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From:	[redacted]			
Date:	[redacted]			

SF/JG/0333/12: WALES BOVINE TB ERADICATION PROGRAMME - DECISION ON CULLING BADGERS IN THE INTENSIVE ACTION AREA

1 Issue

1. This submission provides scientific and other evidence, including research on public attitudes, and draws from the findings of the Science Review commissioned by you, to assist you in coming to a decision on the additional steps you should take as part of the TB Eradication Programme within the Intensive Action Area ("IAA"), including whether or not the Badger (Control Area) (Wales) Order 2011 providing for the destruction of badgers in the IAA is appropriate.

2 Timing

2. Routine.

3 Recommendations

3. It is recommended that you:
   - o Approve the Statement of Information at Document 1 and that it should be published through the Decision Report Process, together with the supporting evidence (including the Science Review) after you have made your decision and informed Cabinet Members.

- o Decide what approach to take to deal with the reservoir of infection that exists in badgers within the IAA and permit authority to proceed with that approach.
- o Decide on whether or not to implement a cull of badgers in the IAA provided for by the Badger (Control Area) (Wales) Order 2011, and;
- o If you consider that destruction of badgers is not necessary that you give consideration to revoking the Badger (Control Area) (Wales) Order 2011.
- o Agree that the enhanced IAA cattle surveillance and control measures (implemented from 1 May 2010) for the purpose of bovine TB eradication in the area should continue.
- o Note that these decisions do not affect the status of badgers as a protected species under the Protection of Badgers Act 1992.

4 Background

4. Bovine TB in cattle is an infectious notifiable disease caused by *Mycobacterium bovis* (*M. bovis*) that has a significant impact on the health and welfare of the national cattle herd in Wales. It is a disease that is transmissible to humans and other mammals, which means it has serious implications beyond the health of cattle. Wales implements a TB disease eradication policy based primarily on the testing and slaughter of cattle**.** These measures are in place to protect public health, animal health and the welfare and the trade of cattle. A glossary of terms has been provided at Annex 1 to explain the terminology used in this submission.

5. The testing and slaughter of cattle, pasteurisation of milk and meat inspection at slaughterhouses ensures that, for people in Wales, the risk of contracting *M. bovis* infection from cattle is relatively low. However, there is potentially a higher risk of infection to certain groups of people such as cattle keepers (and keepers of other susceptible species e.g. goats and camelids), veterinarians and slaughterhouse workers, from consumption of unpasteurised milk and direct exposure to *M. bovis* from animals infected with bovine TB.

4.1 Bovine TB Eradication Policy

6. Current bovine TB policy is driven by a European Union (EU) framework regarding bovine TB formed by legislation. Directive 64/432/EEC is aimed at facilitating intra community trade amongst EU Member States by establishing comparable health requirements. An important extension of this is Council Directive 77/391/EEC, which introduces Community measures for the eradication of diseases such as Tuberculosis in cattle. This requires Member States to develop eradication programmes in order to accelerate, intensify or carry through the eradication of bovine TB.

7. The formal programme to eradicate bovine TB in Wales, which was introduced on 8 April 2008, is taking a comprehensive approach to disease eradication nationally, regionally and locally, effecting change down to the individual farm level. It has been designed around compliance with EU legislation and EU expectations for a successful eradication programme as set out in the Working

Document on Eradication of Bovine Tuberculosis in the EU accepted by the Bovine tuberculosis subgroup of the Task Force on monitoring animal disease eradication (European Commission SANCO/10200/2006).

8. The programme is set out in the UK TB Eradication Plans for 2010, 2011 and now for 2012, (which include measures for Wales, England and Northern Ireland). The Plan for 2012, which was approved by the European Commission on 30 November 2011, also takes account of the initial recommendations of the European Commission's technical experts following a Food and Veterinary Office Mission to England and Wales in September 2011.

9. The programme continues progressively to introduce measures to address known routes of bovine TB transmission and to stamp out infection.

10. Additional controls have been introduced across Wales since the start of the TB Eradication Programme, including policies such as increased cattle testing, improved enforcement procedures and removing infected cattle more quickly on a national basis. Their design is based on the key principles of infectious disease control which are keeping infection out, rapid early identification of infection, and containment and elimination/ eradication of infection, which are explained further at Annex 3.

11. The previous Government introduced a number of enhanced surveillance and control measures for bovines (and farmed non bovines) across Wales. They established the Intensive Action Pilot Area (IAPA), now known as the IAA, and introduced IAA-specific enhanced cattle surveillance and controls alongside the Badger (Control Area) (Wales) Order 2011 (“the Order). The Order specified an area (the IAA) as an area, badgers as a species and TB as a disease for the purposes of section 21 of the Animal Health Act 1981 (“1981 Act”), thus authorising the destruction of badgers within that area under the Act. The Rural Affairs Minister at the time, as one of the Welsh Ministers was satisfied that the threshold test within section 21 was met and that it was appropriate to exercise her discretion in this matter.

12. There is a general consensus with an evidence base that while other wild and feral species such as deer may become infected with bovine TB they do not currently play a significant role in the epidemiology of the infection in the UK (Ward *et al*, 2009). The programme in Wales continues to implement a passive surveillance programme for these species.

13. On 21 June 2011 you announced that there would be a review of the scientific evidence base regarding the eradication of bovine TB in Wales by an independent panel of scientific experts (“Science Review”) overseen by the Chief Scientific Adviser, Professor John Harries. The Science Review is part of the Programme for Government commitment to take a science-led approach to evaluate and review the best way of tackling bovine TB. The composition of the panel and the terms of reference for the Group, together with a list of the meetings held and witnesses seen, is set out in Annex 5.

14. You also announced that there would be no cull of badgers in the IAA while the Science Review was being carried out.

15. Professor John Harries and Professor Christopher Gaskell, chair of the panel, delivered their report to you on 1 December 2011 (see Annex 4). The panel considered the scientific evidence base for the comprehensive programme for the eradication of bovine TB in Wales. The Office of the Chief Veterinary Officer for Wales provided a full account of the science and evidence base considered as part of the implementation and maintenance of the TB Eradication Programme for Wales but had no influence on what evidence they considered or any knowledge of what evidence was considered. The Science Review classified the scientific evidence base considered according to the degree of certainty (general consensus with an evidence-base, general consensus based on expert opinion, majority support and some support (Science Review Report, Page 5, Para 7, see Annex 4).

16. The Science Review recognised that “while a bovine TB Eradication Programme should be informed by the science evidence base, the precise measures adopted will be a political judgement based on an evaluation of a range of factors including the interests of the different stakeholders” (Science Review Report, Page 4, Para 17, see Annex 4).

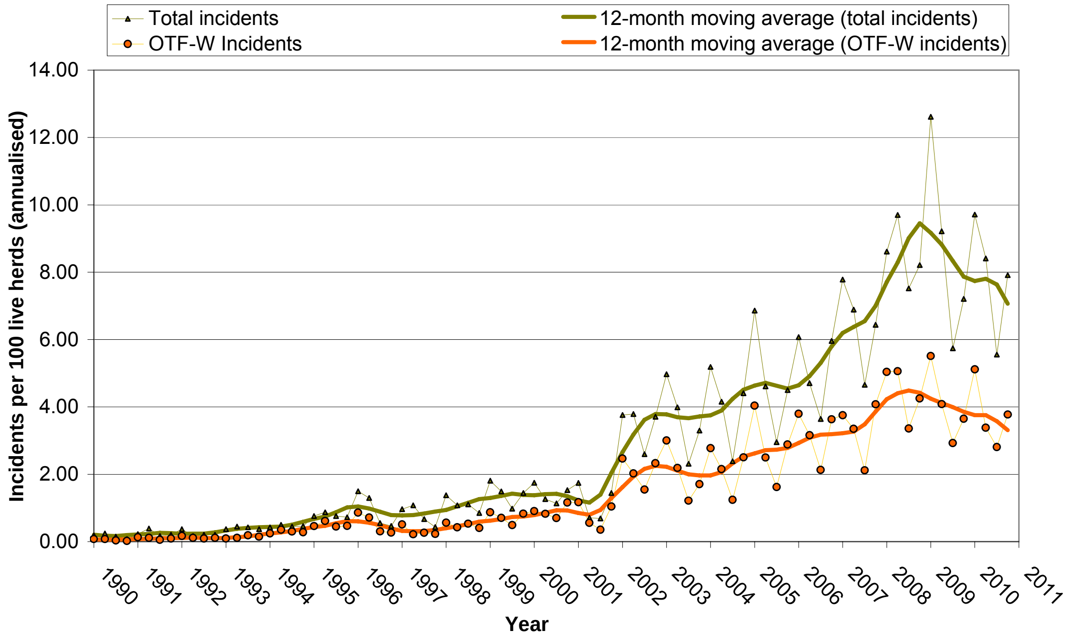
17. For the purpose of this submission we have drawn on those conclusions of the Science Review that are relevant to the IAA and in particular to the interventions for dealing with a reservoir of bovine TB infection in badgers.

18. The conclusions of the Science Review on the wider programme for Wales as a whole are considered in the separate submission on the TB Eradication Programme (SF/JG/0366/12).

4.2 Disease situation in Wales

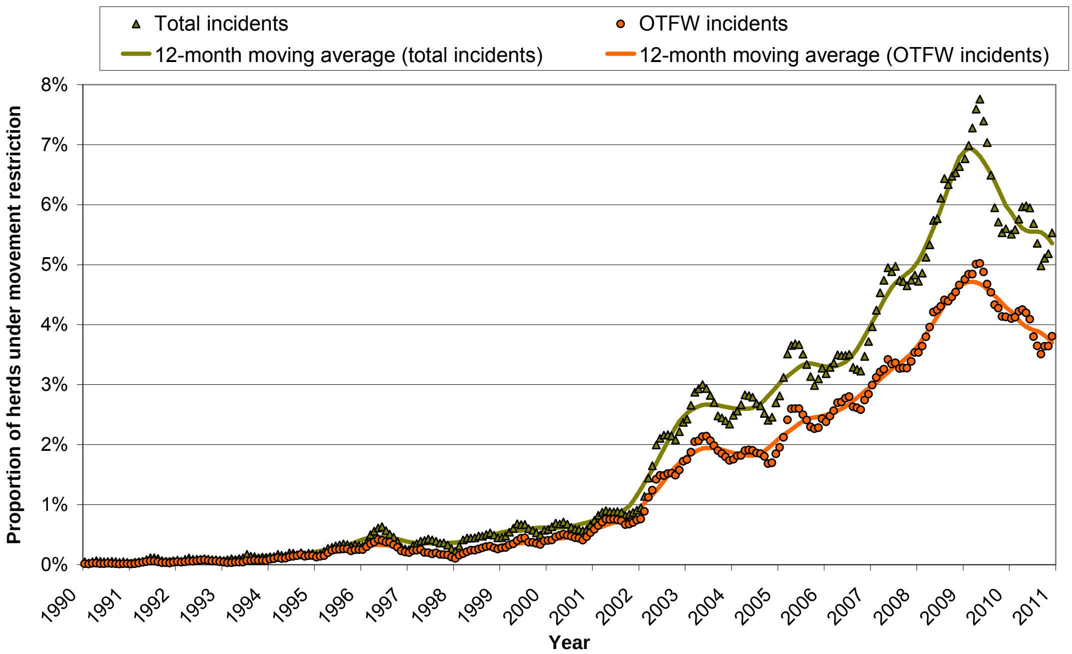
19. The historic trend over the last 20 years has been a worsening TB situation in GB resulting from a combination of both increasing overall incidence and spread of the disease to new geographical areas:
    - Annual herd incidence and animals slaughtered peaked in 2008 then fell in 2009, in Wales. That declining trend continued in Wales throughout 2010, Figure 1 (AHVLA Epidemiology of bovine tuberculosis in Wales, Annual surveillance report, Jan – Dec 2010).
    - Wales has seen a stabilisation during 2011 with little change in the overall number of new TB breakdowns disclosed compared with the same period in 2010 (latest published figures for January - August, Defra National Statistics).

Figure 1: Annualised, quarterly number of total and Officially TB Free Withdrawn status incidents per 100 ‘live’ herds, between January 1990 and December 2010



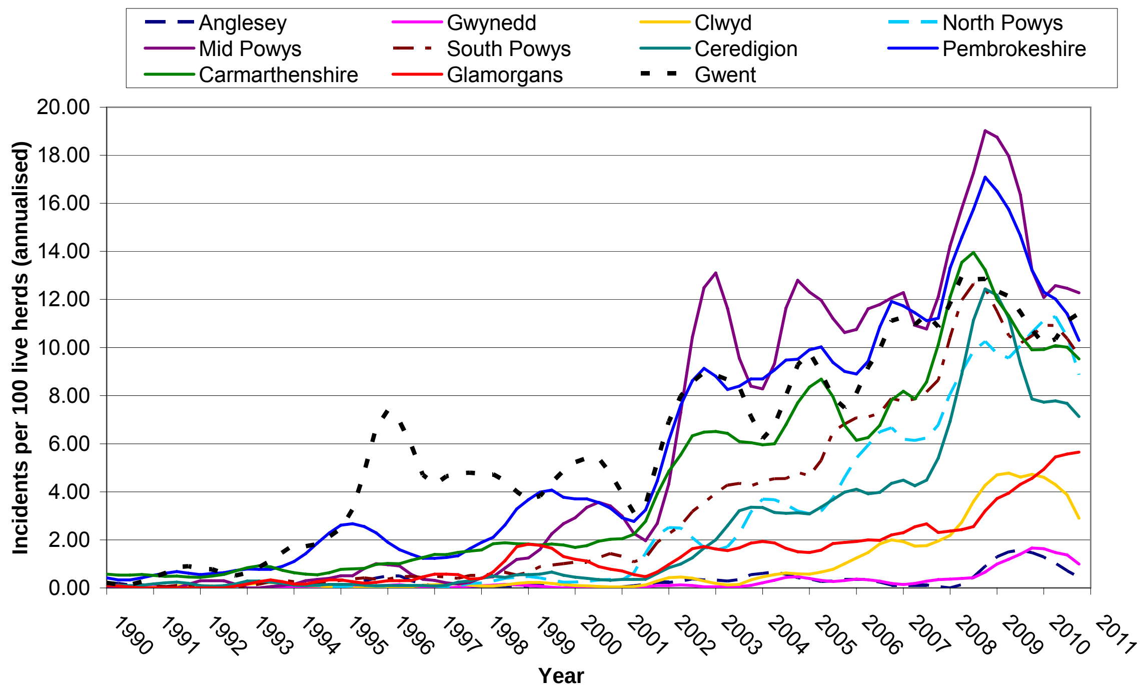
Source: Epidemiology of bovine tuberculosis in Wales: Annual surveillance report 2010

Figure 2: Monthly proportion of 'live' herds that were under movement restrictions between January 1990 and December 2010



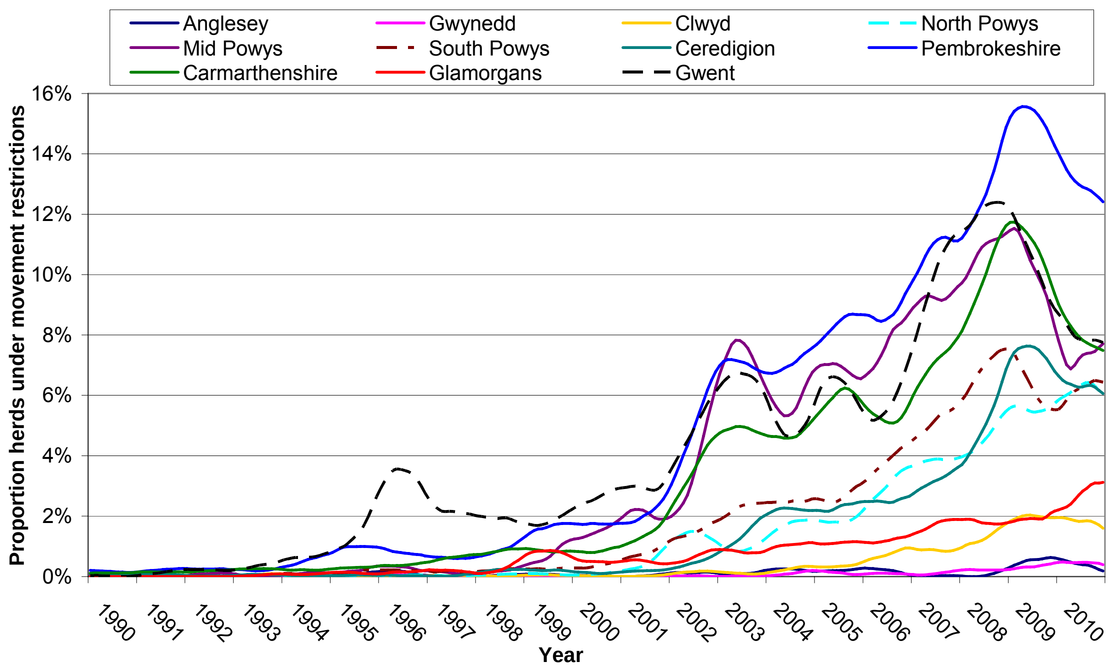
Source: Epidemiology of bovine tuberculosis in Wales: Annual surveillance report 2010

Figure 3: Quarterly (annualised), smoothed (12 month moving average), number of total new incidents per 100 'live' herds, between Jan 1990 and Dec 2010, by Welsh geographical area



Source: Epidemiology of bovine tuberculosis in Wales: Annual surveillance report 2010

Figure 4: The monthly proportion (12-month moving average) of live herds under movement restrictions within each geographical area between January 1990 and December 2010



Source: Epidemiology of bovine tuberculosis in Wales: Annual surveillance report 2010

20. There are parts of Wales that have a consistently high prevalence of bovine TB within the herds in the area demonstrated by the regional variations seen in figures 3 and 4 (prevalence is the proportion of a defined population being infected with a disease at any point in time). These areas account for the majority of the cattle slaughtered because of TB and consequently receive the majority of the compensation paid. These are areas where bovine TB is

regarded as endemic. Endemic means that the disease is constantly present and circulating to a greater or lesser degree and maintained in and by the population or populations of animals, for example wildlife, cattle and/or non bovines.

21. Parameters used to identify endemic areas include the duration of breakdowns, survival times between breakdowns, the scale of breakdowns and the proportion of a herd slaughtered in a breakdown.

4.3 The Intensive Action Area

22. The IAA is a TB endemic area which accounts for a significant proportion of the national TB compensation costs. It was established as an area within which increased measures would be implemented to tackle all sources of bovine TB, in both domestic and wild animal species. It is an approach which has not yet been tried in the UK but is similar to that adopted in New Zealand, where they have successfully eradicated the disease from large areas of the country.

23. The IAA is primarily located in north Pembrokeshire, but includes small parts of Ceredigion and Carmarthenshire. The IAA is approximately 288km². The boundary has been designed to make the best use of geographic and natural boundaries, and non cattle grazed areas, and has included whole farms where land is contiguous (i.e. immediately adjacent) so as to minimise any possible impact from the perturbation of badgers. A map of the IAA can be seen at Annex 6.

