Options for the use of badger vaccines for the control of bovine TB

1 Executive summary

E1. This summary sets out the main constraints around efficacy, legality, acceptability and practicality of badger vaccination. These have been used to define a set of options which represent the 'most likely' scenarios for how badger vaccines might be used. The detailed arguments leading to these conclusions are set out in **Section 2** and referenced throughout this summary. Detailed options scenarios on how vaccines might be used are set out in **Section 3**. These scenarios will be used to help steer the research programme by defining research priorities and the necessary vaccine properties required to deliver vaccination in these ways. An economic assessment is made in **Section 4**.

1.1 Approach

E2. Badger vaccination has potential benefits:

- in high incidence areas to reduce prevalence
- in 'buffer' areas to prevent spread
- in low incidence areas to prevent new hotspots becoming established

E3. As cattle breakdowns are the most readily available proxy for disease in badgers it will be difficult to separate the benefits of preventing spread from other factors such as pre-movement testing (Section 2.2). The effect of reducing prevalence will be most easily identifiable in areas of high cattle disease and this is where 'proof of principle' use should focus.

E4. The disease control benefit from badger vaccination relies on both the efficacy of the vaccine and the level of use. Initial rollout will need to be coordinated and may need to be incentivised and/or compulsory to ensure sufficient uptake to demonstrate a benefit. A regional approach will be required to account for local differences. Not all badgers will need to be vaccinated to cause a reduction in prevalence over time but the greater the use the greater the benefit.

E5. Benefits will be realised over a number of years, in general terms the longer the vaccination campaign the longer the benefit will be maintained.

E6. To maximise the overall disease control benefits it is essential to maximise those areas within our control, particularly: the proportion of land on which vaccination occurs; the degree of coordination; the efficiency of delivery and the duration of use (Section 2.3).

E7. The only potential legal barriers to vaccination are in EU law. However, any compulsory vaccination would require new primary legislation. (Section 2.4)

E8. Large scale badger vaccination policy will primarily use oral vaccine. Widespread use of injectable vaccine is not considered practical. Injectable badger vaccine will be pursued where this progresses the oral vaccination programme (including demonstrating the benefit of badger vaccination) or other minor uses. (Section 2.5)

E9. Badger vaccination should not be compulsory. The longer term aim should be for demonstrable benefits and self sustaining uptake. However, initial rollout will require some form of incentives and/or support to generate uptake. (Section 2.6)

E10. The impact on the individual farmer will be crucial in determining uptake and in reaching the long term aim for vaccine use to be self sustaining. Some form of 'pump priming' investment will be required at roll out to demonstrate benefits and generate sufficient uptake. Government is unlikely to be able to provide 'new' money to fully fund roll out. Funding may need to come from a combination of sources that could include Government, the agricultural industry and the wider community (Section 2.7)

E11. There are potentially roles for Government, farming industry and the wider community in a badger vaccination programme. There is no value in Government limiting vaccination availability to target use.

E12. Coordination is essential and has the greatest chance of success if organised at the local level by the industry and wider community. Government's role is best suited to guidance on best practice. Government would not be involved in delivery, this is best done at the local level.

E13. Some form of Government and industry monitoring is important especially at the early stages. Involvement of the veterinary profession will be important not only to prescribe the vaccine but to assist in ensuring and monitoring its effective delivery.

E14. There are potential commercial opportunities for coordination and delivery in the longer term and any government involvement should diminish with time. (Section 2.8)

E15. Oral vaccine bait may need to be mixed at the time of use and multiple baits will be required for each badger, vaccination will need to be continued for at least 5 years. Baits will be sited near setts out of reach of cattle and the risks to other species including cattle will be minimised and tolerated. (Section 2.9)

E16. Targeting will be used to enhance effectiveness against a background of general availability. The approach used will depend on whether an area is classified as high, buffer or low risk. Assigning the risk category according to parish testing interval (PTI) will provide the simplest most transparent mechanism.

- Targeting in high risk areas will aim to maximise uptake and break up the pattern of disease
- Targeting in buffer areas will aim to maximise the contiguous boundary to prevent further spread
- Targeting in low risk areas will aim to prevent new hotspot formation

E17. Vaccinated areas should aim to be a minimum of $100km^2$ to maximise the potential benefit and this could be a criteria to receive support. Priority will be given to high risk and buffer areas in terms of resources to support vaccination. However, use in other areas will not be prevented. With a high level of uptake a maximum of around 2 million vaccine doses will be required per year. (section 2.10)

1.2 Scenarios for use

E18. All scenarios rely on non-compulsory use of oral badger vaccine. Scenarios are not necessarily mutually exclusive and Scenario 7 – individual use, assumes the vaccine will be generally available for use by those wishing to purchase it to do so and can be used alongside all other scenarios.

1.2.1 High risk areas

E19. For high risk areas there are three scenarios:

- Scenario 1 – Government/Farming industry coordinated 'proof of principle' roll out to demonstrate a benefit and encourage long term uptake.
- Scenario 2 – Community coordinated use involving farmers and other landowners and potentially other interested parties such as wildlife groups will help maximise coverage over a given area.
- Scenario 3 – Supported individual use to allow those who perceive a need to take action having weighed up the potential costs and benefits to themselves within a framework of support which could include funding.

1.2.2 Buffer areas

E20. Two scenarios have been identified for 'buffer' areas:

- Scenario 4 - Government/industry coordinated buffer preventing further spread of the disease by developing a continuous vaccinated buffer around endemic areas to maximise the containment effect.
- Scenario 5 - Community coordinated buffer involving farmers and other landowners and potentially other interested parties such as wildlife groups using natural boundaries to help maintain the benefits of a non-contiguous buffer

1.2.3 Low risk areas

E21. Two scenarios have been identified for low risk areas although the second of these is equally applicable to all areas and is effectively untargeted use:

- Scenario 6 - Reactive area vaccination in response to an isolated breakdown to help prevent infection being transferred to the local badger population or from establishing a significant pool of disease.
- Scenario 7 - Individual use to allow those who perceive a need to take action having weighed up the potential costs and benefits to themselves.

1.3 Economic assessment

E22. This economic assessment will help give an indication of how badger vaccines should be prioritised relative to other approaches to control bTB both on the individual level and for national disease control.

E23. The assessment uses a model which makes a number of assumptions which may in future prove to be inaccurate, as with all models the results should therefore be treated with caution.

E24. The model has been used to assess widespread use of badger vaccines in high-risk areas (PTI1). This is equivalent to high take-up of Scenarios 2 or 3.

E25. 5.The potential costs of vaccination are also uncertain as these will depend to a high degree on the final formulation of the oral vaccine. Two different costs per bait of £4 and £10 have been considered to allow for different doses of vaccine.

E26. Two sets of costs and benefits have been assessed based on different assumptions, one ‘low cost’ and one ‘high cost’:

E27. The low-cost scenario predicts a cost of around £320 per km^2 per year and provides a net benefit the size of which depends on the badger contribution to disease used in the model. As might be expected, the greater the badger contribution modelled the greater the net benefit. This net benefit is in terms of the costs of vaccination being offset by savings due to reduced costs from breakdowns. It is also predicted there would be an improved disease picture at the end of this period.

E28. The high-cost scenario predicts a cost of around £950 per km^2 per year and provides a net cost. As above the greater the badger contribution modelled the greater the potential benefit and therefore the closer vaccination is to breaking even. However, it is important to note that although there would be a net cost in this model there would still be a predicted improvement in the disease picture at the end of this period.

1.4 Conclusions

E29. This paper sets out the most feasible scenarios for the widespread use of badger vaccines. The analysis demonstrates that these are likely to rely on oral vaccination on a non-compulsory basis and that such a programme of vaccination could be cost-effective.

E30. These are the lead options and therefore give a reasonable basis on which to make decisions regarding prioritisation of the vaccine programme. The next step of the process will be to develop a business case for badger vaccination based on these findings

E31. However, it is recognised that changes in the disease picture and other factors may alter some of the issues discussed. No options have been completely eliminated.

E32. This paper was discussed with stakeholder groups at a meeting on the 3rd of April 2008 and has been endorsed by them.

E33. The groups who have agreed to endorse this paper and its conclusions are:

- NFU
- NBA
- BVA
- BCVA
- Badger Trust
- RSPCA
- FUW
- NFU Wales
- LAA
- The National Trust
- The Wildlife Trusts
- Defra TB Advisory group

2 Key Issues

1. This section discusses in detail the key issues surrounding vaccination of badgers to control bTB. At the end of each section is a summary of key which have been used to develop the options scenarios in Section 3.

2.1 Introduction

2. Vaccines for badgers are seen as potentially significant future contributors to the control of bTB. However, it needs to be recognised that vaccines can never represent a single answer to the problem of bTB.

3. As for many other disease control strategies, a combination of control measures is most likely to be successful in controlling bTB. Vaccination is only being considered alongside other disease control measures; it cannot be successful on its own.

4. Whilst considerable efforts are being made to identify and develop new vaccines against bTB both within the UK and elsewhere, BCG (Bacille Calmette Guerin) is currently the only candidate that could be available for use in badgers in the near future.

5. BCG has been shown to be safe and to evoke an immune response in badgers. It has been shown to offer protection against experimental challenge with *M. bovis*. BCG is a good candidate for badger vaccination without interfering with existing control measures. The present programme of research into the use of a vaccine for badgers has been underway since 1999.

2.1.1 Vaccination policy development

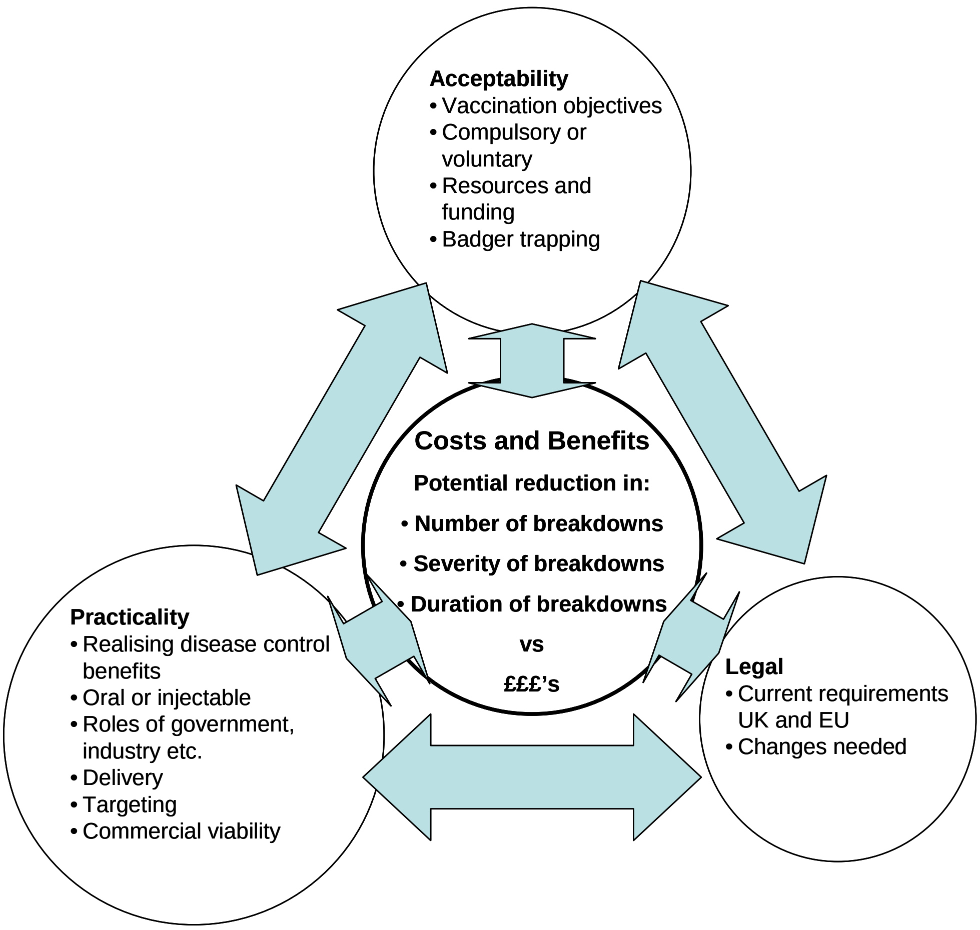
6. To date work on bTB badger vaccination has been primarily research led - the aim has been to show that vaccines for bTB in badgers are possible and to identify the lead candidates. This work has been successful and candidates have been identified.

7. Now that we know vaccination of badgers against bTB is scientifically possible we need to determine how vaccines might be used. The need for this is two fold:
   - To ascertain if the benefits of vaccines will be sufficient to ensure uptake and justify their use when balanced with the costs associated with developing and using them; and
   - To understand the properties required of the vaccines to influence further development: both scientific e.g. what is the minimum efficacy required; and practical e.g. how do they need to be stored and used.

8. The ultimate aim of this work is to develop a business case for vaccine use. This business case will support a decision on the future of the bTB vaccines programme in mid 2008.

9. There are a number of different ways in which vaccination could be used to tackle bTB in badgers, each with associated benefits and issues, these are discussed in the sections below. At the core of these is the balance of costs versus benefits in terms of disease control but there are also wider issues that need to be taken into account and balanced, primarily:
   - Acceptability: It may be possible to vaccinate but do people want it and would they use it?
   - Practicality: Can it actually be done on the ground? This includes whether the vaccine can be commercialised; and
   - Legal: What is allowed? This includes discussions with the EU and other Member States.

10. These issues cannot be considered in isolation and will interact and constrain each other. The diagram below summarises these issues and their interactions. For badger vaccination practicality issues are the greatest potential barrier.



11. The policy approach being adopted is to examine the issues in turn to balance the limitations of practicality, acceptability and the legal framework in order to maximise the benefits and minimise the costs, this is set out in the remainder of

Section 2. Ultimately a number of scenarios for potential use of a vaccine are derived from these constraints and outlined in **Section 3.** An economic assessment of badger vaccination is made in **Section 4**.

