OFFICIAL SENSITIVE

Advice to Natural England's Operations Team on Supplementary Badger Culling 2024

Introduction

1. The ultimate aim of England's Bovine Tuberculosis (bTB) control policy is to eradicate this disease from England by 2038, including through tackling the persistent reservoirs of disease in both cattle and wildlife (focussing on badgers, the perceived principal wildlife host). In order to address disease in badgers, there is a need is to reduce prevalence of bTB in some badger populations so that the infection risk that they pose to cattle is lowered, and so that the disease is no longer self-sustaining in the badger populations (in epidemiological terms, this means reducing the basic reproduction rate, R_0, below 1).

2. To tackle the disease in badgers, Government policy has been to carry out an intensive cull (IC), broadly modelled on the evidence derived from the Randomised Badger Control Trial (RBCT). A supplementary badger cull (SBC) has been implemented subsequently to maintain the lowered badger population (and any associated disease risk) achieved through IC.

3. I have been asked to give my scientific opinion to inform Natural England's decision on whether to issue the 2024 authorisations for continued SBC in 17 areas and for the initiation of SBC in 9 areas.

Evidence review

4. When I provided my advice to Natural England's Operations Team in August last year I noted:

   "The evidence regarding the control of bTB is evolving, and I will continue to review any further changes to the evidence base ahead of next year's operations. However, with regards to preparation for future years, Natural England's Operations team should be aware of the following opinion which is based on the evidence currently available: given that vaccination is now being deployed, and there is strong evidence of likely sustained disease risk benefits following the cessation of culling, there is a weaker evidential basis for issuing licenses beyond the 3rd year, including for Supplementary Badger Control, from the perspective of disease risk alone."

   In the subsequent months, I have continued to assess changes in the evidence base and have also commissioned Natural England's specialist evidence review team to critically appraise the body of evidence most relevant to the SBC licensing decision. This review benefitted from input by Defra and APHA who advised on relevant sources of evidence and commented on drafts. Specifically, we have reviewed evidence regarding the persistence of disease reduction benefits in cattle after the cessation of badger culling operations and the impact of different interventions post intensive culls. This evidence is summarised in Annex 1. The citations in the body of this document refer to the references listed in Annex 2.

5. In terms of the decision to authorise SBC, I consider the key insights arising from this critical appraisal to be:
   - Disease reduction benefits to cattle achieved through badger culling are sustained in the long term (likely at least 7 years post-cull). The most relevant evidence to the current English situation is from Donnelly (2013) who found from the Randomised Badger Control Trial (RBCT) that the disease reduction benefits from four years of intensive culling of badgers are greatest 1-2 years post-cull and are sustained for at least 7 years, albeit at a diminishing level over this period. Although potentially less relevant to the current English

context, long-term disease reduction benefits of badger removals were also found in Ireland (Byrne *et al.* 2014) and in Southwest England (Clifton-Hadley 1995). Statistical modelling also supports the conclusion of long-term disease reduction benefits under low perturbation scenarios (i.e. where the impact of interventions does not lead to increased badger movements or other changes to their activity, which could result in an increased per-capita contribution to disease risk).

- There is no evidence of any additional disease reduction benefits of SBC over and above that achieved through the intensive cull (this is consistent with the aims of the SBC policy, which was to maintain any disease reduction benefits of the intensive cull, not to achieve additional disease reduction).
- Badger vaccination can be successfully deployed, including in post-cull situations (e.g. APHA 2016a).
- Although field trials are still at an early stage in England, there is empirical evidence that badger vaccination reduces the prevalence of *Mycobacterium bovis* (the causative agent of bTB) in badgers and can be effective in reducing disease risk to cattle (e.g. in Ireland; Martin *et al.* 2020).
- Cattle-based measures (including enhanced testing regimes, more sensitive tests, movement controls and cattle vaccination) may all play an important part in reducing bTB incidence in cattle (e.g. Godfray *et al.* 2018).

Additional considerations

6. Compared to the experimental areas in the RBCT, the intervention areas for the recent culls are significantly larger. They are also mostly contiguous, in contrast to the RBCT areas. In addition, the post-RBCT areas often have boundaries such as major roads and rivers that act as significant barriers to badger movements. Potential immigration and perturbation effects are therefore likely to be less significant in the recent badger cull areas than in the RBCT. Consequently, the duration of disease-reduction benefits observed by Donnelly (2013) may underestimate the duration of those achieved in the recent culls.