24. On 1 May 2010, on the introduction of the enhanced IAA specific cattle surveillance and control measures (“enhanced regime”), there were 317 cattle herds in the IAA (AHVLA, Project OG0142, see Annex 7) in comparison to 13,095 in the whole of Wales (source: National TB Statistics August 2010).

25. The total amount of compensation paid to TB breakdown herds within the IAA in the last full year (2011) accounted for 13.7% of the total TB compensation paid for cattle slaughtered across Wales.

Figure 5: Comparison of compensation paid for cattle slaughtered due to bovine TB 2004 to 2011.

Year	All Wales (£)	IAA (£)	IAA as a %

	(Source: WG finance system)	(Source: TBIS Animal Health)	of All Wales
2004	8,862,898	166,510	1.9%
2005	13,307,126	1,732,455	13.0%
2006	11,845,000	1,926,212	16.3%
2007	14,512,885	2,138,096	11.1%
2008	21,970,865	4,125,020	18.8%
2009	22,104,670	2,158,230	9.8%
2010	12,805,324	1,427,504	11.1%
2011	12,735,829*	1,747,764*	13.7%

**The compensation figures for 2011 have been extracted from internal payment records held by the TB Team (briefing was provided January 2012 - MB/JG/0246/12).*

26. When looking at TB data it is important to note that a small number of large breakdowns within an area can impact on the overall figures quite dramatically as was seen in the IAA in 2008 where the number of cattle and associated compensation costs were substantially higher than the previous and subsequent year.

27. It is recognised that in the absence of a wildlife reservoir, eradication of bovine TB in cattle can be based upon the reduction of the rate of cattle-to-cattle transmission such that the disease can no longer maintain itself. Bovine TB has been eliminated from cattle on such basis in developed countries, for example in Australia (Radunz, 2007). In areas where there is a wildlife reservoir, measures to control cattle-to-cattle transmission will need to be augmented by the prevention of transmission from wildlife to cattle (Science Review Report, Page 6, Para 6, see Annex 4). These options (interventions) are discussed later in section 5.

28. The intention of the previous coalition Government, as agreed by the then Minister for Rural Affairs, was to introduce a comprehensive suite of measures (discussed in more detail below) in the area aimed at tackling all sources of infection, as recognised above. Namely;

- o additional cattle surveillance and controls;
- o enhanced biosecurity measures;
- o additional surveillance and controls for non bovines (goats and camelids); and
- o a government-managed cull of badgers.

4.3.1 Additional Cattle Surveillance and Controls

29. Over the last three years national cattle surveillance and controls have been enhanced across Wales for example annual testing, reducing the number of Pre-Movement Testing (PrMT) exemptions and increasing the use of the gamma interferon (g-IFN) blood test. In addition to these national surveillance and controls, further interventions have been in place within the IAA area since 1 May 2010.

30. The additional cattle surveillance and control interventions in the IAA were developed to minimise the risk of further disease spread into the IAA, and between herds in the area. They are all interventions that in themselves are expected to have an impact on disease incidence, although it is recognised that they do not, alone, address all sources of infection. The Chief Veterinary Officer’s view is that these measures are appropriate, proportionate and necessary to tackle a number of important routes of disease transmission, as part of a comprehensive policy that deals with the known main sources of infection.

31. The additional cattle interventions, for cattle farms with land or cattle in and around the IAA include: six monthly (as opposed to annual) interval testing of whole herds including cattle in associated holdings outside the IAA; restricting cattle movements within and outside the IAA; more stringent veterinary classification of all cattle breakdowns in the area, and; greater use of g-IFN (g-IFN testing is used widely throughout Wales and is seen as an important diagnostic tool to support skin testing). The additional cattle interventions are described in greater detail in Annex 2.

4.3.2 Enhanced Biosecurity Measures

32. In addition to the above controls, cattle farmers in the IAA and surrounding area have received detailed, structured and individual biosecurity advice from their own private veterinarian. These veterinary visits, which were offered to all cattle keepers on a voluntary basis within and bordering the IAA, involve the assessment of biosecurity practices, they are supported by a tailored action plan to allow cattle keepers to make informed decisions on improvements to reduce the risks of bovine TB being introduced and spread within their herds. The intention is that these visits will be completed annually to re-assess the risks within individual farms and to update the biosecurity action plans for those farms.

33. The Science Review recognised that there “is good reason to support the further development, application and monitoring of biosecurity tools, and to believe that such measures can form an important part of an eradication programme” (Science Review Report, Page 9, Para 2, see Annex 4). However as discussed in section 5.6 enhanced biosecurity will not solve the problem on its own.

4.3.3 Additional Surveillance and Controls for Non Bovines

34. Current national policy is that goats and camelids (for this purpose llamas, alpacas, vicunas and guanacos) are not routinely tested for bovine TB, although there is passive surveillance (clinical examination as necessary) as a consequence of bovine TB being a notifiable disease. During 2012, all known goat and camelid herds in the IAA will receive a one-off test to assess the level of disease within their populations. Future surveillance policy of these species within the IAA will depend on these test results.

4.3.4 A Government-managed Cull of Badgers

35. The previous government, in deciding on the need for a government-managed cull of badgers made the Badger (Control Area) (Wales) Order 2011 ("the Order"), which specified the IAA as an area for the purposes of section 21 of the Animal Health Act 1981 ("1981 Act"), thus authorising the destruction of badgers within that area under the Act. The Rural Affairs Minister at the time, as one of the Welsh Ministers was satisfied that the threshold test within section 21 was met,

- o namely that:
    - (a) tuberculosis ("bovine TB") existed in wild badgers in the IAA;
    - (b) it was being transmitted to cattle; and
    - (c) it was necessary to destroy badgers to eliminate, or substantially reduce, the incidence of TB in cattle in the IAA.
- o The Minister was also satisfied that it was appropriate to exercise her discretion to make the Order.

36. The Order was subject to negative procedure and following its laying, a motion was tabled seeking annulment of the Order. At the subsequent debate in plenary on 23 March 2011 the motion was rejected by 42 votes to 8. The Order came into force on 31 March 2011 and can be seen at Annex 7.

37. On 21 June 2011 you announced that no cull of badgers would take place during the period of the Science Review.

38. This submission provides advice to you on the next steps i.e. to proceed with a cull of badgers in the IAA or consider an alternative control measure to deal with the infection reservoir that potentially exists in badgers and its transmission to cattle in the IAA.

5 Options to deal with the reservoir of infection in badgers in the IAA

39. The Science Review recognised the "general consensus based on expert opinion that the eradication of bovine TB infection in domestic animals in an area where the infection is endemic in a sympatric wildlife population requires the control of the infection in the wildlife host and high levels of biosecurity" (Science Review Page 10, Para 1, see Annex 4).

40. The epidemiology of TB is complex, with the possibility of transmission between a range of domesticated species and also wildlife happening concurrently. Recent estimates from Donnelly and Hone (2010) (Annex 8), for the Randomised Badger Culling Trials (RBCT) in England indicated that on average roughly 50% (49.85%; with a range from 16.8% - 72.7%) of bovine TB incidents could be attributed to infectious badgers, based on the average of trial-area-specific estimates of the proportion of bovine TB attributed to infections badgers (Donnelly personal communication Annex 12(f)).

41. The initial source of infection for a herd may not be the reason for the subsequent persistence of infection. For example, a breakdown may start through the introduction of infected cattle, before spreading to cattle native to

the herd, and/or spilling over into a previously uninfected local badger population. Testing and slaughter of reactor cattle over a series of 60 day TB tests will normally clear up infection in the herd unless re-infection occurs from other sources such as badgers. This re-infection scenario is reported frequently in TB endemic areas of Wales including the IAA.

42. The following sections present seven options that may deal with the reservoir of infection that potentially exists in badgers and its transmission to cattle in the IAA. You are advised to consider these sections again when addressing the issues for decision.

5.1 Option 1: Continue with the enhanced regime

43. The consequences of the additional cattle surveillance and controls, on herd breakdowns, that are in place in the IAA are not quantifiable at this early stage. Animal Health Veterinary Laboratories Agency (AHVLA) has been commissioned to produce an annual report on differences in various TB statistics between herds in the IAA and comparison herds, outside the IAA. Their first report (AHVLA, Project OG0142, see Annex 9), for the 12 months following the introduction of the additional cattle surveillance and controls, provides a useful indication of the disease picture, although the number of months observed is too small, and the variability of TB statistics in all groups of herds is too large, to allow firm conclusions to emerge. Even if the anticipated reduction of bovine TB prevalence in the IAA does occur, it may take a number of years before differences between the IAA and comparison group become unmistakable.

44. However, there is practical evidence that the risks associated with cattle to cattle transmission in the area are being addressed. For example the cattle measures have increased the traceability of movements and reduced the risks of transmission of bovine TB, through reduced movements and increased use of Pre-Movement Testing (PrMT). The keepers in and around the IAA are currently co-operating with these measures despite the additional practical and financial burden, especially for those keepers with land both inside and outside the area.

45. To date, all cattle keepers within the IAA have cooperated with the voluntary biosecurity scheme and as a consequence have received two biosecurity visits from their private veterinarian. Visits are continuing on an annual basis and the third series of visits, which now include cattle farms just outside the IAA and goat keepers, are due to be completed by March 2012. The biosecurity action plans are in place for all cattle farms in the area and some surrounding it, with specific recommendations on reducing their risks of bovine TB. These recommendations range from advice on changing their approach to buying cattle and grazing patterns, and measures to separate badgers from cattle, particularly around cattle housing and feed stores.

46. Detailed statistical analysis from the results of years 1 and 2 has seen an initial positive reduction in risk scores (i.e. improved biosecurity):

- At the time of the Year 2 assessments, 87% of Year 1 actions had been completed and being maintained or started and progressing.
- 85% of actions agreed in Year 2 were expected to be completed within 12 months.
- For farms which had biosecurity assessments in both years, around 70% had a lower score in Year 2 (i.e. improved biosecurity) and overall the mean total risk score was lower in Year 2.
- Farmers' perceptions showed little change from Year 1. Comparing farmers in the IAA to those in the buffer area, the only significant difference was that IAA farmers of unrestricted farms considered the risk of their herd going down with TB to be higher than farmers in the buffer area. There were significant differences in the views of farmers under restrictions due to TB compared with farmers of unrestricted farms.

47. Within the IAA, investigations by AHVLA have identified 26 goat-only keepers, 8 cattle and goat keepers and 1 camelid keeper who will also be offered a biosecurity visit by their private vet, at no cost to them (i.e. financed by Welsh Government), to assess their risk from bovine TB and to develop an appropriate action plan (in line with the cattle keepers).

5.1.1 Veterinary Opinion

48. The enhanced measures (additional cattle surveillance and controls, enhanced biosecurity measures and addressing the disease in non bovines), described above are designed to minimise the risk of spread of infection between different cattle populations (and other susceptible species) and within populations.

49. The additional cattle surveillance and controls are designed to identify infection at an early stage and reduce the risk of spread. Additional controls, in particularly the biosecurity risk assessments, have been implemented at farm level. It is not possible to conclude if these changes are having an impact on the incidence of bovine TB in cattle herds in the area. It may take a number of years before any differences between the IAA and comparison group become unmistakable (Analysis of IAA Biosecurity Assessments, Welsh Government (2012), Annex 28).

50. It is recognised that in endemic areas, badgers are the cause of an estimated 50% of cattle breakdowns (Donnelly; Personal Communication). Whilst this wildlife reservoir exists (such as the IAA), measures to control cattle-to-cattle transmission will need to be augmented by the prevention of transmission from wildlife to cattle through alternative measures.

51. It is therefore advised that the enhanced regime that was initiated in and around the IAA in May 2010 is retained and that its delivery continues to be evaluated. However, when applied in isolation, it is not sufficient to eradicate bovine TB from the IAA where there is a reservoir of infectious badgers. Additional interventions are required to address the wildlife reservoir.

5.2 Option 2: Non selective badger cull

52. Culling to reduce host population density is recognised as a potential tool for disease control with the aim of reducing it to a level at which transmission of the disease is impaired (e.g. reducing the number of opportunities for contact between individuals in the host species and other susceptible populations) (Delahay *et al*. 2008 (a)).

53. A non-selective cull of badgers involves the reduction in the badger population in a specific area for a required time period to reduce opportunities for transmission of infection from badgers to cattle through direct and indirect contact. This does not usually mean elimination of the reservoir species, but that its density is reduced below a threshold where an initial case results in less than one secondary case. However, the Science Review recognised that "the complex social ecology of badgers means that the rate of infection is not a linear function of their population density, and so the reductions in density required to produce a major benefit is large. In addition, the disease pattern in an individual animal, and hence its infectivity, is also complex" (Science Review Report, Page 6, Para 9, see Annex 4).

54. In both the UK and the Republic of Ireland (RoI), a number of badger culling strategies have been implemented to control TB in cattle or to assess the effects of badger culling on TB in cattle:

- The gassing of badger setts between 1975 and 1981 from a 104 km^2 area of high cattle TB incidence (endemic area) around Thornbury in Gloucestershire was followed by a period of 10 years with no herd breakdowns. (Clifton-Hadley *et al.* 1995).
- There were no herd breakdowns for seven years following the live-trapping and shooting or gassing of badgers from a farm of 12 km^2 at Steeple Leaze in Dorset between 1975 and 1979, which had previously experienced repeated breakdowns since 1970 (Wilesmith *et al.* 1982).
- Herd breakdown rates declined from 15% to 4% after badger removal over 62 km^2 near Hartland in North Devon in 1984 (Krebs *et al.* 1997).
- The culling of badgers from a 740 km^2 area in East Offaly, Republic of Ireland over six years was followed by significantly fewer confirmed herd breakdowns in the removal area than in a surrounding area in which no systematic badger removals had taken place (Ó Máirtin *et al.* 1998 and Eves 1999).
- The Four Areas Trial in Ireland compared the effects of two different badger culling strategies on TB infection in cattle and was carried out in four counties in the Republic of Ireland between 1997 and 2002 (Griffin *et al.* 2005). Badgers were culled throughout four 'removal areas', which varied in size between 188 and 305 km^2. The incidence of TB in cattle in the removal areas was subsequently compared with that in four nearby 'reference areas' (varying in size from 199-275 km^2) where badgers were locally culled in response to herd breakdowns. Results indicated that the probability of a confirmed herd breakdown was significantly lower, and the time between two TB breakdowns in one herd was significantly longer, in areas where badgers were proactively culled than in paired 'reference areas' where badgers were not culled.

55. While these operations provide evidence that badger culling influences the risks of infection in cattle, a lack of replication and strict experimental controls in some of these studies means that the confidence with which the results would be attributable or replicable to the culling is limited.

56. The Randomised Badger Culling Trial (RBCT), which was overseen by the Independent Scientific Group on Cattle TB (ISG) was designed as a controlled field experiment to try and overcome some of the difficulties of previous trials. The RBCT was conducted between 1998 and 2005 (ISG 1998 and Bourne *et al.* 2007) in 30 areas of high cattle TB risk in England, each measuring approximately 100 km^2. The core aim of the trial was to present UK Government with a range of scientifically-based policy options for badger culling. The 30 areas were grouped into ten 'triplets', each comprising three areas randomly allocated to one of three experimental treatments. These were:

- o Proactive culling – badger culls conducted annually when possible on all accessible land.
- o Reactive culling – localised culling of badgers geographically associated with cattle TB incidents.
- o Survey-only – experimental control areas where no culling was carried out.

57. The effect of the badger treatments in the RBCT was evaluated by consideration of the incidence of TB in cattle expressed as the number of new confirmed herd breakdowns. Analysis was also undertaken on the effect of culling badgers on all herd breakdowns and also solely unconfirmed herd breakdowns. It did not however consider other bovine TB parameters, for example the duration of breakdowns, survival times between breakdown or the scale of breakdowns.

58. A confirmed herd breakdown is a TB breakdown where *M. bovis* has been isolated from at least one animal in the herd or pathological changes (lesions) typical of infection with *M. bovis* are detected at post mortem examination in at least one reactor taken from a herd.

59. An unconfirmed herd breakdown is a TB breakdown where no TB lesions are detected during the post mortem examination of reactor cattle and all laboratory examinations fail to isolate *M. bovis*. In infected cattle, gross pathological changes (development of visible lesions) often take longer to develop than positive responses to the tuberculin test. It is also the case that the majority of post mortem examinations of TB reactors takes place within the abattoir and is for this reason less detailed than would be the case within a laboratory situation, and less likely to identify lesions, particularly if these are small. Veterinary opinion is that an unconfirmed breakdown normally means that the disease has been identified at an earlier stage before lesions become visible. It does not normally mean that the cattle were not infected or infectious.

60. A very small proportion of unconfirmed herd breakdowns may be due to genuine false positive cross-reactions to bovine tuberculin tests (even in the endemic TB areas where the RBCT took place). We would therefore expect to find a low background level of unconfirmed herd breakdowns that remain

unaffected by any reduction in the number and prevalence of *M. bovis*-infected badgers but would correlate with the frequency of herd testing.

61. As part of the RBCT, confirmed herd breakdowns were measured in the area where culling took place ('culling area') and an approximately 2km wide area just outside the cull area where no culling took place (2km area).

62. Analysis of the data from the RBCT "showed that proactive badger culling as conducted in the trial resulted in an overall beneficial effect on confirmed bovine TB cattle herd breakdowns compared with 'survey only' (no cull) areas. This beneficial effect was still in evidence 5 years after the final annual proactive cull (Jenkins *et al*. 2010) but wanes gradually over time towards the incidence seen in the control areas" (Science Review Report, Page 11, Para 3, see Annex 4).

63. It is worth noting that a more in depth, laboratory based post mortem examination was carried out on reactor cattle slaughtered during the RBCT. This may have resulted in an overall greater proportion of confirmed herd breakdowns within the RBCT areas compared with standard current abattoir based post mortem examination.

64. To investigate the apparently smaller impact of proactive culling on all breakdowns (as compared with confirmed herd breakdowns) the ISG also examined analyses of unconfirmed herd breakdowns only. They found no apparent effect of proactive culling on unconfirmed breakdowns and on this basis they concluded that there was no evidence of an impact of proactive culling on unconfirmed herd breakdowns within trial areas and they therefore focused their attention on the analyses based on confirmed breakdowns only.

65. Analysis conducted by the ISG identified that there was "considerable over-dispersion" in the unconfirmed breakdown data from inside trial areas. The former deputy chairman of the ISG (Donnelly C., personal communication, 2011) is of the view that this over-dispersion does not explain the apparent absence of effect on unconfirmed breakdowns. The ISG were unable to determine, from the data, why there was no apparent effect of proactive culling on unconfirmed herd breakdowns (Bourne *et al*. 2007, page 95) but believe that the data point towards a biological explanation. However they remain unable to identify such an explanation. In the absence of a biologically plausible explanation the situation remains that the reason for this apparent difference remains unknown. It is unlikely that additional analyses will be able to resolve this situation.

