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Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

PROJECT LICENCE APPLICATION

UNDER THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

PROJECT TITLE (<50 characters including spaces)

Badger Intervention in the NI bTB Regionalisation Project

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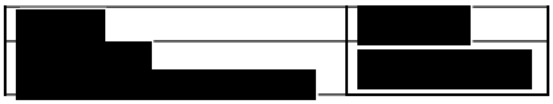

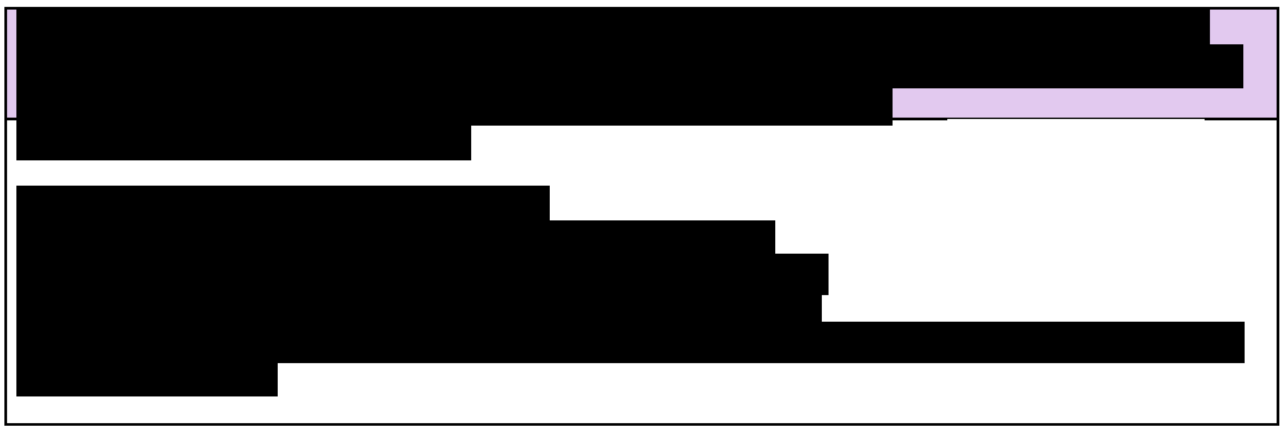

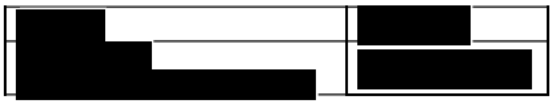

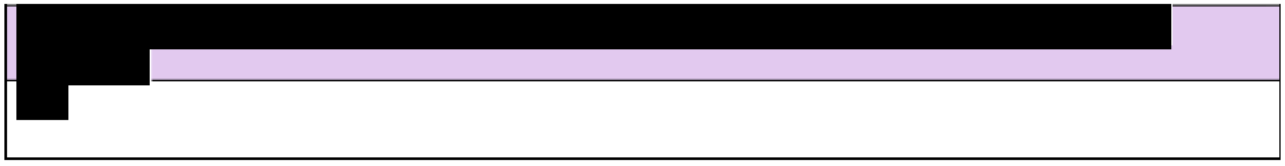

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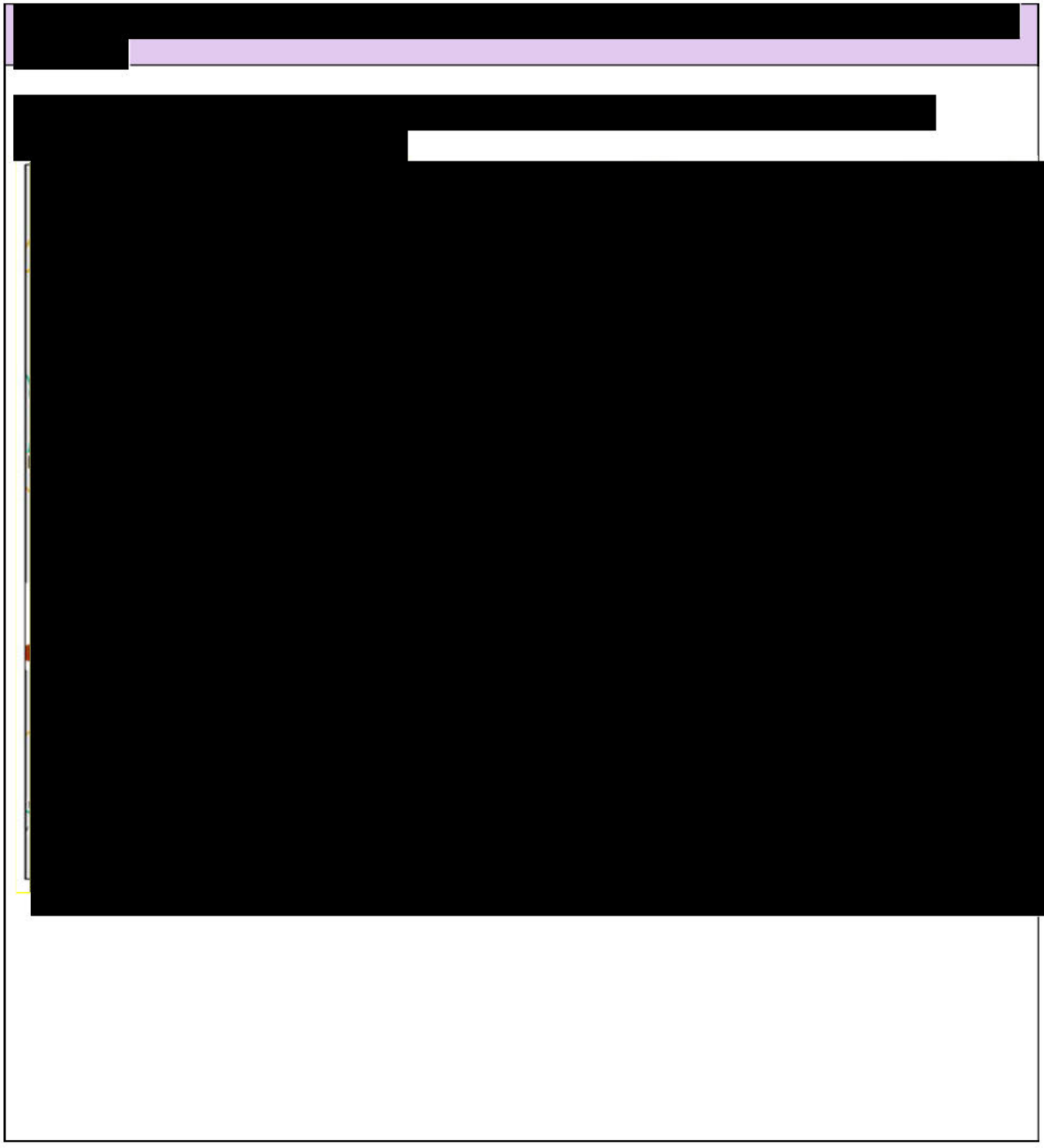

