A review of the international evidence for an interrelationship between cattle and wildlife in the transmission of bovine tuberculosis

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Executive summary

This review is to assist Defra to address the growing problem of bovine TB (bTB) in Great Britain (GB) and allow Government to re-examine bTB control policies.

Sir John Krebs carried out a comprehensive study of bTB in cattle and badgers and reported in 1997 (the "Krebs Report": Krebs *et al.*, 1997). He and his group established that there was very strong qualitative evidence for a link between cattle and badgers in the transmission of bTB. He recommended that a complex replicated experiment be set up to establish the quantitative relationship in disease transfer between cattle and badgers. This experiment, known as the Randomised Badger Culling Trial (RBCT) was commissioned in 1998, and is due to cease in 2006 and finally report early in 2007. The RBCT was designed and is being monitored by the Independent Scientific Group on Cattle TB (ISG), established by Defra.

This report reviews the available outputs of the ISG and other scientific literature and reports on bTB in cattle and wildlife, concentrating on material produced since 1997 that presents new knowledge about interactions between cattle and wildlife (especially badgers) in disease transmission and/or presents evidence for; evidence against; or uncertain evidence for culling badgers as a bTB (in cattle) control policy. Specifically pertinent to the question of badger culling, we review material covering aspects of badger ecology and behaviour that are relevant. As well as the RBCT in GB, we review results of badger culling trials in the Republic of Ireland (RoI).

Already, from Australian experience, Government has learnt that elimination of a wildlife host (feral Water Buffalo) needs to be followed by a long and extensive programme of cattle testing, slaughter, movement control and public awareness campaigns before bTB is eventually eradicated. And from New Zealand experience, population reduction of the wildlife host (possums) does not by itself reliably control bTB in cattle. In both Australia and New Zealand, Government was dealing with feral reservoirs of bTB rather than indigenous wildlife species, as is the case with the badger in this country and there was less difficulty in getting public support for control of what are considered as pests. The situation is different in the United Kingdom (UK) and RoI where the badger is an indigenous species of ecological significance and there is public resistance to culling badgers as a disease control measure, also, there are implications with regard to the Bern Convention to which UK is a signatory. On the other hand, farmers, particularly those in south west England, where bTB is endemic in the badger population and the badger-cattle bTB link is most firmly established, want a Government policy that controls bTB in the badger population as well as in the cattle population. The National Farmers Union (NFU) has made proposals to Defra for badger culling policies in the short term, with the long term proposal that vaccines against bTB should be developed for badgers so that a culling strategy can be replaced by one of vaccination.

The main findings from this review can be summarised as follows:

1) Background

Bovine tuberculosis continues to increase in British cattle, both in numbers of herds affected, and in geographical areas involved. Spread to previously unaffected areas of GB has been caused by long distance movement of infected cattle. In areas such as south west England, where bTB breakdowns are common in the cattle population and disease is endemic in local badgers, molecular studies show that both cattle and badgers are infected with identical strains of *M. bovis*, indicating a connection between cattle and badgers with regard to transmission of the disease.

2) Bovine TB in cattle

The increase in prevalence of bTB in the cattle population, coupled with the large numbers of cattle movements, both locally and over long distances, provide increased opportunities for transmission of bTB between herds. In Northern Ireland (NI), around 20% of breakdowns have been attributed to movement of purchased cattle onto farms, and around 30% to spread from infected to neighbouring farms across farm boundaries, implying, in NI at least, the importance of these two routes of transmission.

Spread of bTB within herds is slow because of the long period between infection and commencement of excretion of tubercle bacilli by an affected animal and the likelihood that an infected animal may be removed from the herd following a herd tuberculin test before it has had the opportunity to transmit infection. Cattle are most likely to be infected by other cattle by inhalation of infected aerosols. This is most likely to occur when cattle are housed and share the same air space.

There is continued need for regular herd testing with removal of reactors and for restriction of movement of cattle from areas where bTB is well established to areas where both the cattle and badger populations are currently free from the disease.

3) Diagnostic tests in cattle

Reliance on the skin test with a sensitivity that can be as low as 70%, can lead to herds with few infected animals not being detected and where a herd test is positive, not all infected animals will be identified for removal. Though the test is imperfect, its use as a pre- or post-movement diagnostic test would help to control infection spreading between herds and into previously uninfected areas.

Until there are more sensitive and reliable diagnostic protocols for bTB in cattle, it is impossible to quantify either cattle to cattle, herd to herd, or suspected badger to cattle transmission. The development for use in GB of the gamma interferon (IFN) test provides the opportunity to introduce more sensitive testing protocols by using the IFN test in parallel or in series with the skin test.

4) Bovine TB in badgers

There is clear evidence that the badger population supports *M. bovis* in parts of the UK and the RoI. Many infected badgers show little clinical evidence of disease, neither do they excrete the organism. However, a small proportion become terminally ill and excrete *M. bovis,* principally from the respiratory tract, and also from infected wounds, in urine and in faeces.

The badger population of UK appears to have increased in the 1990's but stabilised since 2000. Badgers regulate their population according to the capacity of the environment through self-regulation of breeding. Badger density differs between GB and RoI.

Badgers live in loose social groups. Each group can use several setts and establishes and defends a territory. However, movement of badgers between social groups is not uncommon. There is movement of both males and females between groups. Following badger removal operations, it has been noted that there are increased movements, breeding activity and aggression within badger populations, the so-called "social perturbation" effect. While there is no correlation between badger density and prevalence of *M. bovis* infection, increased incidence of disease in badgers has been associated with increased movements within the badger population. For this reason it has been proposed that culling operations, through causing social perturbation, increase rather than diminish prevalence of bTB in the badger population.

5) Diagnosis in badgers

Post mortem examination and culture is performed on badgers that are culled or killed in road accidents but is a lengthy procedure.

