aware of it (especially as the Wildlife Trusts and National Trust have vaccinated badgers on their properties), it is publicly acceptable (unlike culling) and positively supported by the public. This latter point could result in increased numbers of people willing to volunteer (and possibly donate money if required) if a large-scale vaccination programme was undertaken.

12. When the following are considered there should be no doubt that large-scale badger vaccination is possible and appropriate: the short-comings of a cull (in that no significant reduction of TB in cattle has been shown to result by the Randomised Badger Culling Trial), the costs associated with culling, the fact that the costs associated with culling are considered to be significantly greater than the benefit, the effectiveness of the BCG vaccine (proven in field conditions), the avoidance of negative impacts associated with perturbation when vaccination is used and the immense public support for vaccination.

13. As mentioned, the aim of Badger Trust was not to vaccinate all badgers in the UK as part of this feasibility study. To this end, Badger Trust did not target large contiguous areas where several neighbouring farms/sites were linked. It had to go to where individual farmers were interested in having their badgers vaccinated. However, work undertaken to date has shown that, when vaccinating on a farm, neighbouring farmers are aware of what is taking place and the Trust has been approached by several farmers (who about vaccination areas) who are now interested in vaccination. As mentioned previously, the more vaccination is discussed in the media, the more people become interested. As long as the cost to the land-owner is kept low (and this can be done through the use of volunteers) then many are happy for vaccination to take place.

14. Vaccination during 2012 in West Somerset by Badger Trust has included three contiguous holdings. This resulted in more badgers being caught and vaccinated than is typical on individual farms. The benefit of contiguous holdings was primarily that the area encompassed whole badger social group territories that resulted

in more remote trapping opportunities. This benefit also allowed extensive surveys to determine the full extent of badger activity. A combination of trapping in the vicinity of badger setts and remote trapping where badger activity was significant, particularly at territory boundaries, is considered to have produced the results. It is common sense to conclude that vaccinating over a larger area will result in higher numbers of badgers being trapped. Badger Trust is still exploring the results of its vaccination programme to determine how to efficiently maximise numbers of badgers trapped and vaccinated. Regardless of the outcome, it can be expected that the larger the area trapped, the more badgers will be caught. Therefore, any future vaccination initiative should seek to vaccinate on as large an area as possible.

15. Badger Trust has not undertaken a full cost-benefit analysis of the vaccination programme to date. However, after the initial outlay to set-up the project (vaccination fridges at £500 each, cage traps at c.£100 each and disposables (gloves, syringes, FAM30 disinfectant)) the costs could be managed if volunteers were used. It cannot be underestimated how much this reduction in costs to the landowner (Badger Trust only charged £20 per badger vaccinated in 2011) helped when encouraging them to take part in the programme. As stated before, if the cost is considered acceptable then many land-owners are amenable to badger vaccination.

16. Badger Trust has not been involved in the development of the oral vaccine for badgers. However, Badger Trust welcomes any advance in this area and, should the oral vaccine be made available (and a suitable deployment method devised), Badger Trust would encourage its use. An oral vaccine would be easier to distribute and setts could be targeted as opposed to trying to capture wary, mobile animals.

17. Badger Trust has not been involved in the development of a Cattle TB vaccine. Nor has the Trust been involved in discussions regarding the amendment to regulations to allow the vaccine to be administered. However, Badger Trust welcomes all advances in this area. Vaccinating cattle against Bovine TB, as part of regular cattle health checks and vaccines already used against other infections/diseases, seems the most sensible approach. It appears to be the cheapest (if the vaccine is administered when cattle are already together for other checks), it is easier to get the cattle all in one place and farmers can be sure that 100% of their herd have been vaccinated.

18. In the short-term, Badger Trust would advocate that better farm bio-security measures (shown to be both cheap and effective—when maintained), coupled with a large-scale badger vaccination programme, would best serve the farming community. In the long-term it appears that cattle vaccination is the only true sustainable way to control bovine TB in cattle. This will result in both healthy cattle and healthy badgers in the British countryside.

January 2013

Written evidence submitted by Network For Animals

SUMMARY OF POINTS

1. Network for Animals is an international animal protection organisation working in the UK, Canada and the Philippines with approximately 50,000 active supporters in the UK.

2. NFA has a history of advocating for badgers and other British wildlife and has been active on this issue since 1998. In spring 2011, NFA became involved with the campaign against the cull in the IAA in Wales and has been campaigning for viable alternatives to the cull in both England and Wales since that time. The organisation has financially supported regional groups in their local projects to vaccinate badgers in both Somerset and Cornwall.

3. NFA has supported practical grass-roots badger vaccination and sees scope for such projects to be rolled out more widely across affected areas in conjunction with effective biosecurity measures and improved cattle welfare, until such time when a cattle vaccine is permitted for use. For this reason the organisation welcomes this inquiry into badger and cattle vaccination and wishes to submit evidence for the Committee's consideration.

4. The main item NFA would like to direct the Committee's attention to is a short film produced by the organisation explaining how badger vaccination works.

SUBMISSION

5. This submission deals with the topic of badger vaccination; a key tool in the immediate battle against bovine TB (bTB) in England. However, NFA would like to see badger vaccination used in conjunction with improved cattle welfare and animal husbandry, more effective biosecurity and ultimately the vaccination of cattle.

Until the vaccination of cattle is approved for use in the UK herd, a combination of improved biosecurity and vaccination of badgers is more likely to have long-term benefits in bTB control in addition to being by far the highest welfare solution to the problem.

6. Since the first TB infected badger was discovered in 1971, these mammals have been targeted as a likely cause of the spread of TB to cattle. However, a 10-year study performed by The Independent Scientific Group on cattle TB (ISG) at the behest of the previous Government at a cost of £50 million, concluded in 2007 that

“badger culling is unlikely to contribute positively, or cost effectively, to the control of cattle TB in Britain.” The evidence from the trial also suggested that the culling of badgers, if done in strict accordance with the guidelines proposed, would only provide a reduction of bTB in cattle of between 12–16%.

The ISG or “Krebs” trial is the largest piece of peer-reviewed science examining the relationship between badgers and bTB. In light of the findings of the report, NFA feels it is essential that the Government look to alternative methods of bTB control if they wish to effectively manage the spread of the disease.

7. Trials have shown that badger vaccination can reduce the incidence of positive serological TB test results in the mammals by almost 74%, suggesting it will be several times more effective in reducing the disease than a cull. Although vaccination is at present fairly costly, if rolled out across affected areas, the mass production of materials and vaccine will inevitably bring down costs.

8. The Welsh Assembly has opted to vaccinate badgers in favour of culling based on the strength of scientific evidence. Vaccinating badgers has a number of benefits, but a key factor is that it avoids the detrimental effects of the “perturbation effect” by not disrupting badger setts during the process. The disruption of setts has been linked to the potential spread of bTB and is one of the main problems with the policy of culling.

9. Newly published evidence from a four-year field study conducted by FERA and AHVLA has shown that vaccination reduces the risk of bTB infection in unvaccinated badger cubs when they are in vaccinated groups.

The research suggests that the risk of non-vaccinated cubs testing positive was reduced by almost 80% when more than a third of badgers in their group had been vaccinated, providing further strong evidence that vaccination over a consistent period will contribute significantly to a reduction of the disease in wildlife without the need for culling.

9. The process of vaccinating badgers is similar to that used for cage-trapping and shooting badgers; licensed members and volunteers first place peanuts in open cage traps for several nights to allow the badgers to familiarise themselves with them. This process is called “pre-baiting” and can be done by the landowners themselves. The traps are then set to close once a badger enters. Before dawn the traps are checked, then trapped badgers are given a health and condition check, vaccinated, marked and released without harm. This process is repeated the following night to ensure as many badgers as possible are caught.

10. In 2012 NFA gave grants to two organisations, Somerset Badger Group and Cornwall Badger Rescue, to help fund the vaccination of badgers. The Somerset Badger Group will be putting forward their statistical data and findings in their own submission. Somerset Badger Group permitted NFA to accompany a phase of their badger vaccination project in order to better understand the process and capture footage for a short campaign film about vaccination.

We would like to direct the Committee’s attention to this film as it demonstrates the processes and equipment needed in order to effectively vaccinate badgers.

Please see film: <http://www.youtube.com/watch?v=mzdS2luP8YY>

11. The project in Cornwall was of a much smaller scale as Bob Speechley is the only trained vaccinator in the county and operates his rescue service as a full time volunteer. He was able to offer vaccination to interested farmers and small landowners but would like to increase the scale of his operation. Mr Speechley feels that the vaccination of badgers is a viable option if conducted in tandem with the vaccination of cattle, but only if the Government fully backs vaccination financially and in terms of policy.

Via a series of grants, NFA has been able to help Mr Speechley with running costs to supplement a grant from the Badger Trust for his vaccination licence, the cost of 20 traps, a vaccine fridge and vaccines. Combined over the course of a four-year vaccination project, the costs for a single vaccinator wanting to cover a large area are prohibitive.

11. One of the landowners who requested badger vaccination via Cornwall Badger Rescue is Carla Kidd. Following her vaccination experience she has requested a place on the next available FERA training course so that she can support Cornwall Badger Rescue in a not-for-profit capacity by vaccinating badgers for free (with a charge for the vaccine only). Her view is that the injectable vaccine is more viable than the oral vaccine as it guarantees that badgers are vaccinated. Her concerns relating to the process focus on the red tape involved with becoming a trained vaccinator and the associated costs. She believes there would be many more people opting to vaccinate their badgers should more trained vaccinators become available and there was a reduction in material costs for volunteer vaccinators.

RECOMMENDATIONS

12. In light of the evidence contained within this submission, NFA would like to recommend that the Government fully invests in a comprehensive package of measures to tackle bTB.

New evidence and the experience of self-funded vaccination teams suggest that the vaccination of badgers, if rolled out across affected areas, could provide a significant reduction in bTB in badgers.

13. The vaccination of badgers is not enough to make a meaningful difference to TB in cattle. We recommend that the Government take all necessary steps to fast track the introduction of the cattle vaccine and associated DIVA test for differentiation between infected and vaccinated cattle.

14. Although farming in Britain is practised to a high standard by most within the industry, there is no doubt that poor animal husbandry and intensive farming have contributed significantly to the sharp rise in bTB. We recommend that along with the tighter biosecurity measures announced by DEFRA at the end of 2012, a comprehensive package of measures to ensure high standards of animal welfare, a fair deal for farmers and assistance in the implementation of biosecurity measures are rolled out.

January 2013

Written evidence submitted by Veterinary Association of Wildlife Management (VAWM)

INTRODUCTION

The Veterinary Laboratories Agency (VLA) was granted a Limited Marketing Authority (LMA) for the injectable Badger BCG vaccine in March 2010 by the Veterinary Medicines Directorate. However it should be noted that the requirements for a LMA do not include evidence of efficacy simply that the product is of satisfactory quality and safe when administered to the target species. Nevertheless VLA submitted evidence that the high dose injectable BCG vaccine gave limited protection in 2 experiments involving 15 captured naïve badgers (Chambers 2010).

The position of the Veterinary Association of Wildlife Management on vaccination against bovine TB remains essentially the same as that submitted in December 2010 to DEFRA in response to their consultation on tackling the disease and a badger control policy. The relevant section from our submission is therefore copied immediately below:

VACCINATION WITH BCG (EXTRACT FROM VAWM'S SUBMISSION TO DEFRA CONSULTATION 2010)

We are seriously concerned that the Government is presenting vaccination using the BCG vaccine in badgers as a realistic option in its own right as an alternative to culling. This is wholly misleading particularly to the general public and organisations that are not familiar with the science involved.

1. BCG is not a particularly reliable or efficacious vaccine in man and other mammals (only 70% efficacy in man) As stated in the DEFRA consultation document BCG vaccine has been in existence for nearly a century and attempts to improve it over the years, particularly recently, have not met with success.
2. Whilst the experimental studies in naïve badgers have shown an encouraging measure of protection there is no substantial data to show that the vaccine can be expected to be protective in the field. Note that this assessment takes in the latest evidence that the BCG vaccine appears to reduce the incidence of positive blood tests in vaccinated animals. This is not evidence of protection.
3. Even a highly potent and effective vaccine cannot be expected to be effective in the face of the massive burden of infection that exists in parts of the badger population.
4. It is hardly credible that a sufficient proportion of the population to achieve meaningful protection would be caught up and vaccinated (>70%).
5. We are not confident that cage trapping and vaccination will not cause a degree of perturbation, particularly if this statement is based solely on observations from the Woodchester Park colony of badgers that are used to human interference. But in any event we have serious misgivings about the humaneness of cage trapping and the handling of a wild animal that would be involved in parenteral vaccination.

However it is possible that an effective oral vaccine for badgers delivered in bait could have a role in suppressing the disease after the huge burden of infection currently present in the badger population has been removed by culling. Furthermore a substantial reduction in the national badger population would hugely mitigate the risk of transmission of residual infection from badger to cattle.

We do not believe that a vaccine for cattle is either a desirable or realistic option for controlling the disease in cattle. The objective should be to eradicate the disease from both cattle and badgers not to suppress it by vaccination.

FURTHER EVIDENCE AND COMMENT

Since making the assessment above a second paper has emerged that reworks the earlier data of Chambers and others (2010) using an additional more complex serological test (Carter and others 2012). As with the earlier test it demonstrates a significantly different serological response in vaccinated compared with control unvaccinated animals. But it remains that this is not direct evidence of protection.

Furthermore it should be emphasised that captured uninfected badgers vaccinated with the BCG vaccine in the experimental study referred to above were not solidly immune. Vaccinated badgers still shed TB bacilli following challenge albeit to a lesser extent than unvaccinated badgers (Chambers and others 2010).

We concluded in our submission to the DEFRA consultation that Options 3 and 5 (Vaccination only) do not offer any realistic possibility of controlling the disease given the unproven nature of the BCG vaccine in the field.

Finally we have drawn the attention of the veterinary profession to the limitations of the Badger BCG vaccine in letters to the veterinary and farming press for example: Thomas (2011) and Thomas (2012)—(attached as annex 1 and 2)

CONCLUSION

Our position remains essentially that vaccination of badgers with the BCG vaccine should currently be regarded as a highly speculative and unproven strategy, driven it would seem largely by perceived public opinion and not scientific reality. Most importantly vaccination should not deflect from the necessity of removing the disease by culling infected badgers. However if an oral version of the BCG vaccine did become available it might usefully be deployed as a cordon prophylactic vaccination strategy, having removed infected badgers by culling.

As to vaccination of cattle we do not believe that this should be the primary strategy in control of the disease. At present an effective vaccine for cattle does not exist and whilst we consider it prudent to pursue research into a cattle vaccine, vaccination of cattle and all that it entails in cost, deployment on a yearly basis and interference with the tuberculin test cannot be preferred to eradication of the disease.