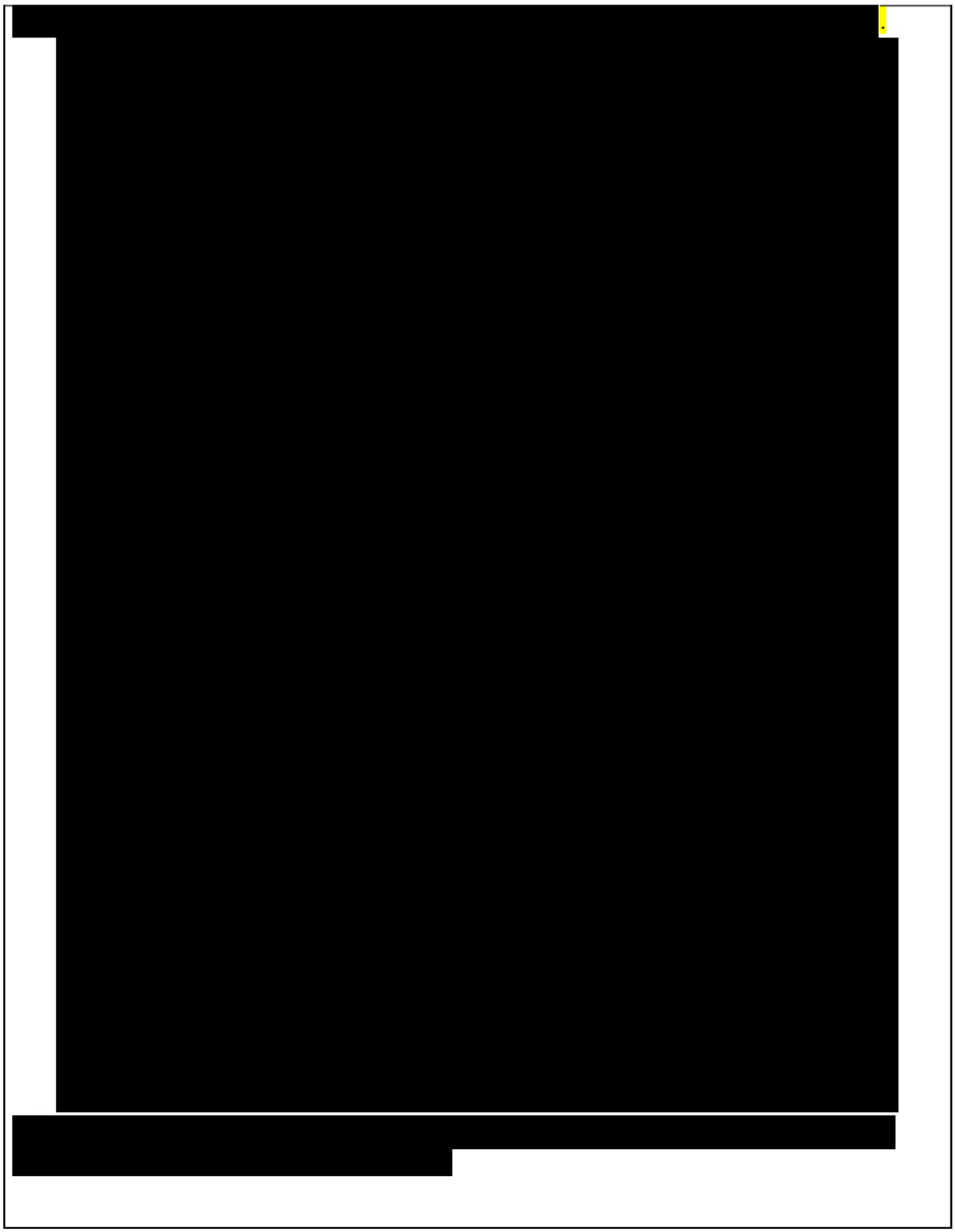

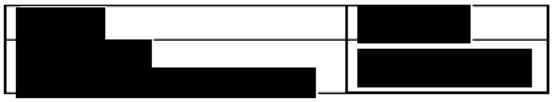

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C. SCIENTIFIC BACKGROUND

The total response to this Part must not exceed 2000 words

Background

To enable us to judge the relevance and value of the aims and objectives of your project we need to understand the current state of knowledge or product availability on which the proposed project intends to build.
For research projects: What is the current position in your area of work and how will this project help to advance knowledge or meet a clinical need?

- For testing or screening projects: What are the relevant statutory requirements or regulatory guidelines?
- For service or production projects: What are the likely demands for the service or product in the lifetime of the licence?
- Where applicable, summarise relevant progress under any previous project licence. Explain the extent to which you achieved the stated objectives of your previous project and list publications or other significant outputs.

History of badger intervention

Bovine tuberculosis (bTB), caused mainly by *Mycobacterium bovis*, is an endemic zoonotic infection in the UK (excluding Scotland) and Ireland. In Northern Ireland (NI), the infection has persisted in its cattle population despite a protracted bTB eradication programme with the current bTB herd incidence being over 9% and the annual programme costs being over £60m (DAERA, 2024).

There are various factors that contribute to the recalcitrant nature of bTB including intensification of cattle production, infection dynamics/diagnostics, farm fragmentation, and a wildlife reservoir, which are shared across the UK and Ireland (Broughan et al., 2016; Chang et al., 2023; Doyle et al., 2016, 2020, 2022; Milne et al., 2020). It is widely accepted that bTB eradication will require all sources of infection to be tackled effectively (Broughan et al., 2016; Chang et al., 2023).

With respect to wildlife, the European badger, *Meles meles*, is commonly accepted as being a reservoir host for *M. bovis* (Godfray et al., 2013, 2025; Griffin et al., 2021). While cattle are still considered as the main driver of bTB infection in cattle, inter-species transmission can play a significant role even though they may be relatively uncommon events; Analysis of data from England estimated that while the overall contribution of badgers to confirmed bTB herd breakdowns was 52% (bootstrap 95% confidence interval 9.1%–100%), only 5.7% (95% confidence interval 0.9%–25%) was directly attributed to badgers as a primary source of infection (with the difference reflecting the role of onward cattle-to-cattle transmission) (Donnelly & Nouvellet, 2013). There is mounting circumstantial evidence that badger-to-cattle transmission and cattle-to-badger transmission is mainly indirect though environmental contamination (Campbell et al., 2019, 2025). When badger-to-cattle transmission occurs, this is then compounded by onward cattle-to-cattle both within and between herds (Griffin et al., 2021). As highlighted later, effective control of *M. bovis* transmission in both species is required to mitigate against the devastating effects of this infection in badgers and cattle.

Use of whole genomic sequencing has facilitated a better understanding of *M. bovis* infection dynamics in bTB hotspots (Crispell et al., 2019; Rossi et al., 2021; Akhmetova et al., 2023). It has enabled quantification of the directionality of intra-species and inter-species *M. bovis* transmission and demonstrated how this dynamic varies between bTB infection hotspots.

