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1 Advances and prospects for management of TB transmission between badgers

2 and cattle

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8

9 Abstract

10 Bovine tuberculosis (bTB) is the most serious endemic disease facing the livestock 11 industry in the United Kingdom (UK) and Republic of Ireland (RoI), where its 12 management has been confounded by the presence of persistent infection in the 13 Eurasian badger (Meles meles). Field evidence suggests that the social structure of 14 badger populations can have an important influence on disease dynamics, and on the 15 outcome of management interventions. Recent, large-scale badger culling experiments 16 in the UK and RoI had complex epidemiological outcomes. In the UK, proactive 17 culling led to reduced bTB incidence in cattle herds inside culled areas, but a 18 temporary increase in adjacent areas. Reactive culling in response to herd breakdowns 19 was associated with an increase in the incidence of bTB in cattle. In contrast, badger 20 culling in RoI was reported to have only beneficial effects on bTB incidence in cattle. 21 The reasons for these differences are not clear. The complexity of the evidence base 22 for culling is highlighted by the different management approaches currently being 23 adopted by the different authorities of the UK and RoI.

It is generally accepted that a holistic approach to bTB management, which targets both cattle and wildlife, is necessary. Consequently recent research activities

have also focussed on cattle and badger vaccines, and biosecurity on farms. This
paper describes recent advances in our understanding of the epidemiology of bTB in
badgers and the consequences of culling, and current research to develop approaches
for the vaccination of badgers, and methods of managing the risks of contact between
badgers and cattle in farm buildings.

6

7 Keywords: badger, bovine tuberculosis, wildlife reservoir, transmission, control,

- 8 management
- 9

10 **1. Introduction**

The eradication of bovine tuberculosis (bTB) from cattle in the UK and Republic of 11 12 Ireland (RoI) has been compromised by the presence of endemic infection in the 13 Eurasian badger (Meles meles). Since the early to mid 1970s when they were first 14 suspected to be sources of infection for cattle, badgers have been culled in both 15 countries under a variety of different strategies. Although badgers have been protected 16 in the UK and RoI since 1973 and 1976 respectively, culling has been employed since 17 1973 as the primary tool for targeting the reservoir of infection in wildlife, as a 18 complement to cattle-based controls (Krebs, 1997). In the areas of cattle herd 19 incidence of the UK, specifically parts of the south-west of England and Wales, an 20 initial decrease in the incidence of herd breakdowns provided some encouragement 21 that culling could be an effective management approach (Zuckerman, 1980). 22 Localised, intensive badger removal operations in England and RoI were also 23 accompanied by reported decreases in cattle herd breakdown incidence (Clifton-Hadlev et al., 1995; Ó Máirtin et al., 1998; Eves, 1999). However, since the late 24

1980s, the incidence of TB in cattle has risen against a background of statutory badger
 culling in England and Wales (Krebs, 1997; http://www.defra.gov.uk).

3 Concerns over the increasing incidence and geographic spread of bTB in cattle 4 led in 1997 to the suspension of badger culling as a management policy in England 5 and Wales and the appointment of an independent advisory committee to MAFF 6 (Ministry of Agriculture, Fisheries and Food; Krebs, 1997), the predecessor to the 7 current responsible government department, Defra (Department for Environment, 8 Food and Rural Affairs). The committee recommended a range of scientific research, 9 including a field experiment to determine the efficacy of badger culling in reducing 10 bTB incidence in cattle. The UK government accepted most of the recommendations 11 and in 1998 an Independent Scientific Group on Cattle TB (ISG) was convened to 12 design and oversee the Randomised Badger Culling Trial (RBCT). In their final report 13 the ISG recommended a range of policy options focussing on more stringent cattle 14 control measures, and concluded that "badger culling cannot meaningfully contribute 15 to the future control of cattle TB in Britain" (Independent Scientific Group, 2007). 16 Despite being supported by numerous publications in peer-reviewed journals, the 17 ISG's conclusions were not universally accepted (More et al., 2007; 18 http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/badgersrep 19 ort-king.pdf). Nevertheless, a subsequent inquiry by a House of Commons Select 20 Committee acknowledged the importance of the ISG's work, which it described as 21 "the only robust evidential basis on which a badger cull could take place" 22 (http://www.publications.parliament.uk/pa/cm200708/cmselect/cmenvfru/130/130i.pd 23 f).