7. Since SBC only maintains the disease risk reduction benefits achieved through the IC, the number of years that it is carried out for (or whether SBC occurs at all) does not affect the disease risk benefits to cattle. Rather, the important consideration is the availability of an effective alternative to ongoing culling within the period of lowered disease risk post-cull.

8. In his witness statement to the High Court (case CO/4848/2017) dated 18 May 2018, Prof. Ian Boyd, then Defra Chief Scientific Advisor (CSA), set out the rationale for using SBC to avoid the disease reduction benefits achieved through the intensive cull being eroded over time. He explained the limitations of badger vaccination as follows:

   "My view on the practicality of vaccination following culling was that the remaining badger population would likely to be harder to catch if it has evaded four years of cage trapping, and so injectable vaccines were unlikely to be effective. I also did not think we could rely on the production of an effective oral badger vaccine in the timescale required."

9. These concerns expressed by Prof. Boyd about the difficulty of deploying injectable vaccines have not been realised; several examples of successful deployment now exist (e.g. APHA-led vaccination in the Low Risk Area and in post-intensive cull situations). At the time, Prof. Boyd also stressed the limits in the evidence base and the importance of adjusting the policy as new evidence becomes available.

10. In the past few years, the policy has shifted from five years of SBC post-intensive cull, to two years of SBC. Current policy is also to end badger culling after 2025. This has created

considerable heterogeneity in implementation and practice. In terms of areas that have previously completed their intensive cull (IC) operations:

- The two original areas (Areas 1 and 2), which undertook four years of intensive cull followed by five years of SBC, have now been without badger culling for two years (2024 will be the third without any culling), and APHA-led badger vaccination is underway in parts of those cull areas.
- Area 3, which undertook four years of IC followed by five years of SBC until 2023, will have no culling underway in 2024.
- Eleven areas (Areas 11-21), which carried out four years of IC and then two years of SBC, have had no culling since 2022, although there is vaccination underway in parts of two of these areas.
- Ten areas (Areas 22-31) stopped culling last year (2023) after two years of SBC and will have no culling this year; in one of these areas, vaccination has been underway since 2022.

11. Based on the best available evidence, all of these areas would be expected to currently be benefiting from the prolonged disease reduction period achieved through badger culling and other bTB control measures, and so there is no reason to anticipate that these different post-intensive cull treatments will have led to different outcomes for bTB in cattle, or will do so in the next few years. In the context of the current SBC licensing decisions, this same rationale also means that continuing SBC for a fifth year, or starting SBC, will not provide additional disease reduction benefits to cattle compared to those already achieved (noting that the benefits are likely to be sustained for several years).

12. Defra are currently consulting on a new targeted badger intervention policy, which has been designed with expert veterinary advice. This proposes time-limited badger culling followed by vaccination in response to those localised bTB breakdowns where badgers are assessed to be part of the problem. The new policy options, potentially amended through the consultation process, are likely to be available within 2 years, possibly by 2025 or sooner. This indicates that practical alternatives to SBC have already been developed and are likely to be available in the near future, well within the period of sustained disease reduction post-cull.

Conclusion

13. In previous years, my view has been that there has not been an effective alternative to SBC to maintain the disease risk reduction to cattle achieved through the IC period. Over the past few years, the balance of evidence has shifted. In my opinion it is now clear that badger vaccination can provide an effective alternative to SBC, and recent evidence demonstrates that vaccination can be deployed before any recovery in the badger population poses an increased disease risk to cattle. Alternatives to a vaccination-only approach are also available and could potentially be deployed rapidly, such as that proposed through a targeted badger control policy currently being consulted upon by Defra.

14. I recognise that this advice may disappoint some people. However, in my opinion, the evidence is clear that the steps that farmers and others have already taken, alongside continued on-farm biosecurity, management practices and other cattle measures, are likely to provide a long-lasting disease reduction benefit that will persist until other options for disease control can be implemented. Consequently, these farmers can avoid the considerable expense and inconvenience of undertaking the SBC without increasing the risk of their cattle suffering from bTB. This is good news for farmers, and I hope it can be clearly communicated as such.

15. As I have said in previous advice, much greater effort is needed to raise awareness of the disease reduction benefits of the alternatives to culling among the farmer community, in my opinion. In this regard, it is disappointing that the recent publication by Birch *et al.* 2024 has been widely reported as providing evidence that badger culling reduces the incidence of bTB by 56%, when in fact the study shows the overall impact of implementing a range of bTB control measures, not culling alone. Further research to establish the relative disease reduction contributions of the different control measures is needed.