Badgers can live for several years with *M. bovis* infection thus acting as a potential source of the infection for both other badgers and cattle and occasionally humans and other species (alpacas, sheep, pigs, dogs, cats etc.) over that time-period. Attempts to control *M. bovis* infection of badgers have mainly focused on proactive badger culling over bTB hotspot areas. The main scientific studies on the field use of proactive culling were the Badger Randomised Culling Trial (RBCT) in England and the four-area trial in Ireland (Donnelly et al., 2006; Griffin et al., 2005). Both trials showed a beneficial effect with respect to a significant reduction in bTB cattle herd breakdowns in the proactive cull areas over the period of the trials. Furthermore, this benefit was observed to have a prolonged beneficial effect within the RBCT (Jenkins et al., 2010; Allen et al., 2018). Moreover, the RBCT showed a transient detrimental effect to the buffer areas surrounding the proactive cull areas. This buffer area effect was not observed in the four-area trial (Olea-Popelka et al., 2009). However, not all peers agree with these RBCT findings who reported no effect from the RBCT data, particularly if all (confirmed and unconfirmed) bTB herd breakdowns were considered (Langton et al., 2022, Torgerson et al., 2024). Conversely, a further re-evaluation of the RBCT data confirmed the original findings (Mills et al., 2024a, b). More recent analysis of farmer led proactive badger culls in England have also suggested a significant reduction in bTB cattle herd breakdowns although other cattle bTB control measures were also deployed in such areas (Brunton et al., 2017; Downs et al., 2019). However, badger proactive culling is indiscriminate and unpopular with the general public, potentially removing large numbers of uninfected badgers and disturbing social groupings.
Badger vaccination trials using *Bacillus Calmette–Guérin* (BCG) vaccines have also been carried out with the Republic of Ireland (ROI) recently replacing culling with vaccination, although culling is being retained as an option in emerging bTB hotspot areas (Chambers et al., 2011; Carter et al., 2012; Gormley et al., 2017; Aznar et al., 2018; Benton et al., 2020; Martin et al., 2020).

Modelling of various badger intervention strategies using English and NI data has indicated that interventions that include a lethal badger component led to a more rapid reduction in infection levels compared to vaccination only with a slow increase in infection levels across all strategies post-intervention (Abdou et al., 2016; Smith et al., 2012, 2016; Smith and Budgey, 2021).
Trap side badger testing enables real time decision making on the fate of each badger where test-positive badgers can be selectively culled while test-negative can be released directly (test and selective removal) or after vaccination with BCG (test and vaccinate or remove – TVR). A TVR badger intervention was undertaken within a 100km^2 in NI during 2015-2018 (Menzies et al., 2021) (under ASPA PPL 2767). One of the outcomes from this research clearly demonstrated that trap side testing was practical (enabling real time decision making on the test result) and helped to validate the trap side use of the test in badgers (DPP test; Dual Path Platform VetTB assay for cervids). Bayesian latent class analysis of the DPP test in NI indicated the sensitivity to be 69% (95% CrI: 48%–88%) and a specificity of 98% (95% Crl: 96%–99%) when whole blood is tested against Band 1 of the DPP test (Arnold et al., 2021). This would indicate a false positive rate of 2% in the unifected badger population in NI. A similar analysis of the DPP test using data from England along with a subset of the NI data indicated a higher sensitivity (79.9% (95% CrI: 66.1–91.4%)) but a lower specificity (93.3% (90.7–95.7%)) (Jinks et al., 2025). However, both analyses identified the poor performance of Band 2 of the DPP test, which will not be used during the current project for diagnostic purposes.
This research project also demonstrated a significant decrease in badger *M. bovis* prevalence (from 14% to 1.9%) and highlighted the heterogeneous nature of both badger densities and test-positive badger densities within the area (Arnold et al., 2021; Menzies et al., 2021). However, this badger intervention appeared to have minimal impact on cattle herd bTB levels and cattle-

to-cattle transmission was dominant in driving bTB infection in the area (Doyle et al., 2023; Akhmetova et al., 2023). This work indicated that effective transmission control is required in both cattle and badgers to reduce bTB levels in an area and more recent modelling outputs have also pointed to effective infection control within both species (Chang et al., 2025).

The TVR study also showed that over 80% less badgers were removed from an area compared to proactive cull approach and, more importantly, TVR did not appear to induce any perturbation/increased movement of badgers and indeed the badger population structure seemed to be unaffected by the intervention (Menzies et al., 2021; O'Hagan et al., 2021; Allen et al., 2022).

A comprehensive annotated bibliography of the recent peer reviewed literature (2015-2024) is available from DAERA, as are all papers published associated with the aforementioned TVR study.

An approach was the subject of an independent scientific working group (SWG) opinion paper requested by the ROI's TB Forum (Griffin et al., 2024), which was further developed in Tratalos et al. (2024). The SWG report indicated that an area/regional approach should be adopted to bTB control and could be successful at driving down disease levels but stressed that key measures are important with respect to achieving success and with respect to area selection. Namely, it identified five criteria that are of high priority; inward cattle movement, trade flows, administration of the region, effectiveness of the badger programme and stakeholder commitment with the latter considered the most important criterion.

The Regionalisation Project

Within the Chief Veterinary Officer's Bovine TB Review (DAERA, 2024), a hybrid badger intervention approach was outlined as a possible way of maximising resource and minimising disruption to the badger population within an area. This review also highlighted the substantive progress made in reducing bTB levels by those countries who had applied a regionalised approach, for e.g. Australia and New Zealand, a concept that has never been trialled before on the island of Ireland as part of bTB eradication measures.

Following on from the CVO review, the Bovine TB Blueprint (DAERA, 2025) proposed a regionalisation pilot project for NI.

The Regionalisation Project is a proof-of-concept research platform that lets DAERA and partners test a full set of interventions at the same time. Its first main aim is to reduce bTB levels in both cattle and badgers in the pilot area and international experience shows that regionalisation can speed up this progress. While difficult to set specific targets as a lot of the success of this project is dependent upon effective stakeholder engagement, the main targets over the five years would be:

- Reduction in *M. bovis* annual prevalence in badgers to under 5%
- A 50% reduction in annual bTB herd incidence in cattle
- A 40% reduction in bTB (CITT; skintest) reactor numbers.
- A change in biosecurity behaviours resulting in increased biosecurity compliance by herd keepers across various metrics including fencing off badger setts and cattle purchasing policy.

Its second main aim is to generate strong evidence about which control measures work and in what circumstances. The five-year programme provides sufficient time to detect real epidemiological change and produce robust research. The initial badger sett survey, which has been conducted in preparation for the rest of the project, creates the essential baseline information needed for later logistics and analysis.

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Measures in the Regionalisation project will be based on cattle, people/biosecurity and wildlife. Cattle and people/biosecurity measures include 6-monthly herd testing, managing inconclusive reactors, providing guidance on sourcing stock, enhanced breakdown testing (Interferon gamma (IFNg) blood testing), bespoke vet biosecurity visits, promoting breeding for cattle with stronger genetic resistance to bTB, partnership working between farmers, vets and DAERA, and improved communication and advice. The cattle testing measures are part of the national bTB Eradication Programme.

Wildlife element of project

This will focus on TVR badger intervention based on cage trapped badgers in the first two years with an adaptable approach after that. In summary, during Years 1 and 2, the work will follow a TVR-only approach, allowing the team to establish baseline infection levels, removing infected badgers, while vaccinating and releasing the majority of badgers. This will give a robust picture of badger *M. bovis* prevalence across the study area. If these data show localised pockets of higher infection, then in Years 3 and 4 those specific sub-areas will move to a combined TVR plus GonaCon (i.e. fertility vaccine) approach, to stabilise local population structure while continuing to remove infected animals. However currently we do not believe that badger *M. bovis* prevalence is, or will be, at the level that would require the use of GonaCon at scale. In subareas where low badger *M. bovis* prevalence is found, there will be a move to a vaccination only regime. Subareas with a medium badger bTB prevalence will remain to be subjected to TVR intervention only.