Culture of material from live badgers is unsatisfactory because infected animals excrete *M. bovis* only intermittently.

An ELISA (Brock) test correctly diagnoses less than 70% of infected badgers. Trap-side tests, where a result can be obtained at point of capture, are being developed and tested but as yet, as with the Brock test, there are problems of low sensitivity. There are potential opportunities to use 'trap-side' testing of badgers to improve targeting of badger culling as a method of bTB control.

6) Transmission of bTB from badgers to cattle

Badgers occupy an ecological niche that brings them into both direct and indirect contact with cattle.

M. bovis has been transmitted from badgers to cattle under experimental conditions. The observed behaviour of badgers shows that there is opportunity for this transmission to occur in field conditions. However, field studies have not been able to fully quantify the role of badgers in cattle TB breakdowns.

Badgers territories often include fields where cattle graze which they visit to search for earthworms that are part of their diet. They often establish latrines in grazing areas and may also contaminate them with urine and discharges. More importantly (because bTB infection has been shown to occur more commonly when cattle are housed), studies have shown that badgers visit farm buildings to forage for food and diseased badgers may take up permanent residence in farm buildings. There is evidence of them contaminating areas to which cattle have access, including feed troughs. This behaviour provides an opportunity for infected badgers to transmit *M. bovis* to cattle. These risks can be mitigated by biosecurity measures to keep badgers out of farm buildings and grazing areas and to keep cattle away from areas contaminated by badgers.

The finding in a study in Gloucestershire that over half of badgers found dead or *in extremis* in farm buildings were infected with *M. bovis*, compared with only 21% infected of badgers in the same vicinity which had been killed by road accidents supports the proposal for biosecurity measures to keep badgers out of farm buildings.

7) Spatial association between infected badgers and infected cattle

In England, a close spatial association has been demonstrated between the strains of *M. bovis* (typed by spoligotype) found in badgers and the strains found in neighbouring infected cattle (1-2km). This is strong supporting evidence that transmission occurs between the two species. This is in agreement with results of spatial analysis of *M. bovis* (by RFLP type) in RoI presented in 2000. More recently, a spatial analysis of strains of *M. bovis* (RFLP types) in RoI was not able to show a significant spatial association of RFLP types between badgers and cattle, neither were

RFLP types clustered within the badger population. The results indicated that there is a lot more movement within the badger population in RoI than there is in GB. This may indicate a general difference in behaviour between British and Irish badgers, or that the badger population of RoI suffers more social perturbation than that in GB, perhaps due to the higher frequency of badger removal operations.

8) Bovine TB in other wildlife species

bTB infection has been shown to occur in many wildlife species in UK, although prevalences are generally much lower than found in badgers. Though currently infected with lower prevalence than the badger, wild deer, notably fallow deer in south west England, are increasing in numbers and range and could be an alternative reservoir of infection, posing a potential risk to cattle because of the relatively high probability of contact between deer and cattle. In other countries, *M. bovis* exploits other wildlife/feral reservoir hosts, notably the possum in New Zealand and in South Africa it has recently adopted the African Buffalo as a reservoir host.

Studies of bTB infection in wildlife in GB have mostly concentrated on the badger. In view of the dynamics of population change of wildlife species and the ability of *M. bovis* to exploit different hosts, studies of bTB in wildlife hosts other than the badger, particularly fallow deer, should continue in UK.

9) Lessons from other countries

Australia provides a good example of eradication of bTB through co-ordinated control activities. There was a reservoir of infection in feral water buffalo. This was easily eliminated as the animals were confined to a small area. However, it took a further 30 years of tuberculin and IFN testing of cattle with slaughter of infected herds, complemented by rigidly policed and enforced cattle movement controls, and full farmer support, before bTB was finally eliminated from the national herd.

In New Zealand, the feral possum population is an important reservoir host for *M. bovis* and a possum culling programme is part of the bTB control strategy. However, it is expected that population reduction will not achieve eradication of *M. bovis* from the possum population and efforts are being directed towards the development of an oral vaccine for delivery to possums, and for cattle, test and slaughter with movement controls, which includes zoning (restriction of movement between 'hot-spot' zones and clean zones.

In the RoI, like GB and NI, the badger has been implicated in the spread of *M. bovis* to cattle. Following intensive control measures, including annual skin testing of cattle with removal of reactors and movement control, bTB has been reduced to a low prevalence in cattle in the RoI (only 0.4% of tested cattle reacted to the skin test in 2002). However, trials of badger culling have been undertaken, and badger removal operations are now part of RoI bTB control policy. But, in the long term, the RoI is committed to the development of a badger vaccine to control the disease in its wildlife reservoir.

In GB, where the frequency of herd testing with the tuberculin skin test is determined by previous information on presence of bTB, herd testing is not being used optimally as a bTB surveillance tool, compared, for example, to its use on an annual basis in RoI and NI. In NI, following very strict application of an annual skin testing regime, giving no opportunities to delay herd tests and testing herds contiguous to breakdown herds, the number of herd breakdowns has reduced by 40%. It is perhaps reasonable to suggest that stricter testing has influenced this trend, although a number of other factors probably also played a part. It should also be noted that the incidence has been decreasing in NI since early to mid 2003.

10) Field trials to study the effect of culling badgers on cattle TB

Recent trials in RoI have concluded that widescale culling of badgers can lead to a reduction in cattle herd breakdowns. But there are serious issues that limit generalisation of this result to GB, and also issues of practicality in the GB situation.