12. It is recognised that, while work on badger vaccination is progressing, a deployable vaccine is still several years away and that a number of factors which would impact on any delivery policy could change significantly in that time. This includes the overall level and distribution of disease, the general farming landscape and Government policy. The aim throughout the paper has been to maximise the choices available rather than to adopt specific policy approaches and the sensitivity of the conclusions to the potential changes identified above has been considered. It is expected that policy development in this area will be an evolving process as more information becomes available. This paper therefore represents a starting point for this process.

2.2 Badger vaccination objectives

13. The disease control objectives of badger vaccination considered here are twofold:
    - to reduce spread of bTB
    - to reduce the level of disease in high incidence areas in both cattle and badgers

14. The focus between these two objectives will help determine how badger vaccination is deployed in different situations.

15. Other potential objectives that have been raised in the context of vaccination relate to its use in conjunction with badger culling were a decision taken to allow it. While no decision has been taken on culling it is not practical to make any detailed assessment of these approaches. This paper therefore does not consider the use of vaccination in combination with culling.

16. Whatever the decision on culling, badger vaccination has the potential on its own to be a valuable tool in combating the wildlife disease reservoir both by reducing spread and the overall level of disease.

17. In addition to the disease control objectives there is also the objective of reducing the overall economic impact of the disease both to the farming industry and the taxpayer.

2.2.1 Reducing spread

18. Spread of bovine TB can occur either through cattle movements and/or contacts or transmission amongst wildlife and then to cattle. The dynamics of spread are different for cattle and wildlife mediated spread.

19. Cattle movements can result in new breakdowns appearing almost anywhere in the country over relatively short time periods. If undetected this could result in subsequent transmission to wildlife and the establishment of a new hot spot.

This risk has been reduced but not eliminated with the introduction of pre-movement testing.

20. By contrast wildlife transmission will result in a slower expansion of endemic areas as the disease becomes more established and spreads between animals. However, disease in wildlife is generally only detectable through transmission to cattle and subsequent breakdowns. The wildlife disease picture is therefore confounded by cattle to cattle transmission - contacts across farm boundaries would result in a slow-moving expansion of endemic areas, although this risk is reduced by contiguous herd testing. The relative contributions of cattle and wildlife transmission are hard to determine and hotly debated.
21. Similarly there can be levels of bTB in wildlife that do not translate into herd breakdowns. It is not clear whether there is a simple relationship with a certain level of disease in wildlife population leading to a tipping point of infection into cattle or whether a number of more complex factors are involved. This makes it difficult to define a clear ‘edge’ or ‘buffer’ in which vaccination of badgers could be used to successfully address the issue of spread.

22. Given these uncertainties badger vaccination will have the best chance of tackling spread when used in a large-scale coordinated manner so that treatment area has a good chance of including the most effective ‘buffer’ zone using cattle breakdown history as a proxy to identify this.

23. Outside of these buffer zones in low incidence areas where the level of wildlife infection is thought to be low or non-existent, vaccination could provide benefits by preventing the establishment of new hotspots: from the introduction of infected cattle and subsequent transmission to wildlife; or prevent any low level disease that is circulating in the wildlife population from tipping over into cattle. However, as the most realistic measure of success is a reduction in herd breakdowns, which are sporadic and minimal in these areas, it would not be possible to distinguish the benefits of such an approach from other approaches such as pre-movement testing.

2.2.2 Reducing prevalence

24. Reducing the number of susceptible badgers and the level of bacterial shed from animals which become infected will inevitably lead to a reduction in disease prevalence. The magnitude of the reduction will depend upon the vaccine efficacy, the number of badgers vaccinated and how sustained that vaccination is both in time (over a number of years) and space.

25. In an area where badgers contribute significantly to disease in cattle, any vaccination will have a beneficial effect in reducing prevalence with a more co-ordinated and coherent approach achieving a greater potential benefit.

2.2.3 Veterinary advice

26. Detailed veterinary advice can be found in **Annex 1**. Any level of vaccination of badgers is likely to have a positive effect on the prevalence of disease in the vaccinated population. The greater the proportion of the total badger population that is vaccinated and protected at any given time the greater the benefit is

likely to be, and the more likely that this will appear as a reduction in the number of cattle breakdowns.

Summary
Badger vaccination has potential benefits
- in high incidence areas to reduce prevalence
- in buffer areas to prevent spread
- in low incidence areas to prevent new hotspots from becoming established
- as cattle breakdowns are the most readily available proxy for disease in badgers it will be difficult to separate the benefits of preventing spread from other factors such as pre-movement testing

2.3 Realising disease control benefits

27. For bovine TB the primary aim is not to protect the badger population but to reduce the number of herd breakdowns. However, protection of badgers from disease and any associated animal welfare benefits are potentially valued by the public and should not be ignored particularly in terms of wider engagement.

28. The benefits to cattle are not in terms of animal welfare as cattle are culled prior to clinical symptoms as part of the current control measures. The benefits of badger vaccination are in terms of overall disease control in cattle and depend on a number of factors.

29. The effect of the badger vaccine on cattle breakdowns is dependent on cattle not encountering bacteria shed by badgers. This ‘disease control benefit’ will be a combination of
    - the protective effects of the vaccine for badgers - vaccine efficacy
    - the proportion of badgers which are vaccinated, and;
    - the subsequent overall prevalence of disease in the badger population - does vaccination reduce the weight of infection below the level at which it can self sustain and /or it doesn’t tip over into cattle.

2.3.1 Vaccine efficacy

30. A vaccine targeted at badgers needs to reduce transmission to cattle. This can be done by protecting badgers from infection, thus reducing the level of infection (prevalence) in the badger population and the likelihood of cattle encountering an infected badger or contaminated material (e.g. urine/faeces/sputum). It will also be helped by reducing the level at which badgers excrete organisms and thus reducing the likelihood they will pass it on to cattle (or each other). Therefore a badger vaccine that is either protective and/or reduces transmission risks could help reduce the number of breakdowns.

31. The efficacy of BCG in badgers has not been quantified under experimental challenge and it will be hard to do so in a way that could be adequately extrapolated to the situation in the wild. This makes it difficult to estimate efficacy and policies around use need to be sufficient to allow for benefits to be achieved if actual efficacy in the wild is lower than hoped for.

32. In a recent field trial of oral BCG vaccination of possums in New Zealand, efficacy[1] was 88% against natural bTB infection (Frank Aldwell, personal communication). Extrapolation of results from possums to badgers is not advised as different species may well react differently to the vaccine, but the data can be used indicatively. If the same were true for badgers, this would mean that for every 100 disease free badgers vaccinated:
    - around 88 will be protected from either acquiring or developing infection to a level where they shed bacteria, i.e. in disease transmission terms they will be uninfectious;
    - of the remaining 12 some will be partially protected, i.e. if they subsequently become infected they will be less likely to shed bacteria or shed them in fewer numbers (the disease will progress more slowly) and so will be less infectious to other badgers and cattle.

33. The badger vaccine is protective rather than therapeutic it is therefore not expected to have any benefit for badgers which are already infected at the time of vaccination. As it is not practical to distinguish diseased badgers from uninfected ones so diseased badgers will end up being vaccinated as part of any programme. The vaccine could not be licensed if the risk of any adverse effect on already infected badgers was thought to be significant.

34. It should be noted that lifelong protection following a single dose of BCG is unlikely and that figures of vaccine efficacy should be viewed in light of duration of protection and any attempts to revaccinate a population of badgers.

2.3.2 Vaccine uptake

35. Vaccinating a sufficient proportion of badgers to have a significant effect depends on
    - Oral vaccination
        - the bait being palatable to badgers
        - bait being laid often enough and in the right place
    - Injectable vaccination
        - the trapping efficacy (proportion of trappable badgers)
        - timing and location of traps
    - the proportion of uninfected badgers
    - sufficient uptake from farmers

36. For oral vaccine the issues highlighted are technical aspects of the bait itself and the guidance on its use. Even with the right bait and approach to

[1] Efficacy defined as the proportion of vaccinated animals that were lesion and culture negative for *M. bovis* compared with non-vaccinated controls

distribution there will be some badgers which refuse to eat it or others which consume more than their ‘share’. To allow for this it is estimated that it will be necessary to lay an average of 12-14 baits per badger to give a high probability of each badger eating at least one. Work is ongoing to refine this estimate.

37. For injectable vaccine there will always be some badgers which are ‘trap shy’ and therefore will not be caught. As with oral vaccination correct timing and location and number of traps will be important.

38. As the vaccine only benefits uninfected badgers the proportion of the population which is uninfected will influence how quickly benefits are seen. Benefits may take longer to appear in high prevalence areas as it will take longer for the proportion of uninfected badgers to rise.

39. Farmers will only use the vaccine if it has been demonstrated to be beneficial in relation to the costs. Feedback from the industry has indicated that just making the vaccine available and leaving individual farmers to decide to use it may not be sufficient to generate enough use for the benefits to become apparent and thus lead to further use.

40. Vaccine roll out would need to be managed to encourage a large degree of coordination and uptake. This could include incentives for use, sharing the burden to reduce the cost to individuals or making vaccination compulsory.

2.3.3 Modelling of efficacy and uptake

41. The effect of vaccine efficacy and uptake on the prevalence of disease in badgers has been mathematically modelled. As with all models there is a degree of uncertainty surrounding the exact values produced, however, the trends can give some valuable guidance.

42. For simplicity in the model efficacy and uptake are combined into a single parameter “apparent efficacy” which can be increased by increasing uptake or efficacy or both.

43. The modelling indicates that as apparent efficacy increases so does the benefit in terms of reducing the level of disease in badgers. The benefit is maximised by maximising the apparent efficacy i.e. maximising uptake and vaccine efficacy. However, importantly the relationship is not linear, a greater proportion of the total benefit is achieved going from an apparent efficacy of 0% to 20% than is from 20% to 60% and so on. This means that even if a vaccine only has an apparent efficacy of 60% it might produce more than 60% of the potential benefit of a theoretically ‘perfect’ vaccine.

44. The implications for vaccine use are that while it will give the greatest benefit if all badgers can be vaccinated, and therefore maximising uptake should be the aim, if some badgers are missed the resultant decline in benefit realised will not be so dramatic and that trying to get the ‘last few’ will probably not be worth the additional effort.

2.3.4 Disease prevalence – herd immunity

45. The discussion above indicated that not all badgers need to be vaccinated for the benefit to become apparent, this is related to the concept of 'herd immunity' - the infectious pressure of disease in a population that contains a majority of individuals which are vaccinated is significantly reduced. For example, if badger A has bTB and contacted badger B, which was immune because of vaccination, badger B would not become infected and could not pass on the disease to badger C when it comes into contact with it. So even if badger C is not vaccinated, it indirectly gets protection from the disease. Hence herd immunity may be used to reduce spread of an infectious disease.

46. The proportion of a population that needs to be vaccinated to achieve herd immunity varies with the disease and the infectious dose and the transmission dynamics of the disease. We do not know what level of vaccination is required to give herd immunity in badgers - this effect will only be determined by use in the field.

47. While driving down the prevalence will eradicate infection eventually (providing immunity is maintained), the process may be slow in a chronic disease with a long infectious period such as bTB, instant results should not be expected.

2.3.5 Timescale of benefit realisation

48. Vaccination will take a number of years to demonstrate a benefit as it does not help already infected badgers. These need to die out naturally to remove the infection from the population which, based on average lifespan, could take 3-5 years. While these infected animals exist in any number it will be necessary to continue vaccination to ensure new cubs are vaccinated and protected from these infected individuals.

49. Of course in reality it is not this simple. The vaccine is not perfect and not all animals will be vaccinated, therefore each year some new badgers will become infected. These will remain infected and infectious until they too die. In the long term this leads to an increasing disease pressure unless vaccination is maintained.

50. Modelling indicates that the longer vaccination is continued the greater and more persistent the benefit in disease reduction terms. However, the additional reduction in disease for each additional year of vaccination gradually reduces. It is difficult to interpret these models into reality. However, a five year vaccination campaign may be sufficient to produce a significant benefit and would be consistent with the above rationale of a reduction in infected animals as these die off. Periodic less frequent vaccination following the initial campaign may be sufficient to maintain the benefit. Further modelling work is required to refine these estimates.

2.3.6 Realising the disease control benefit in practice

51. There are a number of different factors discussed above which affect the overall disease control benefit only some of which it is possible to actively manage in practice.

52. The issues highlighted will compound on each other, for example: If only 50% of badgers can be trapped and injected with a vaccine which is only 50% effective, and only 50% of farms are involved the disease control benefit becomes rapidly diminished in any given year - 50% of 50% of 50% = 12.5% of the potential available benefit. While there will be a benefit, as any level of vaccination will produce a benefit, it will take substantially longer to appear in terms of reduced cattle breakdowns and vaccination will have to continue for a much longer time in order to accrue the benefit.

53. While modelling indicates that there is potentially a law of diminishing returns this potential 'slack' in the system will be absorbed by less than 100% vaccine efficacy and less than 100% uptake by badgers (either trapping or consuming bait). With a threshold of protection required to achieve herd immunity unknown it is essential to try and maximise those remaining factors which are within our control:
    - Proportion of land on which vaccination occurs
    - The degree of coordination
    - The efficiency of delivery
    - The duration of use

54. How these factors might be maximised is discussed in later sections.

Summary
- The disease control benefit relies on both the efficacy of the vaccine and the level of use
- Initial rollout will need to be coordinated, incentivised and/or compulsory to ensure sufficient uptake to demonstrate a benefit
- A regional approach will be required to account for local differences
- Not all badgers will need to be vaccinated to cause a reduction in prevalence over time
- Benefits will be realised over a number of years, in general terms the longer the vaccination campaign the longer the benefit will be maintained
- To maximise the benefits it is essential to maximise those areas within our control, namely
    - Proportion of land on which vaccination occurs
    - The degree of coordination
    - The efficiency of delivery
    - The duration of use

2.4 Legal position

55. The introduction of vaccination to control bovine TB (bTB) in the badger population is governed by strict legislation. For badger vaccination, unlike cattle, there are no trade or food chain issues. However, the badger as a protected species is afforded special domestic and international protection.