REFERENCES

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Thomas LH, (2011) VAWM's Supplement to the bovine TB consultation, letter to Veterinary Times, February 28, 2011 (see annex 1)

Thomas LH, (2012) Welsh decision to vaccinate badgers against bovine TB, letter to Veterinary Record April 7, 2012 (see annex 2)

January 2013

Annex 1

TO THE EDITOR VETERINARY TIMES JANUARY 2011 A SUPPLEMENT TO OUR RESPONSE TO THE GOVERNMENT'S CONSULTATION ON BOVINE TB AND BADGER CULLING

Following our recent submission to the Government's consultation on bovine TB and badger culling we feel it necessary to respond to the hugely misleading statement issued by BBC News on 1st December 2010, that the injectable Badger BCG vaccine reduces the incidence of bovine TB by 74%. The statement refers to a paper published last December in the Royal Society's Scientific Journal, Proceedings B. at: <http://rspb.royalsocietypublishing.org/lookup/doi/10.1098/rspb.2010.1953> The statement is endorsed by Dr. Macdonald, head of FERA, and Dr. Cheeseman both co-authors to the paper.

The paper is in two parts: 1) Experimental challenge studies with captive badgers and 2) Field studies with the Badger BCG vaccine.

The experimental studies confirm earlier work in 1988 at the Central Veterinary Laboratory, Weybridge that vaccinated badgers show a measure of protection following challenge with live virulent *Mycobacterium bovis*.

The field studies identify a different serological response as between vaccinated (4.5% responded) and non-vaccinated badgers (17.1% responded) using the StatPak test. However there was no significant difference in a second serological test (IFN γ) or in the relative shedding rates of *M. bovis* between vaccinated and non-vaccinated animals. There was no attempt to measure the incidence of disease in badgers nor is it known what natural challenge the animals may have experienced, which will almost certainly have varied across the trial.

We submit that the statement on BBC News is misleading because, as we pointed out in our original submission, serological responses alone cannot be regarded as direct evidence of protection. This can only be derived by assessment of disease in vaccinated as compared to control animals. At best the small scale field study, which only involved 262 animals and which was presumably not designed to assess efficacy, has simply

revealed a 74% difference in the serological response between vaccinated and non-vaccinated animals. The statement in the published paper that there was a “beneficial effect of BCG on *M. bovis* infection in free living wild badgers” cannot therefore be justified on the evidence presented.

The mischief appears to derive from the juxtaposition of the experimental studies and the field studies in the same paper. The protection demonstrated in the experimental studies seems to have been extrapolated to the field studies which are reflected in the BBC statement above. That the statement is misleading is demonstrated by recent statements from the single issue, badger protection lobby which is now collectively promoting vaccination as a viable alternative to culling and an overall solution to bovine tuberculosis.

January 2011

Annex 2

TO THE EDITOR VETERINARY RECORD, MARCH 2012

WELSH DECISION TO VACCINATE BADGERS AGAINST BOVINE TB

What the Welsh Environment secretary and other organisations, such as the RSPCA and National Trust that are climbing onto the band wagon of vaccination should know is that a proven vaccine against bovine TB currently does not exist for use in the field either for cattle or for badgers (see article Vet Record, 24.3.12). Although the injectable Badger BCG vaccine (the only vaccine licensed for use in the UK) gives a measure of protection from disease in naïve badgers following experimental challenge with live tubercle bacilli it does not prevent infection or shedding of the organism. And the vaccine has not yet been properly trialled in the field.

A small scale study on 262 animals (Chambers et al 2011) trumpeted in December 2010 by FERA on BBC On Line may have shown encouraging serological evidence of vaccine efficacy but this alone cannot be regarded as evidence of protection. Protection can only be assessed by comparison of disease in vaccinated as compared to control animals in a properly controlled field trial. And this does not appear to be part of the protocols proposed by the National Trust and others.

Vaccination is therefore currently not a realistic strategy for controlling the disease moreover prospects for it becoming so are not encouraging. BCG has been in existence for nearly a century and attempts to improve it over the years, particularly recently, have not met with success. But even a potent proven vaccine cannot be expected to be effective in the face of the massive burden of infection that presently exists in parts of the badger population (over 30% infected in some areas). Furthermore it is beyond the bounds of credibility that enough animals will be caught up and vaccinated to make an impact, even supposing the vaccine to be effective.

The Welsh secretary should support the more realistic Intensive Action strategy of his predecessor and his CVO.

Chambers, M A, Rogers, F, Delahay, R J, Lesellier, S, Ashford, R, Dalley, D & OTHERS (2011) Bacillus Calmette-Guérin vaccination reduces the severity and progression of tuberculosis in badgers. Proceedings of the Royal Society B: Biological Sciences 278, 1913–1920

Dr L.H.Thomas, secretary VAWM

March 2012

January 2013

Written evidence submitted by the Society of Biology

The Society of Biology is a single unified voice for Biology: offering advice to Government and influencing policy; advancing education and professional development; supporting our members, and engaging and encouraging public interest in the life sciences. The Society represents a diverse membership of over 80,000—including practicing scientists, students and interested non-professionals—as individuals, or through the learned societies and other organisations listed below. The Society welcomes the interest of the Committee and is pleased to offer these comments, gathered in consultation with our members and advisors for your consideration.

SUMMARY OF RECOMMENDATIONS

1. The UK must learn from past and current outbreaks in cattle (such as foot and mouth disease and bluetongue) and prioritise the development of allowable vaccination as part of the tool box of control measures for bovine tuberculosis, without contravening EU regulations. Badger vaccination will be useful for isolating infected areas and cattle vaccination will be important in safeguarding future herds. Government must establish a realistic sense of when appropriate cattle vaccinations and DIVA tests could be made available, in order to direct research efforts and funding, and establish a long term bTB eradication plan.

2. We recommend that badger and cattle vaccinations are ultimately employed to combat bTB, given the following:

- (a) Research is needed to ascertain a full understanding of the strength of transmission at the inter- and intra-specific level, for both cattle and badgers.
- (b) Researchers must determine the effectiveness of BadgerBCG vaccination. The development of a good oral vaccine and appropriate administration will be required.
- (c) A cattle vaccine with greater efficacy is needed, and a test to distinguish between the protective and pathogenic immune responses during bovine TB is an absolute requirement. Existing research in these areas must be supported and extended.

3. Field trials are essential and should be coordinated across the UK and Ireland. To aid current research, we recommend that badger vaccination trials (supported by Government and NGO initiatives) are coordinated so that best use is made of the results, training and experimental design. This will decrease costs and generate data indicating which models are most suitable. Trial areas should be large enough and accompanied by control areas to robustly model the effects of the vaccine.

4. Efforts towards improving the UK's reputation and influence regarding cattle health at the EU level must be supported. The UK should continue to aim for "disease-free status" for bovine TB and other infectious diseases, and commit to playing a leading EU-wide role in a vaccination programme that would not only benefit the UK, but could be made globally available.

BOVINE TB IN CATTLE AND BADGERS

1. Bovine tuberculosis (bTB) is a chronic bacterial disease resulting from infection by *Mycobacterium bovis*, a Gram positive, slow growing bacterium. It has a long incubation period and symptoms can take months to develop in cattle, sometimes remaining dormant for years until it becomes reactive due to a stressor (eg illness, pregnancy, or old age). bTB can affect nearly all organ systems, but most commonly develops into a respiratory disease. It most often causes lesions to occur in the lymph nodes of the head and thorax, and in the lung, spleen, liver and surfaces of body cavities. These lesions are areas of localised *M. bovis* bacteria, which are then spread through respiratory secretions, faeces and milk. *M. bovis* is transmitted between cattle through aerosols when confined or in close contact, and can be ingested.

2. Badgers are one of several mammals that can become infected by *M. bovis*. Infected badgers rarely show signs of bTB, with a high proportion of infections resulting in a lengthy period of latency with few obvious lesions at post mortem examination. As such infected and infectious badgers often live with the disease asymptotically throughout their natural lives, and shed *M. bovis* through their urine, faeces, sputum and discharge from bite-wounds. Duration of infection on pasture is fairly brief, with a 99% decay rate of *M bovis* varying from one—four weeks according to excretion in urine, faeces or bronchial pus.¹⁴

3. Transmission of *M. bovis* between cattle and badgers is thought to be through ingestion of the bacterium at badger latrines. Badgers often inhabit woodland close to pastureland (which typically holds a larger number of earthworms), and while cattle generally avoid areas of grass soiled with badger faeces and urine, some cattle will graze contaminated herbage, particularly when over-grazing occurs. Furthermore, bTB infected badgers tend to range further than non-infected individuals, have larger home ranges and forage further away from the main sett, increasing the likelihood of encountering cattle.¹⁵ The strength of transmission between cattle and badgers is largely unknown; more information on this transmission pathway is needed to establish where best to invest in vaccination efforts.

4. bTB has been recorded in "closed herds" (ie in this scenario, herds in which no individuals are introduced from external sources), omitting the opportunity of cattle-to-cattle transmission through imported infected animals. The epidemiology of bTB in badgers and proximity to herds identifies them a major reservoir of bTB for onward transmission to cattle in the UK.

5. bTB diagnostic tools for badgers are limited. Post-mortem detection of lesions can be difficult to locate (in certain studies, more than 60% of infected badgers did not have visible lesions^{16,17}) and may be confused with lesions from other diseases.¹⁸ Ante-mortem serological tests tend to have a low sensitivity (but are likely to identify heavily infected individuals), and tests based on cell-mediated immunity responses to infection are more sensitive but are more difficult (and expensive) to develop. In cattle, serological testing is improving through use of a wider antigen range and more sensitive detection methods.¹⁹ A combination of several tests has achieved a higher level of diagnostic accuracy,²⁰ but again, this may prove expensive and difficult to apply in the field.

¹⁴ Gallagher J & Clifton—Hadley R S (2000)

¹⁵ Garnett B T et al. (2005) Ranging behaviour of European badgers in relation to bovine tuberculosis infection. *Applied Animal Behaviour Science* 94: 3–4: 331–340

¹⁶ Jenkins H E et al. (2008) The prevalence, distribution and severity of detectable pathological lesions in badgers naturally infected with *Mycobacterium bovis*. *Epidemiology and Infection* 136: 1350–1361.

¹⁷ Murphy D et al. (2010) The prevalence and distribution of *Mycobacterium bovis* infection in European badgers (*Meles meles*) as determined by enhanced post mortem examination and bacteriological culture. *Research in Veterinary Science* 88: 1–5.

¹⁸ Gallagher, J (1998). The natural history of spontaneous TB in wild badgers. Doctor of Veterinary Medicine Thesis, University of London.

¹⁹ Vordermeier M et al (2011) *Mycobacterium bovis* antigens for the differential diagnosis of vaccinated and infected Cattle. *Vet Microbiol.* 151(1–2):8–13

²⁰ Drewe JA, Tomlinson AJ, Walker NJ, Delahay RJ (2010) Diagnostic Accuracy and Optimal Use of Three Tests for Tuberculosis in Live Badgers. *PLoS ONE* 5(6): e11196.

VACCINATION

6. The TB vaccine *Bacillus Calmette-Guerin* (BCG) is an attenuated strain of *M. bovis*, used to vaccinate cattle and badgers. BCG has historically been thought to hinder the progression of TB, but not preclude the disease (this has been contested by research in a number of mammals including humans and cattle^{21,22,23}). However it is generally agreed that in infected badgers, the vaccination will have little effect.

INJECTABLE BADGERBCG

7. Defra have invested over £16 million on research into TB vaccinations for badgers since 1994.²⁴ The injectable vaccine (known as BadgerBCG) was successfully licenced by the AHVLA in 2010,²⁵ after it was shown to decrease disease burden in badgers. BadgerBCG did not appear to prevent infection, but reduced the severity and progression of TB in infected animals, which may reduce the risk of onward transmission from badgers to cattle.²⁶ The Food and Environment Research Agency (FERA) has undertaken modelling work on BadgerBCG and its potential to reduce the incidence of confirmed herd breakdowns.²⁷ Most of the current vaccination areas are relatively small and therefore have little statistical power to test these models. Suitable unvaccinated control areas are also needed for comparison to allow researchers to be confident in the effects they attribute to vaccination.

8. Defra introduced the BadgerBCG vaccine in summer 2010 as part of the Badger Vaccine Deployment Project (BVDP), which originally planned to vaccinate badgers in the six areas in England most affected by TB in cattle. The incoming government reduced the number of areas covered by BVDP from six to one, which is near Stroud, Gloucestershire,²⁸ being run mainly to maintain Fera's capability to vaccinate badgers, and to train others who wish to apply for a licence.²⁹ By the end of the season in 2012, 137 lay vaccinators were trained, and a total of 2,167 badgers have been vaccinated since the BVDP began. Defra will continue to fund training courses into 2013.

9. NGOs are also undertaking badger vaccination programmes. The National Trust began a £320,000 trial vaccination programme in Killerton, Devon in 2011 which is set to end in 2015. The work is to be carried out by Fera's wildlife management specialists. The Wildlife Trusts have initiated their own local vaccination programmes on their reserves. Gloucestershire Wildlife Trust's (GWT) five year vaccination programme is the most established. It covers seven sites and is currently ending its second year, with a comprehensive report already available.³⁰ Shropshire Wildlife Trust commenced a vaccination programme in autumn 2012, working in partnership with Cheshire Wildlife Trust, and more Wildlife Trusts are developing future vaccination trials.³¹

10. The Welsh Government bTB strategy includes vaccination of badgers in the "intensive action area" (a bTB endemic area of approximately 288km²) as part of its four year Strategic Framework for Bovine TB Eradication announced in March 2012,³² replacing the proposed culling.³³ Over 1,400 badgers have now been vaccinated in the intensive action area.³⁴

11. The Department of Agriculture and Rural Development in Northern Ireland began modelling a vaccination programme that involves testing live badgers, vaccinating and releasing the test-negative animals and removing the test-positive, known as a TVR approach. The results of this modelling will inform a study to test the TVR approach in field conditions, which is likely to use a serological test which will identify the most highly infected badgers.³⁵

12. GWT have costed their BCGBadger vaccination programme at an average of £51 ha⁻¹ for the first year of vaccination, including capital and consumables, training and staff time (excluding stakeholder liaisons and Public Relations). As this work was largely unprecedented, considerable staff time was spent on planning and design of the vaccination programme.

²¹ Oysal A et al. (2005) Effect of BCG vaccination on risk of *Mycobacterium tuberculosis* infection in children with household tuberculosis contact: a prospective community-based study. *Lancet* 366, 1443–1451.

²² Ameni G et al. (2010) Field evaluation of the efficacy of Bacille Calmette Guérin (BCG) against bovine tuberculosis in neonatal calves in Ethiopia. *Clin. Vaccine Immunol.* 17, 1533–1538.

²³ Corner L A et al. (2009) Oral vaccination reduces the incidence of tuberculosis in free-living brushtail possums. *Proc. R. Soc. B* 276, 2987–2995.

²⁴ Defra; Research into bovine TB

²⁵ VLA; First tuberculosis vaccine for badgers is authorised

²⁶ Chambers et al (2010), Bacillus Calmette-Guérin vaccination reduces the severity and progression of tuberculosis in badgers *Proc Biol Sci.* 278(1713): 1913–1920. Published online 2010 December 1.

²⁷ Smith et al. (2012) Comparing Badger (*Meles meles*) Management Strategies for Reducing Tuberculosis Incidence in Cattle. *PLoS ONE* 2012 1 June 27; 7(6): e39250.