66. The distinction between a confirmed herd breakdown and unconfirmed herd breakdown is, made on the basis of further tests carried out after slaughter (post-mortem examination and bacterial culture) that are less sensitive than the skin test. In areas of high incidence and prevalence of TB (endemic areas), there is a high degree of confidence that the unconfirmed herd breakdowns are caused by *M. bovis*. It follows that estimates of incidence or prevalence in such areas, that are defined solely in terms of confirmed herd breakdowns, are underestimates.

67. Further results from the RBCT are presented and discussed later in section 5.2.5.

5.2.1 Technique of culling badgers

68. The Badger (Control Area) (Wales) Order 2011 specifies the methods for the destruction of badgers namely by shooting or lethal injection after being trapped in a cage or by shooting without being trapped in a cage (free-shooting). These methods are summarised below.

69. Cage trapping with shooting has been demonstrated (by the RBCT) to be a reliable and humane method of destroying badgers. Cage trapping and killing by shooting would be used as the primary culling technique if a decision to proceed with a cull of badgers is made. The Order also specifies lethal injection after being trapped in a cage as a method. This method would only be used in specific circumstances where the use of a firearm is not appropriate and would require a veterinary surgeon to administer the injection.

70. Free-shooting is a technique already widely used to control populations of free ranging wildlife and in the main follows codes of practice such as The British Association for Shooting and Conservation's (BASC) 'Code of Practice - Lamping (Night Shooting)' to reduce potential risks to the welfare of animals and the wider environment including public safety. In considering it appropriateness in Wales, the option of free-shooting badgers, was included within the Badger (Control Area) (Wales) Order 2011 to allow its use as an additional method to cull badgers in particular circumstances where trapping may not be appropriate. At present, the circumstances where free-shooting is envisaged are limited, with these exceptions being used primarily where problems occur over trapping and for animal welfare reasons.

71. Any person carrying out a cull would be either a Welsh Government officer or a person authorised by Welsh Government. Welsh Government would therefore direct the culling method.

5.2.2 Strategy for delivery

72. The Science Review recognised that "there is general consensus based on expert opinion that a reduction in the incidence of bovine TB cattle herd breakdowns associated with the culling of badgers within an area requires the fulfilment of a series of criteria including a large area of land, a high level of land manager compliance, an effective and sustained cull, and where possible boundaries that are impervious to badger movement" (Science Review Report, Page 3, Para 8, see Annex 4).

73. As part of the investigation into effective culling, the Central Science Laboratory (CSL, now part of the Food and Environment Research Agency ("Fera")) was commissioned by Welsh Government to analyse the effect of different badger culling strategies in Wales. They created a model based on cage trapping and shooting and included data from the RBCT as reported by Jenkins *et al.* (2008) and cattle data specific to Wales (CSL, 2009(c), see Annex 10).

74. The CSL culling modelling work highlighted several important factors which were recognised and taken into account when establishing the IAA:

- *Control duration:* Culling should last longer than the period of greatest social disruption to the badger population.
- *Control efficacy:* More than 50% of the badger population should be culled.
- *Control area:* Control areas should be greater than 200 km^2 for the benefits of control to outweigh the disadvantages of social perturbation (more recent reports of analysis of the RBCT data post culling (Jenkins *et al.* 2010 has reduced the minimum cull area to141 km^2).
- *Control Staging:* Simultaneous culling operations, as undertaken for the majority of the RBCT, are likely to provide the greatest confidence of achieving a reduction in cattle TB.
- *Land access compliance:* Land access in excess of 60% is required to ensure an immediate reduction in the number of infected badgers.
- *Control edge permeability:* Using boundaries which reduce the immigration, or social perturbation, of badgers would lead to a greater reduction in cattle TB.

75. It is therefore important that any persons charged with delivering a badger control strategy are able to demonstrate beneficial effects for bovine TB control while ensuring that any strategy is carried out humanely and efficiently. A group of farmers or contractors, working on their behalf might, with sufficient resources, deliver an effective cull of badgers. In England, Defra recently announced that two areas in West Gloucestershire and West Somerset have been selected, from a shortlist proposed by the farming industry, as the most suitable to pilot controlled free-shooting of badgers. The pilots will allow the examination of how safe, humane and effective controlled free-shooting is. The outcome of the Defra pilots may help to inform future decisions in Wales. Farmers and landowners are able to apply to Natural England as a group for a licence to cull badgers, which will be assessed against the criteria in place at the time.

76. The previous administration considered it appropriate that the Welsh Government take responsibility for managing the cull of badgers in the IAA to ensure it is carried out effectively, humanely by properly trained personnel and be appropriately monitored. Operations would need to be carried out with the support and assistance of land owners, the farming industry, and contractors to ensure the delivery of a cull of badgers contributes positively to the control of bovine TB in cattle. In addition, if the Order remains in force, section 22 of the 1981 Act will empower Welsh Government officers, veterinary inspectors or any other persons authorised by the Welsh Ministers to enter land within the IAA for the purposes of carrying out destruction of badgers (and certain related activities).

5.2.3 Timing

77. The duration and timing of any cull of badgers would need to balance the welfare requirements for badger intervention against the disease control requirements. The longer the closed season, to account for the breeding season of badgers (normally the end of January to the beginning of May), the less time is available for control. As recommended by the Countryside Council for Wales (CCW), in their response to the 2010 Consultation on Badger Control in the IAA (Annex 11), a closed season for any culling strategy should be agreed with CCW to reflect the environmental conditions and evidence available at that time.

5.2.4 Effects on badger population

78. The estimated impact of an effective non selective cull on the badger population is based on experiences of culling badgers for disease control purposes in the UK and Republic of Ireland.

79. As discussed in section 5.2.2, to be effective a cull of badgers must achieve the destruction of at least 50% of the population. In the IAA it would be expected that a rate of approximately 70% could be achieved, in line with the experiences of the RBCT. This means that 30% of the badger population could survive. We estimate that there are between 1722 and 2296 badgers in the IAA (Welsh Government Sett Survey - correspondence). This is based on actual sett survey results (conducted in 2010) and modelling work assuming there are 6 to 8 badgers per main sett. For the purposes of this submission we will advise you on the basis of the upper estimate, this means that approximately 1607 badgers would be removed with about 689 remaining.

80. Some opponents to culling have suggested that culling would increase the prevalence of bovine TB in badgers (i.e. fewer badgers but an increase in the proportion of badgers that are infected). However others suggest that it would decrease the net number of infected badgers (i.e. an absolute reduction in the numbers of infected badgers in the IAA) (Summary of the Responses to the [2010] Consultation on Badger Control in the Intensive Action Area, Welsh Government 2011, see Annex 11). A model of the interactions between repeated culling and the permeability of trial area boundaries in the RBCT showed that successive culls led to increased prevalence only in less geographically isolated areas (Woodroffe *et al.* 2006). There is not expected to be a significant change in the prevalence of bovine TB in the badgers that remain following culling, if the cull areas are relatively isolated. The IAA has been designed to have a high level of isolation and to achieve a reduction in the number of badgers infected and, based on the analysis above, no significant change in the prevalence in badgers in the area.

81. We would anticipate the pre-cull population level of badgers to recover naturally within 5-10 years of the end of culling, in the absence of any artificial control of their re-population (Welsh Assembly Government 2009(a)).

5.2.5 To achieve a benefit in cattle

82. The RBCT proactive culling areas provide some of best evidence from which to evaluate the benefits of the proposed government non selective cull of badgers on the incidence of bovine TB in cattle in the IAA. As discussed in paragraphs 56 to 67 the outcome of the RBCT was reported primarily on confirmed herd breakdowns (figure 6).

Figure 6: Comparison of estimates of overall effects of proactive badger culling on the incidence of confirmed herd breakdowns on lands inside and up to 2km outside trial areas derived from successive analyses of RBCT data reported in September 2011 (95%CI in brackets).

	First cull to one year after the last proactive cull	One year after the last proactive cull to 28 August 2011	First proactive cull to 28 August 2011 (during- and post-trial periods combined)
Inside cull areas	-23.2% (-32.7% to -12.4%)	-28.0% (-15.0% to -39.1%)	-25.7% (-18.7% to -32.2%)
Lands ≤ 2km outside culled areas (not culled)	+24.5% (-0.6% to +56.0%)	-4.1% (-25.7% to +23.7%)	+7.6% (-14.2% to +35.1%)

83. The ISG hypothesised that the increase in confirmed herd breakdowns (+24.5%) observed in the 2km area during the cull period was a result of changes in badger behaviour brought about by the dispersion of social groups as a consequence of culling. Badgers typically live in social groups of 6-8 animals, with defined territorial boundaries. Disruption of the organisation of these social groups causes surviving badgers to range more widely than they would normally and come into contact more often with other animals (including both cattle and other badgers). This behaviour is referred to as “perturbation”.

84. Regular 6 monthly analysis of data downloads from the proactive badger culling areas has been carried out by Jenkins *et al.* (2010) and Donnelly (2010 (a & b) & 2011 (a & b)) from one year after completion of the last proactive cull. The original analysis, published updates and an evaluation of their scientific integrity by the Defra sponsored Bovine TB Science Advisory Body are attached at Annex 12. A summary of the effects, on lands inside and up to 2km outside trial areas, of proactive culling is set out in figure 6 (above).

85. The benefit of proactive culling in the RBCT areas would be expected to diminish were no measures in place to protect the benefits, for example through increased cattle controls.

86. Officials have investigated the TB disease picture in the IAA and subjected these data to the analysis of the RBCT to provide quantitative estimates of the effect of culling badgers in and around the IAA using a Microsoft Excel spreadsheet provided by a co-author of Jenkins *et al*. 2010 (Summary of analysis at Annex 13). The Science Review reported that “there is no direct

evidence of the impact of culling [badgers] on TB in cattle in Wales, though there is no reason to believe that the situation is different in areas of high incidence in Wales to that in England" (Science Review Report, Page 10, Para 1, see Annex 4).

87. Recent external analyses of published IAA data (Fenwick, 2011) provides evidence that an efficiently implemented cull in the IAA could be expected to lead to reductions in confirmed herd breakdowns greater than those seen in RBCT areas. Commentary on this paper (Kao, 2012) recognises that the value of the report does not lie in its specific predictions but in demonstrating that simply increasing the restrictiveness of the geographical boundaries of a culling area without any change in the epidemiology could change the benefit of culling from negative to positive. "As such, it provides optimism that the IAA programme, properly applied, could provide a real benefit to farmers" (Kao, 2012) .

88. The Science Review does not make reference to previous estimates of effect of culling badgers on herd breakdowns in the IAA (Welsh Government SF/EJ/0033/11) which are updated below, Figures 7 and 8. Instead, the Science Review makes reference to conclusions from a meeting of scientific experts, held at Defra on 4th April 2011 prepared for the Defra Chief Scientific Adviser; "the impact of the culling of badgers has been assessed, based upon the results of the RBCT (Bourne *et al*. 2007), as being a relative reduction overall (including a cull area of at least 150 square Kms and 2 Km surrounding ring) over nine years of 16% in confirmed bovine TB breakdowns compared to non-cull control areas (Defra 2011)" (Science Review Report, Pages 11 and 12 Para 7, see Annex 4). While accepting that there are wide confidence limits associated with these figures, the Science Review found "no reason to suggest that this assessment is not correct" (Science Review Report, Pages 11 and 12 Para 7, see Annex 4). Although this information is relevant, it is advised that you consider the data specific to the IAA which is discussed below.

89. When considering the potential effects of culling badgers in the IAA, officials have used 288km² as the size of the area to be culled. Although other natural and manmade features associated with the boundary of the IAA will 'restrict' badger movements, the boundary (i.e. the 2km of adjoining land, or 'buffer', outside the IAA) has been calculated as 128.9km² to recognise that the sea is the only proven effective 'barrier' to badger movements.

90. In their original paper based on data from the RBCT areas to July 2009, Jenkins *et al*. (2010a) calculated that the 95% confidence interval for the average effect across the entire affected area excluded net increases in the overall incidence of confirmed herd breakdowns for culling targeted at circular areas greater than 141 km². The size of the IAA (288 km²) exceeds both the area calculated by Jenkins *et al*. and the minimum size recommended by the VLA (200 km²; see Annex 10).

91. The boundary has been designed to make the best use of geographic and natural boundaries, and non cattle grazed areas, and has included whole farms where land is contiguous (i.e. immediately adjacent) so as to minimise any possible impact from the perturbation of badgers. It is approximately 97.6 km in

length, with 28% of this coast. The River Teifi forms approximately 14% of the boundary and the River Cych (a tributary to the Teifi) and its tributaries accounting for approximately 15%. The Preseli Mountain area, which is a less favourable habitat for badgers and would form an obstacle to their movement, comprises approximately 14% of the boundary. The remaining boundary (approximately 29%) was located on the basis of land ownership and land use.

92. As discussed in paragraphs 56 to 67 the estimates of effect derived from the RBCT are measured in terms of the effect on confirmed new breakdowns. The estimated effect of culling badgers in the IAA on confirmed herd breakdowns (based on 5 years of culling and a 5 year post culling period) is presented in figure 7 below. Also presented is the estimated effect of culling of badgers in the IAA on all herd breakdowns, assuming, as with the RBCT, that culling has no discernable impact on unconfirmed herd breakdowns.

Figure 7: Estimates of effects of proactive badger culling in the IAA on the incidence of herd breakdowns, compared to a no cull position (a 5 year period of culling followed by 5 years post culling)

On lands inside the IAA

	During culling period (no.)	Post culling period (no.)	Total (no.)	% change
Confirmed Herd Breakdowns	*142.8 (-43.2)	133.9 (-52.1)	276.8 (-95.2)	-25.6%
All Herd Breakdowns (assuming no effect on unconfirmed)	313.3 (-43.2)	304.4 (-52.1)	617.8 (-95.2)	-13.4%

On lands within 2km outside of the IAA

	During culling period (no.)	Post culling period (no.)	Total (no.)	% change
Confirmed Herd Breakdowns	11.1 (+2.2)	8.5 (-0.4)	19.6 (+1.8)	+10.1%
All Herd Breakdowns (assuming no effect on unconfirmed)	37.8 (+2.2)	35.2 (-0.4)	73.0 (+1.8)	+2.5%

On lands inside and within 2km outside of the IAA

	During culling period (no.)	Post culling period (no.)	Total (no.)	% change
Confirmed Herd Breakdowns	153.9 (-41.0)	142.5 (-52.4)	296.4 (-93.4)	- 24.0%
All Herd Breakdowns (assuming no effect on unconfirmed)	351.1 (-41.0)	339.7 (-52.4)	690.8 (-93.4)	-11.9%

*estimated number of breakdowns (with a proactive cull),
( ) estimated impact on breakdowns as a consequence of culling badgers compared to a cull not taking place.

93. The uncertainty around the likelihood that the proactive culling of badgers in the IAA will have an effect on the incidence of unconfirmed cattle herd breakdowns in the IAA and associated areas means that it is reasonable to consider what the impact of such an effect might be if it were to occur. In the absence of other estimates of effect, it is possible to apply the estimates of effect in confirmed cattle herd breakdowns derived from the RBCT to unconfirmed breakdowns (figure 8). However, it must be recognised that doing so represents a departure from the evidence of the RBCT which found no evidence of effect of proactive culling on unconfirmed breakdowns.

Figure 8: Estimates of effects of proactive badger culling on the incidence of **all herd breakdowns** in the IAA compared to a no cull position (A 5 year period of culling followed by 5 years post culling)

On lands inside the IAA

	During culling period (no.)	Post culling period (no.)	Total (no.)	% change
All Herd Breakdowns (assuming the same effect on unconfirmed and confirmed herd breakdowns	* 273.8 (-82.71)	256.7 (-99.8)	530.5 (-182.5)	-25.6%

On lands within 2km outside of the IAA

	During culling period (no.)	Post culling period (no.)	Total (no.)	% change
All Herd Breakdowns (assuming the same effect on unconfirmed and confirmed herd breakdowns	44.3 (+8.7)	34.1 (-1.5)	78.5 (7.3)	+10.3%

On lands inside and within 2km outside of the IAA

	During culling period (no.)	Post culling period (no.)	Total (no.)	% change
All Herd Breakdowns (assuming the same effect on unconfirmed and confirmed herd breakdowns	318.1 (-74.0)	290.8 (-101.3)	608.9 (-175.3)	-22.4%

*estimated number of breakdowns (with a proactive cull),
( ) estimated impact on breakdowns as a consequence of culling badgers compared to a cull not taking place.

94. There remains some uncertainty in the likely effect of proactive culling on unconfirmed herd breakdowns. Taking into account the disease situation in endemic areas (i.e. that the majority of unconfirmed breakdown herds are likely to be genuinely infected with *M. bovis*), veterinary opinion is that proactive badger culling in endemic areas should also reduce the number of unconfirmed herd breakdowns.

95. We would expect that the comprehensive approach described (which includes, additional cattle controls, enhanced biosecurity and potential benefits of the natural boundaries to the IAA such as the river Teifi, and Preseli Hills to reduce perturbation), combined with culling would deliver greater benefit than those estimated above.

5.2.6 Increase in the 2km area

96. "It is suggested that perturbation [in the RBCT areas] led to increased contact and transmission amongst badgers and between badgers and cattle. This detrimental effect diminished over time. Some 12-18 months after badger culling stopped, the number of confirmed bovine TB cattle herd breakdown in these edge areas was similar to that seen in the survey only areas, and has remained so since" (Science Review Report, Page 11, Para 4, see Annex 4).

97. When considering the impact of culling on herd breakdowns you should be aware that there could be an estimated 2.2 to 8.7 additional herd breakdowns in the 2km area during the period of badger culling for the reasons described above. This is not fully offset by the anticipated benefits in the post culling period (i.e. the 0.4 to 1.5 confirmed herd breakdowns potentially prevented).

5.2.7 Strategies to mitigate for the effects of perturbation

98. Several suggestions have been made (principally in King *et al.* (2007) and Bourne *et al.* (2007)) of ways to mitigate against the detrimental effect of perturbation, some of which have been applied in the IAA approach and are discussed below.

99. *Increased biosecurity on farms* - There is increasing evidence that badger visits to farm buildings are a common occurrence (Judge *et al*. 2011) and that it is possible to minimise the direct and indirect interaction between badgers in these circumstances.

100. A programme of biosecurity risk assessment has been in place in the IAA for the last two years to improve biosecurity on farms. One of the most frequently identified risk factor in both the IAA and the buffer areas was contact with other animals i.e. badgers. The second round of biosecurity assessment visits has evidenced improvements on farms to reduce this risk.

101. *Impermeable boundaries* - It has been suggested that areas that have impermeable landscape features on some or all boundaries may suffer less detrimental effects of perturbation than those where all boundaries are permeable to badger movement (Griffin *et al.* 2005 and Bourne *et al.* 2007). The ISG suggested that impermeable boundaries may include coastlines, mountains, medium to large rivers, motorways and urban conurbations, although the extent to which these features restrict badger movement is limited. Recent analysis by Frantz *et al.* (2010) reported that "a large, wide river represented a barrier to badger dispersal and found evidence that a motorway may also restrict badger movement. Conversely, we did not find any evidence for small rivers and roads interfering with badger movement."