24

25 **2. Recent advances in knowledge**

1 2.1. Epidemiology of bTB in badgers

2 Bovine TB is a chronic infectious disease caused by the bacterium 3 Mycobacterium bovis. It affects a broad range of mammalian hosts including humans, 4 cattle, deer and wild carnivores such as badgers. Although the extent to which badgers 5 contribute to infection in cattle is still unclear, the results of the RBCT suggested they 6 accounted for around 50% in the experimental areas (Jenkins et al., 2008). The precise 7 routes of transmission amongst badgers and between badgers and cattle have yet to be 8 described. The distribution of lesions in badgers at *post mortem* examination and the 9 observation that *M*. bovis is most frequently isolated from sputum during live 10 sampling, suggest that the respiratory route may be most important for badger to 11 badger transmission (Clifton-Hadley et al., 1993; Corner, 2006). Onward transmission 12 to cattle may potentially occur through either direct contact with badgers themselves, 13 or with their excretory products. Incidence and transmission rates appear to be 14 relatively low in badgers and bTB apparently has little detectable impact on badger 15 population size or turnover (see Rogers et al., 1997, 2000). Infected badgers may live 16 for several years, during which time they may continue to breed (Delahay et al., 17 2005), although individuals with evidence of continual excretion appear to exhibit 18 significantly higher levels of mortality (Wilkinson et al., 2000). Counter-intuitively, 19 recent analyses of a longitudinal study of badgers at Woodchester Park, 20 Gloucestershire, UK revealed a significant negative correlation between population 21 size and the detected incidence of excretion of *M. bovis* (Vicente et al., 2007). This 22 study showed that individual and group-level incidence risks were related to changes 23 in social group size and movement patterns of badgers amongst groups, highlighting 24 the profound importance of social structure in disease transmission dynamics.

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1 2.2. Epidemiological consequences of culling badgers

2 Past studies from the UK and RoI provided compelling evidence that comprehensive, 3 localised badger culling operations reduced disease in cattle (see Clifton-Hadley et al., 4 1995; Ó Máirtin et al., 1998; Eves, 1999). However, these studies did not incorporate 5 sufficient experimental controls or replication to provide conclusive scientific 6 evidence, and did not investigate the potential detrimental effects of culling in 7 adjoining areas. The RBCT took place between 1998 and 2005 in thirty 100 km² 8 treatment areas of high bTB incidence in cattle herds in west and south-west England. 9 The treatment areas were arranged into ten triplets, each of which contained an area 10 subjected to reactive culling (localised culling in response to a TB outbreak in cattle), 11 an area of proactive culling (widespread annual culling throughout the treatment area) 12 and a survey-only area, where no culling was carried out. This acted as an 13 experimental control against which the results of the other two treatments could be 14 measured (Independent Scientific Group, 2007).

The reactive culling treatment was stopped early by Ministers in November 15 16 2003 due to an observed 20% increase in the incidence of bTB in resident cattle herds 17 compared to survey-only areas (Donnelly et al., 2003). Despite debate over the 18 magnitude of the detrimental impact of reactive culling, and over the biological 19 plausibility and statistical treatment of the results (More et al., 2007), the ISG 20 concluded that reactive culling as carried out in the RBCT was, "unacceptable as a 21 policy option." Proactive culling, on the other hand, demonstrated a significant 22 reduction (23%) in the incidence of cattle TB breakdowns inside culled areas after 23 approximately five years of culling (Independent Scientific Group, 2007; Donnelly et 24 al., 2007). This beneficial effect increased to 54% in the post-trial period (from one to 25 two years after the last proactive cull; Jenkins et al., 2008). However, this was