16. Based on the evidence, I can find no justification for authorising further supplementary badger culls in 2024 for the purpose of preventing the spread of disease and recommend against doing so.

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April 2024

ANNEX 1

A critical appraisal of evidence regarding the impact of potential post-badger cull responses – Summary

Overview

This paper summarises available evidence of potential post badger-cull interventions on the impact of bTB incidence, following infection with the causative agent *Mycobacterium bovis,* in cattle in England. It represents a shared view of the relevant evidence by Defra and Natural England with respect to two questions:

1. How long are the effects of disease reduction in cattle sustained after the cessation of badger culling activities in the absence of additional interventions identified in Question 2?

2. What is the effect on disease risk (defined as quantitative measures such as incidence of bTB in cattle) in the years post-cull under (a) badger vaccination; (b) targeted badger culling; (c) cattle control measures only; and (d) supplementary badger culling (SBC), either on their own or in combination?

Evidence sources potentially of relevance were identified following discussions with colleagues in Natural England (NE), Defra and APHA with further sources selected for evaluation by NE during the review process (see Annex 2 for reference list). A critical appraisal of these evidence sources by members of NE's expert Evidence Review Team assessed both the strength of evidence and the significance of reported results with regards to the questions of interest. Some reports were reviewed for background information but not included in the appraisal process, if they did not include new evidence relevant to the review questions.

In terms of strength of evidence, the critical appraisal provides a ranking of 1-4, where 1 = very strong evidence (e.g. systematic reviews) and 4 = weak evidence (e.g. studies without underlying data). Where insufficient information was included in the evidence source to conduct a critical appraisal, as may be the case in 'grey' literature, this is indicated 'N/A'. Critical appraisal scores for specific evidence sources below are indicated as "(CA = x)"

Summary of findings

1. Duration of disease reduction effects

Five studies appraised by this review investigated the effects of disease reduction in cattle in the period after the cessation of badger culling. Three of these studies are based on analysis of cattle bTB incidence data following badger culling operations, while two studies involve the use of simulation models.

The strongest empirical evidence is provided by Donnelly (2013) (CA = 2) who found that the incidence of confirmed bTB breakdowns in cattle was significantly lower in Randomised Badger Culling Trial (RBCT) cull areas relative to comparison areas in the 7.5 years post-cull. The greatest reduction was in the period 18 to 24 months after culling ended, with declining but significant reductions in incidence compared to unculled areas in the subsequent years.

The RBCT involved smaller cull areas which were culled for a shorter period using different methods compared to the current badger control policy. As a consequence, the culling operations under the current policy may have resulted in different outcomes in relation to badger behaviour, epidemiology and the duration of benefits in cattle.

Further empirical evidence regarding post-cull reductions in bTB incidence is provided by:

- Byrne *et al*. (2014) (CA=3) who concluded from a trial in four counties in the Republic of Ireland (RoI), that disease reduction benefits persisted in 2007-2012 (5-10 years post-cull) in most areas where intensive badger culling was conducted from 1997-2002. In the intervening years, low-level badger culling had occurred across the whole area both within cull trial areas and controls (approx. 0.59 badgers/ km^2/ year), with higher levels of removals from control than in formerly intensively culled areas.
- Clifton-Hadley *et al.* (1995) (CA=3) who found a prolonged (potentially lasting 8-10 years) disease reduction following the likely complete eradication of badgers in a single area in Southwest England, compared to an area with only limited badger control. Badgers in the survey area were culled from 1975-1981 by gassing of badger setts. As such, the ecological and epidemiological impacts of culling may differ from current/recent culling operations in England.

Two closely-related simulation models suggest that disease-reduction benefits are likely to persist after the cessation of badger cull operations, although the duration of this effect depends upon the assumptions within the models. These models focus primarily on badger control and do not explore the potential impacts of varying cattle-based measures. Although simulation modelling is commonly used to evaluate different disease control methods, these modelling studies are rated as weak evidence when compared to empirical studies.