56. A detailed discussion of the legal requirements can be found in **Annex 2**. Key points are:
    - Council Directive 78/52/EEC prohibits Member States from including “anti-tuberculosis vaccination” in eradication plans for bovine TB. The drafting of the Directive is unclear as to whether this applies just to cattle or all uses of vaccine including badgers.
    - The Bern Convention provides protection to badgers but would not prevent targeted vaccination even by trapping and injection
    - The Protection of Badgers Act 1992 (PoBA) would require anyone trapping badgers for vaccination to be licensed. An oral bait could be used without licence
    - There is no domestic law prohibiting vaccination of badgers against bTB.
    - The power to vaccinate animals under the Animal Health Act 1981 is not considered wide enough to cover a programme of vaccinating badgers on a precautionary basis. Primary legislation would be required before a compulsory vaccination programme could be implemented unless EU law was changed to positively reflect vaccination as an approach.
    - Animal by-product regulations and associated TSE regulations will limit the scope for use of meat based baits for oral vaccination.

57. We are seeking clarification or amendment of the EU legislation to allow vaccination of badgers. Assuming this can be addressed there are no legal barriers to the use of oral vaccines for badgers. The use of injectable vaccines which would require the trapping of badgers so the people conducting the trapping would need licensing.

58. We are investigating possible baits for oral vaccination that would not be affected by the animal by-products regulations. However, if a meat based product was the only realistic option it may be possible, following a risk assessment, to allow use by suitably amending the domestic legislation.

Summary
- The only potential legal barriers to vaccination are at the EU level
- Compulsory vaccination would require new primary legislation

2.5 Oral or injectable vaccine

59. The badger vaccine, which is based on human BCG, could potentially be administered either by intramuscular injection or through an oral bait. There are advantages and disadvantages to either method.

60. An injectable vaccine is likely to be available first, as early as 2010. An oral vaccine will take longer to develop and is unlikely to be available before the end of 2013. A timeline for badger vaccination development can be found in **Annex 3**.

2.5.1 Injectable vaccine

61. Badgers would need to be cage trapped, injected with the vaccine and then released. As this would constitute 'interference' with the badger the person conducting the trapping and vaccination would need to be suitably trained and licensed.

62. There is currently very little appetite amongst farmers for trapping and vaccination even with its potential relatively early availability. Farmers, the veterinary community and wildlife groups agree this is not a practical approach on a large scale.

63. There are a number of reasons for this, primary ones include:
    - the logistics and cost of cage trapping.
    - the need for specialist training and licensing to trap the badgers and administer the vaccine
    - the potential of trapping and releasing infected badgers which cannot be detected and would not benefit from the vaccine

64. Wildlife groups who would be generally supportive of vaccination in principle are concerned that the requirement to trap animals may not be acceptable to their members due to welfare concerns, so may be more difficult for them to support.

65. Laying traps is very labour intensive, multiple visits are required to pre-bait, set and remove traps and to vaccinate animals. There are also significant set up cost in obtaining the equipment and initial surveys.

66. Based on vaccinating an area of $100km^2$ of average badger density in the southwest region Central Science Laboratory (CSL) have estimated the cost of a five year government annual vaccination programme not including equipment costs to be £210,000 in the first year with £160,000 in subsequent years giving a total of £850,000. It would take about 3-4 months to complete. With a vaccine cost of around £16 the total is roughly equivalent to £356 per badger per year. A more detailed cost estimate can be found in **Annex 4**.

67. Without the participation and cooperation of farmers to reduce the cost, trapping badgers for vaccination would be logistically impossible and prohibitively expensive on a large scale. The possibility of infected badgers being released is not acceptable to farmers and is a significant barrier to such participation.

68. Other minor uses for an injectable vaccine do exist such as for hospitalised badgers prior to re-introduction or where an individual farmer wishes to protect particularly high value cattle. However, these uses alone are unlikely to sustain a commercial market.

69. The main use for an injectable vaccine is likely to be as part of government run scientific programmes. These will primarily be experimental in nature aimed at providing evidence to support the development and roll out of an oral badger vaccine. Pilot use of injectable vaccine on a scale sufficient to demonstrate the benefits though reduced breakdowns may be considered but this would be expensive and still over a relatively small area.

2.5.2 Oral vaccination

70. The vaccine will be suitably formulated and mixed into bait either at the manufacturing stage or point of delivery. The formulation component is designed to maximise delivery of live BCG to the badger.

71. The baits would be laid in places and in a manner where badgers are the only species likely to consume them, this will require clear guidance or specialist knowledge. No handling of the badgers themselves will be required and therefore licensing (under PoBA) is not legally required although some form of licensing may be desirable to ensure adequate training.

72. There are a number of practical issues with this approach which are addressed in subsequent sections. However, the industry has expressed an interest in this approach and a willingness to participate. An estimate of the costs of oral vaccination can be found in the economic assessment in **Section 4**.

73. The oral dose is currently the same level of active as the injectable vaccine, although lower doses are being examined for both. The costs do differ as the oral vaccine uses a cheaper precursor product for formulation into the bait whereas this is not suitable for the injectable vaccine which uses the more expensive commercial human vaccine. However, for the oral vaccine there are additional costs associated with the further formulation and bait required. At the current dose the cost per bait is estimated to be £10.

Summary

- Large scale badger vaccination policy should primarily consider oral vaccine
- Injectable badger vaccines will be pursued where this progresses the oral vaccination programme (including demonstrating the benefit of badger vaccination) or other minor uses.

2.6 Compulsory or non-compulsory vaccination

74. As noted above, one of the key requirements to realise the benefits of badger vaccination is wide enough usage. One method of achieving wider usage would be to make vaccination compulsory.

2.6.1 Statutory approaches

75. From a veterinary viewpoint having a statutory requirement for badger vaccination has clear advantages in ensuring that use is maximised giving the greatest probability that herd immunity will be achieved.

76. The key difficulty with compulsory vaccination is that badgers are wild animals and therefore not within the control of the individual landowner.
    - there is no way for the landowner to vaccinate all the badgers on their land
    - badgers cross farm boundaries
    - there is no way to determine if vaccination has taken place, compulsory vaccination would therefore be unenforceable

77. Badgers do not just live on cattle farms. Often the setts may be on adjacent arable or non-farm land with different owners, but the badgers would need to be vaccinated to achieve a disease control benefit. Under a compulsory system there would need to be a requirement for vaccination of these badgers even though the landowner may receive no benefit.

78. Legislation would be needed to require the vaccination of badgers. This would increase the overall regulatory burden and goes against the principles of better regulation as a non-compulsory approach is viable. Compulsory vaccination of badgers is clearly not viable and this is recognised by the farming industry.

79. One area where a compulsory approach might be possible is making a legal requirement to allow access to land for the purposes of badger vaccination. This would have the advantages of ensuring that setts could be targeted rather than the land that badgers forage on, which is likely to lead to more successful vaccination, and that gaps in vaccination coverage could be reduced.

80. There would still be a number of limitations to this approach
    - Some form of official involvement would be required in enforcing access
    - there may be legitimate reasons why a landowner might not wish oral bait to be used on their land e.g. significant risk of non-target bait consumption
    - legislation would still be required on a controversial issue of statutory access

81. Given the difficulties this approach would only be adopted if voluntary access was clearly shown not to be working.

2.6.2 Non-compulsory vaccination

82. While not making vaccination enforceable the aim would be to strongly encourage use. Non-compulsory vaccination will require the correct balance of

perceived costs and benefits to the individuals involved for them to participate. Over time it is hoped that the disease control benefits of the vaccine will be demonstrated sufficient in themselves to encourage participation. However, this may never be achieved without sufficient early take-up and therefore other approaches will be necessary in the early rollout stages. A few possible approaches are discussed below and none are mutually exclusive.

<u>Incentives</u>

83. Incentives for farmers to adopt badger vaccination would need to ensure that they did not also encourage negative behaviours and weren't open to abuse, particularly if financial in nature. One obvious incentive would be for vaccination to have zero cost to the farmer and funding for vaccination is discussed in the next section.

84. An alternative approach would be for some of the costs of a herd breakdown to be mitigated if a farmer can demonstrate they have done everything in their power to minimise the risk - including badger vaccination. Farmers have indicated that although such a scheme may help incentivise vaccine use it would need to be at a level of more than just recovery of the vaccination costs.

85. A difficulty with the incentive approach is that a single package would not encompass all of the landowners who may have badgers requiring vaccination on their land.

<u>Support</u>

86. Support for individuals to use badger vaccination could come from the ‘top down’ with government or industry organisations providing support and encouragement or from the ‘bottom up’ with communities working together to maximise vaccination in an area - peer pressure.

87. Support could include a number of different mechanisms such as training, guidance and coordination.

88. The ‘bottom up’ approach has the advantage of being able to include both farmers and other landowners to help maximise uptake.

89. Potential roles of different groups are discussed in a later section

Summary

- Badger vaccination should not be compulsory
- The longer term aim should be for demonstrable benefits and self sustaining uptake
- Initial rollout will require some form of incentive and support to strongly encourage use

2.7 Resources and funding

90. The potential costs of badger vaccination are considered in the economic assessment in **Section 4**. This section considers potential contributions to meeting the costs of badger vaccination and the form these might take, whether direct financial contributions or benefits in kind e.g. farmers laying baits.

91. Cost benefit analysis can consider whether vaccination as a whole is worthwhile however, uptake is key in a non-compulsory programme and the impact on individuals needs to be considered.

92. The major costs associated with use of badger vaccination are:
    - vaccine purchase
    - delivery (labour costs)
    - monitoring and evaluation

93. The costs of vaccination would need to be met by some combination of:
    - taxpayers (via national or local government)
    - individual farmers
    - the wider agricultural industry
    - other landowners
    - other interested parties and the wider community

94. At this stage it is not necessary nor appropriate to agree who should fund a vaccination programme. It is however, necessary to determine that there are some viable funding routes. The discussion below is therefore aimed at identifying (or excluding) possible funding routes rather than identifying definitive positions.

95. While the different groups listed have been identified as possible sources of funding the potential scale of their contribution will differ significantly and no decision has been made on this. At this stage no assessment has been made regarding what combination or scale of funding would be possible or appropriate from each group.

2.7.1 Taxpayers

96. The costs of research and development are being met by taxpayers. To date badger vaccine research has cost just under £7million. Government could consider taking a royalty from sales – particularly outside the UK to recover some of these costs which could then be reinvested in vaccine use.

97. Sharing responsibility and costs for management of disease risks is a key part of Defra's Animal Health and Welfare Strategy. Further background on responsibility and cost sharing can be found on the Defra website[2].

[2] http://www.defra.gov.uk/animalh/ahws/sharing/index.htm

98. On the timescales under which vaccines are likely to be available it is possible some form of responsibility and cost sharing may have been introduced. Vaccines policy therefore needs to be considered within potential responsibility and cost sharing (RCS) frameworks.

99. A significant farming industry view is that taxpayers will ultimately benefit from the reduction in disease due to lower testing costs and compensation payments and that government should therefore ‘bring forward’ the money saved to pump prime funding for the vaccination programme.

100. A similar argument can also be made that as industry currently bears significant costs in relation to bTB it will also accrue the benefits of vaccination and should also be prepared to invest for the future. Whether this investment could be made by the industry as a whole rather than on an individual business basis is discussed below.

101. It is a realistic assumption that government funding for bTB is unlikely to grow to provide sufficient ‘new money’ to fully support deployment of badger vaccination. Therefore if consideration is to be given to ‘pump prime’ funding it will be vital to understand where bTB vaccination might lie in terms of the industry’s priorities for funding relative to other areas where taxpayers contribute.

102. A demonstrable benefit is crucial to long term uptake, particularly for uptake in buffer and low incidence areas where a benefit may be very hard to measure and the vaccine will have to be used ‘on faith’. It is inevitable that some form of government participation (and therefore funding) will be required in the initial stages of rollout to ensure early success. However, government is very unlikely to be the only funding source required.

103. The availability of government funding could be managed to prioritise use in ways which would maximise the disease control benefit. For example providing funding to a group of landowners who agree to coordinate vaccination over a minimum area. (see later discussion on targeting)

104. It is likely that government will want to monitor the effects of the vaccination policy. This may require specific investment or be conducted as part of the ongoing process of monitoring the disease.

2.7.2 Individual farmers and the agricultural industry

105. Individuals who decide to use badger vaccination could be expected to purchase and deliver the vaccine themselves. This would become a purely business based decision on whether the potential benefits to the individual justified the expenditure.

106. Advice from the industry indicates that for this type of business investment farmers would normally either expect to see returns over a period of less than a year rather than the much longer timescale over which vaccination will have

benefits, or have some form of ‘guarantee’ of success. Farmers would be unlikely to choose to pay to vaccinate badgers, especially if *perceived* ‘cheaper’ and ‘quicker’ options such as culling were available. As a result, vaccination uptake would be low further reducing the benefits and uptake. This approach is therefore unlikely to be successful at least until the vaccine has been shown to deliver significant benefits.

107. If the costs to the individual of purchasing the vaccine were reduced or eliminated an individual farmer may be more willing to contribute to the delivery ‘in kind’ through their time and labour to distribute the bait.

108. The recent consultation on responsibility and cost sharing[3] highlighted a number of possible funding mechanisms for sharing the costs of animal diseases. It is unlikely that a separate mechanism would be set up for badger vaccination but it could be included in a wider mechanism if adopted. The net effect would be to spread the costs of vaccination across the wider agricultural industry and reduce the specific cost to the individual.

109. The availability of funding thorough some form of shared mechanism could be managed to prioritise use in ways which would maximise the disease control benefit.

2.7.3 Other landowners/occupiers

110. Non-cattle farmers and other landowners will have less incentive to pay for badger vaccination. One solution might be for individuals who consider that they are affected by the badgers on surrounding land to pay for their vaccination. This however, would have the effect of increasing the cost to the individual. Industry advice is that this would be particularly difficult and would have a significant further impact on uptake.

111. Some form of cost sharing mechanism where the costs of vaccination are separated from individuals could potentially fund the costs of other landowners as the industry as a whole would benefit from the control of disease. The scope for doing this would depend upon the nature of systems in place.

2.7.4 Other interested parties

112. Landowners are not the only potentially interested parties in badger vaccination. There is a high level of public awareness on the issue of bTB in badgers and numerous badger groups and other wildlife organisations interested in badgers and badger welfare.

113. Discussions with these groups have indicated that they will often have a good local knowledge of local badger activity and sett locations. This information would be useful in ensuring all badgers in an area can be targeted for vaccination.