1 accompanied by a 25% increase in the incidence of bTB breakdowns in a 2 km wide 2 buffer zone around the proactive areas (Independent Scientific Group, 2007; Donnelly 3 et al., 2007), which subsequently disappeared in the post-trial period, 1-2 years after 4 culling ceased (Jenkins et al., 2008). Also, within the culled areas there was a 5 tendency for the incidence of herd breakdowns to increase with proximity to the 6 boundary, although these negative effects of culling diminished with successive 7 annual culls (Donnelly et al., 2007). Ongoing analyses in the post-trial period continue 8 to produce complex results. After three years since the end of culling, benefits inside 9 culled areas were no longer detectable. However, repeating this analysis using a 10 further six months of cattle testing data indicated that the beneficial effects observed 11 within trial areas in the first year post-trial had unexpectedly reappeared, with 12 confirmed breakdowns being 37% lower than survey-only areas (Jenkins et al., 2010). 13 Despite these complex outcomes, the experiment demonstrated that proactive badger 14 culling sustained for several years on a relatively large scale resulted in a positive 15 impact on herd breakdown incidence. However, the overall benefits in terms of the 16 number of breakdowns prevented were considered "modest", and several years of 17 post-culling benefits would be required to offset the costs involved in carrying out the 18 culling (as conducted in the RBCT; Independent Scientific Group, 2007). Another 19 large-scale study in RoI compared the effects of two different culling strategies on the 20 control of bTB in four paired study areas (Griffin et al., 2005). The probability of a 21 cattle herd breakdown was significantly lower in areas where badgers were 22 proactively culled (removal areas) than in paired 'reference areas' where they were 23 only locally culled in response to a severe herd breakdown. Although the reference 24 areas did not represent a strict experimental control, the magnitude of the relative 25 beneficial effect of culling in the removal areas was compelling. In practice, very few

1 badgers were removed from the reference areas and there was no evidence that such 2 small-scale culling led to an increase in herd breakdowns as had been observed 3 following localised culling in the RBCT. This suggests that the negative effects 4 associated with culling on the UK mainland may not necessarily occur in Ireland, 5 where agricultural practices, landscape composition and badger density and ecology 6 may differ. This notion is supported by research from County Laois in RoI which 7 showed that badger removal following herd breakdowns was associated with a 8 beneficial impact on the time to future breakdowns for both index and surrounding 9 farms (Olea-Popelka et al., 2009).

10

11 2.2.1. Unravelling the wider significance of badger sociality to disease control

12 The temporary negative impacts of badger culling on herd breakdown rates observed 13 in the RBCT were attributed to disruption caused to otherwise stable badger 14 populations. There is a substantial body of evidence from the RBCT itself and other 15 studies in the UK and RoI that culling badgers may result in increased immigration 16 into culled areas, disruption of territoriality, increased ranging by individuals and 17 mixing of social groups, which may persist for many years (reviewed in Carter et al., 18 2007). Such "social perturbation" may potentially lead to an increased risk of disease 19 transmission amongst badgers and between badgers and cattle. Culling during the 20 RBCT resulted in significant disruption of badger territories (Woodroffe et al., 2006a) 21 and was associated with an increase in the prevalence of infection in badgers 22 (Woodroffe et al., 2006b; Independent Scientific Group, 2007). Comparable 23 disruption of social structure was observed in previous studies of badger removal 24 operations in England and RoI (Cheeseman et al., 1993; O'Corry-Crowe et al., 1996; 25 Tuyttens et al., 2000). In an intensively studied, undisturbed population, strong

1 associations were identified between badger movement patterns and the risks of bTB

2 infection (Rogers et al., 1998; Vicente et al., 2007).

3 The observed differences between the outcomes of badger culling in RoI and 4 mainland UK are intriguing. The absence of an increase in herd breakdowns in the 5 Irish Four Areas project (Griffin et al., 2005) may in part be due to its design, being 6 deliberately located in areas where natural barriers such as rivers, mountain ranges 7 and sea inlets are likely to have impeded the immigration of badgers from surrounding 8 areas. Another factor may be the lower density of badger populations in Ireland 9 compared to those in the bTB affected areas of Britain (Independent Scientific Group, 2007). Between 0.76 and 2.77 badgers were culled per km^2 in the proactive areas of 10 the RBCT, compared to 0.29 - 0.48 badgers per km² in the Four Areas project. At 11 12 medium to high densities, typical of south-west England and Wales, badgers tend to 13 reside in discrete social groups with well-defined territories and low rates of dispersal 14 (Kruuk and Parish, 1982; Woodroffe et al., 1993; Rogers et al., 1998). At low 15 densities however, badgers may adopt a more flexible social structure (Cheeseman et 16 al., 1993; Revilla and Palomares, 2002). Under these circumstances, it is possible that 17 lower density, associated reduced immigration pressure and the less marked spatial 18 structure may reduce the potential epidemiological consequences of culling. It 19 remains to be seen to what extent future developments in 'trap-side' diagnostics may 20 open the door to selective, and hence potentially less disruptive culling strategies, 21 perhaps also in combination with vaccination.