In RoI, culling badgers was first shown to be an effective strategy through the East Offaly Trial in which a beneficial effect of culling badgers on bTB herd breakdowns was demonstrated. This was followed by the Four Areas Trial to demonstrate the effect of badger removal at a number of sites representing a wider range of farming environments. Again, a decrease in herd breakdowns was observed in the areas where badgers were proactively culled, compared to reference areas where there was limited reactive culling. Criticisms of these trials have been that there have been no control areas for comparison where no culling took place and purposive, rather than random selection of trial sites was made which could have introduced bias; perturbation of the badger populations through culling was neither considered nor discussed. It has also been pointed out that the results of these trials cannot predict effects of culling in the British situation because of differences of ecology and behaviour between Irish and British badgers and because the culling methodology adopted in RoI could not be applied in GB. In RoI, despite the results of the East Offaly and Four Areas Trials, government policy is to replace culling by vaccination of badgers as soon as an efficient vaccine is developed.

In GB, at the instigation of the Krebs Report, the ISG was set up to study the role of badgers in bTB and they devised the RBCT to test policies of proactive and reactive badger culling. In this trial, sites have been selected and distributed randomly and proactive and reactive cull sites are compared with control sites where no culling takes place. The trial commenced in 1998 and was designed to continue for five years. However, activities in the field were delayed, particularly by the FMD epidemic in 2001. Consequently, in order to produce a conclusive result, the trial is now due to finish in 2006.

In 2003, the ISG presented surprising interim results of the reactive badger cull component of the RBCT. Rather than producing a positive effect, i.e. a reduction in incidence of bTB breakdowns of herds in the reactive cull area, it was estimated to lead to an increased incidence in herd infections (with wide confidence limits). As a result, the reactive cull component of the RBCT was abandoned. Others argued that the reactive cull data was analysed too soon for any changes in herd breakdown rate to be attributed to badger culling, bearing in mind the time needed between transmission of disease to cattle and disclosure of infection through testing or clinical disease. However, further analysis of data collected beyond the time of abandonment of the reactive culling, presented in the most recent report of the ISG, appears to confirm the lack of a reduction effect of reactive badger culling on herd breakdown rate.

It has been suggested that the adverse effect of reactive badger culling described could be due to the ‘social perturbation’ effect which has been observed following culling exercises, leading to spread of bTB in the badger population and more opportunities for *M. bovis* to spread to cattle.

In a survival analysis of reactive cull data which looked at individual farms in the reactive areas only, survival time to a herd's next breakdown was calculated for farms where, amongst other variables, (a) no badgers were culled (mostly because the trial was halted before the cull could be implemented), (b) badgers were culled but were bTB culture negative, and (c) badgers were culled and at least one was culture positive. Several variables were significant in the final multivariable model: survival time was shorter for larger herd size and for herds with higher numbers of previous breakdowns. With regard to reactive culling, there was significantly increased survival time in herds associated with culled badgers that were culture negative, and significantly increased survival time (though to a lesser degree) in herds associated with culled badgers, some of which were culture positive, when compared to herds where no badgers were culled. These results appear to contradict those of the first reactive cull analysis where reactive cull areas were compared with no cull areas. One might suggest that, whilst individual breakdown farms may see a medium-term benefit in terms of a longer time before re-infection (the result found in the second analysis), reactive culling, leading to perturbation of the badger population and spread of bTB between social groups, has the end result of spreading disease more evenly among all the cattle farms in a wider area (result of the ISG analyses).

With regard to the results of the proactive cull compared to the no cull areas, results will not be available until after the trial is concluded in 2006. There appears to be some concern that the trial may not reveal statistically significant differences between proactive cull and no cull areas. However, that in itself would be a conclusive result, provided the trial has collected sufficient data to demonstrate a significant difference if one had existed of sufficient size to be important.

11) Simulation modelling of bTB control

Results of modelling have shown that testing badger groups annually, and conducting a badger removal operation on those groups with positive animals, could be a successful strategy in terms of reducing cattle herd breakdowns, but a test sensitivity greater than that currently available is required.

Modelling is a potentially valuable tool in policy decision support but care must always be taken regarding data uncertainty and assumptions in models.

12) Vaccination

The results of this review indicate that all countries with a bTB problem where there is a wildlife/feral reservoir are interested in development of a vaccine, particularly for use in the wildlife/feral reservoir. In this respect, it is important that Defra is continuing to fund collaborative research into the development of vaccines for both cattle and badgers.

In wildlife, work in New Zealand and RoI is focussed on development of a live BCG vaccine to be delivered orally. In GB, efforts have now also been directed towards producing a BCG vaccine and a field test has been planned for a parentally delivered BCG vaccine in badgers. This vaccine is derived from a commercially produced BCG, licensed for human use and meeting Good Manufacturing Practice (GMP) standards. With this background, it should be easier to eventually license the product for field use.

13) Final conclusion

The summary table in section 8 of this review shows strong evidence that the badger population of Britain can provide a reservoir of infection for *M. bovis*. There is also good evidence for indirect contact between badgers and cattle and contamination of fields and cattle housing and feed stores and troughs by excreta and discharges from infected badgers. Molecular studies also reveal that cattle and badgers in the same vicinity share *M. bovis* strains, indicating that there is exchange of infection between them.

Control strategies which include a culling policy have been tested in other countries, and in RoI two trials have demonstrated a reduction in bTB breakdowns in herds in areas where badgers have been removed. However, since the Krebs Report (1997), studies of badger culling exercises in Britain have so far failed to provide any clear indication that culling badgers, either reactively or proactively, has a useful effect on the incidence of herd breakdowns. On the contrary, there is evidence that prevalence of bTB in the badger population is not related to density of badgers and culling them leads to 'social perturbation'. This can result in increased movements of badgers with further dissemination of the disease in the badger population which may lead to more, rather than less, herd breakdowns. This remains an area of uncertainty because models have indicated that in Britain, a reduction in herd breakdowns should follow badger culling exercises.

The summary table also shows evidence for transmission from herd to herd not involving badgers, both locally and over long distances. This, together with experiences from other countries, emphasises the need for effective and comprehensive control measures within the cattle population. Because a culling policy, as it can be implemented in Britain, has not yet been demonstrated to be effective, it is important that research into other strategies, such as separation of badgers from cattle through biosecurity measures, and vaccination of the badger population should be continued.