102. *Soft boundaries with no cattle/low cattle TB risk* – Positioning the area to border areas of lower cattle densities may reduce any detrimental effects of social perturbation in badger populations in the surrounding area, through the reduction in the number of susceptible animals and opportunities for transmission.

103. A discussed in paragraph 91, the IAA boundary has been located to make the best use of geographic and natural boundaries, and non cattle grazed areas, and has included whole farms where land is contiguous.

104. The IAA is designed to gain the maximum benefit from the RBCT approach whilst at the same time incorporating additional measures both in terms of the improvements in location, delivery of a cull and the additional cattle/non bovine measures in the IAA.

105. Ring Vaccination of Badgers potentially reduces the impact of perturbation by reducing the proportion of potentially susceptible badgers in the surrounding 2km area. Recent modelling of potential control strategies in England has suggested that if a 2 to 3 km (approximately) ring buffer is vaccinated around a 150km² cull area, the potential effects of badger perturbation can be partly mitigated. The result showed that ring vaccination had the potential to reduce the time until a reduction in cattle incidence is observed and provide a greater reduction in cattle herd breakdowns compared to culling or vaccination alone (Fera 2010). Ring vaccination is discussed further in section 9.6 when considering your discretion in this matter as the IAA threshold tests apply only to the area inside the IAA boundary.

5.2.8 Veterinary Opinion

106. The Science Review reported that "there is no direct evidence of the impact of badger culling on bovine TB in Wales, though there is no reason to believe that the situation is different in areas of high incidence in Wales to that in England" (Science Review Report Page 10, Para 1, see Annex 4). It is reasonable to expect a similar beneficial effect in Wales to those seen following the RBCT if the same approach is taken.

107. The reliability of the outcome of a cull in Wales, weakens to an uncertain degree should any of the specific criteria applied in the RBCT be varied. For example if a cull of badgers cannot be carried out with the required trapping efficiency, land access compliance or duration there is the potential for the benefits to be less or even for the disease to become more widespread. Therefore it is important to follow the protocols described above.

108. This submission includes evidence on how officials anticipate being able to meet the specific criteria applied in the RBCT and for some criteria to exceed it, for example in the relative isolation of the IAA. In addition, Welsh Government retaining responsibility for a badger cull would ensure it is carried out humanely by properly trained personnel and that all activities are properly monitored.

109. Insofar as the results of the RBCT can be extrapolated to the IAA, it is possible to conclude that the outcome of an effectively managed cull of badgers in the IAA should be an overall reduction in the number of breakdowns (The level of anticipated benefits is reported in section 5.2.5).

110. It is important to recognise that reducing the number of breakdowns will result in an overall reduction in the weight of infection in the area, which should progressively impact on other parameters of TB e.g. the scale and duration of existing breakdowns and survival time between breakdowns.

111. Badger culling in conjunction with the enhanced cattle measures delivers a comprehensive programme aimed at tackling all known sources of infection working towards eradication with benefits exceeding those of culling alone.

5.3 Option 3: Badger vaccination

112. Vaccinating badgers is seen as an intervention which may potentially contribute to the control of bovine TB. The principle of badger vaccination is to raise immunity against bovine TB within the badger population which should over time decrease disease prevalence and weight of infection, therefore reducing opportunities for badger to cattle transmission.

113. "From studies of BCG vaccination in other species, it is probable that vaccination of badgers that are already infected or diseased with bovine TB will have no effect on the progression of their infection or their infectivity" (Science Review Report, Page 13, Para 6, see Annex 4).

114. A Welsh Badger Vaccination Technical Group was established by the Welsh Government in November 2010 with the primary aim of preparing a paper, for the consideration of the TB Eradication Programme Board, on the use of injectable BCG vaccine (BadgerBCG) in badgers as part of a comprehensive

approach to TB eradication in Wales. The group consisted of members who were identified because of expertise in a particular subject (e.g. epidemiology, immunology). The group's conclusions were presented to the Programme Board on 21 December 2011 and are considered in the supporting Submission on the 'Strategic Framework to pursue a sustainable programme of bovine TB eradication in Wales' (SF/JG/0366/12).

115. Vaccination aims to confer a degree of protection from either infection or the effects of infection to the vaccinated individual. The objective being to protect individuals from the disease and to reduce onward transmission amongst the host population and other populations. The Science Review reported that "generally it is not necessary that all individuals be rendered immune before infection can no longer sustain itself in a population; there is a threshold fraction of vaccinated animals at which 'herd immunity' is said to occur and disease starts to decline" (Science Review Report, Page 6, Para 10, see Annex 4). For example, oral vaccination campaigns in Europe have been highly successful in increasing the proportion of foxes that are not susceptible and as a result rabies has been eliminated from large areas (Wobeser 2007).

116. The key requirements for a successful vaccination programme are the existence of an effective vaccine, an effective mode of vaccine delivery, and methods for deploying the vaccine that ensure a sufficient proportion of the population are vaccinated. The level of benefit observed also depends on the prevalence of infection in the population prior to vaccination and the weight of external challenge. The principle is to vaccinate a sufficient proportion of uninfected badgers so immunity is developed at the population level. Repeated vaccination of the population should result in a decrease in the disease prevalence and the potential for onward transmission of infection.

117. The following sections consider:

- the existence of an effective vaccine for badgers,
- an effective method of delivery,
- the ability to vaccinate a sufficient proportion of the badger population, to
- have an impact on cattle herd breakdowns.

5.3.1 Existence of an effective vaccine for badgers

118. The only TB vaccine currently available for field use in badgers is the 'BadgerBCG' (a vaccine containing *M. bovis* Bacille Calmette Guérin (BCG) Danish Strain 13310) which has received a Limited Marketing Authorisation (LMA) for use via intramuscular injection from the Veterinary Medicines Directorate (VMD).

119. The dossier of evidence used to gain the LMA, including information on the Badger Vaccine Study (BVS) (part of the UK funded Badger Vaccine research by Fera and AHVLA), was published on the Defra website in November 2010 (see 'Field trial to assess the safety of Bacillus Calmette-Guérin (BCG) vaccine administered parenterally to badgers' at Annex 14). It was also published in an

article ‘Bacillus Calmette-Guerin vaccination reduces the severity and progression of tuberculosis in badgers’ (Annex 15).

120. The study demonstrated that there was no evidence of shedding of the vaccine ‘badgerBCG’ from vaccinated animals, and that repeated vaccination does not produce any adverse effects and therefore demonstrates that 'BadgerBCG' is safe for use in badgers. Captive badgers vaccinated with BCG did not present any clinical signs following vaccination or after being experimentally challenged with *M. bovis* and their response to *M. bovis* specific antigens was indistinguishable from those of control animals (Chambers *et al.* 2010).

121. Furthermore, at *post mortem* examination, 12 weeks after challenge and 29 weeks after vaccination, vaccinated badgers, in experimental captive studies, had significantly fewer and significantly less severe TB lesions in both the lungs and lymph nodes than non-vaccinated control animals. There were also significantly fewer *M. bovis* bacilli within these lesions and other clinical samples, and the total bacterial count was reduced in vaccinated badgers. All of which confirm that BCG vaccination can induce an immune response in badgers (Chambers *et al.* 2010).

122. The study also demonstrated that:

- o BCG vaccination does not prevent infection in all uninfected animals, as demonstrated by the positive response to the tests within the vaccinated group.
- o The vaccination of non infected badgers with BCG is associated with a reduction in the severity and progression of future infection in some of the badgers.
- o It was not possible to directly estimate the efficacy (how effective it is) of BCG vaccination in this study as the decision was taken by Defra not to subject the vaccinated wild badgers to post-mortem determination of infection.
- o The field trial (Badger Vaccine Study (BVS)) demonstrated that vaccination of badgers, that were negative to all diagnostic tests at initial capture and were, therefore, considered to be uninfected prior to administration of BCG, led to a 74% reduction in the incidence of new cases as detected by the Brock TB Stat-Pak Test (an antibody test) in the vaccinated group compared to an unvaccinated control group. In the vaccinated group 8 out of 179 (4.5%) individuals became positive on the Stak-Pak test compared to 14/82 (17.1%) in the non-vaccinated group (Chambers *et al.* 2010).There were no other statistically significant reductions when comparing gamma interferon (IFNγ), culture or all three tests in combination. However, in all cases the trend was towards a reduction in new incident cases in the vaccinated group. It should be noted that the statistical power of the study was limited due to the small sample size.

123. An alternative delivery mechanism for the vaccine, rather than using an injection, is orally. An oral vaccine requires a formulation which can protect the vaccine during passage through the gastrointestinal tract of the badger and

ensure its uptake into the body. It also requires bait which encourages ingestion by badgers but minimises uptake by non target species.

124. Considerable progress has been made on both fronts but there is currently no oral vaccine candidate that is ready to take forward into the regulatory studies required for licensing the vaccine. Officials in Great Britain and the Republic of Ireland Department of Agriculture, Fisheries and Food (DAFF) continue to cooperate on research on oral vaccine development.

125. Developing an oral vaccine against TB for use in badgers is technically demanding, proving more difficult than originally hoped and not guaranteed to succeed. This means that the possibility of a usable oral badger vaccine is many years away. The Science Review concluded that “there is as yet no evidence available on the value of an oral vaccine in badgers in the field in the UK” (Science Review Report Page 12, Para 4, see Annex 4) and we cannot say with any certainty if or when an oral badger vaccine might be available for use in the field. Even if the vaccine becomes technically possible to produce it must also be sufficiently cheap to manufacture and deploy to achieve large scale take-up.

5.3.3 An effective method of delivery

126. 'BadgerBCG' is being used in the Badger Vaccine Deployment Project (BVDP) in England to examine the practicalities of vaccinating badgers. The project also seeks to increase confidence in the use of injectable badger vaccine. Badgers in a 100km^2 area of Gloucestershire are being cage-trapped and vaccinated via intramuscular injection (this project was scaled back from initial plans for six 100km^2 areas). The project has not been designed to demonstrate an impact on the incidence of TB in cattle. Fera officials, on behalf of Defra, have completed two seasons of the vaccination, with a total of 541 badgers vaccinated in the first season and 628 in the second.

127. Data from four study sites in the south of England suggest that averages of between 51% and 76% of a badger population is caught in any one trapping session (Judge pers. obs.,and Tuyttens *et al.* 1999). The Welsh Badger Vaccination Technical Group recommended that options for increasing the number of individuals trapped should be investigated e.g. trapping each sett twice for two consecutive nights (i.e. four trap nights in total) over a period of approximately one week, with a break for welfare reasons.

128. A licensing process is in place to allow for privately funded vaccination (by injection) of badgers elsewhere in Wales for the purpose of preventing the spread of bovine TB to badgers which are currently not infected with bovine TB. Any lay person wanting to vaccinate badgers in Wales must have successfully completed an approved course and hold a valid certificate of competence in the vaccination of badgers by injection, granted by the course provider (Fera). BadgerBCG is a Prescription Only Medicine – Veterinarian (POM-V). It can only be supplied by a veterinary surgeon, authorised wholesaler or pharmacist in accordance with a prescription from a veterinary surgeon. Vaccination must be conducted under the direction of a veterinary surgeon who has a duty of care to respond in case of any problems arising though the process of vaccinating

badgers (Fera Veterinary Guidelines on use of BadgerBCG). To date, no applications have been made to vaccinate badgers in Wales.

129. It is envisaged that a vaccination programme similar to that delivered by Fera for the BVDP would be required to ensure an effective delivery of a badger vaccination policy in the IAA. Although there is interest in vaccinating badgers in the IAA the proportion of land owners in the IAA that would be expected to have confidence in the approach, and therefore the proportion that would pay for it, is anticipated to be small. A government-managed vaccination programme is expected to provide the greatest opportunity of delivering an effective vaccination programme of badgers over sufficient land coverage.

5.3.4 An ability to vaccinate a sufficient proportion of the badger population

130. Modelling has been used as the primary tool to assess the suitability of vaccinating badgers for TB control purposes. The most recent computer models (CSL 2009d and Fera 2010) have suggested that vaccination could produce a reduction in the number of TB infected badgers and prevalence of TB in badgers by 20% to 50% within 5 years. Previous models (White & Harris 1995 and Wilkinson *et al.* 2004) have suggested a different range of results including vaccination of 70% of the healthy population being predicted as resulting in eradication of TB in badgers in 20 to 30 years (Wilkinson *et al*. 2004).

131. The only field trials currently available state that vaccination of badgers, which are believed to be uninfected prior to vaccination, results in a 74% reduction in the number of badgers with detectable infection when compared to non-vaccinated badgers (Chambers *et al.* 2010).

132. As discussed in paragraph 114, “generally it is not necessary that all individuals be rendered immune before infection can no longer sustain itself in a population” (Science Review Report, Page 6, Para 10, see Annex 4). Simulation modelling of badger vaccination suggests that a minimum of approximately 38% of the local uninfected population would need to acquire some protective effect from vaccination for reductions in cattle incidence to be detectable.

133. The rate at which sufficient group immunity can be established through badgers is partly dependant on the existing prevalence of bovine TB within a badger population and the introduction of additional susceptible individuals (e.g. cubs) .

134. It is difficult to determine the precise prevalence of bovine TB in badgers in an area without culling large numbers and examining them post mortem. Evidence from previous studies suggests that the prevalence of infection in badgers in areas in which TB is endemic in cattle varies greatly, from as little as 1.6% (Bourne *et al*. 2007) to as high as 45% (Crawshaw *et al*. 2008, Murphy *et al*. 2010 and More 2009). The prevalence of bovine TB in badgers in the IAA is likely to be in the region of 27% (IAA Statistics and Epidemiological Information - see Annex 16). Furthermore, the number of healthy badgers that are trapped as a proportion of the healthy badger population in the area is unknown and unlikely to be determined in advance of a vaccination programme.

135. There is limited evidence on the persistence of immunity and annual revaccination is recommended (Fera Veterinary Guidelines on use of BadgerBCG), “particularly to deal with new cubs” (Science Review Report, Page 12, Para 2, see Annex 4).

136. In summary, Fera has developed a methodology for annual vaccination that can be scaled-up for the IAA i.e. to ensure that the proportion of the badger population captured is sufficient. The main risks to this are that the true prevalence of TB in badgers in the IAA, and the proportion of healthy badgers in the population that would be captured, are indeterminable in advance. Both would impact on the rate at which sufficient group immunity can be built up through badger vaccination, although practical measures such as increasing the number of traps could mitigate for these factors.

5.3.5 To achieve a benefit in cattle

137. There is some evidence for the direct effect of badger vaccination on the incidence of signs of bovine TB infection and disease in wild badgers (Chambers *et al*. 2011). However, the Science Review reported that ”there has been no evaluation of the impact of badger vaccination on the incidence on bovine TB herd breakdown[s] in cattle” (Science Review Report, Page 12, Para 5, see Annex 4). Much of the information on the effects of BCG vaccination on badger infection comes from computer modelling exercises (Wilkinson *et al*. 2004, Central Science Laboratory 2009 (d) and Fera 2010) which have also been used to determine what, if any, effect badger vaccination might have on bovine TB in cattle.

138. Previous modelling work carried out by Fera (CSL 2009 (d), Annex 17) indicates that the length of time that it will take for a reduction in disease levels in cattle to occur would depend on a range of factors which may vary locally:

- efficacy of the vaccine in large scale field use;
- proportion of the badger population that are vaccinated;
- proportion of the vaccinated animals that are already infected;
- time taken to achieve group immunity in the population;
- the relative contribution of badgers to the disease in cattle in the area; and
- the effectiveness of the cattle controls in preventing cattle to cattle spread.

139. The most recent model (Fera 2010, Annex 18 & 19) of control strategies in England has predicted that vaccination of badgers in a high incidence area (17% TB prevalence in the badger population, 70% trapping efficacy and 70% sero-conversion probability of the vaccine to give full protection) could produce a reduction in confirmed herd breakdowns. In a 150km² area, the model estimated vaccination could reduce confirmed cattle herd breakdowns by 9% after five years of repeated vaccination, 28% in the five years following vaccination with an overall reduction of 19% over 10 years within the core area.

140. In comparison to other intervention strategies this model predicted that culling outperformed vaccination; over the combined 10-year period (control and after control) the model predicted that culling would reduce cattle herd breakdowns (confirmed) by 34% within the core area and 17% across the core and 2km surrounding area (Annex 18, Table 3, Page 21). The risks of modelling, as discussed below, can be seen in the difference between the model outputs for culling and comparative figures for the IAA using specific IAA data (Annex 13) Information on the overall impact of vaccinating badgers, on the disease in the IAA is not available and as such a direct comparison between badger vaccination and culling in the IAA can not be made.

141. The report by Fera recognises that great care must be taken not to over-interpret the outputs of such models or to extrapolate the results beyond the limitations imposed by the method or data. In common with other models, a number of assumptions are made which vary from the IAA. For example:

- Badger parameter data were mostly derived from a single study population in Gloucestershire (Woodchester Park). Cattle parameters were based on means from an area of six counties in the South West of England (Avon, Cornwall, Devon, Gloucestershire, Hereford and Worcester, and Wiltshire) derived from a number of national datasets including the 2004 UK June Census, the Cattle Tracing Scheme (CTS) and the Animal Health VetNet database. This model assumed that these data were representative of the situation in hypothetically proposed areas for badger control.
- Sensitivity analysis of the model indicated that some parameters had a large uncertainty associated with them, and this may impact on the outcome.
- The model assumed that the background rate of confirmed herd breakdowns, farm size, herd size and cattle management do not change over the 10-year period over which the strategies are compared.

142. Modelling does offer a useful tool with which to advance our understanding of the relative performance of the three badger control strategies that the model investigates (culling, vaccination and combined test, vaccinate and cull strategy), but its limitations must be recognised.

143. Despite there being data on the effects of vaccination in badgers from laboratory and clinical field trial studies, we do not know how deployment of the vaccine in the field would affect TB incidence in cattle. The Science Review reported that “there has been no evaluation of the impact of badger vaccination on the incidence on bovine TB herd breakdown[s] in cattle” (Science Review Report, Page 12, Para 5, see Annex 4). The predictions of an effect of badger vaccination on TB incidence in cattle are derived from modelling.

144. The Science Review concluded that “no trials have been undertaken to assess whether the vaccination of badgers would reduce the number of bTB cattle herd breakdowns; however it is logical to assume that over time this would be the case”.(Science Review report Page 3 Para 10, see Annex 4).

145. There are no known plans to undertake further trials to assess the potential impact of the vaccination of badgers on TB herd breakdowns.

5.3.6 Timing

146. The duration and timing of badger vaccination needs to balance the welfare requirements for badger intervention against the disease control requirements. The longer the closed season, to account for the breeding season of badgers, (normally end of January to the beginning of May) the less time is available for control. In line with CCW's recommendation, in their response to the Consultation on Badger Control in the IAA (Annex 11), a closed season for badger vaccination would be agreed with CCW to reflect the environmental conditions and evidence available at that time.