The effects of social perturbation present a significant challenge to the management of infection risks from a reservoir in wildlife, and such problems are not unique to badgers and bTB. There is also evidence that culling-induced social perturbation may have hampered the control of rabies in red fox (*Vulpes vulpes*)

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- 1 populations (Macdonald, 1995) and of Classical Swine Fever in wild boar (Sus scrofa;
- 2 Maillard and Fournier, 1995).
- 3

4 **3.** Current research directions

5 3.1. Vaccination of badgers

6 The vaccination of badgers and cattle has long been viewed as an attractive disease 7 control option. The basic aim of a badger vaccination strategy is to reduce the risk of 8 onward transmission of bTB from badgers to cattle. Inherent attractions of vaccination 9 as a disease management tool are that, unlike culling, it is not expected to disrupt 10 badger social behaviour and is unlikely to be opposed by conservationists, welfare 11 groups and the general public. However, the development of an effective vaccine, 12 with an appropriate strategy for its delivery, and its realisation as a commercially 13 available, licensed product involves considerable technical and regulatory challenges 14 (Blancou et al., 2009). Options for vaccinating badgers include capture and manual 15 delivery of the vaccine either directly into the oral cavity or by intra-muscular 16 injection, or oral delivery through deployment of bait without the need to capture 17 animals.

18 BCG (Bacille Calmette-Guerin) is presently the only candidate vaccine and 19 has been shown to be safe when administered parenterally to captive badgers 20 (Lesellier et al., 2006). A field study in the UK to evaluate the safety of intramuscular 21 delivery of BCG in badgers and to collect supporting data on vaccine immunogenicity 22 and efficacy was completed in November 2009. This study of approximately 90 23 contiguous badger social groups in south-west England began in 2006 and results are 24 anticipated by mid-2010. Badger social groups were allocated to either vaccination or 25 control treatments. Individuals captured in vaccinate groups were injected with 2-8 x

1 10^6 colony forming units (cfu) of BCG. All captured badgers were uniquely marked, 2 physically examined and had a suite of clinical samples taken to determine disease 3 status and to detect the presence of *M. bovis* or BCG in clinical samples. The safety of 4 the vaccine was assessed by comparing vaccinated badgers with unvaccinated 5 controls in terms of body temperature following injection and local reactions at the 6 vaccination site on recapture. Samples were also taken for histological examination 7 from any vaccinated animals found dead in the study area.

8 Laboratory studies have been conducted in the UK and RoI on captive badgers 9 to determine the efficacy of BCG delivered via several routes. Evidence of a 10 protective effect, measured in terms of the immunological response and the severity of 11 pathology observed at *post-mortem* examination following experimental infection in 12 uninfected badgers, has been demonstrated (Corner et al., 2008; Lesellier et al., 2006, 13 2009). The results of the above field and laboratory studies formed the basis of an 14 application submitted to the Veterinary Medicines Directorate (the UK veterinary 15 medicines licensing body) in 2009 to obtain a Marketing Authorisation (MA) for the 16 intramuscular administration of BCG Danish 1331 to wild badgers. This was granted 17 in March 2010.

18 The UK Government began using the licensed injectable vaccine in the Badger 19 Vaccine Deployment 2010 Project in July (BVDP: 20 http://www.defra.gov.uk/fera/bvdp). This is a six-year project to deploy vaccine to 21 wild badgers in a bTB-affected area in England. Badgers are captured in cage traps and vaccinated in the field by government staff on up to 100 km² of predominantly 22 23 cattle land. Unlike other components of the vaccine programme this is neither a 24 research project nor a regulatory study, but rather aims to provide training for lay-25 vaccinators, assess the viability of field application of an injectable badger vaccine,

1 and build industry confidence in the principle and practicalities of wildlife 2 vaccination. It is intended that the project will provide valuable information on the 3 true costs and practicalities of large-scale vaccine deployment. It will also provide an 4 opportunity to engage the farming community, and potentially, to begin to make a 5 positive impact on a badly affected area before an oral vaccine formulation is 6 available. A social science study is also being conducted with participating and non-7 participating farmers, to establish levels of farmer confidence in the use of vaccination 8 before, during and after vaccine deployment.