While selection of areas in which to apply the different interventions will depend on the findings from Years 1 and 2, as an example, the current estimated national badger *M. bovis* prevalence s approximately 20% (based on the results from the ongoing badger road traffic accident survey carried out by DAERA (Courcier et al., 2018). Using this prevalence and the DPP test characteristics then sub-areas with a *M. bovis* seroprevalence of <5% would be allocated to a vaccination only intervention, those with a seroprevalence of 5-20% would remain on a TVR regime while those with a >20% seroprevalence would be subject to a TVR and fertility control (GonaCon) intervention.

In Year 5, the protocol will revert to TVR-only for the whole area, enabling a direct comparison with the baseline data from Years 1 and 2 to assess how prevalence has changed over the course of the intervention. During the duration of the project all trapped badgers will be individually micro-chipped, which will enable baseline information to be recorded on infection prevalence and various ecological measurements.

Initial two years of TVR

The TVR badger intervention project in Co. Down indicated that there was heterogeneity in both badger density and the proportion of badgers that were DPP-test positive within the 100km^2 area (Menzies et al., 2021). Within the current project, it is proposed to use this heterogeneity to identify areas which can be switched over to vaccination only at an early stage after initial TVR monitoring of the entire area.

Using the available published data regarding capture rates and DPP test performance (Menzies et al., 2021; Arnold et al., 2021; Jinks et al., 2025), 44-47% of the badger population would be DPP test-negative/BCG vaccinated at the end of Year 1 while 66-71% would be DPP test-negative/BCG vaccinated at the end of Year 2. The more informed evidence base provided by two years of TVR monitoring for implementation of different intervention strategies over

different sub-divisions within the area is therefore going to be utilised within Years 3 and 4. A larger proportion of the badger population within sub-areas being switched to vaccination only will have a much higher level of immunity. Moreover, given that there will be soft boundaries between the vaccination only sub-areas and those that will remain on a TVR intervention will provide more resilience to any *M. bovis* infection challenges posed by these bordering sub-areas.

Badgers will be microchipped upon first capture so that vaccination status can be monitored but will also enable badger population monitoring (capture/recapture methodologies). A detailed examination will be carried out on each trapped badger after it is anaesthetised. The study provides a valuable opportunity to obtain a comprehensive range of samples from each trapped badger which may be analysed or stored for use in other projects.
Plucked hair samples may also be obtained from badgers which would enable badger genetic profiling. Whiskers (taken from dead badgers) may also be removed to facilitate stable isotope analysis on the whiskers for diet reconstruction. As badgers will be anaesthetised for blood sampling for testing (by the DPP test or suitable replacement test), the opportunity will be taken to obtain each badger's physical attributes (e.g. weight, condition, parasite burden, lactation status, injuries), which can then be made available to third parties. Note that badgers within a vaccination only sub-area (Years 3 & 4) would not be anaesthetised but simply scanned for presence of a microchip, vaccinated and released. (Only those found without a microchip would be anaesthetised to enable a microchip to be inserted and vaccination given). All procedures carried out on badgers will be detailed in agreed Standard Operating Procedures including any additional sampling for further laboratory analysis e.g. clotted and whole blood samples, swabs for *M. bovis* culture.

Badgers testing positive to the DPP test (or suitable replacement) will be submitted to a suitable laboratory for post-mortem examination/culture of *M. bovis* so that such isolates will be available for a potential project on *M. bovis* whole genomic sequencing along with cattle *M. bovis* isolates and those obtained from road traffic accident badger isolates.

The overall regionalisation pilot project aims to decrease *M. bovis* infection in both cattle and badgers, targeting a badger prevalence below 5%, a 50% drop in annual bTB cattle herd incidence, a 40% reduction in bovine reactor numbers, and improved biosecurity behaviours.

Key wildlife related research questions, amongst several others, include how different sub-area interventions affect annual badger *M. bovis* prevalence, how badger populations change in response and what evidence can refine closed-season dates. The use of geodatabases, Northern Ireland Farm Animal Information System (NIFAIS) cattle data, and structured behavioural assessment tools will create a multi-layered research dataset that supports robust, integrated data analysis.

The research pilot is also structured to generate a suite of peer-reviewed outputs, cross-border comparators, integrated data systems, and long-term behavioural monitoring. Ongoing collaboration with others allows both jurisdictions to advance a coordinated, evidence-based approach. Joint research will include AFBI studies on bTB genetics, drivers of farmer behaviour in relation to bTB related biosecurity measures, and eDNA; UCD work on badger movement, trap-ability, and diet; and DAFM cross-border studies comparing cattle bTB levels between NI and ROI sites.

This regionalisation pilot is fundamentally a research initiative designed to generate the evidence Northern Ireland has lacked for decades. By integrating cattle measures (targeted use of

measures already used within the NI wide bTB Eradication Programme), wildlife, and behavioural science, aligning with County Donegal, and applying adaptive methods informed by prior TVR experience, the project will deliver the robust evidence base needed to inform future policy and accelerate progress toward bTB eradication.

Although not an exhaustive list, specific wildlife outputs expected from the pilot project include:

Impact on annual badger M. bovis prevalence
While TVR was shown to be successful in significantly reducing the annual *M. bovis* prevalence in badgers (Arnold et al., 2021), it was a study in only one area so some form of replication of TVR will continue to build the evidence base for such an intervention. However, given the success of the previous TVR intervention in badgers, including the exponential decline in annual badger *M. bovis* prevalence and absence of social perturbation (O'Hagan et al., 2021), this study will monitor if it is feasible to accelerate the move to a vaccination only approach in appropriate situations. In this respect, it aims to take advantage of the spatial heterogeneity of *M. bovis* seroprevalence that was observed in the previous TVR study (Menzies et al., 2021). This is assuming that it also occurs in this study area which is thought to have a different badger demographics/lower badger density.
The characteristics of the DPP test were elucidated during the previous TVR study (Menzies et al., 2021) and these can be used to provide an estimation of annual badger *M. bovis* prevalence in this area with a before-and-after and trend statistical analysis approach being used to assess changes over time. If there is a need to use a suitable alternative test to DPP (in the event of any supply issue), then there will also be the need to characterise this test and the subsequent need for additional samples taken from the badgers.

Impact of badger demographics
Capture/recapture data from badgers will enable badger populations to be estimated annually to monitor for any changes; none were observed during the previous TVR project (O'Hagan et al., 2021). These data will enable monitoring of changes in badger social groups over the project timescale.
It is also proposed to GPS collar (with a customised drop-off system) a maximum of 10 badgers, clustered in one area (neighbour clans) in order to estimate territory size and contact rates across neighbour clans. This will be paired with a similar area in Co. Donegal, ROI (similar ecological conditions but heavy culling history).

Cattle bTB herd incidence in the intervention area will be monitored over time and compared with the rest of Northern Ireland. Levels of cattle bTB will also be monitored in the immediate area surrounding the intervention area. Scientific assessment will use before-and-after and trend statistical analysis approaches to evaluate changes over time while controlling for confounders (using multivariable logistic regression models).