5.3.7 Veterinary Opinion

147. A BadgerBCG licensed injectable vaccine is available. "There is evidence that it [vaccination of badgers] is feasible, though labour-intensive and relatively costly, to use an injectable vaccine in wild badgers" (Science Review Report, Page 12, Para 3, see Annex 4).

148. There is increasing evidence for the direct effect of badger vaccination on the incidence of signs of bovine TB infection and disease in wild badgers (Chambers *et al*, 2011). However, the Science Review reported that, "there has been no evaluation of the impact of badger vaccination on the incidence on bovine TB herd breakdown[s] in cattle" (Science Review Report, Page 12, Para 5, see Annex 4), except through computer modelling, the difficulties of which are considered in paragraph 141.

149. Vaccination does not provide complete protection against infection; rather it reduces the risk of infection, the progression of disease in badgers vaccinated prior to infection, and onward transmission of disease. The Science Review reported that "from studies of BCG vaccination in other species, it is probable that vaccination of badgers that are already infected or diseased with bovine TB will have no effect on the progression of their infection or their infectivity" (Science Review Report, Page 13, Para 6, see Annex 4).

150. Despite no trials having been undertaken to assess whether the vaccination of badgers would reduce the number of bovine TB cattle herd breakdowns, the Science Review stated that "it is logical to assume that over time this would be the case" (Science Review Report, Page 3, Para 10, see Annex 4) and they concluded "in the medium to long term, repeated vaccination in an area is likely to reduce the level of bovine TB infection and disease in the local badger population and thus the risk to local cattle from badger-to-cattle" (Science Review Report, Page 13, Para 9, see Annex 4). However, it is difficult to predict the scale or timing of any impact on the transmission of infection to cattle and ultimately in the number of confirmed herd breakdowns that are prevented.

151. In conclusion, the potential of vaccinating badgers to prevent cattle herd breakdowns is recognised and practically possible to deliver. In conjunction with the enhanced cattle measures this could deliver a comprehensive approach aimed at tackling all known sources of infection working towards eradication. However, it remains unproven for large scale field use and the

potential to reduce the number of cattle herd breakdowns has been only been demonstrated through modelling.

5.4 Option 4: Combined test, vaccinate and cull strategy

152. In theory, adding selective culling into a programme of vaccination of badgers might be beneficial in two ways; animals with a positive result are likely to represent the greatest risk of transmitting infection to cattle so their removal may reduce this risk; and vaccination of clear/negative tested badgers may then help to build a level of immunity in the badger population. A combined approach such as this could therefore have the benefit of high risk badgers being removed, and a high proportion of the remaining population being vaccinated.

153. Selective culling in combination with vaccination may therefore have the potential to contribute to bovine TB eradication, whilst minimising the impact of any negative effects associated with culling. However, the success of such an approach would depend on being able to take blood samples from trapped badgers, availability of a sufficiently accurate and practical trap-side test that could be used in real time, an effective vaccine, the ability to capture and test a sufficient proportion of the badger population, the proportion of the badgers already infected and the level of social disruption (perturbation) that may be caused.

154. There are a number of tests for bovine TB in live badgers. Bacteriological culture of samples, gamma interferon and ELISA tests, can take up to three days for results to be available making them unsuitable for use in this context as badgers would either have to be held captive until the results were available or tested, marked and released then recaptured in the future. The Stat-Pak test is the most promising test for use in a combined vaccination and selective cull strategy. The test is relatively simple to perform, although blood sampling would require badgers to be anaesthetised. The test produces results within 20 - 30 minutes, and has a sensitivity (the ability to identify infected badgers) for detection of bovine TB of 49.2% meaning that half of the truly infected badgers would test negative (and therefore be assumed to be uninfected, vaccinated and released). As discussed later the accuracy of the test is insufficient for the purposes of this option.

155. A combined test, vaccinate and cull strategy would aim to remove infected badgers from the population and confer a degree of protection to those individuals vaccinated and released back into the population. The number of badgers that would be removed from the population and the proportion of those remaining that would need to be vaccinated in order to deliver benefits in cattle TB are uncertain. However, estimates based on the number of infected individuals per social group and the efficacy of the vaccine, as discussed above, are available from modelling.

5.4.1 Potential outcomes

156. There is no evidence of the effects of this strategy in the field as it has never been implemented before. Therefore, the only information available on the

potential effects of a combined strategy on confirmed herd breakdowns is from the modelling exercises completed by CSL and commissioned by the Welsh Assembly Government (CSL (2009) (b), Annex 20). These models predict that if no social perturbation occurs in a control area of 100km^2, with a control duration of 5 years, 70% trap efficiency, 60% vaccine efficacy and a land access of 80%, a minimum of 40% of healthy badgers need to be vaccinated for there to be any effect on the confirmed incidence of bovine TB in cattle.

157. However, the report suggests that the size of the remaining badger population, the level of infection remaining in that population and their disturbance (perturbation) could result in an increase in contact between badgers and between badgers and cattle causing a sustained increase in confirmed herd breakdowns. The incidence of confirmed herd breakdowns was reported as increasingly steeply with the ultimate consequence being a 10-20% increase above that which would otherwise have been observed.

5.4.2 Veterinary Opinion

158. There is no field trial evidence to suggest that the combined test, vaccinate and cull approach would reduce the number of confirmed herd breakdowns.

159. The modelling of potential outcomes from the combined test vaccinate and cull approach indicated that the size of the remaining badger population, the level of infection remaining in that population and their disturbance (perturbation) could result in an increase in the number of infected badgers and the number of confirmed herd breakdowns.

160. “There is some support though no evidence base for the value of the removal of individual badgers or setts that are infected and by implication may be epidemiologically important. There is currently no trap-side test that allows for the rapid identification of infected badgers, and there is no information on the outcomes of such an approach with respect to perturbation of badger social structures” (Science Review Report, Page 7, Para 13, see Annex 4).

161. In conclusion, there is no evidence to suggest that this is a suitable or viable approach to deal with a reservoir of infection in badgers in endemic areas such as the IAA.

5.5 Option 5: Immunocontraception

162. The principle of immunocontraception is the targeting of a population to reduce the potential for reproduction and therefore future population density. The theory is to reduce the population density to a level at which transmission of the disease is impaired (e.g. reducing the number of opportunities for contact between individuals in the host species and other susceptible populations) usually similar to the impact of culling.

163. Immunocontraceptives in badgers need to be able to overcome the badgers’ natural population control strategies of delayed implantation and infanticide. It is reasonable to assume that if some of a social group are infertile (such as the alpha sow), other animals will reproduce to compensate.

164. The use of immunocontraceptives has been discussed by the TB Eradication Programme Board. They recognised that large scale use of immunocontraceptives in badgers is by no means a realistic option.

5.5.1 Current position

165. There are no known immunocontraceptives currently licensed as being safe for use in wild badgers.

166. Modelling has been conducted to look at the effect of immunocontraception in badger populations. Cowan and Massei (2008) conclude that "modest levels of induced infertility should have significant (badger) population consequences, although these effects take a relatively long time to be realised". Swinton *et al*. (1997) modelled the relative effects of fertility and lethal control and concluded that both can act to reduce the number of badgers from a population, hence decreasing transmission rates.

167. Defra, through the Environmental Stewardship and Wildlife Management research programme, is funding research to look at the effect of the USA-licensed GnRH vaccine in wild boar, urban badgers and parakeets. Monitoring of this work should give an indication of whether fertility control could contribute to a strategy for controlling bovine TB in badgers, by reducing the proportion of susceptible animals in the population. Further years of observation and development would be required before the potential benefits, in terms of changes in population size and structure, could be quantified.

5.5.2 Veterinary Opinion

168. Whether fertility control of badgers could contribute to a strategy for controlling bovine TB in cattle, by reducing the number of badgers in the population (and thus reducing the opportunity for transmission to cattle) is not known.

169. With no known immunocontraceptives currently licensed as being safe for use in wild badgers and only minimal data from national research field trials, this option is not considered a viable solution to deal with a reservoir of infection in badgers in endemic areas at present. The Science Review did not consider immunocontraception.

5.6 Option 6: Biosecurity – separation of badgers and cattle

170. "There is general consensus with an evidence base for the epidemiological link between infection in cattle and badgers (Bourne *et al.*, 2007). It follows that biosecurity measures that reduce or prevent contact between the species should reduce the risk of transmission in both directions. While there is no direct evidence on the precise mode of transmission between badgers and cattle, and there is limited evidence of the efficacy of individual husbandry measures at directly preventing transmission, there is mounting evidence that on-farm procedures can reduce contact between badgers and cattle (Judge *et al.* 2011). Such measures should reduce the transmission of infection from badgers to cattle, and also from cattle to badgers. The latter is particularly

relevant in areas where infection is not present in wildlife" (Science Review Report, Page 9, Para 1, see Annex 4)

171. Enticott (2008) provided the following definition for biosecurity: "Biosecurity is a broad concept. It can refer to almost any method that can help reduce animal disease. However, biosecurity tends to be associated more with applying specific activities to specific farms to reduce the risk of disease. In other words, biosecurity is not a single activity that applies to all farms. Biosecurity refers to a whole range of different actions that is tailored to suit the needs of an individual farm to help reduce the spread and transmission of infectious matter. Many biosecurity activities may have broader animal health benefits. Other activities may be specific to particular types of animal disease. Whatever form biosecurity takes, for it to work, it should be specific to individual farms, the activities within them and the specific animal health challenges it faces."

172. Biosecurity in the IAA to deal with a potential reservoir of infection in badgers refers to exclusion measures that can be used to prevent badgers coming into direct or indirect contact with cattle within the farmyard and at pasture. Measures around the farmyard can be relatively inexpensive to install and effective in reducing entry by badgers into farm buildings if properly used and maintained. The practicality and the cost of these exclusion measures can make them prohibitive for some farms.

173. It is extremely difficult if not entirely impossible for some farms to exclude badgers from pasture and therefore prevent their interaction with cattle for a large proportion of the year.

5.6.1 Current position

174. The South West Wales Biosecurity Intensive Treatment Area (ITA) was established by the (then) Welsh Assembly Government in December 2006 across an area of approximately 100km^2 with high TB incidence of in cattle on the Carmarthenshire/Pembrokeshire border. The overall aim of the ITA was to raise awareness, understanding and ultimately, the uptake of improved biosecurity measures on farms.

175. The ITA ran for 15 months. Local vets were involved in the project along with the Assembly Government and the Royal Veterinary College who helped to design a biosecurity scoring tool. Vets assessed the level of biosecurity on farms that had volunteered to participate and paid at least two visits to each farm. At the first, levels of biosecurity were measured and a series of recommended actions were provided to farmers. At the second visit, a new measurement of biosecurity was recorded and recommendations updated.

176. In his evaluation of the ITA, Enticott (2008) concluded that: "The biosecurity gains achieved by the ITA were small but beneficial. The time period during which the ITA operated was not long enough to realistically expect large scale changes in cultural attitudes towards biosecurity. As a result, the small changes that occurred to biosecurity levels represent a realistic level of change from an area with high levels of bovine TB. Potentially, the biosecurity benefits arising from the ITA may help to reduce incidents of bovine TB. Repeating the ITA in

other areas of Wales is likely to have similar effects, depending on current levels of bovine TB."

177. Between 2007 and 2009 Fera undertook an experimental study to evaluate the effectiveness of simple exclusion measures in improving farm biosecurity and preventing badger visits to farm buildings. A report on the study by Judge et al. (2011) concluded that: "The simple exclusion measures were 100% effective in preventing badger entry into farm buildings, as long as they were appropriately deployed. Furthermore, the installation of exclusion measures also reduced the level of badger visits to the rest of the farmyard. The findings of the present study clearly demonstrate how relatively simple practical measures can substantially reduce the likelihood of badger visits to buildings and reduce some of the potential for contact and disease transmission between badgers and cattle."

178. The study did not however mitigate for the risks of direct and indirect contact between cattle and badgers at pasture.

5.6.2 Veterinary Opinion

179. There is increasing evidence that badger visits to farm buildings are a common occurrence (Judge *et al.* 2011) and that it is possible to minimise the direct and indirect interaction between badgers in these circumstances. The ability to do this depends on the individual farm circumstances.

180. There is very little that can be done to prevent direct and indirect contact between cattle and badgers at pasture.

181. Biosecurity refers to the precautions that can be taken to reduce risk (Enticott, 2008) and in respect to the risk of direct and indirect contact between badgers and cattle, there is evidence to substantiate the ability to reduce risk, however biosecurity on its own is not sufficient.

182. It is logical to assume that a reduction in the risk of transmission of TB would reduce the number of herd incidents, but this has not been proven in any field trials.

183. It can be concluded that the continuation of enhanced biosecurity measures to separate badgers and cattle in the IAA are a critical part of the programme but are not sufficient in isolation to deal with the potential reservoir of infection in badgers in the IAA.

5.7 Option 7: Vaccination of Cattle

184. In theory, cattle vaccination has the potential to reduce the frequency of transmission to otherwise susceptible animals from any infected source (including both other cattle and wildlife) and to reduce the frequency of onward transmission from animals that do become infected. The impact of vaccination would be seen both as a reduction in the frequency of new breakdowns and a reduction in the severity of those breakdowns that did occur. However, as with all vaccines (discussed in greater detail in section 5.3), a cattle vaccine will not

guarantee that all cattle vaccinated are fully protected and a proportion may still become infected. Recent research also indicates that to maintain sufficient levels of protection annual re-vaccination is likely to be necessary.

185. Vaccination of cattle does not address the reservoir of infection in badgers or the potential transmission TB from badgers to cattle.

5.7.1 Current position

186. A cattle vaccine has the potential to make an important contribution to the TB Eradication Programme in the future. The development of a viable and effective cattle vaccine remains a fundamental element of the Government-funded TB research programme.

187. Vaccination of cattle against TB is currently prohibited by EU legislation because BCG, on which the vaccine is based, interferes with tuberculin-based tests including the tuberculin skin test, the primary TB test that confers herd TB health status under EU and international rules. As with human BCG, cattle injected with a BCG-based vaccine are likely to react to the tuberculin skin test for a variable period after vaccination, thereby appearing as if they were infected with TB. In the current circumstances implementation of cattle vaccination would be associated with a significant negative impact on the Member State’s ability to trade live cattle and cattle products, such as milk. Under current legislation animals sensitised against tuberculin (the antigen used in the skin test) have to be slaughtered or re-tested, they would not be eligible for trade and their herds of origin would lose their officially TB free status. To overcome these problems, a fundamental part of the research programme involves developing a test to Differentiate Infected from Vaccinated Animals (a so-called ”DIVA test“).

188. The dossier required to support an application for a marketing authorisation for Cattle BCG vaccine has been submitted by Defra (in its role as lead on GB research) to the Veterinary Medicines Directorate (VMD) for validation. If this initial phase is successful, the dossier will then enter a process of formal assessment. The duration of this process is not certain but might be expected to be in the region of 9-12 months. Even if this process is completed successfully, it is understood that the VMD would not issue a marketing authorisation for a product in the face of a legislative prohibition on the use of that product. Instead it is anticipated that the VMD would issue a statement confirming that one would have been granted in the absence of the prohibiting legislation.

189. Changes will be required to EU legislation to allow both vaccination of cattle and the DIVA test to be used in place of, or alongside the tuberculin skin test. Changing EU legislation is a lengthy and uncertain process which, if successful, is likely to take several years. The VMD statement referred to above would, if issued, form a key part in the evidence presented to the European Commission in support of changes to the legislation.

5.7.2 Veterinary Opinion

190. A cattle vaccine has the potential to make an important contribution to controlling TB in the future by generating immunity in non-infected cattle. Used in conjunction with a test and slaughter policy it could make a meaningful contribution to TB eradication. The eradication of brucellosis (caused by the bacterium *Brucella abortus*) was achieved through a combination of a voluntary (introduced in 1962) and compulsory calf vaccination scheme, followed by the introduction of a voluntary attested herds scheme in 1967. Compulsory area eradication commenced in 1971 and by 1979 all herds in GB were attested and the calf vaccination programme was ended. GB gained Officially Brucellosis Free status in 1985. TB is a totally different disease but similar principles could be applied in the development of a strategy to make best use of vaccination alongside a test and slaughter policy working towards eradication.

191. “It is feasible that a vaccine, perhaps in combination with a test that differentiates between an infected and a vaccinated animal (a DIVA test) might prove of value, but vaccination of cattle cannot form a part of an eradication programme for bovine TB at present” (Science Review Report, Page 9, Para 1, see Annex 4).

192. The possible future use of cattle vaccines is the subject of ongoing discussion with the European Commission and international research. These discussions have identified a number of legislative and technical obstacles that must be addressed before the vaccination of cattle becomes an option.

193. We do not expect to be able to deploy a cattle vaccine for use in the field for several years and cannot predict the time to deployment with certainty. Therefore the vaccination of cattle is not considered currently to be a viable alternative approach to deal with the potential transmission of infection from badgers to cattle in the IAA.

5.8 Summary of options to deal with the reservoir of infection in Badgers in the IAA

194. “There is a general consensus based on expert opinion that the eradication of bovine TB infection in domestic animals in an area where the infection is endemic in a sympatric wildlife population requires the control of the infection in the wildlife host and high levels of biosecurity” (Science Review Report, Page 10, Para 1, see Annex 4), to limit the spread of infection between cattle and other susceptible populations.

195. It is therefore advised that the enhanced cattle and surveillance and control measures (**Option 1**) that have been established in and around the IAA in May 2010 are retained and that their delivery continues to be evaluated. The additional cattle surveillance and controls and the separation of badgers and cattle using biosecurity measures (**Option 6**) should also be regarded as critical parts of the programme but in isolation are insufficient to remove the potential 50% of breakdowns in endemic areas, such as the IAA, that are caused by badgers, and which need to be addressed directly.

196. Two of the four options considered, the combination of culling and vaccination (**Option 4**) and immunocontraception (**Option 5**) are unlikely to be worthy of further consideration for a number of years, primarily due to limitations in the technology available. There are no known immunocontraceptives currently licensed as being safe for use in wild badgers and the effect of this approach on TB incidence is not known. The option of combining the testing, culling or vaccination of badgers currently is of little value due to the unavailability of a sufficiently accurate real-time trap-side test, and the risk of perturbation that may increase the number of confirmed herd breakdowns in cattle.

197. The legislative and technical limitations on the use of a cattle vaccine **(Option 7**), explained above, make this option inappropriate for consideration at this time. Further work is necessary to address the technical and legislative issues, as well as in developing an appropriate strategy for the role of cattle vaccination in the future.

198. Culling of badgers (**Option 2**) has been proven in the field through a number of trials to reduce in the number of confirmed herd breakdowns.

199. The largest of these, the RBCT was designed as a controlled field experiment with 30 areas grouped into ten 'triplets', each comprising three areas randomly allocated to one of three experimental treatments. The effect of the badger control treatments in the RBCT was evaluated by consideration of the incidence of TB in cattle expressed as the number of new confirmed herd breakdowns.