9 It is generally recognised that delivery of vaccine in oral baits holds the best 10 long-term prospect for deployment to badgers over a wide area (see Delahay et al., 11 2003). The large-scale eradication of sylvatic rabies in Europe through the vaccination 12 of red foxes using oral baits (Brochier et al., 1991) represents an important precedent 13 for the wide-scale vaccination of badgers in the UK and RoI. The success of such an 14 approach will depend on how many badgers consume the baits and the effectiveness 15 of the vaccine. Collaborative research and development studies are currently 16 underway in both countries towards a common aim of identifying how this might be 17 achieved in practice. Work has already taken place on bait delivery systems for 18 badgers (e.g. Delahay et al., 2000) and on identifying the most palatable baits. Current 19 research is aimed at identifying the most appropriate bait formulation to ensure that 20 BCG remains viable for prolonged periods in the bait, is not incapacitated by acidic 21 conditions in the stomach, but can be delivered where it is most likely to induce 22 protective immunity to M. bovis. A recent study in New Zealand achieved an 23 estimated efficacy of 95% in wild brush-tail possums (Trichosurus vulpecula) using a 24 lipid-formulated oral vaccine containing 10^7 cfu BCG delivered to the rear of the oral 25 cavity (Tomkins et al., 2009). In light of these promising results, a large field trial

1 began in 2009 in RoI, designed to measure the protection generated by BCG 2 vaccination in wild badgers, and to estimate vaccine efficacy by comparing the 3 prevalence of *M. bovis* infection in vaccinated and non-vaccinated badgers (Corner et 4 al., 2009). Badgers are trapped in an area comprised of three zones, in which 100%, 5 50%, or none of the captured badgers are vaccinated using the lipid formulation 6 delivered directly into the pharynx under general anaesthetic. These proportions were 7 selected such that effects on vaccine efficacy due to changes in the force of infection 8 as a result of vaccination could be estimated (Corner et al., 2009). Badgers will be 9 vaccinated annually for three years, at which point the area will be depopulated and 10 all captured badgers submitted for *post mortem* examination, histology and bacterial 11 culture.

12 Field studies to determine the optimum deployment method for an oral vaccine 13 bait began in England in May 2010. The relative uptake rates of the most promising 14 candidate baits, devoid of vaccine, will be assessed at different times of year. The 15 study will also investigate variations in bait uptake rates relative to deployment of bait 16 above and below ground (i.e. down sett entrances), and the duration of bait provision. 17 The aim is to identify the most cost-effective and practical strategy for maximising 18 bait uptake by badgers. Alongside this, studies will be conducted on the efficacy of 19 the oral vaccine under experimental, controlled conditions. The results of this work 20 are expected by 2012 at which point it will be necessary to conduct regulatory studies 21 to demonstrate safety of the final product to both captive and wild animals. The 22 earliest anticipated date for a licensed oral vaccine is 2015. In addition to the science, 23 there are a number of key policy, legal, commercial, regulatory and manufacturing 24 issues surrounding the implementation of a vaccine against bTB.

25

1 3.2. Farm biosecurity

2 The principal routes of *M. bovis* transmission between badgers and cattle are unclear. 3 Badgers forage for earthworms on grassland and their preference for grazed pasture 4 creates opportunities for cattle to come into direct contact with them and their 5 excretory products (Muirhead et al. 1974; MAFF 1979; Wilesmith et al. 1982). Direct 6 contact between live badgers and cattle on pasture has been documented (Böhm et al., 7 2009), and there are anecdotal reports of cattle investigating badger carcasses. Most 8 research on potential transmission risks has in the past concentrated on the 9 contamination of cattle pasture with badger faeces and urine, particularly at latrines 10 (Benham, 1985; MAFF, 1979; Cheeseman and Mallinson, 1981; Benham and Broom, 11 1989; Hutchings and Harris, 1997; 1999). However, evidence suggests that badger 12 visits to farm buildings might also give rise to opportunities for transmission (MAFF, 13 1979; 1981; 1987; Cheeseman and Mallinson, 1981; Benham, 1985; Kruuk and 14 Parish, 1985; Shepherdson et al., 1990; Brown, 1993; Sleeman and Mulcahy, 1993). 15 Studies using intensive nocturnal observations, radio tracking, video and camera 16 surveillance revealed that badger visits to buildings on some farms occurred on over 17 50% of nights investigated (Garnett et al., 2002; 2003; Tolhurst, 2006; Ward et al., 18 2008). Visiting badgers used a variety of resources including feed stores, silage 19 clamps and cattle housing. Badgers, including known infected individuals, were 20 recorded defecating and urinating in buildings, sometimes directly onto feed and 21 regularly came within 2m of housed cattle (Garnett et al., 2002; Roper et al., 2003, 22 Tolhurst, 2006). These studies highlighted the potential for this phenomenon to be an 23 important risk factor for disease transmission on some farms, although the 24 contribution of such behaviour to cattle herd breakdown rates has not been quantified. 25 Nevertheless, it is clear that the development of practical means of managing badger-