[3] http://www.defra.gov.uk/corporate/consult/ahw-nextsteps/index.htm

114. Groups also have many members who are also part of the local community and may be willing to assist through coordination or labour with a community based programme of vaccination.

115. Beyond these groups there may be a general appetite within rural communities, and indeed beyond, to help lessen the impact of bTB. There may even be scope for fund raising to support such activity.

116. Industry groups have indicated that they would welcome the opportunity to work with wildlife groups to take forward vaccination and see this as an opportunity to work together on what is otherwise a polarised and divisive issue which often sees wildlife groups and farming industry pitted against each other.

Summary

- The impact on the individual will be crucial in determining uptake
- A long term aim would be for vaccine use to be self sustaining
- Some form of 'pump priming' investment will be required to achieve sufficient uptake at roll out to demonstrate benefits
- Government is unlikely to be able to provide 'new' money to fully fund roll out
- There are a number of sources that could contribute to this funding in some combination including
    - Government
    - The wider agricultural industry
    - The wider community

2.8 Roles of Government, industry and others

117. There are a number of different roles in the deployment of a badger vaccine beyond just providing funding. As with funding there are a wide number of interested parties who could potentially fulfil these roles.

2.8.1 Manufacture

118. As noted above the research and development costs of vaccines are being met by the government. However, it is not the role of government to manufacture such products on a commercial basis and we will be looking for a commercial partner to manufacture the product, and to hold the marketing authorisation required to produce and sell a veterinary medicine. In addition to allowing the manufacturer to sell the product this marketing authorisation also implies certain legal responsibilities in terms of maintaining and assuring quality, and checking for, identifying and addressing any adverse effects. In addition to the manufacture and sale of the vaccine the company will therefore also need to be

involved in some form of monitoring. The manufacturer may also wish to promote use.

119. It is by no means certain that a suitable commercial partner can be found and this is a significant risk to the overall programme.

2.8.2 Distribution

120. The badger vaccine will be a prescription only medicine. This means that a vet (government and/or private) will need to write a prescription to enable the user to purchase the medicine, however, it does not mean that the vet will necessarily be the distributor. This is in line with other veterinary medicines.

121. An important consideration for who prescribes the vaccine will be that a veterinary surgeon may only prescribe medicines to animals under their care. There is a 'duty of care' subsequent to the prescription in terms of pharmacovigilance for safety and efficacy. Prescribing a badger vaccine would imply such a duty of care for the vet on a wild animal. The potential difficulties this causes need to be carefully examined and discussed with the Royal College of Veterinary Surgeons (RCVS).

122. As a live vaccine it is very likely the BCG formulation will need to be refrigerated or frozen to enable sufficient shelf life. Equally the bait may need to be stored cold or frozen. The bait and vaccine formulation may be stored separately and under different conditions, needing combination at point of delivery. Distribution channels will need to accommodate these requirements.

123. One potential method of targeting vaccine use (see later) would be for government to limit the availability of the vaccine to situations likely to give the greatest benefits. However, the veterinary advice is that although targeted use will have the greatest disease control benefit, any use will have some disease control benefit and won't have negative effects. Therefore rather than limiting use the aim will be to promote use in certain situations but to make the vaccine generally available. This has the additional advantage of not limiting the market or distribution channels and allowing the manufacturer to promote wider use.

2.8.3 Coordination

124. Coordinated use of badger vaccine is both desirable to maximise uptake and use over a contiguous area and also necessary to ensure that badgers on non-cattle farms and other land can be effectively targeted for vaccination.

125. The role of vaccination coordination could be performed by a number of different groups either individually or in combination and the most effective solution may vary depending on circumstances particularly related to the source of funding (discussed above). Potential groups include:
    - Government
        - Central Government/Devolved Administrations
        - Local Authorities
        - Animal Health

- Farming industry
    - o National industry organisations (NFU, NBA etc.)
    - o local industry groups
    - o individuals
- Veterinary profession
- Other landowners
- Private contractors
- Other groups
    - o wildlife groups
    - o community groups

126. Key aspects of the coordination role will be
    - ensuring sufficient participation by being credible to the users
    - providing the necessary support to ensure vaccination is used correctly
    - maintaining participation over the multi-year timescales over which vaccination will need to be used

<u>Government</u>

127. Government coordination would have the benefit of ensuring consistency in how vaccines are used across a wide area and ensuring application over the necessary timescales and this has not been ruled out as an option. However, in a non-compulsory scheme government may be much less effective at encouraging uptake than more locally focused and tailored approaches. Government points of interaction with different landowners can be quite different depending upon how the land is being used. Animal Health would only be in regular contact with farms with livestock. Local authorities can be expected to have broader level of contact but again this will be through different departments depending upon the nature of the interaction and may be difficult and expensive to coordinate.

128. An initial proof of principle roll out may well involve significant Government coordination to ensure that the benefits are realised and clearly demonstrated. However, Government directly coordinating a non-compulsory scheme may not be the best approach in the long term. Where government can have an ongoing role is in providing the necessary support, training and particularly guidance to allow others to effectively take on the coordination role. Government would want to see its role in vaccination diminish over time with the programme becoming self sustaining.

<u>Farming Industry</u>

129. For the individual farmer, industry groups will potentially be much more credible in terms of coordinating vaccination and encouraging participation. Involvement of representatives of the national groups may be beneficial in helping ensure consistency of use and in maintaining coordination over the period of time required for vaccination to be effective.

130. Industry groups have demonstrated that they can bring landowners together to address this type of issue at the local level.

131. The difficulty with industry groups may be in coordinating with non-agricultural landowners to ensure the required level of contiguous uptake.

Veterinary profession

132. Veterinary practices will have regular contact with farmers but these may not be in a contiguous fashion and again may have more difficulty with landowners who don't have animals they may therefore be unsuited to the coordination role.

Other landowners

133. Other landowners or land management organisations may be able to coordinate vaccination on behalf of an area. In this context we are particularly considering large landowners such as members of Defra's 'Major Landowners Group' which includes amongst others the National Trust, The Royal Estates, Forestry Commission and the National Parks Authorities. Due to the size of their holdings these organisations may already have in place significant land management structures and potentially personnel that could be involved in coordinating badger vaccination on or around their properties. The level of interest from such organisations may well be dependent upon specific circumstances including whether there are agricultural cattle holdings within their control (e.g. tenant farmers).

Private contractors

134. If there is sufficient demand for badger vaccination this may encourage private contractors to offer services for both the delivery and coordination roles. The nature of this interaction will depend upon sources of funding available. Such contractors could be national businesses or local companies/individuals. This could include individual farmers offering to carry out vaccination as an additional business opportunity.

135. The commercial nature of the transaction should help ensure a degree of professionalism although government may seek to require minimum levels of training and to licence or accredit such contractors. This approach may develop more once initial rollout has demonstrated sufficient success and a clear market.

Other groups

136. A wide range of other groups may be interested in coordinating badger vaccination either nationally or in their local area. To be most successful a national campaign would also require a significant local component. Potential groups include animal welfare organisations, wildlife groups, conservation groups or local community groups.

137. The may be difficulties regarding credibility of such groups with farmers where there is a history of disagreement on the issue bTB.

138. Local community groups could be particularly powerful as they would be geographically located and potentially be able to bring together all parts of the community rather than approaching the issue from a certain standpoint. The difficulty with ad hoc groupings may be in ensuring the level of continuity of vaccination required to maximise the benefits. Again the source of funding for such groups will be important.

139. In all the above situations some form of veterinary involvement will be required in order to prescribe the vaccine.

2.8.4 Training

140. The level of skill, and therefore training required, to enable the effective use of badger vaccine will depend upon the nature of the final formulation. It is likely that some form of training will be necessary.

141. As part of the approvals and licensing process for the vaccine information will be required on how it should be used. The government can issue guidance on use through Animal Health.

142. Training of individuals will depend upon who is distributing the bait and who is coordinating. If part of a large commercial operation it would be expected that the company involved would give sufficient training to its employees. National farming organisations could build up or buy in expertise and then provide training to individuals or groups.

143. As a prescription only medicine veterinary input will be required to at least approve the use of vaccination. Local veterinary practices or state vets could provide training to individuals or groups on how to use the vaccine prior to providing the prescription. This would ensure some level of quality control on delivery at local level.

2.8.5 Delivery

144. The groups and individuals identified under the coordination section (2.8.3) might also be involved in the delivery of the vaccine on the ground.

145. Laying vaccine baits over a large area would require resources in terms of time and labour. Government and its agencies are unlikely have the capacity to fulfil this role and would be very expensive, however, this option has not been ruled out.

146. The industry has indicated that although not necessarily willing to pay for the vaccine itself farmers might be willing to contribute in kind by providing the necessary labour to lay baits on their own land. Wildlife groups have indicated they might also be willing to contribute labour to lay baits and assist in identifying setts. A potential difficulty with such an approach might be unwillingness of farmers to let such organisations onto their land.

147. Where a ‘neutral’ third party is required private contractors could lay the baits. If the approach is being organised on a community basis then the range of participants could be involved in laying the bait as appropriate.

2.8.6 Monitoring

148. Government and industry alike will want to understand the effects of a badger vaccination programme to help inform continuing development of the bTB control policy and associated business decisions for farmers.

149. Monitoring by Government could be through analysis of the overall TB statistics or more detailed study. Using overall statistics would be complicated by the need to separate out effects from other controls. This may not be possible particularly in buffer or low incidence areas. Depending on the funding mechanism reporting data to assist in the monitoring process could form part of the funding agreement. In terms of initial monitoring of efficacy it would be helpful to have routine records of the approximate time, location (holding) and quantity of vaccine used. In the long-term once use is established this may not be necessary. It may be accurate enough to collect approximate information at the time of prescription.

150. As noted above the manufacturer will also have some monitoring responsibilities to ensure ongoing vaccine safety.

151. As there is expected to be no perturbation effect associated with vaccination there is no need to understand the social structures and territories of the badger groups and therefore routine large-scale survey of setts will not be required. However, there is clearly a benefit in being able to identify, and target vaccination at, all badgers in a given area. The industry view is that farmers themselves will often have a good idea as to where badgers are located on their property. Local badger groups may also have knowledge of local setts. This knowledge can be used to target vaccination without the need for widespread surveys and also to assist in monitoring.

152. There may be a desire for government or other bodies to conduct research on the effect of badger vaccination which may lead to a more detailed monitoring and analysis in certain areas.

153. As there is no interference with the badgers there is no need for significant monitoring of how vaccination is deployed. However, there will be benefits in spot checking to ensure that training and guidance is sufficient and baits are being used correctly. This could be performed by state vets or local authorities or through an industry run scheme.

Summary

- There are potentially roles for government, industry and the wider community in a badger vaccination programme
- There is no value in Government limiting vaccination availability to target use
- Coordination is essential and has the greatest chance of success if organised at the local level by the industry and wider community.
- Government's role is best suited to guidance on best practice.
- Government would not be involved in delivery this is best done at the local level although it may be necessary for Government vets to prescribe the vaccine
- Some form of Government and industry monitoring is important especially at the early stages.
- There are potential commercial opportunities for coordination and delivery in the longer term and government involvement should diminish with time.

2.9 Delivery

154. Who might deliver the vaccine has been discussed in the previous section. This section discusses the practicalities of vaccine delivery.

2.9.1 Vaccine format

155. The vaccine will be formulated in such a way as to ensure the vaccine is adequately protected from the environment and delivered in a viable state to the badger. The vaccine will need to be mixed into a bait to make it palatable to badgers.

156. Ideally the vaccine formulation and bait would be supplied premixed. Depending on the relative stability of the different vaccine and bait components this may not be possible and the vaccine and bait would have to be prepared mixed shortly prior to use or on site.

157. Without the surrounding bait it is unlikely the vaccine formulation alone will be consumed by badgers. The final choice of bait will be dependent on a number of factors including palatability to badgers and the restrictions on the use of animal by-products outlined above (section 2.4)

158. Some badgers may eat more than one vaccine bait preventing others from doing so. In order to allow the majority of badgers the opportunity to consume at least one bait there will need to be a number of baits laid 'per badger'. Without a detailed and expensive survey to determine exact numbers the number of badgers in any given sett will be an estimate and therefore so will the

appropriate number of bait to be laid. However, as noted above it is not essential all badgers are vaccinated so an estimate should be sufficient. Work is ongoing on how best to determine the number optimum number of baits to lay. The best current estimate is that around 12-14 baits will be required ‘per badger’.

2.9.2 Location and timing

159. The location and timing of vaccine delivery need to be optimised to:
    - Maximise the likelihood of uptake by the maximum number of badgers, including cubs
    - Minimise the risk of uptake by other species, including cattle

160. Placing vaccine baits close to badger setts, particularly the main sett provides the greatest chance that they will be consumed. If the sett is not accessible then less favourable options would be to place them where badgers are known to pass or forage.

161. Baits will not be placed within sett entrances. There are two key reasons for this:
    - Badgers tend not to eat food within their sett so placing bait in this way would actually reduce uptake
    - Placing bait within the set constitutes interference and would therefore require licensing

162. The baits should be placed to minimise uptake by other species especially cattle. This could include approaches such as placing them under stones or slabs that badgers can move and excluding cattle from the baited area. How best to lay baits is being considered as part of the vaccine development programme.

163. The timing of vaccine deployment is equally important and will be dependent on a number of factors potentially including:
    - Most likely time to vaccinate cubs as they first emerge
    - Frequency of badger foraging (depending on availability of other food)
    - Least risk to cattle of consuming bait
    - Weather forecast (effect of rain on bait)
    - Availability of people to lay bait
    - Ease of access to sets (less vegetation in early summer)

164. Optimum timing to lay bait will be considered as part of the development programme. It may be that there are a number of opportunities to vaccinate badgers throughout the year.

165. Industry have indicated a preference for laying bait in the winter when cattle will be indoors and the risk of them consuming bait is minimised. However, there may be adverse weather and reduced badger activity at this time.

2.9.3 Duration of vaccination programme

166. As discussed above, vaccination will need to be continued for a number of years in order to maximise the benefits.

167. The replacement rate for badgers is estimated to be around 30% per year so each year there will be new cubs needing vaccination.