²⁸ Defra; Changes to badger vaccine deployment project

²⁹ Fera; Badger vaccine deployment project

³⁰ McGlone G (2011) Gloucestershire Wildlife Trust Nature Reserves Badger Vaccine Deployment Programme 2011

³¹ The Wildlife Trusts Briefing (2012) Bovine TB: A vaccination strategy for badgers and cattle

³² Welsh Government Bovine TB Eradication Programme

³³ Ares E (2012) Badger Culling. House of Commons Library Standard Note SNSC-5873

³⁴ Welsh Government Badger vaccination total tops 1400

³⁵ Northern Ireland Assembly Committee for Agriculture and Rural Development. Bovine TB Review: DARD Briefing, 11 September 2012. Official Report (Hansard)

13. Vaccinator training for the Wildlife Trusts is purchased from FERA. Defra are providing funding for Voluntary and Community Sector (VCS) organisations covering 50% of the cost of becoming an accredited and certified lay vaccinator in 2013. Defra also provides start up grants for licenced schemes.

14. GWT recommend that costs are cut through;

- (a) A free advisory service at the planning and deployment stages of a vaccination programme.
- (b) A faster and cheaper licensing service for the FERA Certificate of Competence.
- (c) A more coordinated approach to badger vaccination at the national level. This would enable information to be shared more effectively, reduce costs to landowners and sharing of equipment to lower capital costs.

ORAL BADGERBCG

15. Defra have spent £6 million on research into oral badger vaccines since 2005–06,³⁶ and are planning to invest a further £15.5 million in vaccine development over the next four years to continue this work, according to Defra’s chief scientific adviser and chief veterinary officer.³⁷

16. Oral vaccination is likely to be more cost effective than the injectable vaccine, requiring less staff time and equipment, and may offer the best long-term prospect for delivering BadgerBCG over a wide area,³⁸ given steps are taken to minimise or prevent dominant animals from consuming large quantities of vaccine baits,³⁹ and ensuring non-target animals are not adversely affected⁴⁰ (including cattle). However it is likely to be several years before these vaccinations are available; Defra predicts it will be available in 2015.⁴¹

17. Research areas include formulation and bait development, efficacy and safety studies, field deployment studies and preparing and submitting a licensing dossier for assessment by the Veterinary Medicines Directorate. Corner *et al.* (2010)⁴² found “a significant protective effect of BCG vaccination” in their study of oral vaccinations. Aznar *et al.* (2011)⁴³ used oral application of the BadgerBCG in their report on field trials to assess different control and eradication options for bTB in cattle in the Republic of Ireland, and trials using badger bait completed in 2011 and 2012 revealed that once developed an oral vaccine would be taken up by the population with ease.

CATTLE TB VACCINE

18. By the end of March 2010, Defra had invested over £23 million on the development of cattle vaccines and associated diagnostic tools.⁴⁴ Defra has budgeted £15.5 million for research into developing effective cattle TB vaccines over the next four years.

19. Defra models predict vaccinating cattle that are tested annually will cost around £170 million to £180 million over the period from introduction in 2012 to the end of the modelled period in 2026. The expected fewer breakdowns and less routine testing potentially saving up to one fifth of the costs of the current policy measures.⁴⁵

20. BCG is currently the vaccine used in cattle, and provides a certain degree of herd protection. It may fully protect or decrease disease severity in some cattle, but is unlikely to have any effect on cattle with existing infections. It is important to note that field trials of efficacy have not been possible in the UK due to EU regulations (see below); however testing in overseas cattle shows a protective efficacy of BCG between 56% and 68%.⁴⁶

21. Defra state that development of an alternative vaccine is a “longer-term goal”.⁴⁷ The most promising vaccination strategy to date involves using BCG to prime the immune system, then introducing subunit vaccines with protective antigens present in BCG to boost the immune system.⁴⁸

³⁶ Mr Paice, Written Answers (Hansard) 504–505W Bovine Tuberculosis: Disease Control 14 July 2011

³⁷ Boyd I & Gibbens N **Badger cull furore is distracting attention from the real problem**. Guardian.co.uk 11 October 2012.

³⁸ Delahay, R *et al.* (2003). Vaccinating badgers (*Meles meles*) against *Mycobacterium bovis*: The ecological considerations. *Vet. J.* 166, 43–51.

³⁹ Buddle B M *et al.* (2011) Update on vaccination of cattle and wildlife populations against tuberculosis. *Vet Microbiol.* 2011 Jul 5;151(1–2):14–22

⁴⁰ Robinson P A *et al.* (2012) BCG vaccination against tuberculosis in European badgers (*Meles meles*): a review. *Comp Immunol Microbiol Infect Dis.* 35(4):277–87

⁴¹ Defra, Annex C: Badger TB Vaccines, September 2010

⁴² Corner LA *et al.* (2010) **Oral vaccination of badgers (*Meles meles*) with BCG and protective immunity against endobronchial challenge with *Mycobacterium bovis***. Vaccine. 2010 Aug 31;28(38):6265–72. Published Online 2010 July 15.

⁴³ Aznar I *et al.* (2010) Trial Design to Estimate the Effect of Vaccination on Tuberculosis Incidence in Badgers, *Veterinary Microbiology* 151, 104–111

⁴⁴ Defra; Research into bovine TB

⁴⁵ Defra; Options for vaccinating cattle against bovine tuberculosis

⁴⁶ Ameni G (2010) Field Evaluation of the Efficacy of *Mycobacterium bovis* Bacillus Calmette-Guérin against Bovine Tuberculosis in Neonatal Calves in Ethiopia. *Clin Vaccine Immunol.* 17(10): 1533–1538.

⁴⁷ Defra; Cattle Vaccination

⁴⁸ The Jenner Institute; Bovine Tuberculosis Vaccine Programme

EU LEGISLATION & DIVA TESTING

22. The UK farming industry relies heavily on trade within the EU, and would be severely impacted if cattle trade was restricted. It is also important to note that the UK is believed to have a poor reputation at the EU level regarding cattle disease. We must be seen to be making a serious commitment to cattle health through research and farm-based measures, and learn from past outbreaks (such as with foot and mouth disease⁴⁹) in order to have influence within the EU.

23. There are legal and practical barriers to vaccinating cattle against Bovine TB. bTB vaccination of any kind is currently prohibited under EU Directive 78/52/EEC and associated directives; this legal framework needs to be addressed before cattle vaccinations can be made available.

24. bTB vaccinations are prohibited because there is not a suitable diagnostic test that differentiates between infected and vaccinated animals (ie a DIVA test). Cattle are routinely tested for TB using a skin test called the Single Intradermal Comparative Tuberculin Test (SICTT), which relies on the use of tuberculin as a diagnostic antigen. As BCG is a sensitising vaccine it can interfere with the skin test producing a false positive in some uninfected, vaccinated cattle. “Reactors”, whether they are vaccinated or infectious animals will be culled and trade restricted.

25. Diagnostic tests with suitable sensitivity and specificity are needed so that all and only infectious cattle with bTB are identified and removed. It is also worth noting that cattle can carry bTB and not be infectious (ie the lesions are contained), and some cattle can be infectious without showing symptoms of infection (known as “anergy”). False-negative responses to testing can also be seen in animals that are immunocompromised; for example those animals with a poor immune response, which have recently calved or are at the late stages of the disease. False-negative responses can also occur in tests soon after infection.

26. DIVA antigens have been defined using comparative genome and transcriptome approaches. These include ESAT-6 and CFP-10; antigens whose genes are expressed in *M. bovis*, but absent from BCG or environmental mycobacteria.⁵⁰

27. ESAT-6 and CFP-10 have been used in the Bovigam test (a blood-based gamma interferon release assay which is used in support of the SICTT) to improve the specificity of the test,⁵¹ and in skin test reagents; this resulted in a response rate of 78% of naturally infected tuberculin-positive cattle, and induced no skin responses in BCG-vaccinated cattle despite their being sensitized for strong tuberculin responses. Inclusion of antigen Rv3615c enhanced skin test sensitivity in naturally infected cattle without compromising specificity.⁵² Research on further biomarkers is being done, to both enhance diagnostic performance and sensitivity directly, or to alleviate negative effects by suppressing these biomarker responses.

28. If a suitable DIVA test was developed, it would have to be approved at the EU and international levels before legislation is changed. This would be led by the Health Commissioner, and is thought that once agreement is reached, these changes could be made relatively quickly.⁵³

January 2013

Written evidence submission submitted by Brock Vaccination

As a team of commercial providers of badger vaccination, please find below our points for consideration:

1. OUR ISSUES IN OBTAINING FUNDING FROM THE BADGER VACCINE FUND FOR ENGLAND

1.1 We have found obtaining funding from the Badger Vaccine Fund for England, for one of our clients, very difficult and frustrating. Both our vaccination company and the farm we vaccinated for are small, rural businesses and have incurred costs for the work for which we hoped there would be financial assistance. Cash flow is a major issue for small businesses and the delay in receiving any award from the fund could impact on our ability to run sustainable rural businesses.

1.2 Please see below the listed timescale of our application for support from the fund as example of the challenge we have faced:

- 29/03/2012: Application on behalf of our client for support from the fund made to the NFU.
- 15/07/2012: Vaccination work completed for our client.
- 23/07/2012: Correspondence from the NFU that the application to the Fund has not yet been made.

⁴⁹ The Royal Society; Infectious Diseases in Livestock. Policy Document 19/02 July 2002

⁵⁰ Vordermeier M et al. (2001) Use of Synthetic Peptides Derived from the Antigens ESAT-6 and CFP-10 for Differential Diagnosis of Bovine Tuberculosis in Cattle. *Clin Diagn Lab Immunol*. 2001 May; 8(3): 571–578.

⁵¹ Vordermeier M et al (2011) Mycobacterium bovis antigens for the differential diagnosis of vaccinated and infected Cattle. *Vet Microbiol*. 151(1–2):8–13

⁵² Whelan A O et al (2010) Development of a skin test for bovine tuberculosis for differentiating infected from vaccinated animals. *J Clin Microbiol*. 48(9):3176–81.

⁵³ European Commission Press Release Statement from the European Commission regarding an article in the Mail on Sunday 21 October

- 28/08/2012: Confirmation from TB Programme staff (DEFRA) that the NFU have made the application on our behalf.
- 12/11/2012: Confirmation from TB Programme that the fund has been offered (amount not disclosed), but cannot yet award as “we are still working with the NFU over the legal drafting of the award document”.
- 18/12/2012: Correspondence from the TB Programme confirming that the updated grant offer acceptance form has been sent to the NFU for their completion and signature, upon which they will be in the position to make the payment.
- 10/01/2013: We are still awaiting any form of payment.

2. OUR EXPERIENCE OF A NEED FOR FUNDING OUTSIDE OF THE CURRENT AREAS ELIGIBLE FOR SUPPORT FROM THE BADGER VACCINE FUND FOR ENGLAND:

2.1 As one of the only full time commercial companies offering a service of badger vaccination to farmers we have experience of the demand for vaccination from farmers across the UK. We have experience of several farms across several counties, who are very keen to undertake badger vaccination on their land, however have found the financial costs prohibitive and urgently need financial assistance.

2.2 By extending the access to the fund outside of the current areas, will allow those farmers wishing to undertake badger vaccination on their land to do so. Importantly it will also raise confidence in the practicalities of vaccination among other farmers, who can see examples of vaccination being undertaken on other farms (not confined to nature reserves or government project areas). Also badger vaccination has the potential to be an important tool to help tackle this disease, not just in hotspot areas (ie where the cull pilots are located), but crucially on the edge of disease areas. By extending the fund to support farmers in these additional locations it would allow us to demonstrate the potential of badger vaccination as a usable, preventative tool.

3. THE ALLOCATION OF FUNDING

3.1 It is our opinion and experience there is currently more than a sufficient number of trained lay vaccinators to meet the demand for vaccination. Therefore we strongly feel that the allocation of financial resources would be far better directed towards the financial assistance for farmers wishing to undertake vaccination (potentially on a match funding basis), rather than assisting additional Voluntary and Community Sector organisations with the costs of training and certification; this is a disease that has a severe impact on farmers and these are the individuals who desperately need the financial assistance.

4. INCREASE IN TRAINING REQUIREMENTS

4.1 We have a highly experienced team of badger trappers and vaccinators. Several of our team worked on the Badger Vaccine Deployment Project for two years, and therefore have an in-depth understanding on the skills required to successfully trap and vaccinate a good proportion of the badger population. We are concerned on the limited trapping skills and experience which is required by lay vaccinators being certified after attending the FERA run Cage Trapping and Vaccination of Badgers Training Course. Trainees do not get the opportunity to learn the vital skills of trap placement and pre-baiting, as this work is completed prior to their arrival on the course.

4.2 To allow confidence in the lay vaccinator’s ability to successfully trap badgers (a necessary prerequisite for a successful vaccination programme), we feel it is of great importance that lay vaccinators gain more experience trapping badgers, in a wider variety of habitat types and population densities than that which is currently provided by the training course. This will ensure that when working alone in the future, they can successfully undertake their work with confidence. This view has been corroborated by several trainees who we have spoken with and assisted after they have obtained their certificate of competence.

4.3 We would call for a longer training period, for example like that necessary to obtain Dormice or Bat handling Licences, to ensure high working standards are met and farmers can have confidence that if they decide to pursue badger vaccination, the work will be undertaken competently.

5. PUSHING FOR A CATTLE VACCINE

5.1 It is in our opinion that to have the best chance of successfully tackling this disease we need to employ a variety of methods, ie enhancing biosecurity, badger vaccination and, importantly, cattle vaccination. It is our understanding that the cattle vaccine has reached the stage where it is ready for licensing. We therefore feel that MP’s, and other individuals and organisations, need to take action to ensure all legal and political obstacles that could prevent farmers from having the choice to vaccinate their cattle, are removed.

Written evidence submitted by the Roslin Institute

VACCINATION OF BADGERS OR CATTLE FOR CONTROL OF BOVINE TUBERCULOSIS

THE CURRENT STATUS OF BOVINE TB IN GREAT BRITAIN

1. The introduction of a herd testing and slaughter policy for cattle TB in the 1950s initially had a dramatic impact on the disease, reducing the number of herds affected annually in England and Wales to <100 by the early 1980s. However, despite continued herd testing, localised foci of infection persisted in the south-west of the country and since the mid-1980s there has been a progressive increase in the number of affected herds, which currently exceeds 3,000 per/year. Throughout this time, TB infected cattle have been identified using the comparative intradermal tuberculin test (CITT), which involves injection of *M. bovis* and *M. avium* protein extracts (tuberculin) into the skin at two sites on the neck and then measuring the change in skin thickness 72 hours later. In the last few years, this has been supplemented by use in some herds of an additional laboratory test based on measuring release of interferon- γ in cultures of blood incubated with tuberculin antigens (the IFN γ test).