- Smith and Budgey (2021) (CA = 4), modelled the likely levels of bTB infection in badger populations post-cull under a low perturbation scenario (increased movement of badgers and transmission in badger populations following culling) comparing no further culling with various types of intervention including: ongoing culling (SBC), periodic interventions, and vaccination of badgers against bTB. The modelled outputs suggest that the number of infected badgers per social group would be reduced by approximately 70% following five years of intensive culling. All post-cull scenarios considered in the model, including further culling and badger vaccination, reduced the number of infected badgers by a similar level for more than three decades after culling ended, although the levels of infected badgers increased fastest in the no-cull scenario. This study did not model the likely impact on disease levels in cattle. However, low levels of infectious badgers in simulated populations may be indicative of scenarios where badgers would play a limited role in any cattle infection.
- Birch *et al*. (APHA unpublished Powerpoint presentation) (CA = N/A) extended these models to include high perturbation scenarios and the impact on

bTB infection levels in cattle. They found that, in the High Risk Area, predicted infection levels in cattle remained low for up to 15 years following the end of culling in no-cull and various vaccination scenarios. In high perturbation scenarios, models predicted that infection levels would increase more rapidly after two years and return close to pre-cull levels by about 10 years. In the Edge Area, cattle infection levels were predicted to increase more quickly but these models were considered less reliable.

2. Effectiveness of different post-cull strategies

2.1 Badger vaccination

Badgers can be vaccinated against bTB using an injectable BCG vaccine. Experimental trials demonstrate that this provides some though not perfect protection against infection and does not cure existing infection; the duration of immunity is unknown. Studies assessing the efficacy of bTB vaccination in badgers are summarised in Godfray *et al.* (2018) and are not reviewed here. Only studies that evaluated the effect of badger vaccination on cattle were included within the critical appraisal. However, limited empirical evidence exists on the efficacy of badger vaccination as a means of reducing bTB infection in cattle. Three sources of evidence were evaluated: one relates to a large-scale field trial in the Republic of Ireland (Martin *et al*. 2020) where differences in culling approaches mean that the results may not be directly comparable to England, and the other two are largely descriptive.

- Martin *et al.* (2020) (CA=2) compared the disease reduction benefits of badger vaccination and badger culling, measured as cattle herd bTB incidence, in 7 counties in the Republic of Ireland. Badger culling had been carried out previously in the areas subjected to both the culling and vaccination treatments. They found that badger vaccination was not inferior to badger culling in 4 out of 7 counties, inferior in 2 counties, with ambivalent outcomes in the remaining area.

- APHA (2016a) (CA = N/A) carried out a 'Badger Vaccine Deployment Project' in a single 100km^2 area in Gloucestershire, vaccinating badgers over a four-year period and using a series of relatively simple descriptive statistical analyses to investigate trends in bTB incidence in cattle within the BVDP and comparison areas. The OFT-W incidence rate of cattle in the BVDP area fell significantly over this period, but similar rates of decline were observed in three of four comparison areas. The authors conclude that they found no significant disease-reduction benefit in cattle but note that it is inappropriate to draw firm conclusions due to a range of factors including there being only one intervention area and the short-term nature of the study.

- APHA (2016b) assessed the impact of a range of measures in an 'Intensive Action Area' (IAA) in Wales, over a six-year period (2009-2015). This involved a range of enhanced cattle biosecurity and testing measures along with badger vaccination which was carried out from 2012-2015. Over the period assessed, bTB infection incidence in cattle in the IAA decreased by 35% compared to 23% in comparison areas. However, it is not possible to separate the impact of vaccination from other measures in this area and there are marked differences between the IAA and comparison areas analysed which also make it difficult to draw firm conclusions.

Further recent empirical evidence exists that indicates that badger vaccination reduces the prevalence of bTB in badgers, indicating the likelihood of disease risk reduction in cattle:

- Woodroffe *et al.* (in press) (CA = 3) found from a four-year vaccination trial in Cornwall that the prevalence of badgers infected with *M. bovis* declined from 16.0% (95% CI: 4.5%-36.1%) at the start of vaccination to 0% (95%: CI 0%-9.7%) in the final year of the trial.

- Arnold *et al.* (2021) (CA = 3B) conducted a 5 year 'Test and Vaccinate or Remove' study in Northern Ireland in an area where badgers had not previously been culled. The study found a reduction in badger bTB prevalence from 14% (95% CI: 0.10–0.20) in year 1 to 1.9% (95% CI: 0.8–3.8) in year 5. This represents an approximate 40% annual reduction in prevalence. Although the removal of infected badgers will have contributed to this reduced prevalence, relatively low numbers of removals occurred each year and these results are therefore consistent with vaccination making a significant contribution to the observed reduction in bTB prevalence in the badger population.