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Abbreviations used in the text

AHCS	Animal Health Computer System (Republic of Ireland)
BCG	Bacille Calmette-Guérin
bTB	Bovine tuberculosis
CMMS	Cattle Movement Monitoring System (Republic of Ireland)
CSF	Classical Swine Fever
CSL	Central Science Laboratory
Defra	Department of Environment, Food and Rural Affairs
ELISA	Enzyme-linked Immunosorbent Assay
ERAD	Eradication of Animal Diseases Board (Republic of Ireland)
FMD	Foot-and-mouth Disease
FMQ	Farm Management Questionnaire
GB	Great Britain
GMP	Good Manufacturing Practice
HIV/AIDS	Human Immunodeficiency virus/Acquired Immunodeficiency Disease Syndrome
IFN	Gamma interferon
ISG	Independent Scientific Group on Cattle TB
LTA	Lymphocyte Transformation Assay
MAFF	Ministry of Agriculture, Fisheries and Food
NFBG	National Federation of Badger Groups
NFU	National Farmers Union
NI	Northern Ireland
PPD	Purified Protein Derivative of tuberculin
RBCT	Randomised Badger Culling Trial
RFLP	Restriction Fragment Length Polymorphism
RHMS	Reactor Herd Management System (Republic of Ireland)
RoI	Republic of Ireland
RTA	Road Traffic Accident
SAT	South African Territories
SVS	State Veterinary Service
TB	Tuberculosis
UK	United Kingdom
VLA	Veterinary Laboratories Agency
VLR	Visible lesion rate

1. Background

1.1 *Mycobacterium bovis* is a zoonosis. Infection in human beings has become rare in most countries following the introduction of heat treatment of milk before consumption. Infection is now more likely to be contracted through direct contact with infected cattle that are excreting *M. bovis*, and is therefore an occupational hazard of people in the livestock industry, such as livestock keepers, veterinarians and slaughtermen. However, the HIV/AIDS pandemic introduces a new dimension, as the compromised immunity renders human beings more susceptible to all forms of tuberculosis (Grange, 2000).

1.2 In Great Britain (GB), though bovine tuberculosis (bTB) affects a small proportion of the national herd (6% of cattle herds sustained a bTB breakdown at some point in 2003), the percentage is much higher in so-called ‘hotspot’ areas: 95% of confirmed new incidents took place in south west England, west Midlands-Powys-Monmouthshire, Staffordshire-Derbyshire and south west Wales. The long-term trend is an increase in numbers of new herd breakdowns at an average rate of 18% per year. Recently, bTB has been spreading to areas where previously it has not been a problem, notably Cumbria and north east England. The vast majority of confirmed bTB incidents in this area have occurred in cattle herds restocked after Foot-and-mouth disease (FMD), or can be attributed to bought-in infected cattle (Defra, 2005).

1.3 Against this background of increasing bTB incidence in British cattle is the knowledge that the disease is endemic in the badger population, particularly in areas where the disease is most prevalent in cattle. Knowledge of the part the badger plays in the epidemiology of bTB, and the role of the badger in spread of the disease to the cattle population, is essential to policy makers in Defra in order for them to introduce and implement appropriate and effective control measures.

1.4 Since the genome of *M. bovis* has been sequenced, scientists have been able to show that the bTB epidemic in GB is being driven by a number of clonal expansions, which cannot be explained by random mutation and drift alone (Hewinson *et al.*, 2005; Smith *et al.*, 2003). The ability to identify these clonal isolates of *M. bovis* (for example as spoligotypes) from cattle and wildlife, in space and time, is creating new knowledge about the epidemiology of bTB and the interrelationships between disease in cattle and wildlife.

Analytical Summary Box 1

Bovine tuberculosis continues to increase in British cattle, both in numbers of herds affected, and in geographical areas involved. Spread to previously unaffected areas of GB has been caused by long distance movement of infected cattle. In areas such as south west England, where bTB breakdowns are common in the cattle population and disease is endemic in local badgers, molecular studies show that both cattle and badgers are infected with identical strains of *M. bovis*, indicating a connection between cattle and badgers with regard to transmission of the disease.

2. Bovine tuberculosis in cattle

Factors associated with transmission of bTB to cattle

2.1 According to the Independent Scientific Group on Cattle TB (ISG), there is growing evidence that emphasises the need for a greater focus on reducing cattle-to-cattle transfer of bTB in UK (ISG, 2005a).

2.2 In a seminar on bTB for MPs (Defra, 2004a), Richard Clifton-Hadley reported that 20 years ago there were about 100 confirmed cases of bTB a year or less. At that time, looking at the reports of those cases, he considered that about 80% could justifiably be put down to badger origin, because there were closed herds and no cattle movement on or off the farm. The situation now is entirely different. Data sets on cattle movements are available that show that large numbers of cattle are moving, especially locally. Although there are long-distance movements from south west to north, for example, they are fairly few compared with local movements. The situation has changed: there is a weight of infection in the south west and midlands that was not there previously. Consequently, there is a lot more movement of infected cattle. The short-term gains are far greater from controlling cattle movement than from killing badgers (Defra 2004a).

2.3 Denny and Wilesmith (1999) describing their case-control study, suggested that in Northern Ireland (NI), purchased cattle probably accounted for 15-20% of herd breakdowns (this compares with 23% estimated by Government veterinarians in NI). They used a questionnaire for their case-control study of risk factors for bTB associated with farm boundaries, neighbours and wild life. Questions that were asked included the number and nature of farm boundaries, number of neighbours and their bTB history, number of hedgerows, presence of badger setts, whether badger carcasses had been found on the land and presence of deer. Case farms that ascribed infection as brought in by purchased cattle were excluded from further analysis. In the remaining farms there were two main associations with bTB breakdowns: presence of badgers (approximately 40%); contiguous neighbours who had had confirmed bTB breakdowns (approximately 40%). The aetiological fraction for neighbouring cattle with confirmed bTB of 40% implies that the spread of bTB from herd to herd, across farm boundaries, may play a significant role in the epidemiology of bTB, at least in NI.