THE REASONS FOR PERSISTENCE OF INFECTION IN CATTLE

2. Wildlife: By the 1970s most of the remaining TB-affected herds were found in the south-west of England. Around this time, the discovery of infection with *M. bovis* in badgers implicated wildlife as a source of infection in these areas and led to the introduction of a number of badger culling strategies as additional means of trying to control the disease. However, despite these measures the incidence of disease continued to increase during the 1980s and 1990s. A review of the role of badgers in the disease chaired by Professor John Krebs led to the establishment of a trial to determine the impact of badger culling policies (the Randomised Badger Culling Trial—RBCT), which was carried out between 1998 and 2006. The results of this trial provided for the first time unambiguous evidence that badgers are a significant source of infection for cattle, although their relative contribution could not be quantified. However, extensive and sustained culling was found to result in only a modest reduction in herd breakdowns (20–30%) and localised culling (as practiced prior to the trial) actually resulted in a small increase in breakdowns. Field observations indicated that this was due to dispersion of infected badgers as a consequence of disrupting territories and incomplete culling.

3. A reservoir of infection in cattle: Information from a variety of sources has provided clear evidence that the CIIT test used in routine herd testing does not detect all infected cattle—estimates of sensitivity ranging between approximately 65% and 80%. The most convincing evidence comes from the finding that application of the IFN γ test in affected herds following routine CIIT testing detects significant numbers of additional infected cattle not detected by the CIIT. A proportion of cattle in high TB risk areas suffer repeat TB breakdowns. While these are often interpreted as due to re-introduction of infection from wildlife, it is likely that a substantial proportion of these breakdowns arise from infected cattle not detected by the previous herd test. The low level of reduction in herd breakdowns achieved by badger culling, which was estimated to remove about 70% of the resident badgers, is also consistent with this conclusion. These undetected animals provide a source of infection both for transmission to other animals within the affected herds and also for infecting other herds as a result of animal movements between herds.

OPTIONS FOR IMPROVED CONTROL USING CURRENTLY AVAILABLE METHODOLOGIES

4. The wildlife reservoir: Although badgers are clearly a source of infection for some cattle herd breakdowns, the ability to control transmission to cattle presents a number of difficulties. Localised culling of badgers on affected farms (as practised prior to 1996) has been shown not only to be ineffective but to increase transmission. The Randomised Badger Culling Trial demonstrated that extensive culling of badgers over large areas of land (at least 70% of the land over an area of at least 100sq km), sustained over a number of years (at least 5 years in the trial), is required to achieve a significant reduction in cattle TB and even then the expected level of reduction is relatively modest. Such culling exercises are logistically complex and expensive and attract significant adverse public opinion. Although the Government has approved the use of culling in defined areas, given the current widespread distribution of the disease, it is unlikely that culling can be applied on a sufficiently large scale to have a significant impact on the overall problem.

5. Improved control measures for cattle: There is scope for improving the sensitivity of diagnosis by more extensive use of the IFN γ test. Studies in the UK have shown that this test has comparable or better sensitivity than the CITT skin test, but it's slightly inferior specificity precludes its use as a primary test for herd screening. More importantly, there is evidence that the two tests detect slightly different populations of infected animals, so that combined use of the tests enhances sensitivity. Thus, the test can be used as a follow-up test to detect additional infected animals in breakdown herds. It is currently used predominantly in breakdown herds in low risk areas in order to prevent establishment of infection in these herds. Given appropriate resources, the test could be used more extensively to assist in clearing herds of infection in the high risk areas. Detailed options are discussed in greater detail in a recent review submitted to Defra (Report by DPAG on the use of the gamma interferon (IFN γ) test for the diagnosis of bovine TB in GB.).

THE POTENTIAL CONTRIBUTION OF VACCINATION

6. Given the current inability to control bovine TB and the uncertainty concerning the likely impact of wildlife culling or modifications in cattle herd surveillance, there is a need to consider alternative options for improving control of the disease. The most obvious option is vaccination. The attenuated Bacille Calmette Guérin (BCG) strain of *M. bovis* was produced about 90 years ago and has been used extensively to vaccinate against human TB caused by the closely related organism *M. tuberculosis*. Although its efficacy varies in different parts of the world, it has generally proved to be effective against childhood TB but less so against other forms of the disease in adults. BCG vaccination has been tested experimentally in both cattle and badgers, but until recently has not been used in the field.

7. Vaccination of badgers: Vaccination with BCG offers the potential to reduce the infectious burden in the badger population, in the hope that this would reduce transmission both between badgers and from badgers and cattle. Experimental evidence suggests BCG has a protective effect in badgers reducing the extent of disease and bacterial colonisation. Unfortunately, there are no reliable experimental models to test the effects of vaccination on transmission from badgers. Hence, it is difficult to predict the impact of vaccination on transmission to cattle in the field. This can only be achieved by field testing the vaccine. Nevertheless, vaccination offers a potentially more sustainable, cost-effective and publicly acceptable alternative to culling. However, in order to have a substantial impact, vaccination would need to be applied widely across the region. This can only be achieved with a vaccine that can be delivered orally in the form of a baited vaccine. Use of an injectable vaccine, which has been licenced and is currently undergoing field testing, will be of limited practical value. In the past, BCG has been used orally in humans and development of a suitable bait formulation for badgers should be technically feasible.

8. Vaccination of cattle: The use of vaccination in cattle represents a more complex and challenging problem. The practicalities of how the use of vaccination would fit into cattle TB control policy require careful consideration.

9. The first point to make is that the currently stated policy objective of TB eradication in England and Wales is quite unrealistic in the short to medium term. The disease is essentially endemic, and indeed is increasing, in a large part of the South East of the country; the immediate objective should be to bring it under control before contemplating eradication. The use of vaccination may help to achieve control, but the circumstances in which vaccination might be used, the precise objectives of applying vaccination and the levels of protection that would be needed to make vaccination worthwhile need to be thought through in much greater detail than seems to be the case at present. Moreover, approval would need to be sought from the EU for sensible and flexible use of vaccination as a component of TB control policy.

10. Studies in neonatal cattle vaccinated with BCG and experimentally challenged with *M. bovis* have shown that BCG vaccination reduces the severity of pathology and the bacterial load but has only a minor effect on the incidence of infection. Current research is investigating vaccination protocols that can enhance the immunity conferred by BCG, by applying a follow-up booster vaccination with defined *M. bovis* proteins.

11. In ideal circumstances, a highly efficient vaccine would give sufficient protection to prevent disease in most animals and potentially allow discontinuation of test and slaughter in vaccinated herds (with reliance on routine slaughterhouse inspection to detect residual infection). While this may still be considered a long-term objective, it is clearly unrealistic in the shorter term, given the level of protection that can be achieved. Hence, continued surveillance for TB would be needed. The use of BCG for vaccination would result in positive reactions in the current CITT and IFN γ tests in vaccinated animals and would therefore require a new companion diagnostic test to differentiate vaccinated and protected animals from those that become infected with *M. bovis*. A modified IFN γ test using defined mycobacterial antigens (expressed by native *M. bovis* but not BCG) is currently under development at AHVLA and initial results from experimental studies indicate that it has a level of sensitivity similar to that of the CITT. The aim should be to use this as a stand-alone test in vaccinated herds.

12. The requirements of a vaccine for TB in cattle are somewhat different than those for badger vaccination. Vaccination would be expected to reduce the weight of infection, the level of transmission to and from vaccinated animals and ultimately the numbers of infected animals. Current experimental evidence indicates that although BCG vaccination of cattle reduces the severity of infection following challenge, it has only a minor protective effect against infection. Given these data, it is questionable whether BCG will be sufficiently effective to justify its use in the field. Therefore, it may be prudent to focus research efforts on developing vaccine protocols that improve the levels of immunity obtained with BCG, for example by boosting with defined antigens, before considering field testing. In any event, introduction of a vaccine into the field will require a carefully planned field trial of both the vaccine and a companion diagnostic test to determine their efficacies under field conditions.

IMPLICATION FOR ANIMAL EXPORTS

13. If a TB vaccine were approved for field use in cattle in Great Britain, export of vaccinated live animals to mainland Europe is likely to be prohibited because they would test positive in routine TB surveillance testing. The negative economic consequences of this would need to be balanced against the benefits gained from improved control of the disease. Although I am not familiar with detailed figures on export of live

animals, my understanding is that the number of breeding animals exported to mainland Europe is relatively low and any animals exported for direct slaughter should not have any impact on disease surveillance.

January 2013

Written evidence submitted by Rethink Bovine TB

1. INTRODUCTION

1.1 Rethink Bovine TB is an independent group with an interest in agriculture, animal diseases, animal welfare and the financial viability of farming.

1.2 We confine our submission to vaccination of cattle against Bovine TB and Defra's recent handling of associated regulatory issues.

2. SUMMARY

2.1 Paradoxically vaccination against Bovine TB was banned so that Bovine TB could be detected.

2.2 Defra's claims for vaccine efficacy are misleading as they ignore the way vaccines work in a herd to stop the spread of disease. Defra have not modelled the effect of vaccination on herd breakdowns.

2.3 Defra had scheduled all regulatory work except changing EU law for completion in 2012. The vaccine and DIVA test are ready but not licensed or approved because Defra had not appreciated the requirements.

2.4 Little has been done to change EU law to enable vaccine use.

2.5 Enquiries into the delays and reasons for delays have been evaded by a Defra Minister and by civil servants.

2.6 Defra only realised around 2011 that a vaccine could not be licensed until the EU ban on use had been lifted.

2.7 Defra were taken by surprise when the OIE demanded field trials which would involve vaccination in the field which is illegal. Defra have still not decided whether to try to perform the trials, putting the whole programme in doubt.

3. CATTLE VACCINATION

3.1 The principal means of preventing epidemics and protecting against infectious diseases is almost always vaccination. Bovine TB in cattle is an exception only because vaccination was made illegal as the readily available vaccine, BCG, interferes with the test used to detect the infection. In other words *the leading solution to BTB, vaccination, was banned so BTB could be detected*.

3.2 However a "DIVA" test which distinguishes between vaccinated and infected cattle is now awaiting approval, and work to enable licensing of BCG (a vaccine used on humans for many decades) as a cattle vaccine is complete.

3.3 Although modelling data is scarce it would be reasonable to expect vaccination to produce a dramatic reduction in the number of herd incidents and individual cattle slaughtered, even at the lower estimates of vaccine efficacy.

4. EFFICACY OF CATTLE VACCINATION

4.1 The results of the majority of studies of BCG use on cattle have demonstrated considerable protection with field studies in Mexico and Ethiopia indicating 56–68% protection of individuals.⁵⁴ (Note that this is often incorrectly rounded down to 50–60%. Correctly rounded it becomes 60–70%).

4.2 Defra repeatedly caution that BCG will not provide complete protection. As for any vaccine this is correct, but very misleading because of the way vaccines work in a herd.

4.3 There are two reasons for vaccinating against infectious disease:

- (a) To protect an individual. Any protection helps but as near 100% as possible is preferable.
- (b) To protect a population. It is only necessary to achieve a level of immunity at which that the disease cannot spread through the population, and goes into decline—the herd immunity threshold. Less than full protection of each individual is generally sufficient, and not every individual need be vaccinated.

4.4 For cattle the aim is to protect the herd so the disease goes into decline, not to protect any one individual animal.

4.5 Any level of efficacy will help reduce incidence, even if herd immunity is not achieved.

⁵⁴ 4th para www.defra.gov.uk/animal-diseases/a-z/bovine-tb/vaccination/cattle-vaccination/

4.6 Defra claim that “It is not clear what effect BCG vaccination of cattle would have in reducing the incidence of TB herd breakdowns.”⁵⁵

4.7 Why has no modelling of this critically important aspect been carried out for Defra?

4.8 Further unanswered questions include:

4.9 What efficacy would be needed to achieve herd immunity?

4.10 What would be the equivalent efficacy if vaccination was combined with other measures, such as properly designed and enforced cattle movement protocols?

4.11 What efficacy, using cattle vaccination alone, would be needed to achieve the same effect as the current policy?

4.12 If vaccination was used alongside the existing test and cull policy (obviously with use of the DIVA test) what reduction in the number of cattle slaughtered could be expected?

5. PROGRESS

5.1 Defra included the following statements in their September 2010 Consultation;⁵⁶

5.2 “We aim to have a licensed cattle vaccine by 2012.”

5.3 “Our aim is also to have the DIVA test approved by 2012.”

5.4 “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.”

5.5 From this, Defra had scheduled a 2012 completion for all scientific and regulatory work.

5.6 The remaining obstacle would be EU legislation.

6. CURRENT STATUS UNDER EU LAW

6.1 The ban on cattle vaccination was introduced because the BCG vaccine can interfere with the Tuberculin skin test. This is no longer a problem because of the DIVA test. Yet we cannot repeal the obsolete law ourselves, but must go cap in hand to the European Commission.

6.2 It is not clear why Defra thought 2015 marked a watershed in changing EU law. They were hoping that proposed new animal health legislation might allow vaccination of cattle against BTB but they admit they have no control and limited influence.

6.3 If changing EU legislation is as Defra claim “a lengthy process” Defra should have started the “lengthy process” at the same time as work on the vaccine and DIVA test.

6.4 In Defra’s September 2010 consultation they stated at Para 63: “As part of the ongoing consultation on the new EU Animal Health Law, we will be using the strong scientific and technical evidence on the efficacy and safety of the cattle vaccine and the role of a DIVA test to request the necessary changes to EU legislation.....”⁵⁷

6.5 In the “Bovine TB Eradication Programme for England July 2011” Defra state at Para 87: “We will be using the scientific and technical evidence on the efficacy and safety of the cattle vaccine and the role of a DIVA test to press the case in Europe.....”⁵⁸

6.6 The use of the definite article in “The strong evidence” and “The evidence” implies such evidence already existed. The repeated term “We will be” clearly means *we have not yet*.

6.7 From Para 88 of the same 2011 document: “Changing EU legislation is a lengthy and uncertain process and preliminary discussions with the EU Commission have indicated that a change to the legal framework on vaccination and DIVA testing cannot be considered until sufficient evidence of their effectiveness is available. This is likely to take some time and as a result we anticipate that a cattle vaccine and DIVA test will not be available for use in the field for many years.”

6.8 Does “cannot be considered” mean cannot be lobbied and prepared for, or cannot be implemented? The former meaning seems to be the one accepted by Defra. The latter is the likely reality. We note that “...until sufficient evidence of their effectiveness is available” contradicts “the strong scientific and technical evidence” in the 2010 consultation quoted above.

6.9 The 2015 target has become an indeterminate delay of “many years”. The vaccine and DIVA test are ready for licensing, but little or nothing has been done to change the law to allow approval and use.

⁵⁵ 4th para www.defra.gov.uk/animal-diseases/a-z/bovine-tb/vaccination/cattle-vaccination/

⁵⁶ paras 62 and 63 of www.archive.defra.gov.uk/corporate/consult/tb-control-measures/100915-tb-control-measures-condoc.pdf

⁵⁷ www.archive.defra.gov.uk/corporate/consult/tb-control-measures/100915-tb-control-measures-condoc.pdf

⁵⁸ www.defra.gov.uk/publications/files/pb13601-bovinetb-eradication-programme-110719.pdf

7. CORRESPONDENCE WITH THE MINISTER OF STATE

7.1 Letters⁵⁹ from Jim Paice, (when Minister of State) in reply to correspondence with Mark Williams MP failed completely to explain what steps have already been taken to change EU law. After ignoring the EU aspects the then Minister finally (letter 19 March 2012) discusses procedure for changing EU law, still ignoring the question.