In terms of modelling studies:

- Smith *et al*. (2012) (CA = 4) modelled the effects of culling, badger vaccination and core-culling with ring vaccination (i.e. badger vaccination in the area surrounding a cull zone) on cattle bTB incidence. The authors concluded that all of the modelled interventions could lead to reductions in cattle infection, although vaccination is generally slightly inferior to culling, but culling with ring vaccination generally outperformed both other strategies.

- Smith & Budgey (2021) (CA = 4) modelled a range of interventions in a post-cull scenario including: intermittent culling, badger vaccination, and use of a vaccine combined with fertility control. The authors concluded that all scenarios with an active intervention maintained a reducing level of infection in badgers for the duration of exit strategy control, suggesting bTB eradication may be possible in the long term. The lowest level of infection prevalence in badgers was achieved with vaccination alone due to the assumption that the badger population would increase without culling or fertility control. Birch *et al.* (unpublished presentation) (CA = N/A) modelled several badger vaccination scenarios, varying both the timing of vaccination (post-cull) and the effectiveness of vaccination. They found that, in low perturbation situations, all vaccination scenarios led to similar outcomes to ongoing culling. In high perturbation models, when vaccination was delayed or less effective, there was a temporary increase in predicted cattle infections but this declined over time.

2.2 Ongoing badger culling

Research questions 2(b) targeted culling and 2(d) supplementary badger culling (SBC) are considered together here because the vast majority of studies investigating the impacts of badger culling assume a 4-5 year culling period with no further culling thereafter. Very limited empirical evidence is provided by Birch *et al.* (2024) (CA=3) who found disease reduction benefits during SBC were maintained at the same levels as observed after 3 and 4 years of intensive culling. In the Birch study, due to low sample size, all SBC years were considered a single treatment, and the confidence intervals were broad, so it is not possible to assess any trend during this treatment.

In terms of modelling studies:

- Smith and Budgey (2021) (CA = 4), modelled the likely levels of bTB infection in badger populations post-cull under a low perturbation scenario and with various types of culling interventions (SBC, biannual culling, culling every third year and culling two out of every four years). They concluded that all of these interventions were likely to be effective in maintaining low population size in badgers and low infection rates in badgers. They did not investigate the impact on disease incidence in cattle.

- Birch *et al.* (unpublished presentation) (CA=N/A) concluded that indefinite culling was likely to maintain disease reduction benefits under high or low perturbation scenarios, although it is unclear how long perturbation effects will last following culling.

2.3 Cattle control measures (testing, vaccination, biosecurity and management)

- There is scant quantitative empirical evidence on the effect of individual cattle bTB control measures in the UK, and no studies have investigated the impact of a change from intensive culling and existing cattle control measures to substantially increased cattle control measures alone. Godfray *et al.* (2013) (CA=3), in summarising the available evidence base, concluded that there was good evidence that pre- and post-movement testing of cattle could reduce disease transmission, and that the low sensitivity of the SICCT test can lead to undetected persistence of bTB-infected cattle in herds. They also suggest that measures to separate badgers from cattle can make a contribution to reducing disease risk (e.g. excluding cattle from badger setts and latrines, restricting badger access to cattle water and food sources) and that uptake of such biosecurity measures may be low in some areas. They note that neonatal BCG vaccination is effective in reducing the risk of cattle becoming infected but that this can lead to a false-positive bTB test result.

- Godfray *et al.* (2018) (CA=N/A) stress the benefits of using more sensitive bTB tests to reduce the risk of within-herd persistence and, in particular, in pre- and post-movement testing for cattle. Field studies in Ethiopia and Mexico have shown that vaccinated cattle are 30-60% less likely to contract bTB. The authors also suggest that there may be a genetic basis to vulnerability to bTB and that breeding for disease resistance may be an option for the future. The studies described by the Godfray review group were not evaluated independently for this critical appraisal and low weighting has been attributed to this evidence.

- APHA (2016b) (CA=N/A) found that enhanced cattle controls and surveillance, together with badger vaccination, led to a 35% decrease in bTB incidence in cattle over a 6-year period compared to a 23% reduction in a comparison area. It is not possible to separate out the effects of the enhanced cattle measures from badger vaccination.

ANNEX 2

References assessed through the Critical Appraisal

Citation	URL	CA Rating
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