2.4 Menzies and Neill (2000) analysed data from veterinary field investigation reports of bTB herd breakdowns in NI. They suggest that 25% are due to purchase of diseased cattle, 47% to local spread from diseased cattle and 2.5% were attributed to wild life sources with a further 24% where the source could not be established.

2.5 White and Benhin (2004) investigated the effects of agricultural and farm-management characteristics on the occurrence and scale of bTB in cattle in south west England (1988-1996) using logistic and linear regression. They found that factors relating to the existence of previous infection in cattle and the management of cattle and badgers are all linked to the incidence of the infection-but those related specifically to the management of cattle are of overriding importance in determining the scale of the problem. They suggest that improvements to the procedure for testing and managing bTB in cattle, reductions in cattle stocking density, a greater human input in herd management and more-carefully targeted badger culling all might contribute to reducing the incidence and/or number of herd breakdowns.

2.6 In parallel with the Randomised Badger Culling Trial (RBCT) in GB, a matched case-control study (TB99) has been running to identify and quantify risk factors, particularly in relation to cattle husbandry and environmental practices, which may predispose farms to have bTB breakdowns. The study, mainly confined to the RBCT areas, was operated through the TB99 questionnaire which was used to collect information from farms where herd breakdowns had occurred and then from an additional three uninfected farms from nearby localities (matched controls).

2.7 Implementation of the TB99 study has been severely hampered, as described by Godfray *et al.* (2004) and the ISG (2004). Nevertheless, Johnston *et al.* (2005) have analysed the TB99 data collected from the RBCT areas prior to the FMD epidemic. A large number of explanatory factors from the TB99 questionnaire were screened for association with the risk of a herd breakdown. Four factors were identified as being associated with an increased risk of a bTB breakdown:

- Cattle brought on to the farm from markets or from farm sales;
- Use of covered yard housing;
- Use of 'other' housing types;
- A cattle farm operating two or more farm premises.

2.8 The highest odds ratio to be associated with an increased risk was 4.22 (95% CI: 1.41 to 12.65) for the use of covered yard housing. Two factors were associated with a decreased risk of a bTB breakdown:

- Use of artificial fertilizer – odds ratio 0.21 (95% CI 0.07 to 063);
- Use of farmyard manure – odds ratio 0.42 (95% CI 0.20 to 0.85)

2.9 While factors increasing risk are biologically plausible, the risk reducing factors are difficult to explain.

2.10 It is also useful to note the results of a study on risk factors that affect tuberculosis incidents in cattle using data from badger removal operations between 1986 and 1998 (VLA, 2004). The main findings were that being a dairy farm in 1998 significantly increased the risk of being a case. Larger herds had an increased risk of being a case, and being a beef suckler herd (though not a beef finisher) was protective as compared to dairy farming. Increasing herd size in which the farm has several parcels of land has an increased effect as compared to single units (VLA, 2004).

Within herd transmission

2.11 Phillips *et al.* (2003) considered that the high prevalence of single reactors in herds in GB suggests that within-herd transmission is not common. They considered that in herds with infected cattle, spreading slurry is a risk factor, which can be minimised by prolonged storage of the slurry, by spreading it on fields not used for grazing, or by soil injection.

2.12 Apparent lack of indoor transmission may be because cattle kept in good husbandry conditions are unlikely to excrete significant numbers of *M. bovis* bacilli for 4-9 months (O'Reilly and Daborn, 1995 cited by Phillips *et al.* 2003), so, where herds are tested annually, many infected cattle will be removed from the herd before they excrete large quantities of infectious material.

2.13 Phillips *et al.* (2003) suggest that the best evidence of the transmission route of *M. bovis* between cattle is the pattern of lesions observed in slaughtered animals, many of which are in lungs and associated lymph nodes. In situations where infected cattle are removed through regular testing programmes, and contaminated pasture is rare, infection is likely to be via the pulmonary route. The minimum infective dose by aerosol route is very low, perhaps just one infective particle containing about five bacteria (Dean *et al.*, 2004) when delivered to the correct location, compared with the oral route, where several million bacilli are required to establish infection.

2.14 Phillips *et al.* (2003) recommend that to control cattle-to-cattle transmission: stocking densities in cattle housing should be limited to recommended maxima and good ventilation provided. Tuberculin skin testing of cattle before housing and removal of reactors will reduce the risk of within-house transmission.

2.15 Menzies and Neill (2000) reporting on cattle-to-cattle transmission in NI, also considered that respiratory excretion and inhalation of *M. bovis* is the main route by which cattle-to-cattle transmission occurs. In developed countries, shedding in milk, urine and faeces is an insignificant feature of the disease in cattle. The possible role played by environmental contamination in maintenance of *M. bovis* infection within cattle is uncertain, but some work on this aspect is being carried out currently (information gathered during preparation of this report). In outdoor conditions, cattle-to-cattle transmission occurs at a lower rate than when cattle are confined within the same enclosed air space. Fifty five percent of confirmed herd breakdowns over a nine year period had only one reactor with 79% of herds having three or fewer reactors.

2.16 In RoI, in the face of the vigorously applied test, slaughter and movement control measures, prevalence of infection in cattle is now low and approximately 50% of herds which disclose bTB test reactors contain only one reactor (O'Grady *et al.*, 2000). Even allowing for the lack of sensitivity of the skin test, it appears that there is little within herd transmission of bTB, again because, in many cases, before infected animals become clinical cases advanced enough to excrete *M. bovis* they are identified by another herd skin test and are removed.