200. Applying the experience of the RBCT of a proactive, non-selective badger cull to the IAA provides strong empirical evidence that culling would reduce the level of confirmed herd breakdowns within the culling area from the first year (Jenkins *et al.* 2010, figure 5). The reduced opportunities for infection to be transmitted between badgers and cattle are expected to continue to accrue throughout the period of culling and a five years post culling.

201. Experience from the BVDP suggests that the vaccination of badgers **(Option 3)** via injection is practically possible and with sufficient trapping efficacy should result in the vaccination of a large proportion of the badger population in the IAA.

202. However the impact that the vaccination of badgers could have on TB in cattle is unproven in the field. In their expert opinion, which is offered due to the lack of direct evidence, the Science Review recognised that "repeated vaccination in an area is likely to reduce the level of TB infection and disease in the local badger population and thus the risk to local cattle from badger-to-cattle transmission" (Science Review Report, Page 13, Para 9, see Annex 4).

203. Vaccinating badgers should at the very least not result in an increased incidence of infection in cattle. The only available data on the potential for a reduction in confirmed herd breakdowns from vaccinating badgers in terms of the scale and timescale of any effect is reliant on statistical computer modelling.

204. The limitations of modelling have already been discussed (para 141), in particular that the calculations are based on a number of assumptions For

example in this case, badger parameters were mostly derived from a single study population in Gloucestershire (Woodchester Park), cattle parameters were based on the South West of England, and the hypothetical area was 150km^2.

205. The report by Fera recognises that great care must be taken not to over-interpret the outputs of such models or to extrapolate the results beyond the limitations imposed by the method or data. The model does offers a useful tool with which to advance our understanding of the relative performance of badger control strategies including culling and vaccination (i.e. Options 2 and 3) but cannot be expected to predict the outcome of a particular option with accuracy.

206. The model cannot provide for, or even allow, a direct comparison between the anticipated results of culling in the IAA (based on the field trial experiences of the RBCT) and the potential impact vaccination of badgers in the same area (based on a number of assumptions). When considering Option 2 (Culling) and Option 3 (Vaccination) in the following sections the limitations of the data presented and the risk of making direct comparisons between two datasets should be taken into account.

6 Issues arising for decision

207. The Badger (Control Area) (Wales) Order 2011 ("the Order") provides for the destruction of badgers within the IAA for the purposes set out in section 21 of the Animal Health Act 1981 ("1981 Act"). The following section considers the issues that arise for decision regarding the implementation of a badger cull or alternative measures in the IAA.

6.1 Animal Health Act 1981 - Section 21

208. The Order is made under section 21 of the 1981 Act. Section 21(2) specifies:

"(2) The Minister, if satisfied in the case of any area--

(a) that there exists among the wild members of one or more species in the area a disease to which this section applies which has been or is being transmitted from members of that or those species to animals of any kind in the area, and

(b) that destruction of wild members of that or those species in that area is necessary in order to eliminate, or substantially reduce the incidence of, that disease in animals of any kind in the area, may, subject to the following provisions of this section, by order provide for the destruction of wild members of that or those species in that area."

The Court of Appeal considered this test when hearing the appeal of the Badger Trust against the decision of the High Court to refuse their application for judicial review of the Tuberculosis (Eradication) (Wales) Order 2009 ([2010] EWCA Civ 807). A copy of the judgment is attached at Annex 29.

209. The Welsh Ministers (in whom these powers, so far as exercisable in relation to Wales, are now vested) must be satisfied that the tests in subsections (a) and

(b) **("the threshold test")** are met in order for the Order to be made and to remain appropriate. In turn section 21 empowers rather than requires the Welsh Ministers to make an Order. Therefore you will need to exercise your discretion in determining whether the Order is appropriate, if you are satisfied that the threshold test in section 21 is met.

6.2 Threshold test

210. In order for you to consider that the Order is appropriate, you must be satisfied that TB exists among badgers in the proposed IAA, that it is being spread to cattle and that culling is necessary to eliminate or substantially reduce TB in cattle. These issues are considered in the following section.

6.2.1 Threshold test 1 - TB exists in badgers in the IAA

211. The decision of the previous Government to make the Order included consideration of data (Annex 16) on the IAA and modelling of the relative isolation of Wales (CSL 2009 (a), Annex 21). The evidence that TB exists in badgers in the area includes:

- o The Badger Found Dead Survey (Welsh Assembly Government 2007, Annex 22) variogram analysis strongly suggested that cattle and badgers had been infecting one another and that the results indicated that tuberculosis in badgers in Wales is closely associated with the disease in cattle.
- o 15% (95% CI 7–26%) of the badgers found dead in the Pembrokeshire area (Badger Found Dead Survey) were confirmed with bovine TB post mortem.
- o Bovine TB was confirmed in 3 badgers within the IAA boundary (Welsh Assembly Government 2007, Annex 22).
- o Evidence from other endemic areas suggests that the prevalence of *M. bovis* in badgers in the IAA could be approximately 27% (Annex 16).
- o There is no evidence to suggest that TB does not exist in badgers.

212. The Science Review reported that "in the United Kingdom and Ireland bovine TB is present in badgers, and to a lesser extent in other wildlife, and an epidemiological link between the badger and infection in cattle is accepted." (Science Review Report, Page 10, Para, see Annex 4) and that "the presence of bovine TB in the badger population in Wales was confirmed through the collection of animals killed on roads" (Science Review Report, Page 10, Para 1, see Annex 4).

213. You need to be satisfied that the evidence within this submission demonstrates that TB exists in wild badgers in the IAA.

6.2.2 Threshold test 2 – TB being transmitted from badgers to cattle in the IAA

214. Similarly, in deciding whether to make the Order, the previous Government was satisfied that TB was being transmitted from badgers to cattle within the IAA based on the following evidence. The ISG final report (Bourne *et al*. 2007) suggests that transmission from badgers is a very important route of infection in

cattle in high incidence areas such as the IAA. Estimates from Donnelly and Hone (2010), for the RBCT indicated that roughly 50% (49.85%; with the triplet data ranging from 16.8% - 72.7%) of bovine TB incidents could be attributed to infectious badgers (Donnelly personal communication).

215. The evidence that TB is being transmitted between badgers and cattle in the IAA includes:

- The molecular types of *M. bovis* in badgers in the IAA, from the Badger Found Dead Survey (Welsh Assembly Government 2007, Annex 22) were found to be common with *M. bovis in* cattle in the area. The survey report concluded that tuberculosis in badgers in Wales is closely associated with the disease in cattle, indicative of transmission of infection between the two species.
- There are herds in the IAA that have suffered repeated confirmed breakdowns over many years despite the fact that no cattle have moved into those herds. This suggests a local reservoir of infection in badgers.

216. On this issue the Science Review concluded that “there is a general consensus based on an evidence base that there is an association between the incidence of bovine TB infection in badgers and in cattle in areas where the infection occurs in both species” (Science Review Report Page 2, Para 6, see Annex 4).

217. You need to be satisfied that the evidence within this submission demonstrates that TB is being transmitted from badgers to cattle in the IAA.

6.2.3 Threshold test 3 – That culling is necessary to eliminate or substantially reduce the incidence of TB in cattle

218. Section 21 of the 1981 Act requires that in making an order providing for the destruction of wildlife in a specific area the Welsh Ministers must be satisfied that destruction of wild members of that species is necessary to eliminate or substantially reduce the incidence of disease in animals of any kind in the area. Information provided indicates that the enhanced cattle and surveillance and control measures that have been established in and around the IAA since May 2010 are insufficient to stop the large proportion of breakdowns in endemic areas such as the IAA that are caused by badgers. Therefore you are advised to consider additional measures to those already being implemented. Advice in section 5.8 is that of the potential options (1. Continue with the enhanced regime, 2. Non selective cull of badgers, 3. Badger vaccination, 4. Combined test, vaccinate and cull strategy, 5. Immunocontraception, 6. Biosecurity and 7. Vaccination of cattle) only vaccination and culling of badgers merit further consideration, at present as additional elements to the measures already being implemented.

219. In considering culling as an option, you must consider the effects of culling on herd breakdowns in the light of the effects which could be achieved by other reasonably practicable alternative methods in order to ascertain whether culling is necessary to substantially reduce the incidence of herd breakdowns within the IAA.

220. We have examined and reported in this submission on the outcome of numerous successful badger culling activities including the latest findings in relation to the RBCT, published in August 2011 (Annex 12(e)).

221. The Science Review noted the results of the RBCT, stating “the impact of the culling of badgers has been assessed, based upon the results of the RBCT (Bourne et al, 2007), as being a relative reduction overall (including a cull area of at least 150 square Kms and 2 Km surrounding ring) over nine years of 16% in confirmed bovine TB breakdowns compared to non-cull control areas (Defra)” (Science Review Report, Page 11, Para 7, see Annex 4).

222. As presented in section 5.2.5 we have analysed the TB disease picture in the IAA and subjected these data to the analysis of the RBCT to provide an estimation of the effect of culling badgers in and around the IAA (excluding only the coastline as being 100% impermeable to badger movement), using a Microsoft Excel spreadsheet provided by a co-author of the Jenkins et al. reports (see Annex 13).

223. In relation to this test we advise that you should consider two of the scenarios presented i.e. the effect of culling on all herd breakdowns (but with no effect on unconfirmed breakdowns) and separately the effect on all herd breakdowns (with an effect on both confirmed and unconfirmed herd breakdowns) in the IAA.

6.2.3.1 All Herd Breakdowns (with no effect on unconfirmed herd breakdowns)

224. Analysis of the estimated effect of culling of badgers in the IAA on all herd breakdowns, assuming that culling has no discernable impact on unconfirmed herd breakdowns is the closest to the analysis and results of the RBCT.

225. On this basis, applying results from the RBCT this would see a reduction of 95.2 herd breakdowns within the IAA, (43.2 during the cull period and 52.1 in the post cull period), producing an estimated 13.4% reduction in herd breakdowns in the area as a consequence of culling badgers, when compared to what would have been seen in the absence of culling.

6.2.3.2 All Herd Breakdowns (with an effect on confirmed and unconfirmed herd breakdowns)

226. The apparent absence of an effect of proactive culling of badgers on unconfirmed cattle herd breakdowns in the RBCT as discussed in paragraphs 64 - 66 means that an alternative scenario might arise when extrapolating the RBCT results to the IAA i.e. one where the culling of badgers also has an impact on unconfirmed herd breakdowns.

227. Taking into account the disease situation in the IAA and the basis on which a new breakdown is defined as confirmed or unconfirmed (discussed in paragraphs 58 and 59) i.e. assuming a similar effect of culling badgers on unconfirmed and confirmed herd breakdowns, proactive culling of badger is

estimated to prevent approximately 182.5 herd breakdowns (82.7 during the cull period and 99.8 in the post cull period). This would be an estimated 25.6% reduction in herd breakdowns in the area as a consequence of culling badgers, when compared to what would have been seen in the absence of culling.

228. Veterinary opinion of the RBCT data is that there remains some uncertainty in the likely effect of proactive culling on unconfirmed herd breakdowns. Taking into account the disease situation in endemic areas (i.e. that the majority of unconfirmed breakdown herds are likely to be genuinely infected with M. bovis), it is concluded that proactive badger culling in endemic areas should also reduce the number of unconfirmed herd breakdowns. For these reasons, insofar as the results of the RBCT can be extrapolated to the IAA, the expectation is that the outcome of culling badgers in the IAA will be at least 13.4% over 10 years.

229. Veterinary opinion is that 13.4% is an under estimate of the effect likely to be seen in the IAA and that the effect is expected to be towards the higher end of the range i.e. 25.6%.

230. In addition to this we would expect that the comprehensive approach described (which includes, additional cattle controls, enhanced biosecurity and potential benefits of the natural boundaries to the IAA such as the river Teifi, and Preseli Hills to reduce perturbation), combined with culling would deliver greater benefit than those estimated above.

6.2.3.3 Vaccination

231. Fera have modelled figures on the effect of vaccination control strategies in England on herd breakdowns. Based on an assumption of a hypothetical 150 km^2 area, on the basis of 70% trapping efficacy and 70% sero-conversion probability of the vaccine, their model forecasted a reduction of 9% in confirmed herd breakdowns by the end of 5 years of vaccination operations, 28% in the 5 years following those operations and an overall reduction of 19% over 10 years within that area from commencement of vaccination.

232. In considering these figures you should be aware that they are only applicable to confirmed herd breakdowns, no modelling having been undertaken on the effect on unconfirmed herd breakdowns. Further you should note the advice on the limitations of modelling, together with Fera's recognition of the need for caution not to over-interpret the outputs of such models, which were based on assumptions (as more specifically detailed in paragraphs 140-145).

233. The Science Review acknowledged that “there has been no evaluation of the impact of badger vaccination on the incidence of bovine TB herd breakdown in cattle” (Science Review Report, Page 12, Para 5, see Annex 4). Their conclusion is that “in the medium to long term, repeated vaccination in an area is likely to reduce the level of bovine TB infection and disease in the local badger population and thus the risk to local cattle from badger-to-cattle transmission” (Science Review Report, Page 13, Para 9, see Annex 4) although they offer no definition of “medium to long term” or commentary on the potential scale of impact.

6.2.3.4 [redacted]

Information redacted as it is subject to legal professional privilege, which the Welsh Government considers to be exempt under section 42 of the Freedom of Information Act and / or regulation 12 (4) (e) of the Environmental Information Regulations.

234. [redacted]

235. [redacted]

236. [redacted]

237. [redacted]

238. [redacted]

239. [redacted]

6.2.4 [redacted]

Information redacted as it is subject to legal professional privilege, which the Welsh Government considers to be exempt under section 42 of the Freedom of Information Act and / or regulation 12 (4) (e) of the Environmental Information Regulations.

240. [redacted]

241. [redacted]

242. [redacted]

243. [redacted]

244. [redacted]

245. [redacted]

7 Legal powers and requirements

7.1 Protection of Badgers Act (PoBA) 1992

246. In order to kill or take a badger, a person must be licensed by the Welsh Ministers under section 10(2) of the Protection of Badgers Act 1992 ("PoBA"). Killing or taking a badger without a licence is an offence under section 1 of that Act. The function of granting such a licence vests in the Welsh Ministers.

247. The purposes for which a licence may be granted include preventing the spread of disease or preventing serious damage to land, crops, poultry or any other form of property.

248. To the extent that licences would be required for a cull, it is considered that this would be justified on the basis that a cull would be implemented for the purpose of reducing the incidence of TB in cattle by limiting the opportunities for badger-to-cattle transmission. Evidence has been provided to you in this submission of the effects of a cull and the Science Review accepted “there is an evidence base that the culling of badgers in areas where the incidence of infection is high will produce a reduction in confirmed bovine TB cattle herd breakdowns when compared to non-cull areas” (Science Review Report, Page 2, Paragraph 7, see Annex 4).

249. In the event of a vaccination programme being commenced, that would involve the taking of badgers, which would need to be licensed. Similarly it is considered that licences could be granted on the basis that vaccination would be undertaken for the purpose of preventing the spread of disease. This submission refers to evidence which suggests that vaccination would have a positive contribution in reducing the incidence of TB both in badgers and in cattle. The Science Review concluded that badgers which had been vaccinated would “be epidemiologically less important in the transfer of bTB between badgers and cattle” (Science Review Report, Page, 13, Para 8, see Annex 4) and “in the medium to long term, repeated vaccination in an area is likely to reduce the level of bTB infection and disease in the local badger population and thus the risk to local cattle from badger-to-cattle transmission” (Science Review Report, Page, 13, Para 9, see Annex 4).

250. Additionally, the marking of badgers would require a licence, to avoid that activity constituting an offence under section 5 of PoBA. The function of granting such a licence is conferred on CCW. A licence may simply be granted for the purpose of ringing or marking badgers.

251. The Order does not affect the status of badgers as a protected species and any policy (whatever your decision) has to be accompanied by clear communication on this matter and all suspected cases of illegal activity would be reported to the appropriate authorities.

7.2 The Wildlife and Countryside Act 1981

252. Section 11(2) of The Wildlife and Countryside Act 1981 prohibits, except under licence, the use of certain methods of control or capture of mammals including badgers.

253. To the extent that a licence may be required for the purposes of trapping badgers whether as part of a culling or vaccination programme, a licence may be granted by the Welsh Ministers after specified consultation under section 16 of the Act for the purpose of ringing or marking or for the purpose of preventing the spread of disease. It is considered that this would be possible for the same reasons as those outlined above in relation to licences issued under PoBA.

7.3 [redacted]

Information redacted as it is subject to legal professional privilege, which the Welsh Government considers to be exempt under section 42 of the Freedom of Information Act and / or regulation 12 (4) (e) of the Environmental Information Regulations.

254. [redacted]

255. [redacted]

256. [redacted]

257. [redacted]

258. [redacted]

259. [redacted]

260. [redacted]

261. [redacted]

8 Ecological impacts

262. Badgers are protected under the Protection of Badgers Act 1992 and the Bern Convention on the Conservation of European Wildlife and Natural Habitats. However, they are not an endangered species.

263. No large scale study of the badger population has been undertaken since the National Badger Sett Survey in 1997 which was a follow-up to the original survey carried out in the mid 1980s. The 1990s survey revealed that badger numbers had increased substantially in the intervening decade. There is a commonly held perception that the badger population has continued to increase since then but there is no reliable evidence to support or refute this.

264. A badger survey of Wales and England is being undertaken by Fera, as part of national research activities, to obtain an updated, realistic, evidence based, estimate of the current size of the badger population. The intention is for the final report to be available in August 2013 (you were briefed on this in November 2011 - MB/JG/7341/11).

265. An assessment of the potential ecological impact of badger control on other species in the designated area of (west Wales area) was undertaken (December 2009) in accordance with article 6(3) of the Habitats Directive and

section 40 of the Natural Environment and Rural Communities Act 2006 (NERC) - this is considered to still be relevant and is discussed below.

8.1 Environmental legislative requirements

8.1.1 The Habitats Directive

266. The Habitats Directive (92/43/EEC) on the Conservation of Natural Habitats and Wild Flora and Fauna provides protection for habitats and species of European importance. The directive allows for the designation of Special Areas of Conservation and Special Protection Areas, together known as European Sites or Natura 2000 sites.

267. With regard to the requirements of the Habitats Directive, if you are minded to proceed with a cull or vaccination of badgers, Article 6(3) requires that you consider whether the destruction of badgers or their vaccination is likely to have a significant effect on Natura 2000 sites which were created under the Directive and under the Birds Directive (Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds). Officials consider that a vaccination programme would not be likely to have a significant effect on any such sites, and therefore no assessment will be required under Article 6 of the Habitats Directive.

268. The previous Government commissioned an Ecological Impact Assessment (EcIA) and Habitats Directive Assessment which were prepared in December 2009 at the time the cull was initially considered (as set out in Annexes 23 and 24 – Welsh Assembly Government 2009 a & b).