- This research project also integrates into investments through the DAERA-Directed AFBI Research Programme, with the following FFPs current in review:
    - 25/T3/02 FFP - Bovine TB pathogen genetic surveillance in an intensive action intervention area
    - 25/T3/01 FFP - BASE bTB Behavioural Analysis of Societal and Economic Factors in Bovine Tuberculosis (bTB) Control.
    - 25/T3/12 FFP - MENSCH – Microbial eDNA Surveillance of Cattle Housing

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Benefits

Under Animals (Scientific Procedures) Act 1986, 5B (3)(d), the Department of Health is required to carry out a harm-benefit analysis of the programme of work to assess whether the harm that would be

caused is justified by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment.

To enable us to do that please set out the expected benefits of your programme of work; and explain why those benefits will be worthwhile. We need to understand:

- What data or product outputs will be generated by your programme of work
- Who will use those outputs (e.g. your group, other researchers, the pharmaceutical industry, clinicians, patients)
- How will the outputs be used
- The short-term, medium-term and long-term benefits

The following data will be generated by our programme of work:

- Badger vaccination status: Badgers will be microchipped at the point of first capture to facilitate long-term monitoring.
- Badger population status: microchipping will support population assessments using capture–recapture methodologies.
- Badger movements.
- Social group demographics: individual badger identification and georeferencing will enable badger movements and social group demographics to be monitored.
- Other non-invasive ecological studies on badgers can be performed e.g. use of camera traps to measure badger trappability and badger densities.
- A full suite of physical and health-related data will be recorded for badgers undergoing anaesthesia as part of blood sampling and diagnostic testing, including body weight, body condition, parasite burden, lactation status, and any observed injuries. In contrast, badgers located within vaccination-only sub-areas will not be anaesthetised; they will simply be scanned for an existing microchip, vaccinated, and released without further intervention.
- If evaluation of a new diagnostic test is undertaken, clotted and unclotted blood samples will be taken and tested under laboratory conditions. Tracheal aspirate samples, oropharyngeal swabs and swabs from bite wounds will also be subjected to bacteriological culture with the results of all of these tests being used to estimate the test characteristics and also the *M. bovis* prevalence in the badger populations. Clinical samples of urine and faeces may also be subjected to microbiological culture on media selective for *M. bovis* growth.
- Postmortem examination and culture for *M. bovis*: badgers removed during the TVR testing element of the study will be submitted for post-mortem.
- Sett locations, trap deployment, processing of trapped badgers during TVR: recorded in real-time on a geodatabase, similar to the system used during the previous TVR project (but using more up-to-date equipment and platform). Automated capture of badger identity and geolocation data will minimise transposition errors and hence provide accurate outputs for studying badger demographics and *M. bovis* seroprevalence estimates/densities.
- Cattle testing and movement data: routinely recorded on NIFAIS. Examples of such outputs would include annual bTB animal and herd incidence, annual number of bTB reactors, bTB herd breakdown duration and cattle movements into the area.
- Ecological data including proposed hair samples.

The outputs will be used by:

- The physical and health-related data on badgers may subsequently be made available to approved third parties.
- Any resulting isolates from postmortems will be retained for potential whole-genome sequencing projects, alongside *M. bovis* isolates obtained from cattle and from road-traffic-accident (RTA) badgers found within the study area.
- DAERA will analyse cattle herd and bTB parameters.
- Research institutes across UK and Ireland can utilise the ecological data for general badger ecological research studies/models.
- The project will generate a large amount of data and samples that will complement and be utilised within supplemental research projects to be conducted in DAERA and by collaborators (for example the AgriFood and Biosciences Institute (AFBI) in NI, the Department for Agriculture, Food and the Marine (DAFM) in ROI and University College Dublin (UCD) in ROI including:

- Using camera trap images to assist in the development of an Artificial Intelligence (AI) model for recognition of individual badgers, which will enhance the ability to estimate social group size and hence facilitate in obtaining more accurate badger population estimates (UCD).
- Badger trappability and density study using camera traps (UCD). By analysing video footage from the study region, the study aims to improve accurate monitoring of population estimates, and generating insight in key parameters like trappability, without invasive methods. This approach could provide detailed longitudinal data on badger populations, group size, and behaviour, supporting more precise epidemiological models.
- Studying badger movement and their interactions with other badgers and cattle using GPS collars (UCD).
- Stable isotope analysis of badger whiskers for spatial and temporal variation in badger diet (UCD).
- Cross border study; retrospective matched risk factor study of herd breakdown in ROI and NI, with the aim of assessing differences in herd risk associated with varying levels of wildlife intervention (UCD/DAFM/DEARA).
- Genomics of all *M. bovis* isolates of the study region (AFBI/UCD).
- Enhancement of an existing Susceptible–Infected–Recovered (SIR) model by incorporation of genomic data. The improved model will simulate disease dynamics under different intervention scenarios, supporting policy decisions; data from the Region will feed into the project (UCD/AFBI).
- BTB-MOSAIC project; adaption of an established ROI TB model for use in NI. Although not exclusively focused on regionalisation, it contributes to harmonising modelling approaches across jurisdictions (UCD/QUB/DAERA).
- Use cattle and pathogen genetic data to assess disease spread within TB-affected herds and support infectivity analysis. Led by AFBI, this project will sequence all *M. bovis* isolates from the study region. High-resolution genomic data will allow for detailed tracking of transmission pathways and clustering of infections, providing robust evidence for regionalised control strategies.
- Use . a herd-level "TB Advantage score" based on genotyping data, including data from the Region, and relate it to secondary bTB cases. Such a metric could become a valuable tool for risk stratification and targeted interventions (AFBI).
- Impact on annual badger *M. bovis* prevalence assessed using before-and-after and trend statistical analysis approaches to evaluate changes over time (DAERA project objective).
- Impact of badger demographics: capture/recapture data from individually identified badgers will enable badger populations to be estimated annually to monitor for any changes. Changes over time in badger distribution/social group stability can also be evaluated. (DAERA project objective).
- Impact on cattle *M. bovis* incidence/prevalence assessed using before-and-after and trend statistical analysis approaches to evaluate changes over time while controlling for confounders (using multivariable logistic regression models). (DAERA project objective).
- Change on farmer's biosecurity behaviour. Use of a quantitative biosecurity assessment application (HerdSafe) provides a tool for monitoring of a herd over time and will enable analytical comparisons between farms, as well as measurement of temporal changes. (DAERA project objective).

Given that this project is based on the observations in one area, any publications will necessarily be based on a 'before and after' analysis although components may be compared to other parts of NI.
Independent peer review of the badger interventions research will substantially strengthen assurance and provide insight to stakeholder concerns that could be proactively addressed through communication plans, and future collaboration.
Publications for peer review will be prepared on the following research areas:

- Effect of the proposed badger interventions on *M. bovis* prevalence
- Effect of the proposed badger interventions on badger demographics
- Evaluation of alternative lateral flow tests to DPP test, for bTB in badgers (only if required).

However, as noted from the previous TVR project, it is anticipated that other publications will be forthcoming particularly as the area will form a solid platform for other researchers to carry out subsidiary and collaborative research projects.
Other publications for peer review from the wider project (outside of ASPA):

- Effect of the use of targeted control measures on bTB cattle
- Assessment of changes in bTB risk behaviours by herd keepers.

In general terms, the overall project will generate robust data to produce credible evidence on the effectiveness of different measures which will inform future NI bTB policy to enable scalability and replication across NI. There will be reduced losses and improved herd productivity leading to more efficient agricultural production. This higher health status of livestock will also benefit domestic and international trade.