cattle interactions is likely to be more achievable in and around farm buildings than
 on pasture.

3 A recent field experiment employing a factorial design investigated the effects 4 of a series of badger exclusion measures on 32 farms in south-west England 5 (Unpublished Defra report). Badger-proofed gates, feed stores and doors, and electric 6 fences, were deployed on cattle feed stores, cattle housing and silage clamps (all of 7 which were known to be visited by badgers) and monitored using remote camera 8 surveillance. The results yielded unequivocal evidence that when exclusion measures 9 were employed and adequately maintained they provided 100% protection of feed 10 stores and cattle housing from badger incursions. However, levels of farmer compliance varied widely, suggesting the existence of cultural/behavioural barriers in 11 12 the farming community to changing established working practices.

13 The costs of badger exclusion are likely to vary widely, depending on the 14 characteristics of the particular farm in question. As the contribution of such measures 15 to a reduced risk of experiencing a cattle herd breakdown is unknown, their cost-16 effectiveness cannot be quantified or communicated to farmers at present. Therefore 17 presenting a convincing argument for the value of investing time and money in 18 improved biosecurity measures is a significant challenge. Given the potential disease 19 risks associated with badgers visiting farm buildings, encouraging farmers to take 20 steps to reduce this risk has obvious value. In an attempt to address this, the Welsh 21 Assembly Government established a biosecurity Intensive Treatment Area (ITA) in a 22 high incidence area of west Wales (G. Enticott, 2008) with the aim of raising 23 awareness, understanding, and adoption of biosecurity measures. Local veterinarians 24 visited farms, assessed the existing biosecurity arrangements and provided advice on

- practical improvements. Farmers appeared to respond positively and improvements in
 biosecurity were observed (G. Enticott, 2008).
- 3

4 **4.** Translating science into policy

5 Bovine TB continues to have a devastating impact on the farming industry in some 6 parts of the UK and RoI, as well as on the public purse. However, owing to the 7 chronic nature and complexity of the disease, translating our scientific understanding 8 into effective policy is not a straightforward task. It is clear that bTB risks to cattle are 9 multi-faceted, requiring an integrated approach including both cattle and wildlife-10 based controls. The compulsory test and slaughter of positive (reactor) cattle and 11 associated movement restrictions remain the principal method of controlling bTB in 12 cattle herds in the UK and RoI. While vaccination of cattle is seen as a potential 13 important longer-term policy option in the UK, the eradication of bTB from cattle in 14 high-incidence areas of both countries is unlikely to be achieved without addressing 15 potential re-infection from badgers. The three main ways in which this may be 16 addressed are culling, vaccination and bio-security measures to prevent or at least 17 reduce contact between badgers and cattle. The complexity of this problem is 18 highlighted by the different management approaches currently being adopted by the 19 respective authorities of the UK where bTB is a problem (England, Wales and 20 Northern Ireland), and in and RoI. In light of a range of considerations including the 21 ISG's conclusions from the RBCT, the previous UK Government decided that 22 licences would not be issued to farmers to cull badgers for bTB in England, and 23 increased investment in research into vaccination for badgers, as well as cattle. In RoI 24 routine reactive culling continues to form part of government policy, supported by 25 evidence from field studies, in particular the Four Areas project. Reactive culling has

1 been conducted throughout RoI since the early 1990s where it is viewed as an interim 2 wildlife control strategy. Badgers are removed under licence within a 1-2 km radius 3 around a farm that has suffered a herd breakdown and where badgers are suspected to 4 be the source of infection. The Welsh Assembly Government (WAG; the devolved 5 government of Wales) announced in 2009 that in addition to a range of bTB control 6 measures nationally, proactive badger culling would be conducted alongside more 7 stringent cattle controls within an Intensive Action Pilot Area (IAPA) in Wales. In 8 Northern Ireland (NI), limited badger removal remains a potential option, in the 9 context of investigating badger-related risk factors on farms with and without bTB 10 infection. The Department of Agriculture and Rural Development in NI recently 11 funded a national survey, establishing that there had been little change in badger 12 distribution and population size in NI since an initial baseline survey in the early 13 1990s (Reid et al., 2008).