7.2 If the Minister ignores the question, one would assume no action has been taken.

8. FOI REQUESTS

8.1 Requests under FoI 2000⁶⁰ were fielded with a more direct and honest form of evasion—simple refusal to answer difficult questions.

8.2 “When we came to publish the [TB] Eradication Programme [July 2011] it was clear that significant technical and regulatory challenges remained and this led us to conclude that the 2015 date should be dropped until matters had been clarified. We still do not have a fixed date by which we expect cattle vaccine to be deployed in the field. However, the details underpinning these uncertainties as requested in your freedom of information request are withheld under exemptions 27 (international relations) and 35 (formulation of government policy) of the Freedom of Information Act.”

8.3 We have been unable to establish what the “significant technical and regulatory challenges” are, nor how they might affect international relations and formulation of government policy.

9. LICENSING AND APPROVALS

Vaccine

9.1 In RFI 4469⁶¹ Defra admitted “By the time we came to publish the TB Eradication Programme in July 2011 we were aware that a TB cattle licence could not be issued by the Veterinary Medicines Directorate until the ban on vaccination had been lifted”

9.2 Why were Defra not aware of this crucial information from the outset?

DIVA Test

9.3 Before (and if) the EU lifts the ban on vaccinating cattle against BTB, the DIVA test must be approved by the OIE. Defra submitted an application following Easter 2012. This was rejected by the OIE as no UK field trial data was submitted. Field trials cannot be conducted in the UK without a derogation from the EU because vaccination of cattle is illegal under EU law.⁶²

9.4 Why did the demand for field trials take Defra by surprise? It should not have done. They were aware of the potential requirement long ago when the Vaccine Advisory Group highlighted the absence of experimental systems to measure vaccine efficacy in a natural transmission setting. In 2005 Defra announced the necessary research, albeit to be done in contained facilities not as field research.⁶³

9.5 In any properly organised development programme, approval and licensing is discussed with the regulators at every stage in development. Any element that would not be approved is altered or dropped and all trials the regulator requires are designed into the programme at every stage.

In most cases licenses or derogations can be obtained for necessary veterinary research which would otherwise involve illegal acts.

9.6 Why did Defra not discover in advance the OIE requirement for field trials and corresponding need for an EU derogation?

9.7 It appears that the vaccine licence cannot be issued unless the vaccination ban is lifted:

The vaccination ban cannot be lifted;

Until the DIVA test is approved;

Which cannot happen until field trials are conducted;

Field trials cannot be conducted until the vaccination ban is lifted.

9.8 The matter was further confused by FoI 5189 of 19 December 2012,⁶⁴ in which Defra stated: “*But as yet no decisions have been taken on whether or not to undertake experimental or field trials.*”

9.9 This is a shambles, and one which Defra must have foreseen yet failed to prevent.

⁵⁹ www.rethinkbtb.org/rethink_documents/corrs_with_jim_paice.pdf

⁶⁰ www.rethinkbtb.org/rethink_documents/freedom_of_information.pdf

⁶¹ RFI 4469 of 1st February 2011 www.rethinkbtb.org/rethink_documents/freedom_of_information.pdf

⁶² Defra email July 31 2012 www.rethinkbtb.org/rethink_documents/freedom_of_information.pdf

⁶³ Defra Project SE3227

⁶⁴ Last page at www.rethinkbtb.org/rethink_documents/freedom_of_information.pdf

10. CONCLUSIONS AND RECOMMENDATIONS

10.1 The test and cull strategy has failed to achieve OTF status and arguably has worse effect than the disease itself. The only proportionate solution likely to achieve better results is cattle vaccination.

10.2 Defra's attempts to achieve regulatory and legal approvals for vaccine use have descended into farce.

10.3 Defra Ministers must put an end to this and order officials to find solutions—not create more bureaucratic muddles—so as to deploy cattle vaccination without delay.”

11. POSTSCRIPT

The 2010 Rethink Bovine TB report “Bovine TB: Time for a Rethink”⁶⁵ concluded that:

Bovine TB is not a significant human health risk in the UK. Hardly anyone catches Bovine TB from cattle or cattle products in the UK.

The effect on animal welfare, and on farmers, of cattle testing and culling is worse than the disease itself.

Farmers should be free (or required) to vaccinate cattle.

Milk pasteurization and meat inspection should continue.

The tuberculin skin test is woefully inaccurate, even worse than generally believed.

Some 60 years from introduction the test and cull policy has failed.

10 January 2013

Written evidence submitted by the British Veterinary Zoological Society

1. The British Veterinary Zoological Society (BVZS) represents around 450 veterinary surgeons with an interest in exotic animals and indigenous wildlife. Our membership includes specialist wildlife, zoo and exotic veterinary surgeons, but also represents those in small animal practice with an interest in these species.

2. Although BVZS is a division of the British Veterinary Association, BVZS views on bovine tuberculosis (bTB) in cattle and badgers, especially with respect to the targeted cull of badgers, differ significantly from BVA policy. BVZS believes, for reasons based upon strong scientific data, that there is no evidence to support the culling of badgers as part of policy to control bTB in cattle. Other methods of controlling the disease, such as vaccination, must be used and are already available to us. BVZS therefore welcomes this opportunity to provide evidence to the Committee on the vaccination of badgers and cattle in relation to bTB.

BADGER VACCINATION

3. An intramuscular BCG vaccine was licenced for use in badgers in the UK in 2010 following considerable experimental research in the UK and Ireland (Lesellier *et al.*, 2006; Corner *et al.*, 2007; Corner *et al.*, 2008; Lesellier *et al.*, 2008; Lesellier *et al.*, 2009). Vaccination of badgers has been shown to result in significant reduction in the severity of disease, the number of tissues containing acid-fast bacilli, and reduced bacterial excretion (Lesellier *et al.*, 2011). Field studies have shown the vaccine to reduce positive serological results in badgers by 74% (Chambers *et al.*, 2011). Modelling studies have additionally suggested that vaccination of badgers can make a significant contribution to controlling TB in cattle (Wilkinson *et al.*, 2004; Smith *et al.*, 2012). As well as reducing disease in individual animals, BCG vaccination has been shown to have significant positive indirect effects on a population basis, including reducing bTB infection in unvaccinated badger cubs in social groups where only a proportion of the adults have been vaccinated (Carter *et al.*, 2012).

4. Negative comments have been made regarding badger BCG, suggesting for example that it is a poor vaccine because it fails to protect animals that are already infected—in reality very few vaccines offer protection once an individual is infected with a disease and it is unreasonable to expect BCG to perform in this way. Another criticism is that the vaccine does not offer complete protection, but instead reduces severity and excretion of disease. Whilst this is a valid comment, TB is not a simple disease in terms of immunity and developing a completely protective vaccine is unlikely to happen in the near future. The spread of disease, both between badgers and potentially to cattle, is governed by excretion of mycobacteria and a vaccine that reduces this is a powerful tool. Much is also made of the fact that there is no published scientific evidence that vaccinating badgers will have an impact on the disease in cattle. This is indeed the case at present as the very much reduced vaccine field trial is still underway. Extrapolating our knowledge of how the vaccine works to how it might reduce potential transmission of disease between badgers and cattle, would however suggest a significant benefit. The disease in cattle is of course, influenced but many more factors than just the disease in badgers.

5. Badger BCG vaccination has been used in FERA field trials in some areas of England and is currently an important part of bTB control methods in Wales. The vaccine has also been used by many non-government

⁶⁵ www.rethinkbtb.org/rethink_documents/BTB_rethink_2nd_edition.pdf

organisations (NGOs) in England and Wales to protect badgers on farmland at the request of farmers and organisations such as the National Trust.

6. Delivery of the injectable vaccine is time and resource consuming. Members of NGOs such as the Badger Trust have ensured that they are trained and equipped to vaccinate badgers, but their efforts are limited and not co-ordinated around the country. A proper system of making badger vaccination easily accessible to farmers is essential, ideally by government. If vaccination is to be left to NGOs then suitable co-ordination and funding is required, whilst at the same time providing these organizations with assurances that badgers they vaccinate will not be culled.

7. It is recognised that there are delivery issues with an injectable vaccine and that an oral baited BCG vaccine would be preferable. An oral lipid matrix vaccine has been shown to be effective with a decrease in the number and severity of gross lesions, lower bacterial load in the lungs, and reduce the number of sites of infection in vaccinated badgers (Corner *et al.*, 2010) and field trials of this vaccine continue in Ireland. There are some delivery issues to overcome with an oral vaccine, ensuring maximum exposure to badgers whilst avoiding ingestion by non-target species, however such vaccines have been deployed successfully to control bTB in possum in New Zealand.

We welcome the Government's commitment to further invest in this area

VACCINATING CATTLE

8. BCG can be used as a vaccine in cattle. Its efficacy is much as in badgers and other species, being not wholly protective against infection, but reducing the progression and severity of the disease in those animals that become infected and consequently reducing disease transmission between individuals. It is of course much easier to vaccinate cattle than badgers and this allows for whole populations to be vaccinated, as well as allowing targeted use of the vaccine, for example in young calves where its efficacy is increased (Buddle *et al.*, 2003). BVZS believes a cattle vaccine should be trialed in the UK as soon as possible.

9. Much is made of the challenges of overcoming EU legislation regarding the vaccinating of cattle with BCG. The evidence that the EU would block vaccination or that vaccination would have significant effects on cattle trade is unclear and further clarification from the EU is necessary. In reality many of the objections to vaccinating cattle come more from within the UK, where the concept of zoning of the country with vaccinated and unvaccinated cattle populations and the perceived impact that this may have on trade makes it unpopular with the farming community. BVZS believes clarification of the EU position would help overcome these fears.

9. A differential test (DIVA test) which allows BCG vaccinated cattle to be distinguished from those with infection is also necessary before BCG vaccination of cattle can take place. The current intra-dermal skin test used in cattle is one of the few types of test where consistent interference is seen when BCG is used. Although this is currently the test most commonly used in cattle, other tests are available which allow for the identification of specific antigens that are present in bTB infected animals but are not found in BCG. In badgers such a commercial test exists in the form of the Brock TB Stat-pak® (Chembio Diagnostic Systems, Medford, NY), which allows differentiation between vaccinated and infected badgers. There may of course be practical and cost issues with DIVA tests compared to the intra-dermal skin test in cattle, but these should not be insurmountable. BVZS believes that a DIVA test should be trialed in the UK, alongside BCG vaccination of cattle, as soon as possible.

SUMMARY

We believe that vaccination can play an important part in the control and eradication of TB. It must take place alongside other control measures including the slaughter of cattle found to be infected with TB, improved bio-security, and surveillance at all levels in the farming industry. We do not feel that humane badger culling will play a meaningful nor useful part in the control of this disease. We feel resources should be focused and targeted towards the development of a coordinated vaccination policy and the development of better more cost effective and targeted methods of delivery.

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January 2013

Written evidence submitted by The Wildlife Trusts

There are 47 individual Wildlife Trusts covering the whole of the UK and the Isle of Man and Alderney. Together The Wildlife Trusts are the largest UK voluntary organisation dedicated to protecting wildlife and wild places everywhere—on land and at sea. We are supported by more than 800,000 members, 150,000 of which belong to our junior branch—Wildlife Watch.

SUMMARY POINTS

Culling is not a quick fix solution to bTB.

The Wildlife Trusts believe that an effective cattle vaccine, used alongside a badger vaccine, improved biosecurity and cattle testing, represents the best long-term solution to the problem of bovine TB (bTB).

Badger vaccination can be used immediately without the negative effects of perturbation associated with a badger cull.

In order to be effective, badger vaccination needs to be deployed in a strategic manner and needs to be combined with improved cattle testing, movement controls and biosecurity measures.

The Wildlife Trusts are concerned that the resources and political capital currently being spent on delivering a badger cull could be more effectively targeted towards vaccination.

The Wildlife Trusts are the leading NGO with experience of deploying the badger vaccine.

There is desire across a range of sectors for increased partnership working on vaccine deployment.

INTRODUCTION

1. The Wildlife Trusts are very conscious of the hardship that bTB causes the farming community and the need to find the right mechanisms to control the disease.

2. There is no quick fix to the problem of bTB. Currently a badger cull is being described as a more immediate solution than vaccination, yet the apparent beneficial effects of culling (between 12 and 16%) were only recorded after nine years.

3. Our involvement with this issue over many years has led us to conclude that a sustained programme of badger and cattle vaccination, alongside improved biosecurity measures, improved testing and controls on cattle movement would be the best means of tackling bTB.

BADGER VACCINATION

4. In the absence of a deployable cattle vaccine, The Wildlife Trusts believe that the injectable badger vaccine, alongside improved cattle testing and biosecurity measures, can contribute significantly to reducing the spread of bTB. The Food and Environment Research Agency advises that only a proportion of the susceptible population need to benefit from the protective effects of the vaccine in order to reduce the prevalence of infection in the population.⁶⁶

5. The badger vaccine can be deployed immediately without the negative effects of perturbation that are associated with badger culling. There is significant support for badger vaccine deployment amongst the wildlife conservation and animal welfare charities and the wider public.

6. In the longer term a badger vaccine that can be delivered orally is likely to be a cheaper and more practical way of vaccinating large numbers of badgers in the wild than an injectable vaccine. However, deployment of the current intradermal vaccine should not be delayed on the hope value of an oral product that is not currently available, yet would be based on the same BadgerBCG vaccine.

7. In a clinical field study,⁶⁷ BCG vaccination of free-living badgers reduced the incidence of positive serological test results by 73.8%. Recently published research also found that when more than a third of their social group had been vaccinated, the risk to unvaccinated cubs was reduced by 79%.⁶⁸ A reduction in the prevalence and severity of the disease in badgers could reduce the degree of badger to badger, badger to cattle and cattle to badger bTB transmission.

8. In 2011, Gloucestershire Wildlife Trust became the first NGO to deploy the badger BCG vaccine. Following the first year of vaccination, the Trust published a report summarising their findings from the vaccination project. The report is attached as annex 1 to this submission and a revised report including the findings of the second year of deployment is currently being produced and will be available in early 2013. In 2012 a number of other Wildlife Trusts began deployment of the badger BCG vaccine including Somerset, Cheshire, Shropshire and Warwickshire.

9. Trusts are primarily deploying the vaccine on their own nature reserves, but where possible they have also been providing advice to other landowners interested in vaccination. Shropshire and Cheshire Wildlife Trusts have developed a partnership with a veterinary practice to promote badger vaccination and have already signed up a number of farms for vaccination programmes this year. In the cases of vaccination on sites other than Wildlife Trust reserves, the landowners are paying for the cost of vaccination. There is clearly an appetite for partnership working on across a range of sectors on this issue.

10. The experience of the Trusts is that there is a demand for advice on badger vaccination, but that many people are unsure of where to access information. One of the key conclusions drawn by Gloucestershire Wildlife Trust in their report was that if the badger vaccine was to be deployed more widely a free advisory service would make deployment easier and potentially cheaper. A farmer who was prepared to use the badger vaccine privately has expressed concern to the Gloucestershire Trust in 2012 that access to badger vaccine fund was not straightforward and that financial support for work undertaken was not provided for many months. Cost and accessibility barriers for farmers and landowners willing to deploy badger vaccine should be addressed if “every tool in the toolbox” is truly to be used.