On the human side, it will lead to a reduction in zoonotic transmission risk from *M. bovis*. The reduced disease burden due to a reduction in bTB levels in wildlife, in the number of bTB infected cattle and bTB breakdowns in the study area and will mitigate against bTB transmission between/into herds and wildlife in the area. Moreover, there will be reduced farmer stress linked to bTB herd breakdowns and financial losses, increasing farmer wellbeing. Indeed, a significant number of calls to the NI Rural Support Helpline are in relation to bTB herd breakdowns.
The environmental impacts of the project include a reduction in non-productive livestock leading to lower emissions and a reduced carbon footprint as well as a reduction in the level of environmental persistence of the pathogen. It will result in a healthier badger population with respect to *M. bovis* prevalence and also provide open access ecological data for other researchers and policy makers to utilise.
Another project benefit will be the upskilling of private veterinary practitioners (PVPs) through training in biosecurity advice and enhanced disease control practices, which will form a platform for ongoing professional development and learning from study's findings. The project will facilitate knowledge-sharing through the formation of regional partnership groups fostering collaboration between farmers, vets, and government leading to stronger community engagement from all stakeholders. This proactive approach will demonstrate visible action on bTB improving confidence in government and programme delivery and helping instill a paradigm shift from bTB fatigue/apathy to a more 'can do' attitude across stakeholder groups.

Research outputs include:
<u>Short-term outputs (Years 1–2):</u>
• Baseline evidence package (badger prevalence, herd incidence, reactor trends).
• Data systems integrated (geodatabase & NIFAIS & biosecurity).
• Initial behavioural-insight findings on biosecurity and farmer participation.

<u>Medium-term outputs (Years 3–5):</u>

[redacted]

• Assessment of wildlife intervention impacts (including pre/post prevalence).
• Epidemiological analysis across cattle, wildlife and farmer behaviour.
• Interim performance metrics (herd incidence, reactors, biosecurity improvements).

Long-term outputs (Years 5+):
• Multi-year causal-impact evaluation of integrated control strategies.
• Longitudinal datasets on badger ecology and TB dynamics.
• Evidence-based assessment of regionalisation feasibility.
• Strategic roadmap for scaling and transferring lessons for the future.

Overall, the benefits of the project will be long term. Northern Ireland has committed to reduce bTB herd incidence by 2% by 2030, to halve current bTB levels by 2040 and achieve bTB eradication by 2050 and to accomplish this a better understanding of the impact of badger intervention on disease, alongside cattle and people measures. Delivering on these targets requires a clearer understanding of the impact of badger interventions on disease transmission, alongside continued improvements in cattle controls and human-mediated biosecurity measures. If this goal is accomplished, the long-term benefits for Northern Irish farmers will be remarkable, including a more stable and productive cattle sector, reduced economic losses associated with breakdowns, and increased confidence in trade and market access.
Even before 2050, there will be immediate gains through improved efficiency of the bTB eradication programme, reduced infection pressure within badger populations, and a lower risk of transmission to cattle. This will directly support better health and welfare outcomes for both badgers and cattle, with fewer animals affected by disease and associated management interventions. Reducing the prevalence of bTB in the national herd will also bring wider benefits. For cattle production and farm income, fewer herd restrictions and losses will improve productivity, profitability, and long-term sustainability. For badgers, lowering infection levels will reduce disease burden and improve overall population health and welfare. In addition, lowering environmental infection pressure will reduce risks to incidental hosts, including other wildlife and domestic animals. Finally, although the risk to the general public is relatively low, reducing bTB prevalence further strengthens public health protection and public confidence by minimising any potential zoonotic risk and supporting a healthier shared environment.

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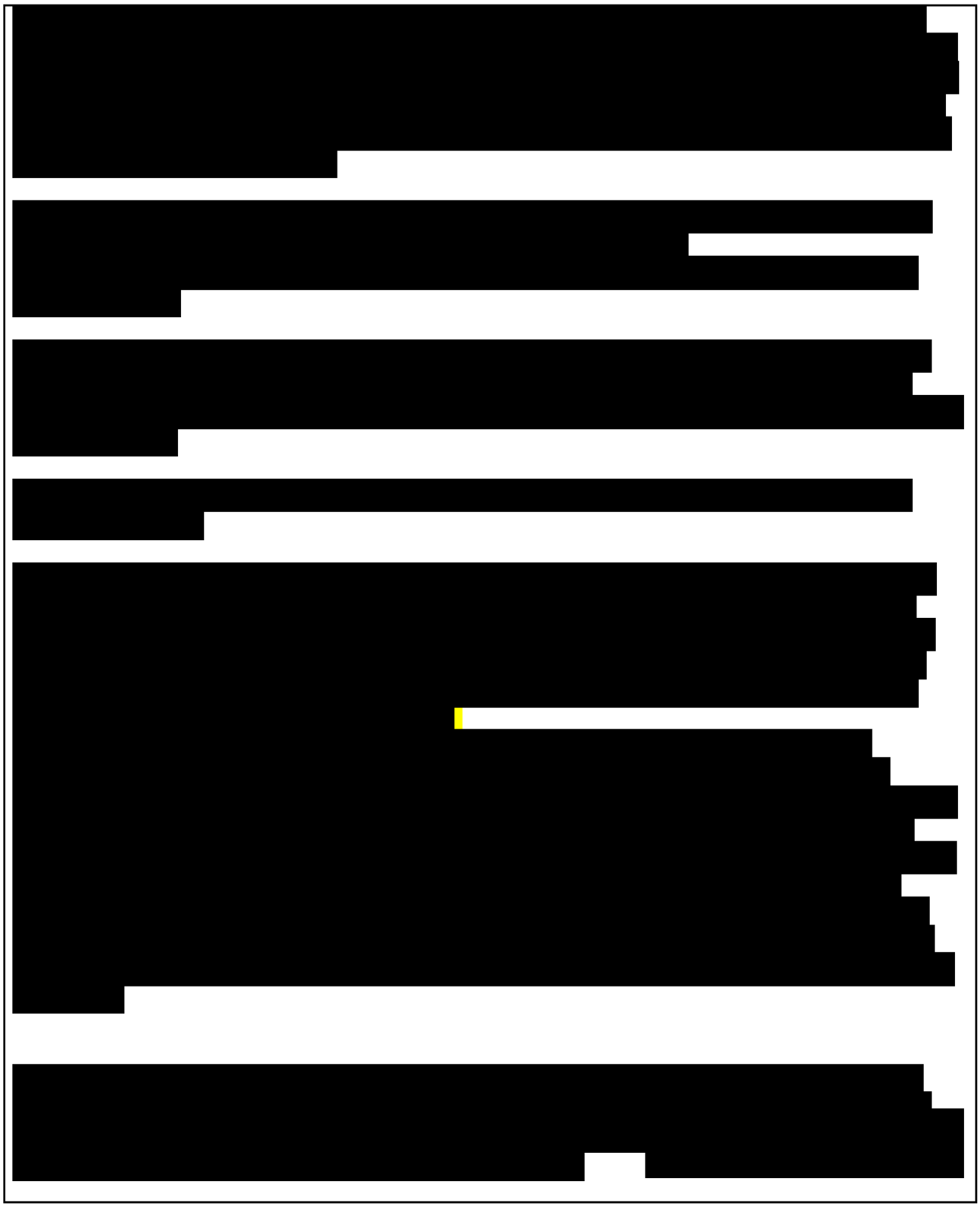