269. Officials have recently received advice from the Countryside Council for Wales, which indicates that there has only been limited changes in circumstances since the completion of those assessments and CCW has agreed that the recommended steps within the conclusions of those assessments of ensuring adequate monitoring of the condition of foraging habitat within or adjacent to the IAA should continue to apply. However, within the IAA a number of farms have entered into agreements under Glastir (committing to enhanced agri-environmental obligations in their farming practice) and therefore, if you decide that the Order is appropriate and a cull should be commenced, consideration will first need to be given whether those individual Glastir arrangements, in combination with a cull, would be likely to have a significant effect on any of the Natura 2000 sites. CCW themselves noted that a number of farms had signed up to Glastir. If it is considered that significant effects on Natura 2000 sites would be likely then appropriate assessments under the Habitats Directive would in turn be required. These would need to be undertaken prior to the implementation of a cull. It should be noted that the Natura 2000 sites have not changed and that no further sites have been added since the date of the Assessments. It should also be noted, that other than the Glastir arrangements, no other plans or projects within the IAA have been identified.

8.1.2 Natural Environment and Rural Communities Act 2006

270. In respect of the Natural Environment and Rural Communities Act 2006 ("NERC Act"), section 40 of that Act requires the Welsh Ministers in exercising their functions, to have regard, so far as is consistent with the proper exercise of those functions, to the purpose of conserving biodiversity. These matters were considered by the previous administration and there has been no material changes, the only changes being as indicated in paragraph 269 above.

271. The Welsh Ministers list species of principal importance for the conservation of biological diversity in Wales under section 42 of the NERC Act, these are species set out in the UK Biodiversity Action Plan and the relevant Local Biodiversity Action Plans to be considered as biodiversity conservation priorities. Badgers are not listed under section 42. However, you must consider the Assessments referred to above in order to ensure that you have regard to the principle of conserving biodiversity generally; the duty is not confined to species of principal importance.

272. In particular, in considering whether to make the Order, the then Welsh Ministers considered the findings of the Ecological Impact Assessment. You should note that whilst that Assessment makes reference to the Intensive Action Pilot Area, that area is the same area as that of the proposed IAA. The Ecological Impact Assessment considered the potential effects of a cull on a number of species, including the chough (which is a species of principal importance). With respect to the chough, the Assessment concluded that monitoring of its foraging habitat is being carried out, which would be sufficient to ensure that remedial action would be implemented should adverse effects on habitat quality arise from the proposed cull. In more general terms it concluded that options do exist to adequately address or off-set any potential effects of the proposed cull on species and sites. These considerations would apply should you deem the Order to be appropriate.

273. Additionally, as noted above, you would need to consider the outcome of any Habitats Directive assessments, should it be determined that any are required, as a result of any potential significant effect which Glastir arrangements could have in combination with a cull, if you consider that the Order is appropriate.

8.1.3 Strategic Environmental Assessment Directive

274. Under the Strategic Environmental Assessment (SEA) Directive (2001/42/EC) a separate environmental assessment is needed for "plans and programmes" to which the Directive applies if those "plans and programmes" are likely to have significant environmental effects.

275. The SEA Directive applies to plans and programmes which are subject to preparation and/or adoption by an authority which are prepared for adoption through a legislative procedure and which are required by legislative, regulatory or administrative provisions (Article 2(a)).

276. If a plan or programme to which the Directive applies is likely to have significant environmental effects, an environmental assessment, in accordance with the Directive, is required (Article 3). The assessment shall be carried out for all plans or programmes which are prepared for agriculture, forestry, fisheries,

energy, industry, transport, waste management, water management, telecommunications, tourism, town & country planning or land use and which set the framework for future development consent or which in view of the likely effect on sites, have been determined to require an assessment pursuant to Article 6 or 7 of the Directive 92/43 EEC (the Habitats Directive).

277. In the event of you deciding to implement a cull, the question of whether any assessments will be required under the SEA Directive will depend on whether assessments may be required under the Habitats Directive, as a result of farms having signed up to Glastir.

8.1.4 Bern Convention

278. In coming to a decision, you should consider the Convention on the Conservation of European Wildlife and Natural Habitats made at Bern on 19 November 1979 (“the Convention”), to which the United Kingdom is a party. The Convention imposes obligations on the United Kingdom in respect of the protection of certain species, including the badger.

279. Article 8 of the Convention requires the United Kingdom to take steps to prohibit the use of all indiscriminate means of capture and killing, and the use of all means capable of causing local disappearance of or serious disturbance to, populations of badgers. One of the means particularly identified by Appendix IV to the Convention is the use of traps for large scale or non-selective capture or killing.

280. It is considered likely that a non-selective badger cull would fall within the scope of article 8 of the Convention.

281. However, article 9 of the Convention provides that in certain cases an exception may be made to the prohibitions required by article 8. Insofar as is relevant, an exception may only be made if:

(a) the exception is made in order to prevent serious damage to livestock;

(b) there is no other satisfactory solution; and

(c) the exception will not be detrimental to the survival of the population of badgers concerned.

282. Some respondents to the 2010 consultation (see section 9.8.1) believed that the requirements of article 9 would not be met. However, it is considered that all three of the criteria laid down by article 9 if it is considered that a cull is necessary, given the separate threshold test which applies under section 21 of the 1981 Act, would be met in the present case.

283. As to criterion (a), section 5.2.5 above sets out advice for the scenario that a cull of badgers in the IAA would reduce the total number of herd breakdowns in the IAA and the immediately surrounding area by an estimated 93, equating to an approximate reduction of 12%. This would avoid the need for approximately 1700 cattle to be slaughtered. It is considered that, on this basis, you would be

are entitled to conclude that a cull of badgers would prevent what would otherwise be serious damage to livestock.

284. As to criterion (b), sections above set out advice that a cull of badgers is necessary to avoid the serious damage to livestock referred to in the proceeding paragraph. If you decide that culling is necessary to substantially reduce the incidence of TB in cattle, then you will need to have been satisfied that there is no satisfactory alternative solution. In this regard you will need to consider whether vaccination would provide a satisfactory alternative solution, bearing in that there are only modelled figures for the effect of vaccination.

285. As to criterion (c), it is not clear exactly what “population” is referred to in article 9 of the Convention. The phrase “the population concerned” could, for example, refer in the present case to the population of badgers in the United Kingdom as a whole, in Wales as a whole, or in the IAA. However, it is not considered necessary to determine this issue, because even if the phrase refers only to the population of badgers in the IAA, it is considered that you are entitled to conclude that a cull of badgers in the IAA would not be detrimental to the survival of the population concerned. Section 5.2.4 above sets out advice that a cull of badgers is likely to result in the destruction of some 1,607 badgers out of a population of some 2,296 (i.e. approximately 70%). It is estimated that the population of badgers in the IAA will return to pre-cull levels within approximately 5 to 10 years after the end of culling (Welsh Assembly Government 2009). It is not anticipated that a cull would pose any threat to the survival of the population of badgers in the IAA (as opposed to individual members of that population). On this basis, it is considered that you are entitled to be satisfied that a cull of badgers in the IAA will not be detrimental to the survival of the population of badgers in the IAA.

286. If, however, you decided not to implement a cull, but rather to authorise vaccination it is considered likely that a wide ranging trapping exercise, which would be a necessary element of any vaccination programme, would also fall within the scope of article 8 of the Convention, given the inclusion of traps for large scale or non-selective capture in Appendix IV.

287. As to criterion (a), it is considered that such an activity would fall within one of the exceptions in article 9 given it would be for the purpose of preventing serious damage to livestock. You have been advised of the modelling work done by Fera on the effect of vaccination on herd breakdowns and the Science Review concluded that “in the medium to long term, repeated vaccination in an area is likely to reduce the level of bTB infection and disease in the local badger population and thus the risk to local cattle from badger-to-cattle transmission” (Science Review Report, Page 13, Para 9, see Annex 4).

288. As to criterion (b), if you determined that culling was not necessary to substantially reduce incidence of TB, then you would have concluded that vaccination was, at present, the only satisfactory solution.

289. As to criterion (c), vaccination will not be detrimental to the survival of the population of badgers in the area.

9 Discretion

290. As indicated above, section 21 empowers, rather than requires, the Welsh Ministers to make an Order. If you are satisfied that the Threshold test has been met, which would in principle allow you to commence a cull, you will still need to exercise your discretion in determining whether or not the Order is appropriate. This is a matter which Smith LJ considered in paragraphs 86 to 92 of her judgement of the Badger Trust appeal ([2010] EWCA Civ 807). A copy of that judgment is attached at Annex 29. You should therefore have regard to all relevant matters, in exercising your discretion, including the following matters contained within this section.

9.1 Overall Impact of Culling on Incidence of TB

291. The evidence from the RBCT relates to a specific set of methods and circumstances. It is accepted that their wider applicability of that evidence, and hence the reliability of the outcome of a cull in the IAA, weakens to an uncertain degree should any of the specific criteria applied to the RBCT be varied. As previously advised, the IAA has been designed to meet if not exceed the criteria of the RBCT.

292. Quantitative estimates of the expected effect of proactive badger culling on new breakdowns in cattle herds in and around the IAA have been based on extrapolation of the results of the RBCT. The following section provides information on the potential harm that may be caused to cattle herds in the 2km area that surrounds the IAA, in order to enable you to balance any negative effects that may be caused against the benefits that may be expected to accrue within the IAA. The information from the RBCT showed that there was a benefit in reduction of herd breakdowns in the culled areas, but there was an initial detriment in the surrounding 2km area as a consequence of badger perturbation, which was not fully offset by subsequent benefits post culling. For the reasons outlined in paragraphs 228 and 229, two scenarios are presented in section 5.2.5 i.e. the effect of culling on all herd breakdowns (with no effect on unconfirmed herd breakdowns) and separately the effect on all herd breakdowns (with an effect on both confirmed and unconfirmed herd breakdowns). These scenarios are now considered for the IAA and surrounding 2km area.

9.2 All Herd Breakdowns (with an effect only on confirmed herd breakdowns)

293. Analysis of the overall estimated effect of culling of badgers in and around the IAA on all herd breakdowns, assuming that culling has no discernable impact on unconfirmed herd breakdowns is closest to the analysis and results from the RBCT.

294. On this basis, applying results from the RBCT would mean that the estimated overall benefits of culling in the IAA and 2km areas would be 93.4 herd breakdowns (41.0 during the cull period and 52.4 in the post cull period) producing an estimated 11.9% reduction in herd breakdowns over 10 years as a consequence of culling badgers, when compared to what would have been seen in the absence of culling.

9.3 All Herd Breakdowns (with an effect on confirmed and unconfirmed herd breakdowns)

295. Assuming a similar effect of culling badgers on unconfirmed and confirmed herd breakdowns within the IAA and the 2km area combined, proactive culling of badger is estimated to prevent approximately 175.3 herd breakdowns (74.0 during the cull period and 101.3 in the post cull period). This would be an estimated 22.4% reduction in herd breakdowns as a consequence of culling badgers, when compared to what would have been seen in the absence of culling.

296. Veterinary opinion of the RBCT data is that there remains some uncertainty in the likely effect of proactive culling on unconfirmed herd breakdowns. Taking into account the disease situation in endemic areas (i.e. that the majority of unconfirmed breakdown herds are likely to be genuinely infected with M. bovis), it is concluded that proactive badger culling in endemic areas should also reduce the number of unconfirmed herd breakdowns. For these reasons, insofar as the results of the RBCT can be extrapolated to the IAA and the 2km area, the expectation is that the outcome of culling badgers in those areas will be at least 11.9%.

297. Veterinary opinion is that 11.9% is an under estimate of the effect likely to be seen in the IAA and that the effect is expected to be towards the higher end of the range i.e. 22.4%.

298. In addition to this we would expect that the comprehensive approach described (which includes, additional cattle controls, enhanced biosecurity and potential benefits of the natural boundaries to the IAA such as the river Teifi, and Preseli Hills to reduce perturbation), combined with culling would deliver greater benefit than those estimated above.

9.4 Increase in the 2km area

299. “It is suggested that perturbation [in the RBCT areas] led to increased contact and transmission amongst badgers and between badgers and cattle. This detrimental effect diminished over time. Some 12-18 months after badger culling stopped, the number of confirmed bovine TB cattle herd breakdown in these edge areas was similar to that seen in the survey only areas, and has remained so since” (Science Review Report, Page 11, Para 4, see Annex 4).

300. As described above, when considering the impact of culling on herd breakdowns, you should be aware that there could be an estimated 2.2 to 8.7 additional herd breakdowns in the 2km area during the period of badger culling. These estimated consequences of culling are not fully offset by the anticipated benefits in the post culling period.

9.5 Ring vaccination

301. As described in paragraph 105 the combination of culling badgers in an area combined with vaccination in a 2km surrounding area could help mitigate the potential negative consequences of culling as discussed above.

302. It is advised that, for the application of the Animal Health Act 1981, you consider the necessity and benefits associated with culling and vaccination separately. Should you be satisfied that one or more of these tests then you are able to consider the possibility of combining the approach.

303. "The effect of the vaccination of badgers against bovine TB in a ring around culling areas is difficult to assess. Modelling studies suggest that ring vaccination around a culled area would be more successful than culling or vaccination alone in reducing the number of bovine TB cattle herd breakdowns. Vaccination would provide protection to uninfected badgers in the ring area which may be at risk from badgers ranging more widely due to the perturbation effect. Evidence on the onset of immunity in vaccinated badgers is limited; it seems logical, however, that vaccination would need to be carried out some weeks before adjacent culling in order to give time for immunity to develop" (Science Review Report, Page 13, Para 11, see Annex 4).

304. The report "comparing badger control strategies for reducing bovine TB in cattle in England" provides the only known comparison of control strategies, using parameters that are different from the IAA, however it does provide a useful mechanism for comparison; over 10 years (5 years of control and 5 years after)

- o Ring vaccination together with culling would reduce cattle herd breakdowns by 28% across the core plus ring area;
- o Culling would reduce cattle herd breakdowns by 17% across the core plus ring area; and
- o Vaccination would reduce cattle herd breakdowns by 11% across the core plus ring area (Fera 2010, Table 3 page 21).

You may consider that cost of ring vaccination when combined with the cost of culling would be disproportionate to the potential benefit which would be accrued by ring vaccination. Information on estimated costs are set out in paragraph 313.

9.6 Effect of Vaccination

305. You have been presented with modelled figures of the potential effect of vaccination of confirmed herd breakdowns as modelled by Fera, together with advice on the nature of modelled figures. If you consider that at present the figures provided on effects of vaccination are not sufficiently robust, as part of the exercise of your discretion you may decide to authorise vaccination and review the potential impact of vaccination in due course, and at that time consider what further or new options should be implemented to tackle bTB within the IAA."

9.7 Financial Impacts

306. The average cost per confirmed herd breakdown in the IAA has been calculated (based on the assessment at figure 9) as £53,759. This is higher than other reported costs, e.g. Defra estimate £30,000 (Defra 2010(b)), as it is a reflection of the cattle industry and disease situation specific to the IAA. For example the average valuation for cattle slaughtered in the IAA in 2010 is £2,124 compared to the Wales average of £1,682. The average cost per unconfirmed herd breakdown in the IAA has been calculated (based on the assessment at figure 10) as £12,728.

307. This average cost is an estimate based on a number of assumptions which will change over time and, as an average, is not representative of all farms. Although this financial analysis includes general assumptions on the main direct costs of bovine TB, such as the slaughter of individual animals, cost of testing etc it fails to represent a true figure with other known, but as yet un-quantified costs, for example loss of genetic merit.

Figure 9: WG estimated cost analysis of confirmed herd breakdown in the IAA (Source: SF/EJ/0033/11, March 2011)

Activity	**Assumption**	**Unit cost (£) to**		**Total cost (£) to**		**Total**
		Farmer	**Gov't**	**Farmer**	**Gov't**	
Slaughter	17.8 animals	320	2124	£5,696	£37,807	£43,503
Restrictions	149 animals in herd for 415 days	0.02	0	£1,237	£0	£1,237
Isolation	17.8 animals for 16 days	2	0	£570	£0	£570
Testing	149 animals in herd with 5.3 herd tests	3.2	7.5	£2,527	£5,923	£8,450
Total cost within herd				**£10,029**	**£43,730**	**£53,759**

Figure 10: WG estimated cost analysis of unconfirmed herd breakdown in the IAA (Source: SF/EJ/0033/11, March 2011)

Activity	**Assumption**	**Unit cost (£) to**		**Total cost (£) to**		**Total**
		Farmer	Gov't	Farmer	Gov't	
Slaughters	2.3 animals	320	2124	£736	£4,885	£5,621
Restrictions	149 in herd for220 days	0.02	0	£656	£0	£656
Isolation	2.3 animals16 days	2	0	£74	£0	£74
Testing	149 in herd for 4 herd tests	3.2	7.5	£1,907	£4,470	£6,377
Total cost within herd				**£3,372**	**£9,355**	**£12,728**

308. The estimated cost of culling badgers is £4,220 per km² per year, assuming that the cull will only be carried out over 80% of the area (the remaining 20% is estimated to be land not colonised by badgers or where culling is unlikely to be undertaken for example along public rights of way), the cost of delivering a cull of badgers for five years in the IAA (an area of 288km²) is estimated to be £4,990,000.

309. The cost of vaccinating badgers over an area of 150km² for five years was estimated by Defra, in its 2010 consultation 'Bovine Tuberculosis: the Government's approach to tackling the disease and consultation on a badger control policy' (see the Impact Assessment at Annex 25), as being £1.59 million (Defra 2010(b)). However, recent estimates for the Defra-managed Badger Vaccination Development Project (BVDP) put costs in the region of £0.6 million a year per 150km² (therefore in the region of £3 million for five years) where there is a high density badger population (Fera, personal communication).Using Fera's estimation for vaccination we can extrapolate that vaccinating in the IAA over five years would cost approximately £5,760,000. This figure needs to be treated with caution and the true cost may be different.

310. For the reasons explained in section 5.2.5, insofar as the results of the RBCT can be extrapolated to the IAA, the expectation is that culling badgers in the IAA will prevent at least 93.4 herd breakdowns (figure 11). This would provide a saving of at least £5,021,090, which would increase to £6,063,513 if 175.3 herd breakdowns are prevented.

Figure 11: Source: Welsh Government

Estimated benefit (herd breakdowns prevented)	Savings in Confirmed herd breakdowns prevented	Savings from Unconfirmed herd breakdowns prevented	**Total**
93.4	93.4 x £53,759	0 x £12,728	**£5,021,090**
175.3	93.4 x £53,759	81.9 x £12,728	**£6,063,513**

311. It is recognised that both the costs and benefits of culling alone have been based on a number of assumptions that could vary over time. Accepting this variability, the culling of badgers alone as undertaken in the RBCT is expected to represent a cost saving, 10 years from the start of culling, or earlier if the outcomes from culling in the Republic of Ireland or other trials are achieved.