11. There is also a clear need to for “myth busting” regarding the use of the vaccine. Wildlife Trust demonstration projects and seminars have been helpful in this regard, but clearer information from Government is also needed.

12. The value of the intradermal badger vaccine as an available and accessible disease management tool is frequently devalued. Defra should issue an authoritative statement that gives an objective and uncoloured assessment of BadgerBCG and the current state of research on its efficacy.

13. Whilst The Wildlife Trusts have successfully deployed the badger BCG vaccine on a number of sites and have been able to develop local partnerships, we recognise the limited impact that our deployment of the vaccine will have on the wider problem of bTB. If badger vaccination is to be successful it needs to be deployed strategically in key areas in order to have the biggest possible impact on bTB.

14. With this in mind, The Wildlife Trusts support Defra’s current work on the development of an edge strategy. The strategy would focus on the edges of high bTB incidence areas and aims to prevent further spread

⁶⁶ Food & Environment Research Agency, Frequently asked questions about the badger vaccination deployment project—
<http://www.fera.defra.gov.uk/wildlife/ecologyManagement/documents/vaccinationFAQs.pdf>

⁶⁷ Chambers MA, Rogers F, Delahay RJ, Lesellier S, Ashford R, et al. (2011) *Bacillus Calmette-Guerin vaccination reduces the severity and progression of tuberculosis in badgers*. *Proceedings of the Royal Society B-Biological Sciences* 278: 1913–1920. doi: 10.1098/rspb.2010.1953.

⁶⁸ Carter SP, Chambers MA, Rushton SP, Shirley MDF, Schuchert P, et al. (2012) *BCG Vaccination Reduces Risk of Tuberculosis Infection in Vaccinated Badgers and Unvaccinated Badger Cubs*. *PLoS ONE* 7(12): e49833. doi:10.1371/journal.pone.0049833

by creating a firewall against the disease. Measures being considered as part of the edge strategy include restrictions on cattle movements, improved bio-security measures and badger vaccination.

15. The Wildlife Trusts are keen to work with Defra on this strategy in order to focus our vaccination efforts on the areas where they will have the biggest impact on bTB. We would encourage Defra form a strategic grouping of stakeholders to ensure as wide a deployment of the vaccine as possible in the edge areas.

16. Alongside working with Defra on the edge strategy, The Wildlife Trusts also plan to continue demonstrating vaccine deployment on key sites in order to support our efforts to provide information about the role of the vaccine bTB control.

17. It appears that in comparison to the political capital being put into delivering a badger cull, very little Government effort has been put into badger vaccine deployment.

18. £250,000 a year is available from Defra to support badger vaccination. This is in comparison to the costs of the two delayed pilot culls, which have already exceeded £1m and are likely to total more than £5m if the pilots go ahead. Currently the £250,000 vaccination fund is only available to use in cull areas. The Wildlife Trusts believe that the fund should be increased and made available to support the strategic deployment of the badger vaccine as part of the edge strategy. Gloucestershire Wildlife Trust was not able to access this fund for use on its nature reserves within the proposed cull area because of the high level of confidentiality placed on the location of the cull boundaries. The Trust was not able to identify what of its land lay within the cull zone and did not progress with badger vaccination. This barrier needs to be removed for future culls if they do proceed.

CATTLE VACCINE

19. The Wildlife Trusts believe that cattle vaccination is a key part of the long term solution to the problem of bTB. However, we recognise that deployment of a cattle vaccine is not yet possible due to European legislation. Opinions on the likely timescale for the availability of the cattle vaccine seem to vary greatly. We would like to see the Select Committee clearly establish the status of the cattle vaccine and the necessary steps that need to be taken in order for the vaccine be deployable. In this regard we believe it is important that the Committee seeks evidence from the European Commission, European Food Safety Agency and World Organisation for Animal Health (in relation to the DIVA test).

20. As with the badger vaccine, Defra appears to have devoted little effort to progressing a cattle vaccine when compared to a cull. Given the costs associated with a cull that would, at best, deliver a 16% reduction in bTB and the ongoing costs of compensation we believe that more effort should be dedicated to securing the deployment of a cattle vaccine as a matter of the highest urgency.

21. The Wildlife Trusts believe that the Government should be preparing a deployment plan for the cattle vaccine in England. This will shorten the timetable between the approval of the vaccine and deployment. On 10 and 11 December 2012 the Welsh Government held a two day conference with leading cattle vaccination experts to begin looking at the role that cattle vaccination can play in bTB eradication. We would like to see Defra taking similar steps in England.

January 2013

Written evidence submitted by the International Fund for Animal Welfare

1. At the end of 2012 the Environment, Food and Rural Affairs Select Committee launched an inquiry into the issue of TB vaccination of badgers and/or cattle, as a solution to the problem of TB affecting the cattle industry in England. Due to the fact that there have been claims that badgers may be hosts of TB and help it to spread among cattle herds, and also the fact that several governments have proposed projects of culling badgers as an attempt to stop the spread of this disease that ended up being very controversial and in several instances withdrawn or postponed, the issue of vaccination of both cattle and badgers as a viable alternative to culling needs to be properly assessed and considered, and we welcome this consultation.

2. Founded in 1969, the International Fund for Animal Welfare was set up to save individual animals, animal populations and habitats all over the world. With projects in more than 40 countries, IFAW provides hands-on assistance to animals in need, including companion animals, wildlife and livestock, or rescuing animals in the wake of disasters. We also advocate saving populations from cruelty and depletion. Our work connects animal welfare and conservation, and therefore we are equally concerned with the wellbeing of badgers and cattle, and we have sufficient scientific expertise on both.

3. IFAW has opposed the badger cull trials planned by the Governments in Westminster and Wales, and welcomed the eventual cancelling of such plans by the Welsh Government and the postponement of plans in England.

4. IFAW's opposition to the cull as a solution to the cattle TB problem is based on the following arguments: 1) reputable scientific studies have shown that the culling would be of little help in reducing bovine TB; 2) the culling could actually cause the disease to spread even more through the phenomenon known as perturbation;

3) there are serious animal welfare and wildlife conservation concerns about the proposed method used to cull badgers; 4) there are viable alternatives to the culling of badgers.

5. Notwithstanding the fact that it is not yet entirely clear what role badgers play in Bovine TB outbreaks, IFAW is of the opinion that vaccination of badgers can help to solve the Bovine TB problem by reducing the chances of badgers contracting TB, and therefore the chances of spreading it to other animals such as cattle. We agree that the vaccination route taken currently by the Welsh Government, which has already successfully caught and vaccinated over 1,400 badgers, is a good way to address the wildlife reservoir issue in the Bovine TB problem.

6. The vaccination of badgers with the BCG vaccine has already been proven to reduce the risk of a positive TB test in the animals by 54%, as shown in the four-year study by the Food and Environment Research Agency and university departments (Carter et al. 2012). IFAW believes this is a sufficiently high percentage to consider this vaccine as feasible. This study also found that unvaccinated cubs were less susceptible to the disease because there was less contact with diseased badgers.

7. Regarding the issue of using PCR (Polymerase Chain Reaction) tests on faeces to be undertaken in badger setts to determine whether their inhabitants are infected with bTB, which is based on the results of a study by Warwick University (Travers et al., 2011), we believe this, when fully developed, may help to estimate how widespread bTB is in a badger population, but it would not help to determine which badgers should be culled. This is because not all the badgers using one sett may necessarily be infected if the sett shows positive test results (as has been found in studies made in the Woodchester Park Research Station), and not all the badgers that may be infected may end up developing the clinical disease and be infectious to others, if the disease has not developed its infectious form. Therefore, such tests may be of some use to assess the effectiveness of a badger vaccination programme, but not to justify a selective culling.

8. We believe that from an animal welfare point of view it would be legitimate to euthanase infected badgers which have clinically developed the Tuberculosis disease in its most infected form, and are already in an incurable terminal stage of the disease (but this is quite different from the application of selective culling of badgers for containing TB antibodies, since such animals may never develop the disease clinically, and may never be infectious). Therefore, if through the process of caging animals for vaccination a terminally diseased individual is diagnosed by a qualified vet, we believe that euthanasing it may both reduce its suffering and the risk of infection to others. However, we must stress that the decision should be taken by qualified veterinarians with expertise on this disease.

9. Although injectable vaccines for badgers have been fully developed and have been applied since 2010 producing positive results, we acknowledge that there is a considerably high cost in their implementation, and also an animal welfare cost in terms of stress, due to the fact that animals need to be trapped. Therefore, we consider that an alternative oral vaccine should be developed, since this would reduce such cost. We understand that an oral vaccine suitable for deployment has already been developed in New Zealand for use in controlling the non-native possum population. In the case of the UK, we believe that such oral vaccine is in development, but not quite yet finalised, and that this research should be prioritised.

10. IFAW believes that although the vaccination of badgers may reduce the spread of Bovine TB, ultimately the disease will not be sufficiently controlled unless cattle are also vaccinated. Bovine TB being a disease for cattle, and the most common form of transmission of the disease being infection between cattle, rather than between cattle and other animals, the problem will not be solved until cattle become immune to the disease.

11. Immunity in cattle to Bovine TB can effectively be achieved by a comprehensive cattle vaccination programme. We acknowledge that this is currently not possible due to the restrictions imposed by EU Directive 78/52/EEC and associated directives which set out the criteria for national plans for the “accelerated eradication” of bTB, but we know that this current status quo can be changed if there is enough political will to do so, and the reasons for such restrictions are addressed properly.

12. We acknowledge that the main obstacle for the use of bTB vaccination for cattle in Europe is the lack of an approved DIVA test, which is an alternative or ancillary test to the skin test, which could be used on animals that have been subjected to a sensitising vaccine to differentiate infected animals from vaccinated animals. Considering the information made public about it, we agree that the gamma interferon (IFN- γ) test currently developed by Professor Glyn Hewinson, of Animal Health and the Veterinary Laboratories Agency in Weybridge, Surrey, seems to be a valid DIVA test to differentiate vaccinated from infected cattle, and therefore there should no longer be a scientific obstacle for the lifting of the EU restrictions to TB vaccination programmes. However, we acknowledge that such test needs to be validated by the Organisation Internationale des Epizooties (OIE—World Organisation for Animal Health), before trials can start in the UK.

13. IFAW agrees with DEFRA that the BCG (*Mycobacterium bovis* Bacille Calmette-Guérin) is currently the most suitable cattle TB vaccine candidate. Experimental studies show that BCG vaccination reduces the progression, severity and excretion of TB in cattle and field studies show that it can reduce transmission of disease between animals. However, like in any vaccination programme, development of better vaccines, especially to address the issue of new strains of the disease emerging, should be an ongoing process.

14. IFAW believes that the effectiveness of the BCG proven to be between 56% and 68% in small-scale field studies carried out recently in Ethiopia and Mexico is sufficiently high enough to have the potential to be

able to control bTB in the UK, since no vaccine is 100% effective and yet many have proven to be able to completely control diseases. This is because the effect of vaccines in reducing the spread of a disease is multiple: it can fully protect the individual vaccinated from being infected, but it can also reduce the severity of the disease in infected cattle, and therefore it can reduce the infectivity of the disease. Although vaccination has no positive effect on cattle that are already clinically showing the disease, it does not increase the risk of transmission from these individuals, nor does it have any other population effect that risks spreading the disease further (as the perturbation effect in the case of the badger culling option).

15. We believe that in order to maximise the effectiveness of a cattle vaccination programme it should be developed alongside comprehensive bio-security measures to prevent the transmission of the disease from cattle to cattle. This should include limiting contact between cattle and local wildlife, stringent application of cattle testing, improving hygiene in cattle husbandry, and perhaps most importantly eliminating the spread of bTB between herds by better control of cattle movements.

16. IFAW believes that the most effective method to solve the problem of bTB is cattle vaccination, and this should be the priority of all governments that are either suffering outbreaks of the disease, or are at risk of suffering from them. In addition to this, we consider that if at the same time a programme of vaccination of potential wildlife reservoirs (in this case badgers) for the disease is applied in parallel or preliminarily, the disease may be controlled faster. However, based on the evidence seen in other countries we are convinced that in no circumstances will outbreaks be stopped by addressing the wildlife reservoir transmission alone, nor will the disease be totally controlled without developing an immunity among cattle (which can be achieved by successful vaccination programmes for the current strains of TB, or any new strains that may appear in the future). We question the claims made by those defending wildlife culling that in other countries bTB has been eradicated because of control measures in wildlife reservoirs, since, first of all, the disease has persisted, and secondly these were not the only measures taken, and therefore it is entirely possible that the effect of the culling alone would not be very significant. Therefore, if there are financial limitations in addressing the problem from multiple fronts, resources should be channelled to cattle vaccination alone, since it has the potential to entirely solve the problem in the long term.

17. Considering the cost that any vaccination programme entails, cattle vaccination may not need to be applied across the whole of England but it could be used to reduce the level of infection in areas of concentrated disease. Vaccination could be applied either on a regional or zoned basis, or as a firewall to prevent further spread to adjacent areas, and still be effective.

18. In addition to vaccination, there are other methods to improve immunity to bTB in cattle. Several factors affect the immunity and susceptibility of both cattle and badgers to infection: nutrition, stress, housing, transportation and selective breeding may all be worthwhile factors to consider, so any measure that may address these factors may have a positive effect in boosting the cattle immune system and in fighting infection so it does not develop into a disease. For example, the farm trials carried out by Mr Dick Roper in Northleach, Gloucestershire and the farms treated by Mr Goodwin Jones of Trace Elements Services Ltd illustrate that there are significant benefits of improved immunity from the inclusion of trace elements in the diet of cattle.

January 2013

Written evidence submitted by Team Badger

1. Team Badger is a coalition of national, local and grass roots animal and wildlife welfare organisations representing millions of individuals. Our member organisations include Animal Aid, Badger Trust, Blue Badger, Born Free, Care for the Wild, David Shepherd Wildlife Foundation, Gloucestershire against badger shooting, HSI UK, International Fund for Animal Welfare, International Animal Rescue, League Against Cruel Sports, Network for Animals, PETA, RETHINK Bovine TB, RSPCA, Save Me (founded by Dr Brian May), Stroud 100 and Viva!

2. We are united in our opposition to badger culling as a means to reduce the disease in cattle as it is not a scientifically sustainable solution that will provide a long-term reduction in the disease. We are convinced that the control of TB in cattle can be achieved without the culling of wildlife through a range of policy options including improved biosecurity and vaccination of badgers, and, in the long-term, vaccination of cattle.

3. We are committed to working with all stakeholders to find a long-term sustainable solution to bovine TB. Whilst the transmission of bovine TB from badgers is not recognised as the single biggest cause of the disease, controlling the disease in the badger population through vaccination could be part of the solution.