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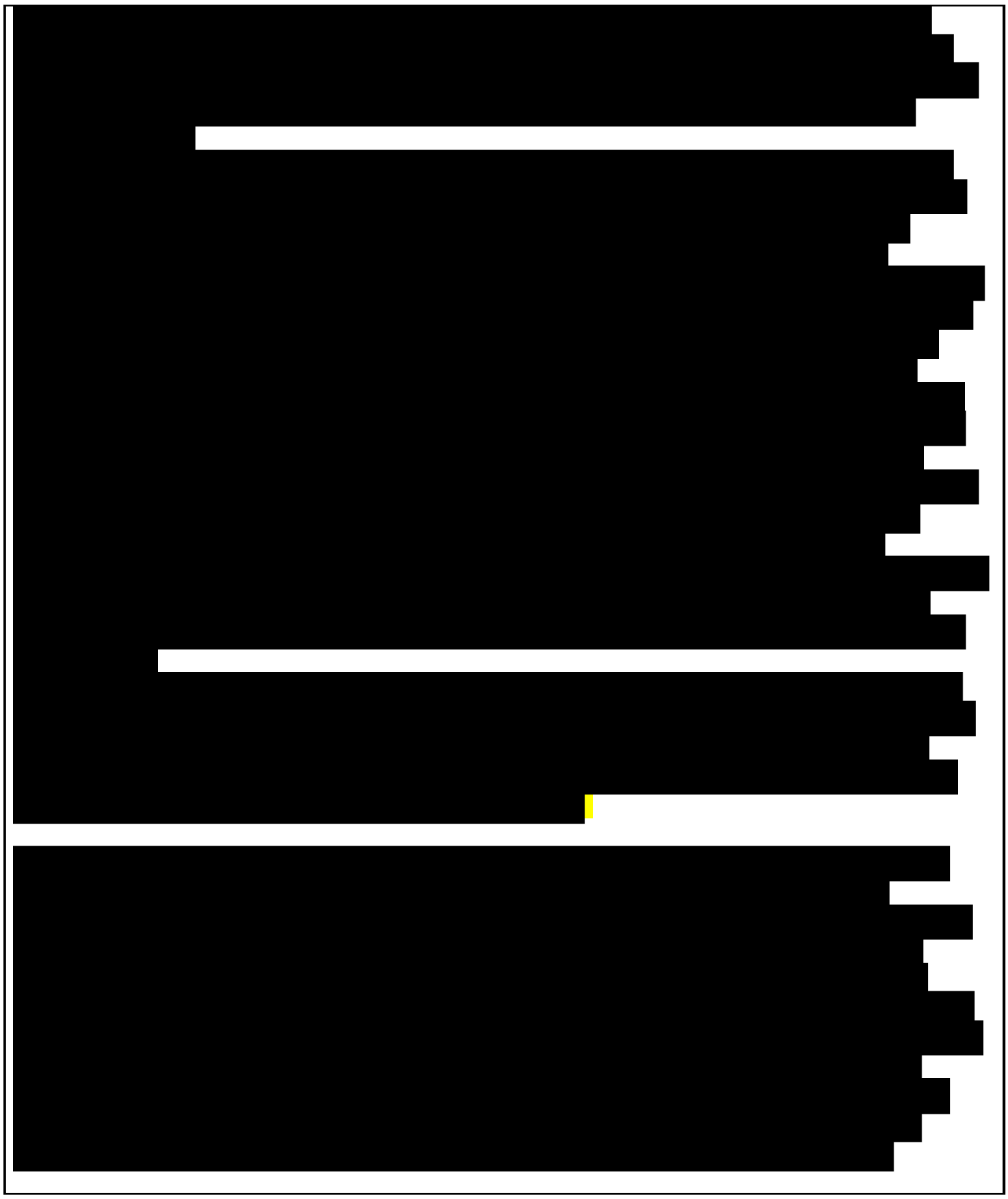

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NON-TECHNICAL SUMMARY (NTS)

NOTE: The Secretary of State considers the provision of a non-technical summary (NTS) is an essential step towards greater openness and requires one to be provided as part of the licence application in every case. You should explain your proposed programme of work clearly using non-technical terms which can be understood by a lay reader. You should avoid confidential material or anything that would identify you, or others, or your place of work. Failure to address all aspects of the non-technical summary will render your application incomplete and lead to it being returned.

This summary will be published (examples of other summaries can be viewed on the Home Office website at www.gov.uk/research-and-testing-using-animals.

Word limit; 1000 words

Project Title	Badger Intervention in the Northern Ireland (NI) Bovine Tuberculosis (bTB) Regionalisation Project
Key Words	Badger, Ecology, Bovine Tuberculosis, Vaccination, Regionalisation
Expected duration of the project	5 years

Purpose of the project (as in ASPA section 5C (3))

Purpose	
Yes/~~No~~	(a) basic research;
	(b) translational or applied research with one of the following aims:
Yes/~~No~~	(i) avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;
Yes/~~No~~	(ii) assessment, detection, regulation or modification of physiological conditions in man, animals or plants;
~~Yes~~/No	(iii) improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes.

~~Yes~~/No	(c) development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feedstuffs or any other substances or products, with one of the aims mentioned in paragraph (b);
Yes/~~No~~	(d) protection of the natural environment in the interests of the health or welfare of man or animals;
Yes/~~No~~	(e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;
~~Yes~~/No	(f) higher education or training for the acquisition, maintenance or improvement of vocational skills;
~~Yes~~/No	(g) forensic inquiries.

Describe the aims and objectives of the project (e.g. the scientific unknowns or scientific/clinical needs being addressed):

This project will provide data relating to the ecological and disease effects of testing live badgers for bovine tuberculosis (bTB) and removing diseased badgers while vaccinating and releasing test negative badgers (Test and Vaccinate or Remove-TVR). The TVR methodology has been tested previously, however this was in a different area of Northern Ireland (NI) and was trialled in isolation i.e. solely assessing bTB prevalence in badgers without implementing and assessing alongside cattle and people measures and so will add to the growing amount of scientific evidence that is available in this subject area. The hybrid TVR methodology, as described, has not been tested previously. Analysis of this data will be used to update government and industry on policy development moving forward as they attempt to eradicate this disease.

[redacted]

What are the potential benefits likely to derive from this project (how science could be advanced or humans or animals could benefit from the project)?

This project will provide ecological data on badger behaviours and their organisation, as well as their bTB levels, in this area over a five-year period. This data is of intrinsic value as it represents unique information on badgers within an area that has above average incidence of bTB in cattle.
BCG vaccination of badgers has been shown to protect them directly from becoming infected with *M. bovis*. It has also been shown to indirectly protect the cubs of vaccinated badgers.
The effects that this badger intervention approach has on overall bTB herd incidence in conjunction with additional cattle and people measures will inform debate around future bTB policy development.

Scientific data will be collected to inform disease transmission and economic modelling. Quantifying the effect of the badger intervention will allow modelling to be used with more confidence to assist the development of potential future intervention strategies.

Quantifying the costs and field logistics of this badger intervention approach will help inform future policy development.

Whiskers will be taken from dead badgers for investigation of diets by isotope analysis. This research helps improve understanding of badger diet/nutrition, supporting better conservation and management to enhance their health and survival.

Fertility control will benefit badgers as less dense populations are less likely to encounter and transmit infections to nearby badgers/setts.