2.17 More (2005) also reported that while brought-in cattle were identified as an important cause of herd breakdowns, there was generally little evidence of transmission from each primary case and substantial breakdowns were not common, despite very close contact during winter housing. As a result of mandatory annual testing and early and ongoing removal of infected animals, there is limited opportunity for Irish cattle to become infectious (that is, capable of transmitting infection) prior to detection. This is supported by field evidence, where breakdowns involving a single reactor accounted for between 38.3 and 44.4% of all breakdowns each year during 1987 – 1997 in RoI. The incidence of infection in cattle detected by skin testing during 2002 was 0.4% (29,162 bovine reactors from a population of approximately 7 million cattle).

Long distance transmission

2.18 Evidence of long distance cattle-to-cattle transmission of bTB is given by Gopal *et al.* (2005) who studied the introduction of bTB by bought-in cattle in north east England, an area until then free from bTB. Of 31 herds in north east England with bTB breakdowns between January 2002 and June 2004, nine had been restocked following FMD in 2001. In 8 of 9 the most likely source was purchased cattle. For 17 breakdowns, reactors were traced to herds from which the same spoligotype was isolated and for 5 breakdowns, a different spoligotype was isolated. Holdings supplying most likely source animals were from Wales, the west and north England, including one Cheshire herd that was the most likely source for 9 north east England breakdowns. Three outbreaks were traced to Irish imports.

2.19 Reactors in five outbreaks included homebred as well as purchased animals, providing evidence of likely within-herd transmission. Lack of geographical clustering of spoligotypes also pointed to source of infection being cattle that moved into the herds.

2.20 The importance of bought in cattle as a risk factor for long distance transmission of bTB is also an output of the TB99 case-control study (Johnston *et al.*, 2005). Also, Defra reported that 60% of herd breakdowns in Cumbria, post FMD, were associated with the movement of infected cattle onto breakdown farms (ISG, 2004).

2.21 Gilbert *et al.* (2005) used statistical modelling aimed at identifying variables that can predict the occurrence of bTB. The authors combined established environmental predictor variables with various variables extracted from the Cattle Tracing Scheme (CTS) database. They found that, "with disease data for 2002 and 2003, the analyses showed unequivocally that movement parameters consistently outperform the other variables in predicting bTB distributions". Areas with a high proportion of 'in' cattle movements from areas of known bTB occurrence were predicted to have high risk of bTB – when compared with actual bTB distributions these predictions fitted well. The authors concluded that their findings support the case for movement controls, especially from 'core' to 'remote' locations, as a disease control measure.

Analytical Summary Box 2

The increase in prevalence of bTB in the cattle population, coupled with the large numbers of cattle movements, both locally and over long distances, provide increased opportunities for transmission of bTB between herds. In NI, around 20% of breakdowns have been attributed to movement of purchased cattle onto farms, and around 30% to spread from infected to neighbouring farms across farm boundaries, implying, in NI at least, the importance of these two routes of transmission.

Spread of bTB within herds is slow because of the long period between infection and commencement of excretion of tubercle bacilli by an affected animal and the likelihood that an infected animal may be removed from the herd following a herd tuberculin test before it has had the opportunity to transmit infection. Cattle are most likely to be infected by other cattle by inhalation of infected aerosols. This is most likely to occur when cattle are housed and share the same air space.

The analysis indicates the continued need for regular herd testing with removal of reactors and for restriction of movement of cattle from areas where bTB is well established to areas where both the cattle and badger populations are currently free from the disease.

Diagnostic tests in cattle

Tuberculin ('skin') test

2.22 The single intradermal comparative tuberculin test has been in use for many years to identify 'reactors' indicating that they are infected with *M. bovis*. The reported sensitivity of the test varies from 70% - 95% (WHO, 1994; Monaghan *et al.*, 1994) which makes it unsuitable as a test for the bTB status of individual animals, but the test is highly specific and it is very useful as a herd test, identifying those herds in which bTB is present. In this role it has enabled control, and in some cases, eradication, of bTB in many countries. The strategy employed has been to test cattle herds on a regular basis and slaughter reactors to the test.

Gamma Interferon (IFN) Test

2.23 The Gamma Interferon (IFN) Test was developed in Australia and is being introduced into UK. An IFN test takes three days to complete (comparable with the skin test but only one site visit and animal handling required, compared with two for the skin test).

2.24 The IFN test is being used in a field pilot study conducted by the VLA. It is being used 25 – 30 days after disclosure tests (routine skin tests where reactors are found) on cattle older than 12 months. Using an optical density cut-off of 0.1 in the test, more positive cattle were found than had been revealed by the skin test. Interim results are that 16% of IFN test positive cattle had visible lesions at *post mortem* examination. The test had 96% specificity compared to 99.98% specificity of the skin test. Work at VLA is being done to improve the specificity of the IFN test.

2.25 The IFN test is considered to be at least as sensitive as the skin test and, in addition, will detect a proportion of infected cattle that fail to disclose to skin testing and may be at an earlier stage of infection. The most beneficial application of the IFN test would appear to be as a parallel test alongside the skin test in herd breakdowns with high incidence of confirmed reactors or with persistent infection that cannot be cleared with the skin test alone. Parallel testing implies that cattle are tested using both tests and a positive result to either test is taken as an overall positive. Serial testing implies that animals positive or perhaps inconclusive to the skin test are subsequently tested using the IFN test, the result of which is then taken as the final result. In GB there are five situations in which the IFN test can be used as an adjunct to the skin test in bTB reactor herds:

- As a parallel test for non-reactor animals at the disclosing test in new, confirmed bTB breakdowns that qualify for entry into the IFN test field pilot study;
- As a parallel test for non-reactor cattle in ongoing confirmed bTB incidents that do not qualify for the field pilot study, but have a chronic bTB problem;
- As a parallel test to support decision-making in relation to whole or partial herds slaughters in severe BT incidents;
- As a serial (i.e. confirmatory) test to resolve the status of reactors/indirect reactors in unconfirmed bTB incidents where there is evidence of non-specific reactions;
- More recently, the SVS has used the IFN assay as a serial test for re-testing of suspected fraudulent skin test reactors (Defra, 2004b).