4. Many individual members of Team Badger have made submissions to this inquiry and we will not collectively repeat ourselves here. Instead, we would like to take the opportunity that this inquiry provides to sketch out a long-term humane solution that we feel will be good for farmers, good for taxpayers and good for cattle and badgers. This solution would be to control the disease in badgers through a sustained badger vaccination programme—the Badger Vaccination Initiative (BVI)—a Team Badger co-ordinated voluntary vaccination programme, which we hope will be supported by farming and landowning organisations including the NFU, and Government and Government agencies including DEFRA, FERA and Natural England.

5. The BVI would deliver in specific areas a targeted programme run by trained volunteers but financially backed by Team Badger members to vaccinate badgers who would then likely become resistant to the disease. The disease would therefore be reduced in the badger population and any risk of transfer to other badgers, and to cattle, would be reduced.

6. Team Badger members already have a great deal of experience in running such a scheme. Many organisations already run or are involved with badger vaccination programmes around the country and are willing to lend expertise to this endeavour. Team Badger members can identify a very large number of individuals who are willing to become volunteer badger vaccinators. Whilst FERA has a waiting list of individuals who want to train as vaccinators and the next training course is proposed to be in August 2013, we are keen to partner with FERA to expand its current training programme and enable those members of the public who want to help to be trained as quickly as possible. We believe that training enough individuals to undertake a sustainable vaccination programme can be achieved before this date.

7. We appreciate that FERA, like all Government agencies, faces budget constraints and so hope that through partnership more training can take place without more public expenditure being required. One option Team Badger is keen to explore is by working in partnership with FERA, and those Team Badger members that have already delivered trained personnel, we could deliver badger vaccination training to professionally supervised and coordinated members of the public in a proactive and timely fashion. We predict that savings can be made to current training and vaccination costs through the economies of scale that will arise as the programme of vaccination is enlarged.

8. We envision that the BVI would be established as a non-profit company limited by guarantee, with a steering committee overseeing its work. We aim for members of this committee to include Team Badger representatives, and representatives from other stakeholders including farmers' bodies, and be led by an independent chairperson who would report to DEFRA on progress.

9. We are very keen to partner with the NFU and individual farmers to assist them in reducing the prevalence of TB in badger populations through this programme. Unlike the policy of culling badgers that is hugely unpopular with the public, not proven to be effective at reducing bovine TB by any significant degree and places a large financial burden on farmers, the BVI will provide an opportunity for farmers to request that badgers in their local area be vaccinated instead. Modelling has shown that the differences between the outcomes of culling or vaccinating badgers are quite modest so using the BVI in targeted areas could see similar reductions in disease cases with less financial cost to the farmer.

10. Initial targeted areas could begin in the areas of West Gloucestershire and West Somerset (perhaps in the identified pilot cull areas). Due to the voluntary nature of the BVI this would certainly be a more cost-effective solution for farmers, with little or no cost to them.

11. We look to partner with Natural England in this initiative, including identifying badger populations in relevant areas.

12. Team Badger is now in the process of engaging with these identified stakeholders, and is confident that a way forward beneficial to all parties can be found. We are also in ongoing dialogue with the Welsh Government to learn lessons from its badger vaccination programme and to explore with the Welsh Government opportunities to assist in expanding and building on the excellent work achieved so far in any way we can.

13. The BVI will follow a similar model to other voluntary farm stewardship programmes, linking industry and environmental groups with DEFRA and Natural England. DEFRA is aware of Team Badger's opposition to culling as ineffective and unscientific, and we hope that the Government will also accept our invitation to partner in this initiative.

14. The Government has made clear its support for healthy cattle and healthy wildlife, and support of the BVI as opposed to culling will provide an opportunity for it to succeed in these aims whilst being sympathetic to the public, parliamentary and scientific opposition to culling.

15. It is unfortunate that the Government decided in June 2010 to reduce the Badger Vaccine Deployment Project from six areas to just one, with the need to consider carefully all public expenditure cited as one reason for this decision. Team Badger is willing to contribute resources, time and expertise into the BVI, which will reduce the public expenditure required and thus prove good value for taxpayers. We hope that through partnering with us to reduce TB in badgers through vaccination, the Government will see this as a more attractive policy option than culling.

16. This is intended to be a summary of a very viable solution that protects wildlife, whilst providing good value for money for farmers and taxpayers. Further detailed work is required and engagement with relevant stakeholders is ongoing. It is envisaged that further information can be provided as the BVI develops, either through a second written submission or through providing oral evidence if required by the Committee.

Written evidence submitted by Secret World Wildlife Rescue

1. Secret World Wildlife Rescue is a large multi-species wildlife rescue, rehabilitation and release centre in Somerset. Our location means that we attend to large numbers of adult badger casualties each year and are the main UK centre for the rearing and rehabilitation of badger cubs. As an organisation we ensure that we are up to date with the issues concerning tuberculosis (TB) in cattle and badgers and have presented research work on the subject at national and international conferences. Our badger release policy takes into account disease risks and includes testing for bovine tuberculosis and vaccination of badgers with BCG.

2. Secret World Wildlife Rescue has been supportive, in terms of both staffing and funding, of badger vaccination programs in the field and consequently has experience of the practicalities of this.

BADGER VACCINATION

3. The intramuscular badger BCG vaccine licenced for use in 2010, has been shown to protect badgers against TB, with significant reduction in the severity of disease in vaccinated animals. Field trials have additionally shown the vaccine to reduce positive serological results in badgers by 74%. As well as reducing disease in individual animals, BCG vaccination also has other significant indirect effects such as protecting unvaccinated badger cubs in setts where a proportion of the adult animals have received the vaccine.

4. Badger vaccination is being used in field trials in England (although these have been reduced because of funding) and extensively in Wales. We would encourage the continuing support of scientific field trials in order to increase farmer confidence in the badger vaccine, especially with respect to its effect on TB in cattle.

5. In addition to official vaccination programs, the vaccine has also been used by many wildlife groups, such as ourselves, to vaccinate badgers at the request of farmers. Using the intra-muscular vaccine is time consuming. It is also costly in terms of equipment (cages, fridges, bait), training and licencing of staff, and the cost of the vaccine itself. Despite this, many people are happy fund vaccination and/or give up their time to help carry it out and we have tried to support their efforts.

6. Whilst organizations such as our own are happy to continue to carry out vaccination, we realize that we are doing this on a very small scale. A co-ordinated large-scale vaccination policy is needed to ensure that those farmers happy to have badgers on their land vaccinated are able to do so and that maximum numbers of badgers are protected. Badger vaccination should be part of a raft of measures, alongside cattle controls and increased biosecurity, put into place on farms where cattle TB reactors occur.

7. Since government policy is still to cull badgers in some areas, to which we are strongly opposed, we would like assurances that badgers that have been vaccinated will not be culled.

8. An oral BCG vaccine is a long way into development in Ireland and has been used successfully in New Zealand. The oral vaccine would overcome many of the delivery issues we experience when using the intra-muscular vaccine. We believe that delivery systems can be developed to prevent the exposure of non-target species (wild and domestic), whilst ensuring maximum vaccination of badgers. We would support the immediate use of the oral vaccine in badgers, when available, in the UK.

VACCINATING CATTLE

9. We believe that the use of a BCG vaccine in cattle is ultimately preferable to the vaccination of badgers. As a domestic species, cattle can be much more easily vaccinated than badgers and this means whole groups of cattle, as well as specifically targeted animals such as new-born calves, can be vaccinated.

10. We believe that a BCG vaccine is already available for use in cattle, as are suitable diagnostic tests to differentiate vaccinated from unvaccinated animals (DIVA tests). We would encourage and support immediate field trials of these.

11. There is much debate regarding EU legislation, the vaccination of cattle with BCG and potential effects on UK trade. EU legislation needs to be clarified immediately in order for this discussion to move forwards. It is our understanding the EU is not standing in the way of vaccination and is instead simply being used as a delaying tactic for those who support badger culling rather than cattle vaccination.

January 2013

Written evidence submitted by the NFU

1. The NFU is pleased to make a submission to the Environment, Food and Rural Affairs committee on the issue of TB vaccination. The NFU represents around 55,000 members, many of whom are affected directly and indirectly by bovine TB (bTB). Almost 35,000 cattle were slaughtered across Great Britain in 2011 as a consequence of the spread of the disease in cattle and wildlife.

2. The NFU strongly believes that a holistic approach is needed to control and ultimately eradicate bTB. No single solution can tackle the disease alone and a mix of solutions—testing and cattle controls, culling of infected wildlife and, in time, vaccination, must all play a part.

3. There has been a tendency amongst some groups to present vaccination of either cattle or badgers as a ready-made alternative to culling of infected wildlife, primarily badgers. From our perspective, vaccination must be seen as a complementary long-term strategy. Further work is needed to bring about effective and efficient deployment of vaccination for both badgers and cattle. Unfortunately, we believe that significant obstacles prevent vaccination from making a meaningful contribution to disease eradication in the short-term. It remains our view that a science-led proactive cull of badgers in TB hotspot areas is absolutely necessary in order to tackle bTB in both badgers and cattle. The organisation is committed to overseeing the execution of pilot culls in 2013 and wider roll-out of culling beyond.

4. To address what we perceive to be a gap the availability of independent information on bTB vaccination, the NFU believes there is a case for government to provide clear public information on vaccination, including research developments and progress towards developing usable vaccines. Above all, investment in research and development in UK field conditions is vital to delivering effective vaccines for cattle and badgers. We understand that government has invested around £23 million in such research since 1998 but it is critical to ensure continued funding is made available to allow vaccination to be deployed effectively in future.

INJECTABLE BADGER VACCINES

5. It is important to state from the outset that *vaccination of already infected badgers will do nothing to prevent transmission of bTB to other badgers and cattle*. Nevertheless, a number of field scale attempts have been made in recent years to deploy injectable vaccines amongst badgers in England and Wales, using the existing BCG vaccine.⁶⁹ At this stage, there is a lack of data thus far to verify the effectiveness of vaccine use in endemic areas. Ultimately, we believe that vaccination of badgers is likely to have the greatest potential for use in areas that do not yet have endemic disease in the badger population but may be considered at risk.

6. There are important practical constraints to deploying injectable vaccine over a wide area. Injecting a badger with vaccine must be done annually and requires considerable skill and expertise. What is more, trapping badgers in sufficient numbers is far from easy. Whilst there are now a reasonable number of trained lay-vaccinators, the cost of starting up as a commercial operator can be prohibitive.

7. Some funding has been introduced by Defra to assist voluntary organisations with the costs of training badger vaccinators. Nevertheless, in the absence of significant government funding, wider deployment of injectable vaccination will rely heavily on private commercial operators offering vaccination as a service. Farmers are not entitled to funding to complete the course themselves, yet it is their land on which access is required to undertake vaccination of badgers. This, combined with a degree of caution about allowing unknown volunteers onto private land, may be playing a small part in holding back potential to see more widespread take-up of injectable vaccine across the largest areas of land where commercial cattle herds are kept. We believe that Defra should reconsider the funding that is currently available to make it less cost prohibitive for a wider range of people to train as a lay vaccinator.

8. Under any circumstances, deployment of injectable badger vaccine is likely to be a costly exercise given the training required, traps, time involved and requirement to repeat the exercise annually to build immunity. The NFU has some practical experience having trained two lay-vaccinators to provide vaccination for farmers and landowners. Feedback from our members who have enquired into feasibility of vaccination has indicated that costs can vary from £2,500 to over £4,000 per square kilometre of land covered. According to information that we have received from the Food and Environment Research Agency (FERA), the total costs of the government-led Badger Vaccination Deployment Project (BVDP) in Gloucestershire have approached £1.5 million on an area just under 100 square kilometres. In our experience, a large proportion of the cost is incurred by the resource required to pre-bait a trapping point, with most vaccinators having to travel many miles for a series of days. These costs have made vaccination an unattractive investment for many farmers and landowners.

9. In order to make vaccination a more affordable option, in some cases farmers have been encouraged to pre-bait cage traps. This lowers the cost of vaccination but if the cost of the farmer's time is included, total costs still amount to £1,736 per km² (excluding travel and subsistence).

10. The ability to successfully trap and inject badgers can also be hampered by climatic and other conditions. Between May and October 2012, the NFU undertook trapping on six separate premises in Gloucestershire and

⁶⁹ A notable example is the Badger Vaccine Deployment Project organised by the Food and Environment Research Agency (FERA) in Gloucestershire <http://www.fera.defra.gov.uk/wildlife/ecologyManagement/bvdp/>.

Somerset representing a land area of over 8.66 km² using a combination of two in-house and one private lay-vaccinator. Due to extremely poor weather, the initial trapping rounds had a low capture rate and further trapping was required. After all trapping had been carried out by the end of the season eight badgers had been successfully caught and vaccinated.

11. At this stage, there is limited research available to demonstrate the effectiveness of badger vaccination in terms of disease incidence in cattle. A recent paper produced by FERA officials⁷⁰ based on research in Gloucestershire appears to present some encouraging signs of immunity build up in young badgers as part of a vaccination deployment project, there is still as yet no demonstrable impact on disease in cattle.

12. In view of this and the high-costs of injectable vaccination of badgers, the likelihood is that many farmers will opt to make precious investments in other disease management methods such as badger proofing of buildings.

ORAL BADGER VACCINE

13. Of all the approaches to vaccination the NFU believes that an oral baited vaccine is likely to make the most important contribution to the long-term eradication of TB and is the only way in which widespread vaccination of badgers can realistically be achieved due to its ease of deployment. In considering the long-term eradication of bTB, it is essential that government understands and seeks to remove the obstacles that lie in the way of being able to deliver an oral baited vaccine to badgers. It must also consider how best such a vaccine could be deployed to give the greatest impact. For instance, it would seem most appropriate for an oral vaccine to be used in areas free of endemic TB that lie on the frontier of disease spread to protect a healthy badger population.

14. The current state of play with regard to deployment of an effective oral vaccine is unclear but appears to remain some way into the future. Feedback from AHVLA and FERA suggests that there remain technical difficulties in creating a suitable vaccine for badgers, in particular the ability to make an ingestible and stable version of the BCG that remains both viable and palatable to badgers. It is vitally important that Government makes available sufficient resources in terms of research that is necessary to accelerate the availability and deployment of an oral baited vaccine that is cost effective and easy to deploy.

CATTLE VACCINES

15. The NFU is keen to see a cattle vaccine brought to the market as soon as possible. Nevertheless, even were an effective vaccine available to protect healthy cattle, steps would still be needed to tackle the reservoir of disease in wildlife. Without this, eradication of the disease will remain impossible as there will always be a source of reinfection.

16. Cattle keepers continue to harbour concerns over the efficacy cattle vaccines. Previous research indicates that the efficacy of the existing BCG vaccine in cattle is questionable at between 56% and 68% and has not been field tested in UK conditions.⁷¹

17. In addition to concerns over efficacy, there are two major hurdles over the use of existing bTB vaccines in cattle. The first concerns the need for a test to distinguish vaccinated from infected animals (a so-called DIVA test). Without this, it is likely that vaccinated cattle would respond to the current skin test, leading to more herds losing officially tuberculosis free (OTF) status. We understand that a test has been developed and approval in principal is being sought by AHVLA.