168. The estimated lifespan of a badger is 3-5 years. An infected badger will not benefit from the vaccine so non-infected badgers need to be protected from infection until infected animals naturally die off.

169. Some badgers may also be missed in any given cycle of vaccination. Further vaccination cycles provide an additional opportunity to vaccinate these. The duration of immunity is also currently unknown so repeated vaccination may be required to maintain immunity.

170. The duration of the vaccination programme required to be effective is currently being modelled. The current best estimate is that vaccination will be required on an annual basis for a minimum of five years. Subsequent less frequent vaccination may be required to maintain immunity in the badger population. The longer vaccination is maintained the greater the disease control benefits.

2.9.4 Risks

171. The major risk with badger vaccination relates to potential uptake by other species, particularly cattle.

172. Cattle will investigate and may consume baits if they are able to access them. There should be minimal risk to the health of any animal consuming a vaccine bait including cattle. However, cattle may for a time become sensitised to the tuberculin skin test as a result of consuming the bait. This sensitivity would be expected to disappear after a period of time but if an animal was skin tested during this period it may appear as an infected reactor.

173. The only way to determine if the animal was a true reactor would be to use a differential diagnostic test (DIVA). The industry view is that it would be ideal to have such a test available for use alongside oral badger vaccines. Any reactor on land where vaccines had been used could then undergo the differential test if there was concern that it was a false-positive to the skin test. However, the test would need to be legally accepted by the EU to prevent trade restrictions and there would be associated costs. Such a legally accepted differential test may not be available by the time oral badger vaccines are expected to be available. The industry have indicated, that although less than ideal, this is not an issue that would prevent the use of oral badger vaccines.

174. In the absence of a cost effective DIVA test it is therefore proposed that reactors on farms where badgers have been vaccinated would be treated as any other and assumed to be infected with the consequential slaughter and restrictions. The risk can be mitigated by placing bait out of reach of cattle, at times when

they are indoors or to graze cattle away from setts until the baits have been consumed. This will be addressed in the guidance for use. Farmers will need to have confidence in the person laying the bait that this will be done correctly.

175. There will be some residual risk as bait could be transported by animals to locations where cattle can access them. The nature of the bait (e.g. texture, consistency) should minimise this by encouraging immediate consumption by the animal rather than caching. Industry have indicated that this level of risk is something that they would be willing to accept in order to benefit from badger vaccination.

176. There is an additional risk that vaccinated badgers may themselves shed small quantities of vaccine which could also cause minor sensitisation in cattle. This risk is being investigated as part of the vaccine development process and is not expected to be significant.

Summary

- Vaccine bait may need to be mixed at the time of use
- Multiple baits will be required for each badger
- Baits will be sited near setts out of reach of cattle
- Vaccination will need to be continued for at least 5 years
- The risks to other species including cattle will be minimised and tolerated and the option of using DIVA test will be considered once an approved test is available

2.10 Targeting vaccination

177. Accurately targeting infection in badgers is difficult as it is not possible to identify reliably the prevalence of disease in badgers. Badger vaccination will have to be targeted using cattle as a sentinel species, with the level of cattle infection as a proxy for badger infection. Although not ideal in badger disease control terms this is consistent with the overall aim of vaccination which is to reduce disease in cattle.

178. Veterinary advice is that any level of vaccination will potentially have disease control benefits and that there are unlikely to be any negative effects.

179. In the context of badger vaccines, targeting will primarily be about focussing resources to maximise vaccination where it will have the greatest disease control effect against a background of general availability and use, rather than restricting use to certain circumstances.

180. A more restrictive approach where vaccines are used only in priority disease control areas might be considered if:

- vaccine supply was limited

- allowing widespread use led to farmers having a false sense of security and subsequent relaxation in the implementation of other controls such as bio-security to the detriment of the overall disease control process.

181. Under normal circumstances the aim would be to make badger vaccination as widely available as possible.

2.10.1 Definitions of target areas

182. In the discussion that follows areas are defined in one of three categories based on cattle breakdown history. These are:
    - High risk
    - Buffer area
    - Low risk

183. As discussed above vaccination has potential benefits in each of these areas either in reducing spread (low risk, buffer areas) or reducing prevalence (high risk and possibly buffer areas). These areas may require different approaches and need to be defined.

184. Using cattle breakdowns as the proxy for disease in badgers means the minimum targeting trigger will be disease history of an individual farm or holding. However, vaccination will be most effective over large areas and therefore disease history over multiple farms may be a more appropriate measure.

185. The target areas could be defined in 'administrative' terms or using a risk based epidemiological approach.

<u>Administrative areas</u>

186. The most easily accessible proxy for disease history is the parish testing interval (PTI). These are based on the average percentage of herds confirmed as infected over the previous two testing cycles.

187. A simple approach might therefore be to define the vaccination areas in line with PTIs. There are a number of ways this could be done. The simplest might be:
    - High risk – annual testing (PTI1)
    - Buffer – 2 or 3 yearly testing (PTI2, PTI3)
    - Low risk – 4 yearly testing (PTI4)

188. The above approach would mean that any 4 yearly testing parish adjacent to a 1 yearly testing parish would not be considered a buffer zone. A slightly more complex approach might be
    - High risk – annual testing (PTI1)
    - Buffer – 2 or 3 yearly testing (PTI2, PTI3) and any parish where the adjacent parish is on a higher testing frequency.

- Low risk – all 4 yearly testing (PTI4) parishes not captured by the buffer definition.

189. These are relatively simple definitions that could be used to focus support for vaccination and also guidance on use. However, there are a number of issues with such an approach
    - parishes are not epidemiological units - badgers are not constrained by administrative boundaries
    - no account is taken of the origin of infection. A single breakdown caused by a cattle movement could trigger a change in PTI and therefore approach. Some additional criteria related to regional risk may need to be added
    - While taking account of disease history it makes no real assessment of future risk

<u>Epidemiological risk based approach</u>

190. In this approach the definition would be based on a more detailed assessment of breakdown history which could include:
    - potential causes of infection
    - levels of incidence over an area and over time
    - cattle herd densities and herd size
    - risk factors such as trading practices
    - geographical features e.g. suitability as badger habitat and thus badger density
    - badger territories

191. As a means of targeting disease control this is potentially a much more effective approach and is likely to maximise the benefits. However, for targeting support such as funding this would be much more difficult and bureaucratic to implement and some information, such as badger territories, would be difficult and expensive to obtain.

192. Epidemiological targeting also needs to consider the balance of potentially opposing factors. As vaccination only benefits uninfected animals it may be more effective in areas of low prevalence of disease in badgers. However, badgers are likely to be a greater contributor to disease in cattle where there is a high prevalence of disease in the badger population. Targeting to maximise the disease control benefit will need to balance these factors.

193. This approach may be most applicable to a top down approach with government identifying key areas to demonstrate the benefits of vaccination rather than a bottom up approach driven by local communities. It would also be applicable if vaccination supplies were limited for any reason.

2.10.2 Targeting rationale

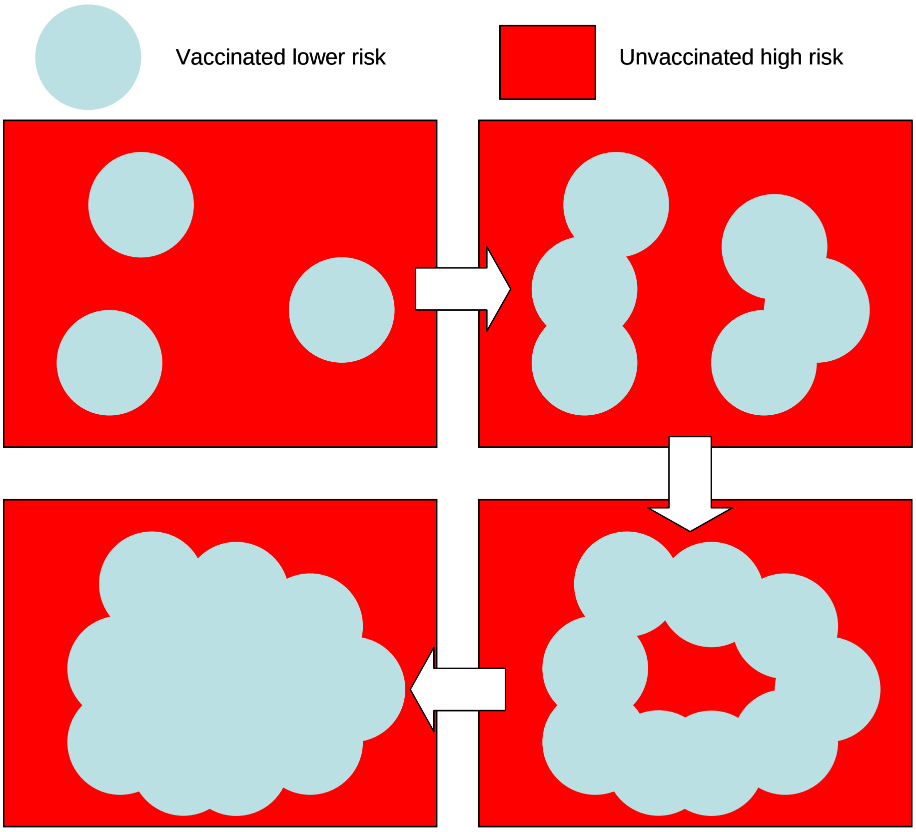
194. The targeting rationale and approach will be expected to evolve over time as the disease situation changes. The examples below illustrate this. It should be noted that the time periods involved are considerable. In any given area once

vaccination is started it should be continued for a period of at least 5 years and may require further 'maintenance' vaccination to keep disease levels low.

High risk areas

195. Targeting in these areas would be aimed at maximising overall uptake alongside maximising the size of contiguous areas over which vaccination occurs .

196. The overall aim would be to reduce the prevalence of disease in badgers and start breaking up the disease. Initially this would create disease free areas within the high prevalence zone. The aim would be to then start linking these areas, breaking the disease into islands with disease free non susceptible areas in-between and finally to shrink these islands of disease. This is illustrated in the diagram below.



197. The larger the size and number of these initial vaccination areas the easier it will be to link them up.

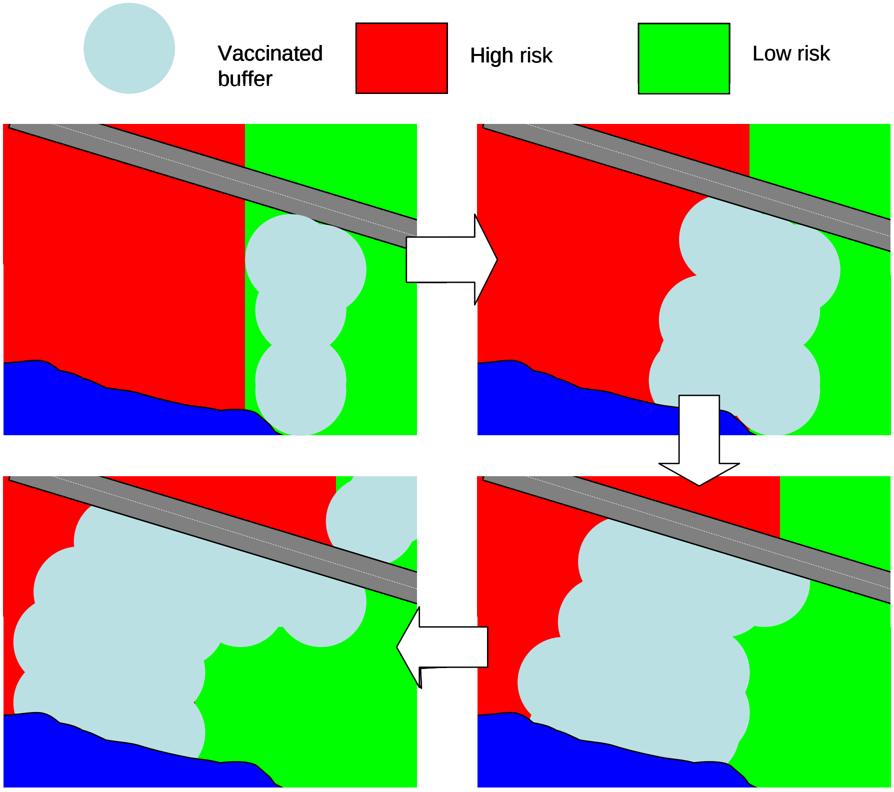
Buffer Areas

198. Targeting in these areas would be aimed at maximising a contiguous buffer to reduce the possibility of disease spreading.

199. The aim would be to provide a continuous vaccination barrier in low prevalence areas to prevent spread from neighbouring high prevalence areas. Once this

has been achieved the vaccination could begin to expand into the high prevalence area. Vaccination would need to be maintained throughout the buffer zone for a significant period of time. If successful, ultimately the low incidence side of the buffer could also move as testing intervals start to change in response to a reduction in disease and buffer areas become low incidence areas.

200. Implementing a continuous buffer around the entire endemic area is a significant challenge so natural boundaries such as rivers, the sea and major roads could be used to provide 'solid' edges to smaller initial areas. These could then be linked in the long term. This is illustrated in the diagram below.