2.26 Defra has set up a working group to review the use of the IFN test for bTB in NI (Defra 2003) and a similar group has recently been set up for GB. Also, the National Federation of Badger Groups (NFBG), in a call for development of better diagnostic tests for bTB, advocates use of the IFN test to augment the current skin test (NFBG, 2005).

2.27 In RoI the IFN test is being evaluated. Although it is considered unsuitable as a screening test, the sensitivity of the testing system approaches 97% when the skin test and the gamma interferon test are used in parallel. Therefore, it is to be used together with the skin test in problem herds where the removal of infected animals is a priority (More, 2005).

2.28 Development of antigen mining techniques that rapidly identify *M. bovis* specific genes is enabling the production of antigens which can be used as reagents in the IFN assay to increase its specificity and to discriminate between BCG vaccinated animals and those infected with *M. bovis* (Hewinson *et al.* 2005). It may also enable the development of IFN tests which identify sub-types of *M. bovis*.

Other tests

2.29 Fend *et al.* (2005) describe the use of an 'electronic nose' to diagnose *M. bovis* infection in badgers and cattle. The test detects the 'bacterial odour' of *M. bovis*. It can be performed on cattle and badger serum and it is claimed that it can detect infected animals as early as 3 weeks after infection with *M. bovis*.

Analytical Summary Box 3

Reliance on the skin test with a sensitivity that can be as low as 70%, can lead to herds with few infected animals not being detected and where a herd test is positive, not all infected animals will be identified for removal. Though the test is imperfect, its use as a pre- or post-movement diagnostic test would help to control infection spreading between herds and into previously uninfected areas.

Until there are more sensitive and reliable diagnostic protocols for bTB in cattle, it is impossible to quantify either cattle to cattle, herd to herd, or suspected badger to cattle transmission. The development for use in GB of the IFN test provides the opportunity to introduce more sensitive testing protocols by using the IFN test in parallel or in series with the skin test.

3. Bovine tuberculosis in wildlife

3.1 Since the 1950s bTB has also been associated with infection and disease in wildlife, particularly the badger (*Meles meles*).

Associations with the badger

3.2 Bovine tuberculosis caused by *Mycobacterium bovis* was first described in badgers in Switzerland in 1957 but it was not until 1971 that bTB caused by *M. bovis* was identified in badgers in GB in Gloucestershire by Muirhead *et al.* (1974). Since that time, a higher prevalence of bTB in cattle in south west England has been associated with the disease in badgers. Experiments conducted at the Central Veterinary Laboratory, Weybridge showed that badgers experimentally infected with a bovine isolate of *M. bovis* developed lesions and excreted the organism for up to 1,305 days and passed on the infection to healthy badgers and calves (Little *at al.* 1982a).

Badger ecology and behaviour

3.3 In UK, the badger is a protected species under the Protection of Badgers Act (1992). Under the Act, cruelty to badgers is an offence and it is prohibited to take, injure or kill badgers, interfere with their setts, possess, or sell, mark or ring live badgers. Licensed exceptions to this Act can be made to prevent serious damage to land, crops, poultry or any other form of property and for livestock disease control reasons.

3.4 With regard to understanding the epidemiology of *M. bovis* infection in badgers and to explore the potential for badgers to spread the disease to cattle, studies have been made of the distribution and behaviour of normal and infected badgers and their interface with farms and livestock.

Population and distribution

3.5 While badgers are distributed throughout UK, densities vary with environmental factors such as habitat, topography, geology and soil (Hazel and French, 2000).

3.6 Phillips *et al.* (2003) noted that badgers have increased in numbers in recent years in UK with a population increase of more than 70% between the first and second national badger surveys in 1988 and 1997. Delahay *et al.* (2003), describing a long term study of badgers at Woodchester Park in Gloucestershire between 1978 and 1993, reported that during the period of the study, the badger population density increased from 7.8/km^2 to 25.3 /km^2 (an over three times increase).

3.7 However, according to written answers to parliamentary questions, the notion that badger populations are ‘over populated’ is erroneous: badgers display a sophisticated regulatory mechanism, where fecundity and mortality are in equilibrium to maintain the population at a level which the habitat will support (Hansard, 2004a).

3.8 Phillips *et al.* (2003*)* reported that, while GB forms about 5% of the land area of western Europe, it has 17-20% of Europe’s badgers. The population is at its greatest density in south west England where prevalence of bTB in cattle is at its highest. They report that the only country believed to have a greater density of badgers than GB is Ireland where a substantial *M. bovis* problem also exists in cattle.

3.9 Denny and Wilesmith (1999) reported that in NI there were 3.5 badger setts per km^2 compared to 0.9 per km^2 for GB and 1.9 setts per km^2 in Republic of Ireland (RoI).

3.10 However, recent evidence suggests that the badger density in RoI may have been driven below that of GB. In RoI, in the Four Areas Trial, badger removal intensity during the first two years in the study's Removal areas averaged 0.57 badgers per km^2 (Griffin *et al.*, 2005) (this with a very intensive removal strategy involving frequent setting of snares). For the first year of the Randomised Badger Culling Trial (RBCT) 3.13 badgers per km^2 were removed from the proactive cull areas (ISG, 2004) (this with an acknowledged less intensive removal strategy than in RoI, involving less frequent setting of baited traps).