What types and approximate numbers of animals do you expect to use and over what period of time?

Badgers (*Meles meles*). Based on current badger population estimates and previous cage capture rates, up to 450 unique badgers will be captured per year over the 5 years.

[redacted]

In the context of what you propose to do to the animals, what are the expected adverse effects and the likely/expected levels of severity? What will happen to the animals at the end?

The procedures applied to badgers in this project are: animal capture by cage-trap and cage-side welfare assessment with release of badgers <2kg without any further processing, anaesthesia and detailed welfare assessment, attaching a collar to the animal, obtaining a blood sample, micro-chipping, collection of small hair samples, intra-muscular injection with *Bacillus Calmette–Guérin* (BCG) vaccine or euthanasia if test-positive, and intra-muscular injection with a fertility vaccine if required. Other samples that may be obtained from anaesthetised badgers include hair samples, tracheal aspirates, oropharyngeal swabs, urine sample, rectal swab or enema for faecal samples.

In terms of adverse effects, animals may get stressed, react to anaesthetics, have minor temporary bruising / abrasions and experience momentary discomfort. It is expected that any adverse effects will be temporary and not cause any long-lasting pain or distress. Any injuries will be recorded with cage injuries being specifically recorded. Other injuries will also be recorded separately including any granulomas caused by the fertility vaccine.

Badger cages will be checked as soon as practicable after dawn and all badgers processed as quickly as possible to minimise time caught during daylight hours.
All captured badgers will be health and welfare assessed by a veterinary surgeon cage side. Only animals that are well enough and >2kg in bodyweight will undergo any procedures. Those that are smaller or considered not suitable will be immediately released.

Location collars will be fitted to up to 10 badgers within a sub-area of the whole study area. With collaring there is a risk of long-term skin wounding. This will be mitigated by using collars with a drop-off mechanism and only badgers heavier than 8 kg and a cranial circumference of at least 1 cm more than the neck circumference, will be deemed suitable to receive a collar.

As badgers are being anaesthetised, there is potential for overdose or adverse reaction as for any general anaesthetic. This will be mitigated by wide safety margin of the drugs used and the presence of trained and experienced staff using weight related dosage charts and animals will be under the care of a veterinary surgeon. If any animal shows signs of distress (e.g. laboured breathing) then the effects of the anaesthetic can be reversed using an injectable reversing agent. Animals will be monitored continuously throughout induction and while under anaesthesia.

A veterinary surgeon will be available during badger anaesthesia and sampling procedures to observe any reactions and determine any remedial actions.

At the end, badgers that test negative to the bTB test will be released back into the wild at the point of capture immediately after recovery from anaesthesia. Badgers that test positive to the bTB test will be euthanised humanely by overdose of anaesthetic while still under anaesthesia

[redacted]

Application of the 3Rs

Replacement

State why you need to use animals and why you cannot use non-protected animal alternatives

Replacement

It would not be possible to meet the scientific objectives of the project without the use of live badgers in their natural environment. A reduction in the incidence of bTB in badgers can be achieved through the vaccination of live badgers, but the bTB incidence will also be reduced by the selective killing of bTB infected badgers. A reduction in population density is an additional measure in reducing bTB transmission but it cannot be achieved without fertility controls when combined with selective killing.
BCG vaccination of badgers has been shown to protect them directly from becoming infected with *M. bovis* and so is of direct benefit to those in this study area. It has also been shown to indirectly protect the cubs of vaccinated badgers. The project will allow the collection of detailed information which will enable the creation of valid epidemiological models to inform future badger models, cattle and on-farm biosecurity controls. This collated information will guide the development of better policies bespoke for the environmental factors specific to Northern Ireland.

Reduction

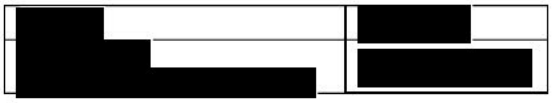
Explain how you will ensure the use of minimum numbers of animals

Reduction

A single study area of 235km² has been outlined in design mandate so badgers will only be captured in this area. Up to 450 badgers per annum are required to provide data for scientific research. Only test-positive badgers will be removed minimising the risk of TB transmission to other species while test-negative, uninfected badgers will be protected through vaccination.

Blood samples will provide enough serum for an archive sample to also be stored (which can be used for evaluation of other TB detection tests if required). These, along with other samples collected may be used to carry out further tests or to test new diagnostic methods as required.
The use of GPS collars on 10 badgers in adjacent social groups will enable assessment of badger-badger connectivity and will provide sufficient data for this purpose.

Refinement



Explain the choice of animals and why the animal model(s) you will use are the most refined, having regard to the objectives. Explain the general measures you will take to minimise welfare costs (harms) to the animals.

Refinement

The choice of species and study design has been determined by badger involvement in the epidemiology of bTB. The majority of the methods used are those that have been used in other badger studies.

Each sub-area in the region will be subjected to a 3-week trapping cycle which will involve 1 week of survey for badger activity and cage deployment, 1 week of pre-baiting of cages followed by a third week involving four nights of baiting and setting of traps. Peanuts will be used as bait. Trapping will occur from July to late October. Cage traps will be of sufficient size for large badgers, constructed from square 8- gauge mesh and have no sharp edges and will have no sharp edges. The traps will be triggered by a twine trip line when a badger pulls on a stone to reach bait at the back of the trap. This releases the trap door, which is then held in place by a brace mechanism. Cages set for trapping will be checked within 2 hours of sunrise and tripped upon inspection then are re-set for capture during late afternoon. Cages will be placed in shaded locations as much as possible and traps will not be set if any official weather warning is issued. These sheltered areas will help to shade from the sun during warm periods and, will be in a location close to natural trees or hedges to protect during periods of wind and rain. Recovery boxes are available also for the badgers' post recovery if indicated by the vet assessment.

All captured badgers will be health and welfare assessed by a veterinary surgeon. Each captured badger will be scanned to record any existing microchip identification number and thereafter checked to see if they had been previously captured during the calendar year. Temporary markings (clip mark and stock marker) will be used to ensure rapid identification if recaptured within short timeframe. If identified as a recapture, its location will be recorded, and the badger will be released if it is observed to be in good health; and sick or injured badgers will undergo more thorough investigation by a vet, which may require the animal to be anaesthetised.

Badgers will have a pre and post anaesthetic assessment by a vet and will be monitored throughout anaesthesia and during recovery. Post recovery as mentioned the badgers will be monitored in the previously positioned sheltered cages which can be covered to help prevent excess heat loss during this phase.

Collars being used weigh 170g, they will only be applied up to 10 badgers where they are found to equate to not more than 2% of the animal's body weight. Badgers chosen for collaring will be those that meet the required weight and neck: head circumference measurements for a suitable fit as mentioned. Collars are designed to drop off naturally in 6-8 months.

If faecal samples are required, then preference will be given to using faecal samples available from the cage rather than using swabs or enemas.

Badgers will be released from the location of their capture (i.e. within their normal social group environment) with cages being placed in shaded areas as much as possible.

Specific training in the techniques to be used will be undertaken by all personal licence holders and standard operating procedures will be in place. Veterinary surgeons will be available and have oversight of all procedures during trapping weeks so animal suffering and welfare assessment will be covered by Animals (Scientific Procedures) Act 1986 (ASPA) and Royal College of Veterinary Surgeons (RCVS) guidelines.