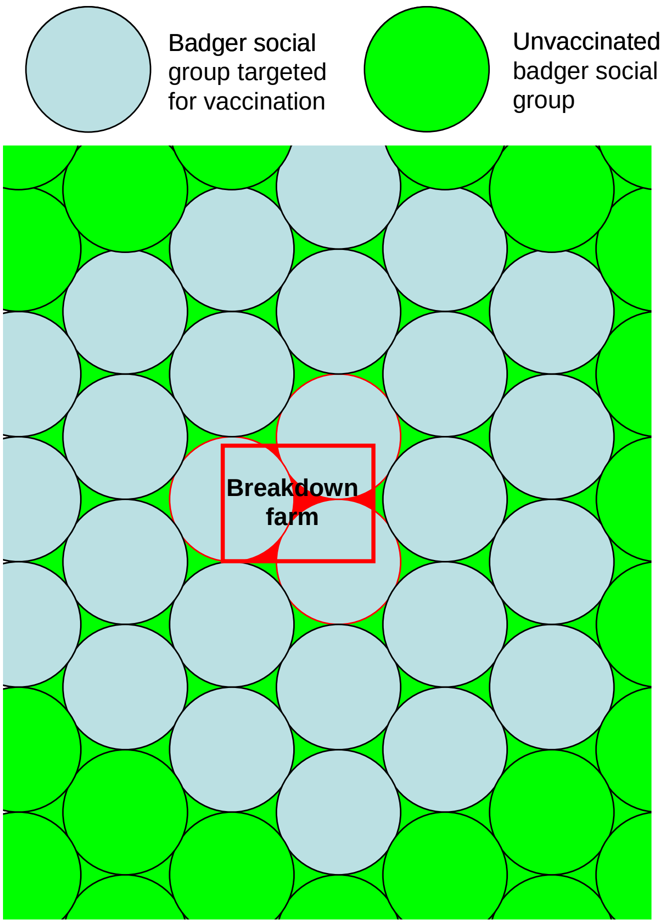


Low risk areas

201. Targeting in low risk areas will be focussed on preventing the development of hotspots and individual protection.

202. Farmers may wish to vaccinate in response to a breakdown on their own or a neighbour's farm to reduce the likelihood of disease becoming established in the local badger population or where the cause of the breakdown is assessed unlikely to be cattle. Under these circumstances some degree of epidemiological assessment may be beneficial. This could be a detailed survey of badger social groups or a 'rule of thumb' approach e.g. vaccinating in a circle a certain distance around the initial breakdown based on 'average' badger ranges.

203. Veterinary advice indicates that to be effective vaccination should aim to cover a minimum distance of at least two social groups outside the “core” social groups on the breakdown farm. This is to ensure that a badger that moves to an adjacent social group and is then moved on, is likely still to be within a vaccinated area. This is illustrated below.



204. In addition to this action in response to a breakdown, individual farmers or groups of farmers may wish to vaccinate badgers on their land as a precautionary measure. This may be to help protect high value animals or indeed to maintain a population of badgers perceived as being ’clean’ to prevent infected badgers entering the area and setting up territories.

2.10.3 Area of vaccination

205. It is not expected that there will be any perturbation effect with vaccination however, there will be an ‘edge effect’. Modelling indicates that the primary benefits of vaccination are restricted to the vaccinated area they will not spread much beyond this.

206. For vaccination in a high risk are the benefits of vaccination are likely to be least at the edge of the vaccinated area. Over time there would be expected to be a

relatively higher prevalence of disease outside the vaccinated area as the level within the target area decreases. As vaccination is not perfect there will still be susceptible badgers within the target area and these will be at greatest risk when near the edge of the target area.

207. Minimising the length of ‘edge’ compared to the overall vaccinated area will therefore improve the overall benefit in terms of disease reduction. Modelling indicates that as the vaccinated area increases the benefit increases up to around $100km^2$. Beyond this the benefit becomes more independent of area. Increasing the area does not increase the average benefit felt but does maintain it.

208. Therefore to maximise the overall benefit the vaccinated area should be as large as possible but with a target minimum of $100km^2$, this could be made a criteria for support to encourage coordination on this scale.

209. An individual farm next to a vaccinated area is unlikely to get much ‘free rider’ benefit from their neighbour vaccinating, however, if they were to join the vaccination programme they would benefit significantly from being part of a large area.

2.10.4 Prioritisation of resources

210. Although the vaccine will be made generally available other resources, particularly financial, are likely to be limited in some way. It will therefore be necessary to prioritise how these are used.

211. One approach would be to focus on eliminating isolated pockets of disease first followed by surrounding the main endemic areas with a buffer zone and moving this inwards. This would give an order of priority of low risk hotspots, buffer area, high risk area. This is the approach that might normally be taken for eradication of a disease.

212. However, there are a number of issues which make this approach less suited to badger vaccination:
- The first step is to try and control the disease before moving to eradication
- There are other controls in place aimed at reducing disease
- The need to demonstrate a benefit to encourage uptake, this will be most visible in high risk areas
- Isolated disease pockets are often considered to be due to cattle transmission rather than being badger related.

213. For badger vaccination industry have indicated our priority must be to demonstrate a benefit in high risk areas. This will help ensure sufficient uptake in buffer and high risk areas to stop ‘creeping’ spread and start reducing disease levels. Low risk areas are lower priority as other controls such as pre-movement testing are targeted at preventing spread to these areas.

Summary

- Targeting will be used to enhance effectiveness against a background of general availability
- Approach will depend on whether an area is classified as high, buffer or low risk.
- Assigning risk category according to PTI will provide the simplest most transparent mechanism
- Targeting in high risk areas will aim to maximise uptake and break up the pattern of disease
- Targeting in buffer areas will aim to maximise the contiguous boundary to prevent further spread
- Targeting in low risk areas will aim to prevent new hotspot formation
- Vaccinated areas should aim to be of a minimum of $100km^2$ to maximise the benefit
- Priority will be given to high risk and buffer areas in terms of resources to support vaccination

2.11 Vaccine market

214. The size of the market for badger vaccines will depend upon level of uptake. As discussed above this will be influenced by a number of factors such as how the vaccine is targeted, the cost and the efficacy.

215. It is estimated by the Central Science laboratory (CSL) that there are around 300,000 badgers in GB. If badgers in high risk areas are primarily targeted then the number of badgers is estimated to be 140,000. Approximately 30% of parishes are in high risk or buffer areas (1,2 or 3 yearly testing interval) and these contain about 45% of cattle herds. Generally badgers are more concentrated in cattle farming regions as the habitat is better suited to them.

216. Using the above figures as a *very* crude estimate the average badger density in high risk areas is twice that of low risk area. Combining the greater cattle and badger densities means that the majority of any market for badger vaccines will be in these areas and therefore basing market size estimates on high risk areas is not unreasonable.

217. Using oral vaccination it is estimated that a ratio of 12-14 baits per badger is required to give a reasonable probability of all badgers consuming at least one bait and therefore being vaccinated. To vaccinate all badgers once annually in high risk areas would therefore require just under 2 million bait doses per year.

218. Not all badgers in hotspot areas will be targeted so the actual UK market is likely to be smaller than this.

Summary

- With a high level of uptake a maximum of around 2 million vaccine does will be required per year.

3 Lead scenarios

219. The preceding discussion has set out a number of requirements for how badger vaccines might be used, key ones being that badger vaccination will most likely not be compulsory and use an oral formulation.

220. We have identified a number of potential scenarios for the use of badger vaccines aimed at meeting these requirements which are outlined below. These have been divided according to the categories of high risk; buffer; and low risk areas outlined above.

221. Each scenario has been given a title followed by the policy rationale and short description.

222. It will be possible for the scenarios to exist in combination within the limits of resources. Scenario 7 is individual purchase and use and could exist alongside all of the other scenarios.

223. It is important to note that these represent what is considered the most feasible scenarios as to how badger vaccination might be used. Although they will be used to help focus policy development and prioritise research this does not mean that all other options will be dismissed. A key aspect will be to maintain a flexible approach in the face of an evolving disease and regulatory picture.

3.1 High risk areas

3.1.1 Scenario 1 – Government/Farming industry coordinated 'proof of principle' roll out

Rationale

224. Demonstrating a benefit will be key to generating long-term uptake. Government/Industry will identify areas where vaccination is expected to have a significant effect and focus additional resources, support and monitoring on these areas to demonstrate the benefits as reliably and rapidly as possible.

Description

225. This would be a short-term initial approach to demonstrate effectiveness that could be expanded by greater industry involvement to a more long-term approach.

- The vaccine would be available generally to allow use in other areas if desired.
- A joint pot of funding would be created, to support vaccination in target areas, with contributions from some combination of government, industry and other interested parties. Full government funding of a small number of target areas is not ruled out but more widespread use would require contribution from other sources.

- Targeting would be based on epidemiological analysis and would select distinct areas of a size sufficient to give a demonstrable impact on herd breakdowns. Areas might be 100+ km^2
- The vaccine would be delivered in oral bait. A pilot using injectable vaccine to demonstrate effectiveness might be considered on a relatively small scale sufficient to detect a benefit through reduced breakdowns. However, injectable vaccines are less likely to be expanded to wider use.
- Government or industry groups would provide coordination. Over time responsibility would shift away from government with the expansion of the programme.
- The vaccine could be delivered by farmers or other interested parties or contractors.
- Vaccination in a given area would be performed for a duration of at least five years on at least an annual basis.
- Use of vaccines would not be compulsory and incentives might be used to encourage take-up within the designated target areas.
- Monitoring would be put in place to determine effectiveness.

3.1.2 Scenario 2 – Community coordinated use

Rationale

226. A community coordinated approach involving farmers and other landowners and potentially other interested parties such as wildlife groups will help maximise coverage over a given area. As a ‘self-selecting’ group this approach will self target in areas of greatest perceived need that may help maintain long-term commitment.

Description

227. This would be a long term approach with the possibility of becoming self-sustaining if proven to be cost-effective.
    - The vaccine would be available generally to allow use in other areas if desired.
    - A pot of funding would be created to support vaccination. This could either be a centralised funding mechanism that groups could bid into, or locally based. Contributions to a joint pot could be from some combination of government, industry and other interested parties. Availability of funding from central sources could be linked to meeting certain conditions such as, for example, a commitment to vaccinate for a minimum number of years.
    - Targeting would be any PTI1 parish. Funding may be related to a minimum area of use of $100km^2$. Guidance would be provided on the most effective approach, ideal areas etc.
    - The vaccine would be delivered in oral bait.
    - Coordination would be at the local level by regional farming industry groups, wildlife groups or even individuals willing to do so. The make up of the groups will vary depending on local needs and enthusiasm.
    - Vaccine will be delivered by members of the group or contractors hired by the group.
    - Vaccination in a given area would be performed for a duration of at least five years on at least an annual basis.
    - Use of vaccines would not be compulsory

- Monitoring would be conducted as part of the overall monitoring of TB statistics.

3.1.3 Scenario 3 – Supported individual use (high risk area)

Rationale

228. Individual use of vaccine will allow those who perceive a need to take action having weighed up the potential costs and benefits to themselves within a framework of support which could include funding. The vaccine can be used in such a way as to maximise the individual benefits and minimise costs. However this may not lead to the greatest overall disease control.

Description

229. This would be a long term approach with the possibility of becoming self-sustaining if proven to be cost-effective.
    - The vaccine would be available generally to allow use in other areas if desired.
    - A joint pot of funding would be created, to support vaccination in high risk areas, with contributions from some combination of government, industry and other interested parties. Availability of funding from central sources could be linked to meeting certain conditions such as, for example, a commitment to vaccinate for a minimum number of years
    - Targeting would be any PTI1 parish
    - The vaccine would be delivered in oral bait
    - There would be no large-scale coordination
    - Vaccine will be delivered by individual landowners or contractors hired by them
    - Guidance would recommend the duration of vaccination. As this will be limited to the individual farm disease pressure from outside the vaccinated area may be maintained and therefore vaccination would need to be performed on an annual basis to maintain the benefit
    - Use of vaccines would not be compulsory
    - Monitoring would be conducted as part of the overall monitoring of TB statistics.

3.2 Buffer Areas

3.2.1 Scenario 4 - Government/industry coordinated buffer

Rationale

230. Preventing further spread of the disease is a government and industry priority. Developing a continuous vaccinated buffer around endemic areas will maximise the containment effect. This will require significant coordination over a large region which is best suited to government or national organisations. It will also require long-term commitment especially if the buffer is ultimately used to ‘push back’ disease. Government would identify the potential buffer zone and focus additional resources and support.

Description

231. This would be a long-term approach to 'seal off' the badger population in an endemic area with a barrier of non-susceptible animals.

- The vaccine would be available generally to allow use in other areas if desired.
- A centralised pot of funding would be created, to support vaccination in the designated buffer areas, with contributions from some combination of government, industry and other interested parties.
- Definition of buffer areas would include all PTI2, PTI3 and PTI4 where adjacent to a higher testing frequency suitably modified by a high-level epidemiological analysis to address any anomalies. The aim would be to create a continuous buffer zone above a specified minimum width (could be 1-2km). An initial approach might focus on hotspots rather than the main endemic area.
- The vaccine would be delivered in oral bait.
- Government or industry groups would provide coordination. Over time responsibility would shift away from government with the expansion of the programme.
- The vaccine could be delivered by farmers or other interested parties or contractors.
- Vaccination in a given area would be performed for a duration of at least five years on at least an annual basis.
- Once the initial buffer zone was established the aim would be to extend the zone on the high-risk side while maintaining the remainder of the buffer
- Use of vaccines would not be compulsory and incentives might be used to encourage take-up within the designated buffer areas
- Monitoring would be put in place to determine effectiveness.

3.2.2 Scenario 5 - Community coordinated buffer

Rationale

232. A community coordinated approach involving farmers and other landowners and potentially other interested parties such as wildlife groups will help maximise coverage uptake. As a 'self-selecting' group this approach will self target in areas of greatest perceived risk need and that may help maintain long-term commitment. While this is unlikely to give a continuous buffer natural boundaries could be used to help maintain the benefits.

Description

233. This would be a long term approach with the possibility of becoming self-sustaining if proven to be cost-effective. Over time the individual projects may link up to provide a continuous buffer.

- The vaccine would be available generally to allow use in other areas if desired.
- A pot of funding would be created to support vaccination. This could either be a centralised funding mechanism that groups could bid into or locally based. Contributions to a central pot could be from some combination of government, industry and other interested parties. Availability of funding from central sources could be linked to meeting certain conditions such as, for

example, using natural barriers to reduce the risk of the buffer being 'outflanked' and ensuring a minimum width of buffer.
- Targeting would be any PTI2, PTI3 and PTI4 where adjacent to a higher testing frequency parish. Guidance would be provided on the most effective approach, and minimum effective width of buffer.
- The vaccine would be delivered in oral bait.
- Coordination would be at the local level by regional industry groups, wildlife groups or even individuals willing to do so. The make up of the groups will vary depending on local needs and enthusiasm.
- Vaccine will be delivered by members of the group or contractors hired by the group.
- Vaccination in a given area would be performed for a duration of at least five years on at least an annual basis.
- Use of vaccines would not be compulsory.
- Monitoring would be conducted as part of the overall monitoring of TB statistics.