312. Assessing the benefits of vaccination is more problematic due to the confidence in achieving a reduction in the number of cattle herd breakdowns. The Defra Impact Assessment of 2010 suggested that vaccinating badgers over an area of 150km² for five years would produce a benefit of £1.20 million. The likely benefit associated with vaccinating badgers in the IAA is anticipated to be higher than this due to the increased breakdown costs in the IAA, compared to Defra's Impact Assessment.

313. We can estimate the cost of culling with ring vaccination in a 2km buffer, over five years, using the above figures. The 2km buffer of the IAA has been

calculated as having an area of 128.9km². Using Fera's estimation for vaccination of £3million for 150km² (Fera, personal communication), we can extrapolate that vaccinating in the buffer zone would cost approximately £2,578,000. When added to the estimated cost of culling in the IAA (£4,990,000), the estimated cost of culling with ring vaccination in a 2km buffer, over five years, is £7,568,000.

314. It is possible that there will be other consequential costs to a culling policy such as policing, but these are likely to be proportionate to other factors that cannot yet be accounted for. We do however recognise the risk that the eventual cost of a cull of badgers in the area may be higher than that predicted here, and the benefits might be lower.

315. In addition to the economic benefits outlined above there will also be an impact in the un-quantified socio-economic effects of bovine TB and the policy to deal with the reservoir of infection in badger which is discussed below.

9.8 Public attitudes to culling and vaccination

9.8.1 Consultation on Badger Control in the Intensive Action Area

316. The following section provides a summary of the consultation on the draft Badger (Control Area) (Wales) Order 2011 (Annex 11), which ran from September to December 2010. Its consideration is not a statutory obligation for this decision, but has been provided to help inform this process.

317. The consultation attracted considerable interest with 13,431 responses being received, from organisations, businesses, groups and individuals. A document summarising the responses to the consultation, that provides a representative summary of the responses but not an exhaustive record of all the issues raised, can be seen at Annex 11. Please note that the annexes of the summary document are not included with this submission but are available on the Welsh Government website at: http://wales.gov.uk/consultations/environmentandcountryside/consbadgercontrol/?lang=en&status=closed

318. The majority of responses received were from individuals and many of these were in the form of pre-populated pro forma. Not all respondents answered every question.

319. Of the 13,431 responses received, 9762 respondents objected to the culling of wildlife for the purposes of controlling disease in farm animals. 2328 respondents said that they did not object to the culling of wildlife for the purposes of controlling disease in farm animals and 1341 respondents did not answer this question.

320. Three Petitions were also received (with a combined total of 3045 signatures) in which the signatories expressed their opposition to badger culling, with one also asking for improved farm biosecurity in conjunction with the vaccination of badgers.

321. You may wish to note that in view of the fact that a license for an injectable vaccine for badgers is available, 5016 respondents believed that vaccination of badgers in TB endemic areas was a viable alternative to culling to prevent disease transmission. 2111 respondents did not believe that vaccination was a viable alternative. In addition 1144 identical Viva! postcards were received, and while not directly answering the question, the respondents objected to culling and stated that, amongst other things *'…..vaccinating badgers would help control this disease further'.* 187 respondents did not answer this question.

9.8.2 Research on Public Attitudes

322. Responses to public consultations on issues relating to a badger cull suggest that the general public are largely against a badger cull. Estimate of public attitudes can also be obtained from survey research that asks a random or representative sample of the public questions about a badger cull. Unfortunately, despite perceived high levels of public concern, there have been relatively few attempts to do this. However, in 2011 three different surveys were conducted. The results of these are presented below.

323. **BBC News Survey, June 2011:** In June 2011, the BBC commissioned GfK NOP to conduct a survey of public opinion on a badger cull. The telephone survey of 999 people simply asked respondents to state their support for or against a badger cull by answering yes or no (http://www.bbc.co.uk/news/science-environment-13684482). In total, 63% of respondents said that badgers should not be killed for cattle TB, with 31% in favour of culling and the remainder undecided.

324. **League Against Cruel Sports, May 2011:** In May 2011, the League Against Cruel Sports (LACS) commissioned YouGov to conduct an opinion survey of public attitudes towards a badger cull. The survey interviewed 2064 adults across Great Britain (http://www.league.org.uk/news/983/Minister-hints-at-u-turn-on-badger-cull-as-polling-shows-public-opposition). The survey asked two questions: whether badgers should be culled or vaccinated; and who should pay for the control of bovine TB. Results indicated that only 16% of respondents supported a badger cull, whilst 67% said badgers should be vaccinated. Results were disaggregated to regions, but responses from Wales are included with those from the Midlands. For these respondents, 18% supported a badger cull, and 63% vaccination.

325. **NFU Survey, May 2011:** In May 2011, the NFU commissioned the independent marketing agency, England Marketing, to carry out an online survey of attitudes towards badger culling. The survey asked 1,032 people a range of questions about farming and the environment, and attempted to get a picture of the level of knowledge each respondent had about bovine TB (http://www.nfuonline.com/News/Majority-of-people-back-badger-cull---survey/).

326. 49% of those surveyed agreed that TB can be spread to cattle by badgers. The NFU's analyse suggests that of those 49%, 62% support a legal cull of badgers in order to control bovine TB. When you include all respondents, the level of support for a badger cull drops to 52%.

9.8.3 Defra citizen workshop

327. In 2006, as part of its badger cull consultation, Defra undertook a series of workshops which introduced scientists, vets, government officials, conservationists and farmers to participants. Participants were presented with a range of materials and were allowed to question expert witnesses. As a result of the workshops, public rejection of badger culling appeared to have softened. At the beginning of the workshops, participants largely reacted against a cull. At the end of the process, however, when participants were pushed to come to a decision on badger culling, there was marginal support for a cull. However, this acceptance was “reluctant” and “heavily caveated”. Moreover, supporters of a cull see it as a temporary measure until such time as a vaccine is available for use.

9.8.4 Attitudes to Badger Vaccination

328. Recent Defra funded research has analysed farmers’ confidence in badger vaccination. This research project is ongoing and will also examine farmers’ confidence in cattle vaccination and participation in badger culling. The research involves surveys and in-depth interviews with farmers. The research is based in England (Enticott personal communication).

329. According to their responses, farmers were classified according to their overall confidence in badger vaccination and trust in Government. Despite generally low overall levels of confidence and trust, 33% of farmers fell into the acceptance category, whilst 19% rejected vaccination outright (Enticott *et al*. 2012).

9.8.5 Community concerns

330. The weight and content of the responses to the consultation on badger control in the IAA (Annex 11) clearly demonstrate the substantial range of views associated with this emotive issue. Several of the respondents highlighted the goodwill and mutual support that exists in rural areas like the IAA. They expressed concern that culling of badgers would threaten the general sense of shared interests and cohesion that existed in these areas (Annex 11 para 15.13). It is possible that this could occur on an individual basis and should a sustained campaign be made, in favour or against culling badgers, could expand further to affect relationships in the community.

331. Some respondents to the consultation believed that access to land for culling badgers in the IAA should be enforced (Annex 11 para 12.2) whilst others suggested that further thought is given to the need to enter all land irrespective of the risks involved (Annex 11 para 12.3). Enforced access onto land to achieve a successful cull would be expected to lead to a negative community and media response. The participation of land owners in the vaccination of badgers is anticipated to be voluntary.

9.8.6 Tourism

332. Responses to the consultation on badger control in the IAA (Annex 11) from the tourism industry highlighted that they are currently witnessing a growth in conservation and green tourism, either as the main reason for visiting or as part of the reason to visit Wales and other destinations. Their responses asked that the Welsh Government ensures that it "allows for mitigation measures" for any negative fallout for the tourism industry that may occur as the result of any possible cull.

333. The Standard Operating Procedures (SOPs) for culling or vaccination of badgers would ensure that the opportunity for visitors and locals to witness such activities, without prior information, would be very limited.

334. Vaccination of badgers is unlikely to attract a negative campaign response from the public and as a consequence such a policy would not be expected to have a negative impact on tourism.

335. We are not aware of any specific evidence that assesses the impact of a badger culling operation on tourism or the local community from the RBCT or other badger culling operations such as in the Republic of Ireland. Given to the consultation responses prior to the 2011 Order, the likelihood is that any decision to cull badgers would receive public opposition (Annex 11 para 13.3). The extent of this opposition is difficult to predict. It is even less clear how far this would lead to action by animal rights activists and others that are opposed to culling in attempts to disrupt any culling operation either by legal or non legal methods. The RBCT did face some disruption by activists, but the ISG argued that this was not significant enough to impact on the efficiency of their culling operations.

336. Protests could lead to additional burden on police resources during any culling activity; however if there was an attempt to disrupt legitimate culling activity this would need to be balanced against the Welsh Government’s stance on domestic extremism. The involvement of the police to enforce legitimate culling activity would lead to an increased profile in the news media, which would continue to publicise the culling operation and possibly extend it to a wider audience.

337. In coming to a view, it is appropriate that you are also aware of the wider implications of bovine Tb and associated policy. A summary of which is laid out below.

9.8.7 The Socio-Economic Impact of bovine TB

338. Much of the analysis of the impact of bovine TB has concentrated on immediate short-term costs that are readily quantifiable and have in the main been accounted for above. Fewer studies have focussed on the longer term impacts largely because they are often very difficult to measure and stretch beyond the period of a TB breakdown.

339. In agreeing that the IAA has a high incidence of bovine TB which needs to be dealt with, some respondents to the consultation on badger control in the IAA

highlighted the stresses that cattle keepers in TB endemic areas have to deal with (Annex 11 para 11.2).

340. Various studies by social scientists of the long term and intangible effects of TB have been completed and these are summarised below.

9.8.8 Farmers Perceptions of TB in the IAA

341. As part of the biosecurity assessment visits in the IAA, farmers have been asked a range of questions about their confidence in farming and attitudes towards TB, Farmers were asked to rate their confidence/risk/worry on a scale from 1 to 10, where 1 is not confident and 10 is extremely confident.

342. Comparing the IAA and buffer area farmers, famers of unrestricted farms in the IAA rated the risk of their herd going down with TB in the next 12 months significantly higher than farmers in the buffer area. For the other questions there was no significant difference between the farmers in the IAA and the buffer area.

343. Farmers of farms under restriction were less confident of the future of farming in their area, less confident there was much they could do to prevent a farm going down with TB and rated their risk of their herd going down with TB higher than farms not under restrictions. Comparing responses in Year 1 and Year 2 the only statistically significant difference was that farmers felt less confident about the future of farming in their area.

9.8.9 Farmer Well-being

344. Evidence from the IAA suggests that farmers have low confidence either in terms of their ability to do anything about avoiding TB or their prospects of avoiding restrictions in future (Welsh Assembly Government (2010(a)), Annual Report 2009-10, Annex 27).

345. Evidence from a survey by the Farm Crisis Network (2009) suggests that 20% of farmers were either panicked or devastated by the news of their latest outbreak and a further 50% were upset or worried by the news. Farmers' reported how the emotional impact of a TB outbreak was spread throughout the farming family resulting in strained relationships (Farm Crisis Network (2009)).

346. Research by Defra suggests that dairy and beef suckler farmers affected by TB can suffer high levels of stress, as high as experienced during the 2001 Foot and Mouth Disease outbreak (Defra (2010)(a) Final Research Report SE3120).

9.8.10 Long-term Economic Costs

347. Recent research of the long-term impact of bovine TB suggests that on TB affected dairy farms, milk production is lower; farmers and their spouses work longer hours; and cash income and farm family income is lower. Beef suckler herds show similar trends: on TB affected farms, output is lower, income is lower, and longer hours are worked. Overall, the data suggest that farms with a

TB breakdown perform less well than those without (Defra (2010)(a) Final Research Report SE3120).

9.8.11 Other industry impacts including genetics

348. In addition to the obvious loss of an animal to a breeding herd, and records will show that many of the UK's finest breeding stock have been lost through TB, there are 'knock-on' effects as well. For example:

349. Genetic improvement is a long term process and the premature slaughter of calves and cattle can have a significant impact on this (sometimes with the complete loss of the genetic group) and devalue the pedigree considerably as the lineage is broken.

350. Consequential losses such as the loss of milk from diary cows and the commercial value of the herd are not accounted for in the valuation of a TB reactor in Wales.

351. In 2010 the Carmarthen Regional Board commissioned a paper on the "Social and Economic Impacts of bovine TB in West Wales" (Annex 26). The report analysed the social and economic costs of TB drawn from 13 interviews with farmers in West Wales with additional data drawn from an Animal Health database of TB incidents in Wales. The report identified that much of the stress experienced by farmers stems from the loss of control over how to farm (in part by the additional legislative restrictions that apply to herds under TB restriction) rather than their ability to complete aspects of their job. Initial results suggest that this could potentially cost farmers about £2000 a year.

352. You should take into account both economic and socio-economic effects as well as the detrimental effects on the badger species, and come to a view whether the overall benefits out weigh the disbenefits.

10 Exit strategy

353. Within the IAA the intention would be to protect the anticipated benefits achieved from vaccinating or culling badgers, which may include:

- Maintain stricter cattle movement controls
- Continue with specific biosecurity advice
- Specific cattle surveillance policies such as those used in Scotland to protect their TB free status.
- The potential use of a cattle vaccine for bovine TB
- The potential use of an oral badger vaccine
- The potential use of immunocontraception.

354. As discussed in other sections of this submission and summarised above, there are a number of potentially significant technical and policy developments that could be introduced in the IAA within 5 years. The design and implementation of a strategy to maintain the benefits will need to ensure that these are considered and introduced in a complimentary and cost effective manner. For

example the use of a cattle vaccine for bovine TB, would need to be reflected in the cattle surveillance and controls for the area.

355. The design and interaction of these potential policies for the IAA will continue to be considered along side their development for Wales.

11 Financial and Governance Implications

356. Funding for each of the badger control strategies set out in this submission exist within baselines and can be implemented within current Environment and Sustainable Development MEG baselines, specifically the bovine TB Eradication BEL. If these budgets vary in future years the progress on implementing the strategy will be accelerated or slowed down to stay within the allocated budget. There are no new financial implications to this paper. The Sustainable Futures Operation Team has had sight of this submission and is content (DESD/408/12).

357. This submission raises matters that are novel and contentious, although they are issues have been previously discussed in a public context. CGU reference number: RM/02/12/04

358. Statistical Directorate have had sight of this submission and are content.

12 Press and Publicity Arrangements

359. A communication plan will be draft to support your announcement of any decision as considerable media interest would be expected. This will be provided separately.

13 Policy Compliance

360. Officials have read the Statement on Statutory Duties and considered them in relation to the development of this policy. In addition, the Policy Appraisal Checklist has been completed and this has indicated that no statutory assessments are required for this policy.

STATEMENT OF INFORMATION

The intention is for this submission and all supporting annexes to be published.

The statement of information should include all sections and annexes of this submission except for sections which constitute legal advice.

Annexes

Ref.	**Document title**
Annex 1	Terminology
Annex 2	Pilot Area – Cattle Controls Guidance
Annex 3	Principles of Infectious Disease Control (with particular reference to bovine TB)
Annex 4	Report of the Bovine TB Science Review Group
Annex 5	Report of the Bovine TB Science Review Group - Annexes
Annex 6	Map of the Intensive Action Area
Annex 7	The Badger (Control Area) (Wales) Order 2011
Annex 8	Is there an association between levels of bovine tuberculosis in cattle herds and badgers? (Donnelly and Hone, 2010)
Annex 9	Differences between bovine TB indicators in herds in the IAA and herds in the Comparison Area (Project OG0142): First year, 1st June 2010 to 30th April 2011
Annex 10	Individual-based special stochastic badger/cattle/TB model - Badger (*Meles Meles*) culling to reduce cattle-herd TB breakdowns in Wales (UK) – Spatial Model to compare strategies (unpublished) (Central Science Laboratory, 2009)
Annex 11	Summary of the Responses to the Consultation on Badger Control in the Intensive Action Area Please note that the annexes of the summary document are not included with this submission but are available on the Welsh Government website at: http://wales.gov.uk/consultations/environmentandcountryside/consbadgercontrol/?lang=en&status=closed
Annex 12	The Duration of the Effects of Repeated Widespread Badger Culling on Cattle Tuberculosis Following the Cessation of Culling (Jenkins *et al*, February 2010) 12a: EWRPAG Review of Jenkins *et al.* (2010) The duration of the effects of repeated widespread badger culling on cattle tuberculosis following the cessation of culling (2010) 12b: Analysis of further data on the impacts on cattle TB incidence of repeated badger culling (Donnelly, May 2010) 12c: Analysis of further data (to 2 July 2010) on the impacts on cattle TB incidence of repeated badger culling (Donnelly, July 2010) 12d: Analysis of further data (to 25 February 2011) on the impacts on cattle TB incidence of repeated badger culling (Donnelly, February 2011) 12e: Analysis of further data (to 28 August 2011) on the impacts on cattle TB incidence of repeated badger culling (Donnelly, August 2011) 12f: Donnelly (Personal communications January 2012)

Annex 13 Intensive Action Area - Estimated impact of proactive culling

Annex 14 Veterinary Laboratories Agency - Field Trial to Assess the Safety of Bacille Calmette Guerin (BCG) Vaccine Administered Parenterally to Badgers. Study Protocol Number: VLAS/05/036

Annex 15 Bacillus Calmette-Guérin vaccination reduces the severity and progression of tuberculosis in badgers (Chambers, *et al*. 2010)

Annex 16 IAA epidemiological information

Annex 17 Spatial strategies of badger vaccination - Badger (*Meles meles*) vaccination to reduce cattle - herd TB breakdowns in Britain – Model to compare spatial strategies (unpublished) (Central Science Laboratory, 2009)

Annex 18 Comparing badger (*Meles meles*) control strategies for reducing bovine bTB in cattle in England (Food and Environment Research Agency, 2010)

Annex 19 Briefing Paper on Fera Modelling

Annex 20 Combined strategy modelling exercises - Trap-Test-Cull-Vaccinate Supplemental Report (unpublished) (Central Science Laboratory, 2009)

Annex 21 An assessment of relative landscape isolation for badgers (*Meles meles*) within Wales (Central Science Laboratory, 2009)

Annex 22 Survey of *Mycobacterium bovis* infection in badgers found dead in Wales (Veterinary Laboratories Agency, 2007)

Annex 23 Ecological Impact Assessment (EcIA)

Annex 24 Habitats Directive Assessment: Screening Report

Annex 25 Consultation: Bovine Tuberculosis: The Government's approach to tackling the disease and consultation on a badger control policy. Measures to Address Bovine TB in Badgers – Impact Assessment (Defra 2010)

Annex 26 Social and Economic Impacts of Bovine TB in West Wales

Annex 27 TB Eradication Programme – Annual Report 2009-10

Annex 28 Analysis of the Year 2 Biosecurity Assessments in the Intensive Action Area and Surrounding 2km (Welsh Government, February 2012)

Annex 29 Badger Trust and the Welsh Ministers [2010] EWCA Civ 807

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Central Science Laboratory (2009)(c). Individual-based special stochastic badger/cattle/TB model - Badger (*Meles meles*) culling to reduce cattle-herd TB breakdowns in Wales (UK) – Spatial Model to compare strategies (unpublished)

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