18. The second major obstacle concerns the need to amend EU legislation (Directive 78/52) surrounding the control of bTB which does not currently permit member states to deploy vaccination in cattle (due to the difficulties of distinguishing vaccinated from infected animals). A change to this legislation would require the European Commission to bring forward a proposal, which would carry support from other member states, the vast majority of whom do not currently have major problems with bTB in cattle. It is not clear from our discussions with the Commission that it is yet minded to consider tabling such a proposal. Indeed, we understand that with current levels of efficacy, it is unlikely that the Commission would propose the approval of cattle vaccination. What is more, any change to legislation could take a number of years.

19. Following discussions with Defra and the Commission's directorate general for health and consumer protection (DG Sanco), it is likely that a large-scale UK based field trial would be required before a cattle vaccine is available commercially. This could take considerable time although we believe it is appropriate for the Government to consider now how such a trial could be undertaken.

20. Without a change in legislation to permit cattle vaccination, the UK risks losing export markets worth over £1 billion were it to go ahead and use vaccination in cattle. Such a move could prove devastating to the industry without viable alternative markets.

21. Directive 64/432/EEC stipulates that raw milk and colostrum must come from cows belonging to a herd which is officially tuberculosis free. Milk from cows that have reacted positively to the tuberculin test cannot

⁷⁰ See Carter et al. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049833#pone.0049833.s006>

⁷¹ Defra : Options for vaccinating cattle against bovine tuberculosis

enter the food chain and must be destroyed by the farmer. Therefore, should animals react to the skin test due to vaccination this could result in milk being unnecessarily discarded.

22. Vaccination of cattle would come at a significant cost to producers (around £8.50 per unit, to be boosted annually). In terms of forward planning it is important that Government sought funding from the EU to pay for a contribution towards the costs of vaccination.

23. Further consideration will need to be given as to the most appropriate deployment of cattle vaccine to provide the best level of immunity.

24. Due to the fact that it would not be cost effective to vaccinate cattle in areas where there is a low disease risk, or that may be going to slaughter, there is a need to also keep a clear record of which animals have been vaccinated. This will ensure that the DIVA test does not have to be used on cattle that have not been vaccinated. It is vital that a record of vaccination remains with each animal throughout its life, during which it may make a number of movements.

25. The NFU would be delighted to discuss any of these points further and provide additional information on any aspects that the committee may be interested in exploring.

January 2013

Written evidence submitted by Carla Kidd

I am writing with regard to hopefully, help, to convince you that badger vaccination is the only acceptable way forward, in the absence of any viable cattle vaccination, to tackle BTB in cattle herds.

We are private landowners, who share their land, with a well established, active badger sett. Since we heard the news, I got in contact with Cornwall Badger Rescue, to find out how we could help in trying to find alternatives to culling, it was then that we found out about badger vaccination. Since that moment, we have arranged to vaccinate our badgers, even though we know BTB is endemic in cattle, but hopefully will show the farmers concerned, there is an alternative and that the general public are trying to be pro-active and also vaccinating our badgers will contribute, to help the small 15% of badger population which is susceptible to BTB. We have managed to vaccinate two badgers so far, which we are thrilled with due to late time in season and unfavourable weather conditions. In 2013, we plan to vaccinate during optimum time. We are paying for this ourselves, along with our neighbours, for no financial gain, peace of mind only. Since then, our MP, Andrew George, has been working towards setting up, a voluntary badger vaccination scheme, for those farmers and landowners who wish to take the initiative now and hopefully avoid the unpleasantness a badger cull will bring.

I won't go into all the scientific evidence which is against this again, I'll leave that to the experts. I am offering you a viewpoint from a general member of the public. However, as a lay person, who got as involved as she could in the vaccinating process, I would like to offer my observations of the actual process as follows:

Bob, from Cornwall Badger Rescue, made the process seem easy, even though he had a lot of paperwork to do re. licences etc, also the prices of cages seems steep even with 50 pounds reduction to charities. There's two things the Government should look into, the vaccination process itself is very straightforward, the difficulties arise with all the red tape our government seems to have wrapped around the process. To us, (members of general public) it almost looks deliberate, that they want it to appear difficult. It takes three—four weeks to get licenses, wasted time, in my opinion, especially for a problem, the Government, NFU, and DEFRA say, needs to be addressed urgently. It's a joke! Sorry, but it is exactly how it looks to me. Oral vaccine, yes, would also be a good idea but better than injectable vaccine? I don't think so. How long would it be before farmers would be hooting about ineffectiveness due to the fact they can't be sure the badgers have eaten the food with vaccine! It's inevitable, since BTB is endemic in cattle and will not go away until farming methods are addressed, not culling badgers. At least, injectable vaccine is tangible, you know it's been done and can confirm to farmers, etc, the numbers of badgers which have been done.

I have been reading that, some organic farmers are adding back vital minerals to their soil and around badger setts, minerals such as selenium. Selenium is a mineral which has been shown to be deficient in cattle with BTB. Maybe I am ill informed, but surely this also is something, all farmers should be doing now, off their own backs. Selenium is not harmful if ingested, so why isn't a suitable mixture, tonic etc available on a large scale for cattle farmers? Maybe it is; if so why isn't it being used? Apart from the fact we want to protect what's left of our wildlife and countryside, these reasons and many more should be a good enough explanation of why so many people oppose this cull.

Please do not hesitate to contact me should you need any further explanations.

January 2013

Written evidence submitted by Dairy UK

EXECUTIVE SUMMARY

1. Dairy UK represents the interests of dairy farmers, producer co-operatives, manufacturers of dairy products, and processors and distributors of liquid milk throughout the United Kingdom. Between them Dairy UK's members collect and process about 85% of UK milk production.

2. Dairy UK proposes to address the issue of vaccination of cattle in relation to exports of milk and dairy products.

3. Our conclusion is that if vaccination of cattle were to be adopted without the agreement and support of the EU then, unless Regulation 853/2004 is changed (requiring the agreement of Member States voting by qualified majority), UK milk and dairy products which use milk from vaccinated cattle would lose their entitlement to their EC identification mark, and would be excluded from international trade.

4. The result would be an overhang of unused product or raw milk seeking an outlet in the UK. This would result in:

- (a) a collapse in UK product prices with a resultant intense squeeze on processor margins;
- (b) a consequential collapse in UK raw milk prices; and
- (c) a contraction of the industry.

BACKGROUND

2. The Environment, Food and Rural Affairs (EFRA) Committee on 8th November announced they would be carrying out a new inquiry into the vaccination of badgers and cattle in relation to Bovine TB.

3. The Committee wishes to receive evidence from interested parties on TB vaccinations for badgers and cattle, including the impact and challenges of vaccination on cattle and cattle products.

4. The Committee is inviting interested parties to address these and related issues in writing by Friday 11 January 2013. Dairy UK has requested that it be permitted to make its submission by 18th January, and this has been agreed by the Committee Clerk.

5. Dairy UK proposes to address the issue of vaccination of cattle in relation to exports of milk and dairy products.

EXPORTS OF MILK AND DAIRY PRODUCTS

6. The European Union allows free movements of milk and dairy products within its borders on condition that these products meet the requirements of Regulation 853/2004 laying down specific hygiene rules for food of animal origin. These requirements cover both the raw milk used, and its processing into milk and dairy products.

7. Milk and dairy products meeting the requirements of the regulation must carry an identification mark (an oval containing the ISO code of the Member State (UK for the United Kingdom), the approval number of the establishment processing the product, and the abbreviation EC). Only products bearing such a mark are permitted to be traded across EU borders.

8. For raw milk, the requirement in terms of bovine tuberculosis is that raw milk must come from cows belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis. However, raw milk from animals that do not meet this requirement may be used with the authorisation of the competent authority if they do not show a positive reaction to tests for tuberculosis, nor any symptoms of the disease, after having gone a heat treatment of at least pasteurisation.

9. There is no provision in Regulation 853/2004 for milk to come from animals which have been vaccinated against tuberculosis, and no category "officially free of tuberculosis where vaccination is practised".

10. This leads to the conclusion that if vaccination of cattle were to be adopted, unless Regulation 853/2004 is changed (requiring the agreement of Member States voting by qualified majority), UK milk and dairy products which use milk from vaccinated cattle would lose their entitlement to their EC identification mark, and would be excluded from trade within the EU.

11. The potential economic impact on the industry is discussed in the annex below.

CONCLUSION

12. Unless Regulation 853/2004 is changed, vaccination of cattle against tuberculosis would mean that UK milk and dairy products using such milk would lose their entitlement to their EC identification mark, and would be excluded from trade with other EU Member States. Cattle in Scotland and Northern Ireland are unlikely to undergo vaccination so products from these parts of the United Kingdom might continue to be able to be exported. Depending on the extent of vaccination of cattle in England and Wales, either all exports to

other Member States from England and Wales would be prohibited, or exports from those establishments using milk from vaccinated cattle.

13. In addition, it is possible that third countries might restrict exports from all parts of the UK if they were not satisfied that these products were made from milk from herds officially free or free from bovine tuberculosis.

14. Whatever the extent of the prohibition on exports, under any conceivable scenario, the UK dairy industry would be subject to a major price collapse and subsequent contraction.

17 January 2013

Annex

ECONOMIC IMPACT

1. The economic impact of the exclusion of any portion of the British dairy industry from trade within the EU would be potentially catastrophic, and it would lead to a severe contraction of the industry.

2. Exports of dairy products are responsible for a significant proportion of UK milk production. The latest annual figures for UK dairy exports cover 2011.

EXPORTS OF DAIRY PRODUCTS FROM THE UK 2011

<i>Product</i>	<i>EU</i>	<i>Non-EU</i>	<i>Total</i>	<i>% of UK production</i>
Raw Milk	495,675	0	495,675	3.6
Liquid milk	81,969	845	82,814	1.2
Cream	72,006	438	72,444	29.2
SMP	14,045	9,653	23,698	35.6
Whole milk powder	29,224	25,713	54,937	124
Evaporated and condensed milk	12,491	441	12,932	12.2
Yogurt	25,162	800	25,962	8.8
Butter	12,527	1,678	14,205	11.1
Cheese	110,080	13,513	123,593	32
of which processed cheese	19,336	350	19,686	54.7
of which Cheddar	33,905	7,515	41,420	16.6

3. Exports are clearly a significant percentage of production for a number of products. In total exports to the EU accounted for 16.0% of the volume of raw milk, (including cream and skim fractions) produced in the UK in 2011. Exports outside the EU account for another 3.3%, to give a total for all exports of 19.3%.

4. The extent of the potential damage from an EU export ban is difficult to assess accurately as it could involve a number of scenarios and separate data to quantify the effect on trade flows is not readily available.

5. Any ban on British dairy products in the EU would probably be replicated by a number of non-EU countries. The number of countries that would take this action is a matter of speculation; however, non-EU countries have in the past followed decisions by the EU when it has imposed trade restrictions on its members. The extent to which non-EU countries may do so would also be influenced by global market situation and whether prices were falling or rising. If prices were falling some countries would impose bans on UK product as an opportunity to renegotiate existing contracts.

6. Conversely, the impact of any EU wide ban on British exports may be mitigated by separate status being given by the EU to the devolved administrations. On several occasions in the recent past Northern Ireland has been treated by the EU as a separate geographic entity for the purposes of managing animal disease outbreaks by virtue of its separation by sea from Great Britain. This may again be acknowledged by the EU.

7. The exclusion of Northern Ireland from any EU trade ban would reduce the impact on UK exports as Northern Ireland accounts for a significant proportion of total UK trade in dairy products. This is especially true of milk powders. However, precise figures for the exports of dairy products from Northern Ireland are not available, but at a rough estimate they could account for over half of UK exports expressed in milk volume.

8. Conceivably similar treatment may be extended to Scotland or even certain regions of England. However this may not happen because of the absence of clear geographic separation from TB infected areas in England and Wales. It is not clear at this stage how the EU authorities may choose to respond. However, even if restrictions were imposed only on infected areas of England and Wales, this would still have potentially catastrophic consequences.

9. The impact of any ban could also be mitigated to a certain extent through import substitution. UK product previously exported from the UK could be discounted in the market to displace imports of dairy products.

IMPORTS OF DAIRY PRODUCTS INTO THE UK 2011

<i>Product</i>	<i>EU</i>	<i>Non-EU</i>	<i>Total</i>
Raw Milk	104,840	0.0	104,840
Liquid milk	65,223	4	65,227
Cream	56,091	0	56,091
Skimmed milk powder	44,017	28	44,045
Whole milk powder	20,239	45	20,284
Evaporated and condensed milk	41,856	46	41,902
Yogurt	147,267	866	148,133
Butter	69,069	4	69,073
Cheese	399,558	9,279	408,837
of which processed cheese	46,883	51	46,934
of which Cheddar	90,999	7,605	98,604

10. In total imports equate to nearly 38.5% of UK raw milk production. However, exports for certain products exceed imports, such as whole milk powder, and whilst some UK products could substitute for certain imports, such as cheddar, the majority of imports are for particular product types not manufactured in the UK, such as continental cheese varieties, branded products or products sold on provenance. This would place a limit on the extent of import substitution that could be achieved.

11. Overall, therefore, in any scenario that obstructs a significant volume of UK exports, the result would be an overhang of unused product or raw milk seeking an outlet in the UK. This would result in:

- (a) a collapse in UK product prices with a resultant intense squeeze on processor margins; and
- (b) a consequential collapse in UK raw milk prices.

12. Whatever the volume of product involved, any price collapse would inevitably be significant. This is because it is one of the characteristics of dairy products that as a staple consumer item demand is relatively insensitive to price. Consumers do not significantly vary their level of consumption in response to price changes. Consequently even small variations in supply can drive large price changes.

13. A definitive econometric analysis is not available but the experience of the world market is instructive. UK and EU prices now generally follow the price trend in the world market. Historically variations in global milk supply of around 1% can induce price changes in the order of 10%. Consequently even if the export ban was restricted to England and Wales, the industry would be subject to a severe shock.

14. The impact on milk producers would vary. A portion of dairy farmers supplying milk for the production of liquid drinking milk are covered by contracts offered by major retailers in which the price is determined according to production costs. These producers would therefore not be affected by a fall in prices for dairy products.

15. These arrangements were entered into by retailers to ensure security of supply. Smaller retailers may therefore seek to enter into similar arrangements if they felt that any price collapse threatened to jeopardise the availability of liquid milk.

16. Retailers have not extended these arrangements to products that are available internationally, such as cheese. The continued availability of imports would mean that they would not have a commercial incentive to do so. The exception would be for those products where UK provenance was of importance. Consumer loyalty to product of British origin is of growing importance to the market, but it is limited to only a portion of the market.

17. This would leave a sizeable portion of UK dairy farmers being subject to prices that would inevitably be far below the cost of production. Current UK prices are at historic levels, but even now, producer lobbying organisations contend that they are inadequate to cover the cost of production. The cost efficiency of dairy farmers varies enormously, but not the extent that they could tolerate a prolonged fall in prices.

18. The UK dairy industry would therefore contract until either a market balance was restored by a cut in production, or access to export markets was regained. More significantly, if the UK dairy industry was unable to access export markets then it would not have the opportunity of participating in the growth in world demand for dairy products. The industry would be unable to grow to realise its full potential to make a contribution to the UK economy.

January 2013