3.3 Low risk Areas

3.3.1 Scenario 6 - Reactive area vaccination

<u>Rationale</u>

234. The majority of isolated breakdowns in low incidence areas are due to cattle movements. Vaccinating in response to an isolated breakdown could help prevent infection being transferred to the local badger population or if it has become transferred, from establishing a significant pool of disease. Vaccinating beyond the breakdown farm would help isolate any infected badgers in a buffer of non-susceptible animals. As a preventative measure it will be difficult to measure the benefits.

<u>Description</u>

235. The vaccine would be available generally to allow use in other areas if desired.
- A pot of funding would be created to support vaccination. This could either be a centralised funding mechanism that groups could bid into or locally based. Contributions to a central pot could be from some combination of government, industry and other interested parties. Availability of funding from central sources could be linked to meeting certain conditions such as, for example, a commitment to vaccinate for a minimum number of years.
- Targeting would be the breakdown farm and surrounding land up to a distance set out in guidance (could be 1-2km). This guidance would provide information on the most effective approach, ideal areas etc.
- The vaccine would be delivered in oral bait.
- Coordination would be at the local level by regional industry groups, wildlife groups or even individuals willing to do so. The make up of the groups will vary depending on local needs and enthusiasm.
- Vaccine will be delivered by members of the group or contractors hired by the group

- Vaccination in a given area would be performed for a duration of at least five years on at least an annual basis
- Use of vaccines would not be compulsory
- Monitoring would be conducted as part of the overall monitoring of TB statistics.

3.3.2 Scenario 7 - Individual use (Low risk/buffer area/high risk)

Rationale

236. Individual use of vaccine will allow those who perceive a need to take action having weighed up the potential costs and benefits to themselves. The vaccine can be used in such a way as to maximise the individual perceived benefits and minimise costs. However, this may not lead to the greatest overall disease control. It will be very difficult to determine if the approach is successful as the badgers in question may never be exposed. Uptake will be based on perception of benefit but use will not be detrimental.

237. As the key to ‘buffer’ vaccination is a large contiguous area, individual vaccination in a buffer zone will be the same as in a low area in terms of actual benefits but may be addressing a perceived higher risk.

238. For high risk areas this differs from scenario 3 as there would be no additional incentives for use.

Description

239. This approach would be down to the individual with no additional support beyond general guidance.
    - The vaccine would be available generally
    - Vaccination will be funded by the individual using it
    - Targeting would be any parish
    - The vaccine would be delivered in oral bait
    - There would be no large-scale coordination
    - Vaccine will be delivered by individual landowners or contractors hired by them
    - Guidance would recommend the duration of vaccination. As this will be limited to the individual farm disease pressure from outside the vaccinated area may be maintained and therefore vaccination would need to be performed on an annual basis to maintain the benefit
    - Use of vaccines would not be compulsory
    - Monitoring would be conducted as part of the overall monitoring of TB statistics subject to being able to separate the effects of vaccination from other initiatives.

4 Economic assessment

240. As it is not intended to make badger vaccines compulsory there is no need for a full impact assessment. However, it will be of value to both Government and individuals to have an understanding of where the balance of costs and benefits potentially lies. This will help give an indication of how badger vaccines should be prioritised relative to other approaches to control bTB both on the individual level and for national disease control.

241. The Veterinary Laboratories Agency (VLA) have developed a model to examine the impact of vaccination of both cattle and badgers to provide some initial assessment of the potential costs and benefits.

242. Although there are potential benefits to vaccination in low risk and buffer areas it will be very hard to measure these as it is not possible to say whether disease has been prevented or would never have emerged. The benefits of vaccination in these areas will have to be taken 'on faith' from those demonstrated in high risk areas and the balance of costs and benefits based on the perceived risk mitigated.

243. To give an initial assessment of the costs and benefits the model has been used to assess widespread use of badger vaccines in high-risk areas (PTI1). This is equivalent to high take-up of Scenarios 2 or 3. A summary of the main conclusion is given below.

244. There are a large number of uncertainties surrounding the contribution of badgers to the level of bovine TB in cattle. The model therefore considered four different 'worlds' with differing contributions to disease levels from wildlife.

245. The potential costs of vaccination are also uncertain as these will depend to a high degree on the final formulation of the oral vaccine. Two different costs per bait of £4 and £10 have been considered to allow for different doses of vaccine.

246. It is assumed that each social group will need 15-20 baits per group per day for 5 days giving 75 to 100 baits per sett per year (assuming an average of 1 social group per km^2). This is based on research by CSL where this level of distribution led to an estimated uptake of greater than 95% or badgers eating at least one bait. A single bait should be sufficient to vaccinate a badger and there will be no harm in eating multiple baits. It is important to note that these levels have not been optimised and experiments are currently underway to do this. It is possible that a larger number of baits would be required over a longer period of possibly up to 10 days, however, it is thought more likely that experiments will show levels could actually be reduced.

247. Based on the costs outlined above two sets of costs and benefits have been assessed:
    - Low cost - Bait cost £4, 75 baits per km^2 per year
    - High cost - Bait cost £10, 100 baits per km^2 per year

248. The low-cost scenario predicts a cost of around £320 per km^2 per year and provides a net benefit in all of the ‘worlds’ with their different badger contributions used in the model. This is compared to a baseline cost of just using current controls over a period of from 2014 to 2026. The baseline costs are projected between 1% and 8% higher than vaccination depending on the ‘world’ chosen. As might be expected, the greater the badger contribution modelled the greater the net benefit. This net benefit is in terms of the costs of vaccination being offset by savings due to reduced costs from breakdowns. It is also predicted there would be an improved disease picture at the end of this period.

249. The high-cost scenario predicts a cost of around £950 per km^2 per year and provides a net cost in all the ‘worlds’. The vaccination costs are projected between 4% and 12% higher than vaccination depending on the ‘world’ chosen. As above the greater the badger contribution modelled the greater the potential benefit and therefore the closer vaccination is to breaking even. However, it is important to note that although there would be a net cost in this model there would still be a predicted improvement in the disease picture at the end of this period.

250. The reduction in costs lags behind the benefits in terms of disease level as a significant proportion of the costs are related to the testing regime and it takes at least six years for a parish to move from being PTI1 to one PTI4 and a single breakdown can significantly set back the process.

5 Conclusions

251. This paper sets out the most feasible scenarios for the widespread use of badger vaccines. The analysis demonstrates that these are likely to rely on oral vaccination on a non-compulsory basis and that such a programme of vaccination could be cost-effective.

252. These are the lead options and therefore give a reasonable basis on which to make decisions regarding prioritisation of the vaccine programme. The next step of the process will be to develop a business case for badger vaccination based on these findings.

253. However, it is recognised that changes in the disease picture and other factors may alter some of the issues discussed. No options have been completely eliminated.

254. This paper was discussed with stakeholder groups at a meeting on the 3rd of April 2008 and has been endorsed by them.

255. The groups who have agreed to endorse this paper and its conclusions are:

- NFU
- NBA
- BVA
- BCVA
- LAA
- Badger Trust
- RSPCA
- FUW
- NFU Wales
- The National Trust
- The Wildlife Trusts
- Defra TB Advisory group

6 Annexes

6.1 Annex 1 – Veterinary advice on Options for Targeting Vaccination Over Single Farms or Small Areas

6.1.1 Executive summary

256. In order for a vaccine against *M. bovis* in badgers to receive regulatory approval and a Marketing Authorisation, it is a prerequisite for it to have been shown to be both efficacious and safe. **It can therefore be assumed that a vaccine, delivered by whatever means, can at worst, be of neutral benefit to disease control** – there is no scenario where it can be envisaged to exacerbate disease.

257. **On veterinary grounds alone, there are no foreseeable reasons to recommend against using a vaccine or to specify a minimum area in high incidence areas**; however, farmers should be urged to co-operate with their neighbours to make the area that is vaccinated as large and complete as possible - the maxim is the bigger and more complete the area vaccinated, the better.

258. When used as a buffer to reduce ‘creep’ of disease in wildlife the same principles of as large and as complete an area as possible apply.

259. Around single cattle herd breakdowns in 4-yearly tested areas, vaccination should cover an area with a radius of at least three social group territories,

260. Other factors such as legal issues, ease of administration and cost will influence the choice of whether or not to vaccinate, the type of vaccine and the approach to be used.

6.1.2 The principles of disease control

261. The principle of disease control is to reduce the absolute number (and hence proportion) of both infect**<u>ious</u>** and susceptible individuals, (a logical consequence of which is to increase the number and / or proportion of uninfected, non-susceptible individuals). Note: Only infect**<u>ed</u>** animals can be infect**<u>ious</u>**

262. Individuals become non-infectious through (1) immune recovery or (2) death (with safe disposal of the carcase).

263. Individuals become non-susceptible through (1) an immune response following recovery (in the case of some diseases), or vaccination. They also become non-susceptible by (2) being culled, or by (3) ensuring that they have no effective contact with the infectious agent.

264. In this context, infection is an all or nothing event – infected badgers may or may not be infectious at any point in time, but repeated contact with infection cannot make them ‘super-infected’.

6.1.3 The role of vaccination

265. The role of vaccination is to increase the number and proportion of non-susceptible individuals, and thus reduce the likelihood of any one infectious individual encountering a susceptible individual and passing on infection to others.

6.1.4 Points of action of vaccination

266. By reducing the number of infected and susceptible badgers, vaccination of badgers will **reduce three of the four components** of the badger-cattle infection cycle:

    1. Badger to badger
    2. Badger to cattle
    3. Cattle to badger

6.1.5 Seasonal factors

267. The seasonal pattern of vaccination is likely to be important, with maximum effect likely to be achievable in the spring when naive cubs are emerging from setts.

6.1.6 Extent of protection

268. The level of protection will depend on:

    1. The proportion of badgers infected at the time of vaccination.
    2. The proportion of uninfected badgers vaccinated:
        a. Injectable:
            i. The proficiency of badger capture (injectable).
            ii. The proficiency of administration Injectable).
        b. Oral:
            i. The proficiency of bait laying (oral).
            ii. The attractiveness of the bait.
            iii. Badger social factors and their influence on bait uptake.
    3. The time of vaccination in the year.
    4. The efficacy of the vaccine.

6.1.7 Injectable v oral vaccine use

269. For the purposes of disease control, if both types of vaccine receive a marketing authorisation, there are no veterinary disease control reasons for selecting one over the other. The choice comes down to practical ease of administration of the vaccine, logistics and cost issues. However, it seems unlikely that injectable vaccine will ever be practical for widespread use by farmers in the field – a vaccination policy for badgers will be most effective using an oral vaccine .

270. It seems likely that the detail of this policy would benefit from specialised simulation modelling of the available vaccine strategies.

6.1.8 Vaccination scenarios

271. There are three vaccination scenarios to consider:

  a. Scenario A: Vaccination of badgers in high cattle incidence area (1, 2 or 3 yearly testing)

  b. Scenario B: Vaccination of a buffer zone

  c. Scenario C: Low incidence areas

6.1.9 Scenario A: Vaccination of badgers in high cattle incidence area (1, 2 or 3 yearly testing)

272. The objective of such vaccination is to reduce the prevalence of infection in the local badger population and therefore reduce the likelihood of transmission to cattle; and also to reduce the spread of infection from cattle to badgers. Epidemiologically, a new case of infection in an already infected area is only of marginally less significance than a new case in a clean area.

273. There are four mechanisms at work:

  1. Infected badgers within the social group cannot infect non-susceptible badgers, and cannot 'super-infect' already infected badgers (Infection is an all or noting event – infected badgers may or may not be infectious at any point in time, but repeated contact with infection cannot make them 'super-infected')

     i. Badger cubs are vaccinated before they can become infected.

     ii. Uninfected, susceptible adult badgers within the social group are vaccinated before they become infected.

  2. Infected badgers within a non-susceptible social group will have a half-life and the proportion of infected badgers will decrease as they die through infection or other causes, or move away, and are not 'replaced' by other infected badgers.

274. In this scenario, vaccination must be contrasted with do nothing.

275. By decreasing both the absolute number and proportion of infected badgers, vaccination is likely to decrease both direct and indirect (via the environment) transmission; in addition to badger-to-badger, badger-to-cattle and cattle-to-badger transmission (see figure one below)

276. In a high incidence area, vaccination at any level of coverage should be encouraged, but the maxim in any of the three scenarios, will be "the bigger the area the better", and ideally a minimum distance of at least two social groups outside the "core" social group to ensure that a badger that moves to an adjacent social group and is then moved on, is likely still to be within a vaccinated area . If used by a individual farmer, it should be made clear that the impact on disease will be minimal but not negative; and that the vaccine will have to be used at least annually, over a minimum period, which will be at least the life-span of an infected badger. Increasing the areas of land and proportion social groups that are vaccinated is likely to have a disproportionately increasing beneficial effect.

6.1.10 Scenario B: Buffer zone

277. The objective is to reduce disease 'creep' at the border of high and low incidence areas, and the above principles of frequency and area apply.

278. The importance of percentage coverage is perhaps greater in this scenario for vaccination to achieve its objective of preventing 'creep' of infection in wildlife (and from there to cattle).