14 The vaccination of badgers is seen as an important potential policy option for 15 reducing the risk of bTB in cattle throughout the UK and RoI. This is reflected in the 16 significant portions of the respective bTB research budgets that have been allocated to 17 these approaches. Within Defra, the total investment in vaccine development for 18 badgers and cattle exceeded £30 million from 1998 up until April 2010. The UK 19 general election in May 2010 resulted in a change in Government. At the time of 20 writing, the new Government is reviewing options for wildlife TB research and 21 management in the light of background economic pressures and their own policy 22 position. Early outcomes of this process include a reduction in the scope of the BVDP 23 from six target areas to one, and renewed consideration of culling as well as 24 vaccination options.

25

1 **5. Conclusion**

2 Bovine TB is the most serious endemic disease currently facing livestock in the UK 3 and the RoI, and its cost to the farming industry and the taxpayer is unsustainable. It is 4 widely recognised that a sustainable solution can only be reached through a multi-5 faceted approach using a variety of available tools, targeting both cattle and wildlife. 6 Such an approach is likely to include continued improvements in cattle testing, 7 enhanced farm biosecurity and the deployment of cattle and badger vaccines as they 8 become available. In the meantime badger culling continues in the RoI, is planned to 9 start in a targeted area of Wales, is still under consideration in Northern Ireland, and is 10 under review in England by the new UK Government.

11 Recent research in the UK and RoI has significantly increased our knowledge 12 of the role of the badger in the dynamics of bTB infection in cattle, and in the 13 outcome of strategies for intervention. It has become clear that aspects of badger 14 ecology may significantly influence the outcomes of culling. How differences in the 15 prevailing density and social structure of badger populations might influence the 16 outcome of culling operations remains unknown. Other crucial gaps in our knowledge 17 include the precise route of transmission of *M. bovis* between badgers and cattle, and 18 the extent to which badgers with advanced disease may exhibit behavioural traits that 19 increase the likelihood of onward transmission. Nevertheless, strategies to reduce 20 disease transmission among badgers and cattle will have to be developed in the 21 absence of complete knowledge.

Practical steps to improve biosecurity have been shown to be sufficient to exclude badgers from farm buildings. However, the cost of such activities in terms of both money and time is a deterrent to farmers. In the absence of proof that improving biosecurity reduces the risks of herd breakdowns, convincing farmers of the value of

implementing such measures remains a significant challenge of communication for
 government and the veterinary profession.

3 Vaccination of cattle and badgers is still considered to have the potential to 4 contribute significantly to a long-term solution to the bTB problem. A wide-ranging 5 research program is underway in the UK and RoI, aimed at developing vaccine 6 products and deployment protocols for the wide-scale vaccination of badger 7 populations. In parallel with this research, badgers are being vaccinated in a badly 8 affected area of England from 2010, and it is intended that the practical lessons learnt 9 will inform future vaccination policy for when an oral vaccine bait becomes available. 10 It is clear that management of bTB in badgers and cattle is a considerable 11 veterinary and ecological challenge. Management of the disease in cattle by reducing 12 badger population densities through culling has mixed, unpredictable and in some 13 cases undesirable outcomes. The ISG's findings in particular highlight the need to 14 consider the ecological complexities of wild animal populations when taking 15 decisions on disease management. Indeed, owing to the complex ecology of not only 16 badgers, but also the characteristics of *M. bovis*, the effectiveness of bTB management 17 may continue to be constrained by an imperfect knowledge of the wildlife host or host 18 community. Going forward, management of bTB will require input from 19 veterinarians, epidemiologists and ecologists, mathematical modellers, economists 20 and others. The current efforts to develop cost-effective vaccine deployment strategies 21 for badgers are promising examples of such a multi-disciplinary approach.

22

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4 Conflict of Interest Statement

- 5 The authors have not declared any conflict of interest.
- 6

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