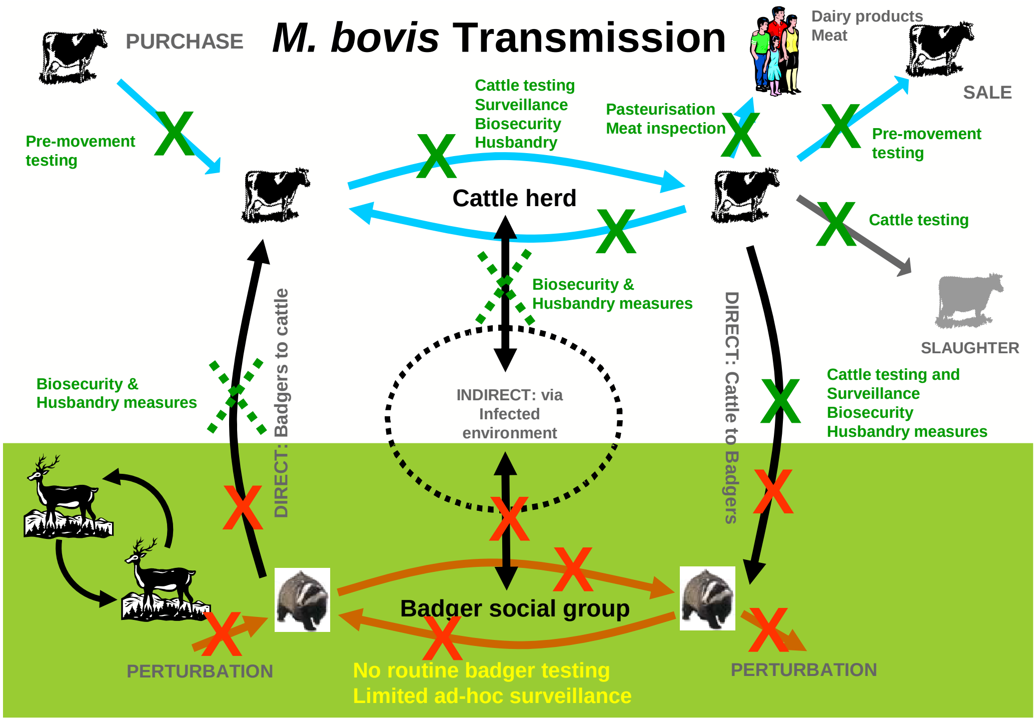
6.1.11 Scenario C: Low incidence areas

279. The objective is to prevent (or minimise spread) of infection in badger social groups around newly cattle outbreaks in low incidence areas, and the above principles of frequency and area apply.

280. N.B. In low incidence areas, cattle herd breakdowns may have been developing for four years before detection; therefore spill-over into the badger host may have already occurred.

Figure 1: Points of action of badger vaccination (shown in red)

Note: Solid green crosses indicate measures that result in a highly effective reduction in disease transmission; dotted crosses indicate measures with less proven efficacy.



281. It is recommend that the minimum extent of vaccination around a breakdown farm in a 4-yearly tested area should be an area with a radius approximating to three social groups.

6.2 Annex 2 – Legal requirements

6.2.1 Prohibition of the use of TB vaccine

282. The introduction of vaccination needs to be done in accordance with the requirements of Council Directive 78/52/EEC (as amended by Directive 82/400) which requires all Member States to have a TB eradication plan which complies with the criteria set out in Council Directive 78/52.

283. Article 13 requires member states to ensure “anti-tuberculosis vaccination” is prohibited under their eradication plans. The drafting of the Directive is unclear as to whether this applies just to cattle or all uses of vaccine including badgers.

284. The possible grounds on which we might argue that they do not require Member States to prohibit vaccination of badgers - separate from any arguments for cattle vaccination - is that Article 13 only requires a prohibition on the vaccination of cattle, even though it is not expressly so limited, on the basis that a reading of the Directive as a whole indicates that its obligations are only intended to relate to cattle.

285. However there is no certainty that this argument could successfully be relied upon as a basis for introducing a badger vaccination policy and we would run the risk of being infracted by the EU Commission if we did so.

286. As a minimum, and to mitigate against the risk outlined above, we will discuss our proposed intentions with the Commission to seek their views as to whether or not it would be a breach of the Directive for the UK to allow vaccination of badgers and seek amendments accordingly.

6.2.2 Bern Convention

287. The Bern Convention is an international agreement, which, in accordance with Article 26 of the Vienna Convention on the Law of Treaties, is binding upon the parties to it (including the UK) and must be performed by them in good faith. It is not part of national law but the UK is bound to comply with the terms of the Convention under its international legal obligations.

288. Article 7 of the Convention requires Contracting Parties to ensure the protection of species listed in Appendix III which includes the badger.

289. Article 8 prohibits the use of indiscriminate means of capture and killing and other forms of exploitation (in particular those specified in Appendix IV of Bern). This includes all types of trap if applied for large scale or non-selective capture or killing. The option of vaccinating all badgers is not feasible - logistically or in terms of cost – and any policy can therefore only be targeted. However, trapping of badgers in order to vaccinate would need to be managed in the context of the convention.

290. Article 9 allows for exceptions to be made from the prohibited means in Article 8 for certain purposes if there is no other satisfactory solution and it will not be detrimental to the survival of the population. Vaccination of badgers would do no

long-term damage and could potentially give a health benefit which would also be beneficial in conservation terms.

6.2.3 Protection of Badgers Act 1992

291. As far as domestic law is concerned, Section 1 of the Protection of Badgers Act makes it an offence to kill, injure or take, or attempt to kill, injure or take a badger, except as permitted by the Act. There are general exceptions to this under Section 6 but capturing badgers for the purpose of vaccination would not fall within any of these exceptions.

292. If a badger vaccination scheme were introduced the persons tasked with capturing the badgers would have to be granted a licence under Section 10 which specifies the conditions under which licences may be granted. The purpose of ‘ preventing the spread of disease ‘ would apply in this case.

293. Section 2 of the Act prohibits the cruel ill-treatment of badgers without exception. Whatever form a potential vaccination scheme takes it will be necessary to satisfy ourselves that the proposed methods of capture and vaccination of badgers do not constitute a cruel ill-treatment. Extensive consideration has already been given to the use of cage traps and they are considered humane and effective as a means of capture.

294. If other methods of capture were to be used, similar consideration would also need to be given to their humaneness, and if the methods of capture were to involve interference with badgers setts this would also need to be licensed to avoid an offence being committed under Section 3 of the Act. However, we do not envisage the development or use of alternative methods at this point in time.

295. If the badgers are not captured or harmed as part of the vaccination process then there are no legal barriers to use. An oral bait could therefore be legally used without the need to licence. This would allow ease of use but might limit the ability of government to control how the vaccine is used without additional legislation.

296. Licensing functions under the Protection of Badgers Act are the remit of Natural England who would need to agree criteria for granting licences for this purpose.

6.2.4 Statutory powers of vaccination

297. The only express statutory power for persons to vaccinate animals lies within Section 16 of the Animal Health Act 1981. This provides that, for the purpose of preventing the spread of disease, Ministers may cause to be treated with vaccine any animal which has been exposed to infection, in contact with a diseased animal or are in an infected area.

298. The power to vaccinate animals under the Act is not considered wide enough to cover a programme of vaccinating badgers on a precautionary basis. As with cattle, it cannot be argued that all caught badgers subject to vaccination, have been in contact with or exposed to infection.

299. The absence of a specific legal power to carry out vaccinations does not necessarily present a legal barrier however, as there doesn’t generally have to be an express legal power to carry out an activity provided there is no law prohibiting it.

300. There is no domestic law prohibiting vaccination of badgers against bTB, though such provisions exist for cattle and deer (Tuberculosis (England) Order 2007 and the Tuberculosis (Deer) Order 1989).

301. However, the significance of Section 16 not applying is that we couldn’t rely on the powers of entry within that section. This in unlikely to present a problem if badger vaccination is to be on a voluntary basis but primary legislation to widen the scope of Section 16 would be required before a compulsory vaccination programme could be implemented.

6.2.5 Animal by-products regulations

302. Animal by-products must be collected, transported, used and disposed of in accordance with EU Regulation 1774/2002. Animal by-products are defined in that Regulation as "entire bodies or parts of animals or products of animal origin…not intended for human consumption". This Regulation lays down strict processing standards for by-products that will ultimately become products, or alternatively requirements relating to their disposal. We enforce the requirements of this Regulation through the Animal By-Products Regulations 2005, which set out the offences in relation to ABPs.

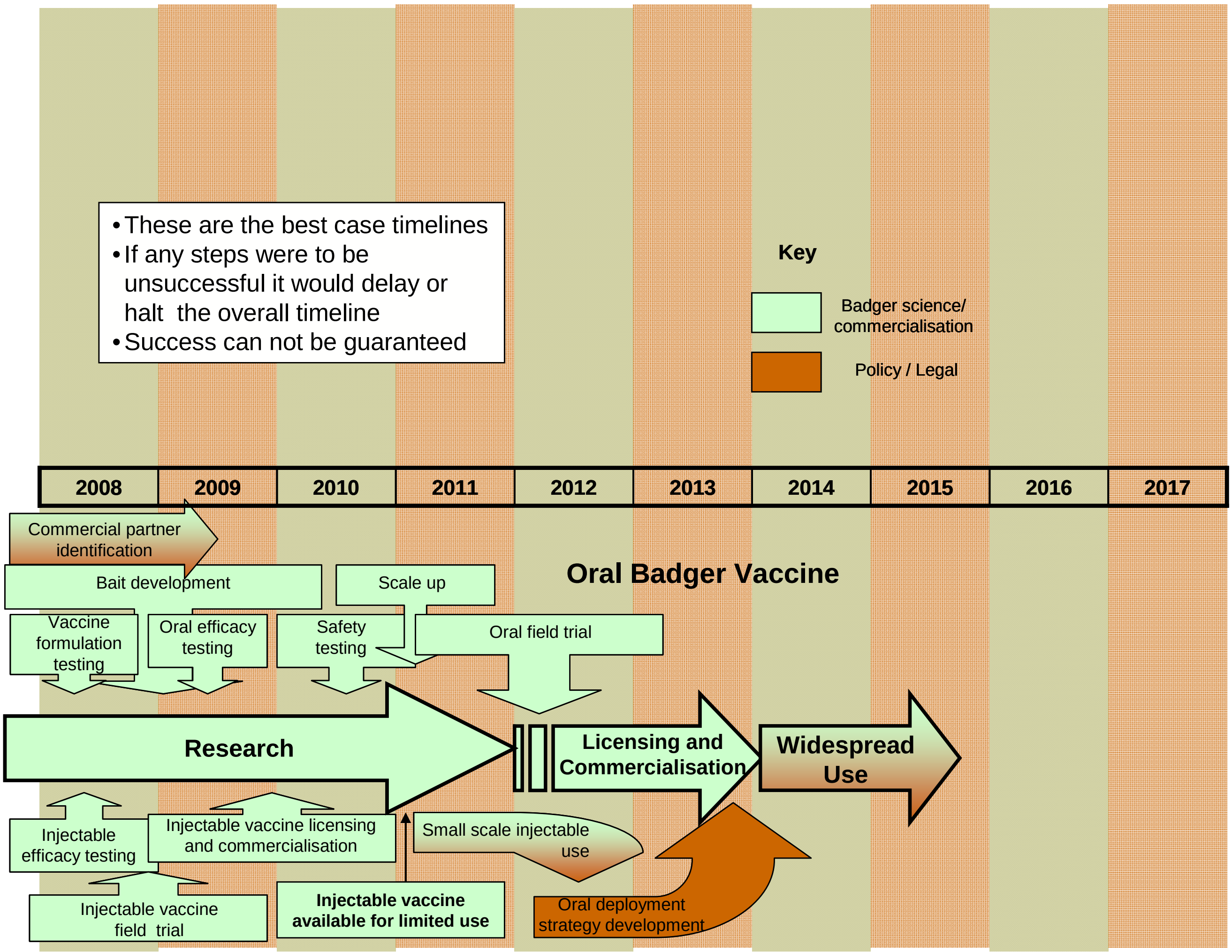
303. Regulation 11(2) of the domestic regulations provides that "any person who brings catering waste or other animal by-product (other than milk, colostrum, manure or digestive tract content) on to any premises where any livestock is kept is guilty of an offence". It is also a separate offence "for any person to allow livestock access to any catering waste or other animal by product" (with limited exemptions) - see regulation 11(5). This regulation applies to those ABPs "that have not been processed or treated" in accordance with the Community and domestic regulations.

304. It is stated that "livestock" means all farmed animals, and any other ruminant animals, pigs and birds (other than wild birds).

305. Whilst it may be possible to put in place stringent measures to ensure cattle did not have access to the bait, the existence of the separate offence relating to taking ABPs onto livestock premises could prove to be a block in the development of a policy of using oral bait consisting of unprocessed ABPs.

6.3 Annex 3 – Timeline for badger vaccination development

306. The diagram below is a high level timeline for the development and commercialisation of a badger vaccine. The dates provided are the earliest estimate of when a vaccine could be licensed and deployed.



6.4 Annex 4 – Costs of injectable vaccination

307. The following is an estimate of the cost to live-trap and parenterally vaccinate badgers in the field for a 100 km^2 area of average badger density in the southwest region of England.

308. These costs are consistent with the work being conducted by a government contractor such as CSL. It may be possible to reduce some of these costs particularly if the work was conducted by farmers themselves.

309. These costs include surveying, trap deployment, pre-baiting, trapping and vaccination (assuming that the same field staff are able to both trap and vaccinate). It assumes that trapping will be conducted over two consecutive nights and that the entire area would be trapped once and all badgers caught vaccinated once. Using a field team of ten staff (plus a project manager and administrative support) it is estimated to take 3-4 months to complete the field work. It is based on an average density of one social group per km^2 and six badgers per social group. This is in line with the higher density triplets in the RBCT.

310. The projected costs are:
   - Initial estimate to trap and vaccinate badgers in a 100 km^2 area = £210,000
   - Follow-up estimate to re-trap and vaccinate badgers in the same area in subsequent years = £160,000

311. Follow-up trapping and vaccination operations (in the same area) would be cheaper than the initial operation as there are considerable costs associated with the initial survey and set-up work.

312. Both estimates includes all staff overheads (including management and administration), vehicle mileage and maintenance costs and consumables. This does not include the initial outlay of vehicles and equipment (badger traps), which could add substantial costs dependent on who was contracted to do the work. For example, if it were necessary to purchase new traps this would incur an additional cost in the region of £80,000 (800 traps @£100 each) for an area of this size.

313. There might also be considerable additional costs of accommodation @ £50 per night per person, plus expenses @ £26 per person per night, again dependent upon who was contracted to do the work and the location of the site(s). It also does not include the cost of the vaccine or any additional costs associated with its delivery (e.g. if it was necessary for a vet to administer). The overall cost may vary according to the actual badger density at the site. A site of particularly high badger density would incur additional labour and equipment costs increasing the cost per km^2 but reducing the cost per badger trapped and vaccinated.

314. A detailed economic assessment of injectable vaccination has not been conducted, however, based on the costs outlined above an injectable vaccine would cost in the region of £2000 per social group per year. It can be assumed

that the potential benefits would be no greater than with oral vaccination but at much greater cost per km^2.