3.11 In GB, setts are more commonly sited within woodland (though not exclusively the case in south west England), but in Ireland, most setts are located in hedgerows. Denny and Wilesmith (1999), reporting on bTB risk factors in NI, commented that the latter distribution would be expected to associate setts more closely with pasture. Phillips *et al.* (2003*)* commented that increased densities may have forced badgers into sub-optimal habitats such as farm buildings.

Badger territoriality, sociality and social perturbation

3.12 Woodroffe and Macdonald (1993) comment that it is unusual for animals which rely on hunting for part of their diet to live in groups, so what drives badgers to do so? They suggest that exploiting an unpredictable but rapidly renewing food source reduces the cost of group living during the process of colonization. However, as population density increases, the spatial distribution of food and sett sites appears to prevent the division of the group range into individual territories, and thus leads to group territoriality.

3.13 Delahay e*t al.* (2003), describing a long term study of badgers at Woodchester Park in Gloucestershire between 1978 and 1993, reported that nearly half of the population of badgers made temporary or permanent moves between social groups. While the number of social groups and their territorial configuration has remained relatively stable, the number of individuals in each group has increased from 2.7 adults per group to 8.8 in 1993, in line with an increase in badger density. In a field study of perturbation conducted by the University of Oxford, badgers in two areas of the RBCT were studied. An increased number of females were found to be reproductively active in Removed groups, although the size of the cub cohort following culling remained unchanged" (University of Oxford, 2005).

3.14 Greatest movement of badgers between social groups occurs in the Spring (Nolan and Wilesmith, 1994). Badgers live in social groups of 3 to 10 in setts and produce litters of cubs in the setts mostly in February. Also, the mating season starts in February, and while they can mate throughout the year, it occurs mostly in the Spring, which involves competition by males for females. This breeding pattern is made possible by an unusual feature of the badger's reproductive system which involves delayed implantation. No matter when the eggs are fertilized, implantation nearly always occurs in late December or early January and is followed by a further 6-7 weeks of normal gestation (www.badgers.org.uk/badgerpages/eurasian-badger-07.html). Females that do not produce litters may act as baby sitters but only the mother suckles her cubs (Woodroffe, 1993). Despite the apparent integrity of the social group, Delahay *et al.* (2003), in their study at Woodchester Park between 1978 and 1993, noted that nearly half of the population of badgers made temporary or permanent moves between social groups.

3.15 Males move more commonly than females and disperse singly to move in on neighbouring breeding females: usually the moving males are the bigger, more sexually active ones. If females disperse, they move as coalitions of 2-3 females and appear to takeover other territories where resident females disappear. Both sexes will temporarily visit other territories for mating (Woodroffe *et al.*, 1993).

3.16 Recent ecology studies have revealed that there is more movement between badger social groups by males in order to breed than was previously thought. Hence, the fathers of approximately half of all cubs are from a different social group to the mother (Defra, 2004b).

3.17 Male badgers can fight over territorial and breeding disputes and wound each other. Bite wounds are most commonly seen on the neck. (Gallagher, 2000)

Social perturbation following badger culling operations

3.18 Badger movements and home ranges have been observed to increase following culling, and such perturbation has been associated with a disruption in territorial boundaries lasting several years (Tuyttens *et al.*, 2000a). In Woodchester Park, after complete clearance of badgers from two clusters, social organisation was severely disrupted with badgers travelling over greater distances and using more main setts than usual for several years following the removal. However, immigrant badgers were identified in the removed areas within one year of the operation, including cubs in one instance (Delahay *et al.*, 2003). A stable social structure only returns to the disrupted area 9 to10 years later (Delahay, *et al.*, 1998).

3.19 Tuyttens *et al.* (2000b) described recovery after a badger removal operation at North Nibley, Gloucestershire and compared it with two nearby high density undisturbed populations (Wytham Woods and Woodchester Park). Badgers moved between social groups more at North Nibley than in the other study areas, particularly in the immediate aftermath of the badger removal operation. Recolonisation occurred firstly by young females. Although in the first year after the badger removal operation, no cubs had been reared in any of the culled groups, and although the shortage of sexually mature boars may have limited reproduction output of the sows in the following year, the population took only 3 years to recover to its (already lowered) pre-removal density.

3.20 Losses from the adult (and cub) population due to mortality or emigration were smaller at North Nibley than at the undisturbed sites, assisting the rapid return to pre-cull numbers. Density dependent effects constrained the reproductive output of the high-density populations, indicating that badgers in unperturbed social groups, through levels of reproduction and cub survival, manage their population so as not to exceed their available food supply and territory.

3.21 In a field study of social perturbation conducted by the University of Oxford, badgers in two areas of the RBCT were studied: a reactive treatment area (E1, where local badgers had been culled following a bTB breakdown in cattle) and a control area (E2) where no culling had taken place. Prior to the culling exercise, badger numbers were between 5-7 per km^2 in both areas. Intensity of culling was low with 30-40% of badgers being culled from targeted social groups. After culling, an increased number of females were found to be reproductively active in the reactive treatment area compared to the control area, although the size of the cub cohort following culling remained unchanged. After culling, the reactive treatment area and neighbouring social groups increased their territorial overlap with adjacent groups with increased and overlapping home ranges and dispersal. Overlapping increased from 0.8 to 2.7 animals after culling. Aggression increased in the reactive treatment area social groups and neighbouring groups following culling, with higher rates of bite wounding (University of Oxford, 2005).

Changes in rates of bTB transmission in perturbed populations

3.22 Wilkinson *et al.* (2005) describe a spatial model of bTB in the badger and its transmission to cattle which was used to determine whether simple changes in movement and social behaviour following culling could increase the incidence of bTB in cattle. The model included density-dependence and local dispersal to give realistic rates of population recovery. Under the assumption that disease transmission between neighbouring social groups becomes equivalent to within-group transmission following culling, the model showed an increase in bTB incidence in cattle. While it is important to highlight that this is a model-based result, not from real life, (there is a key information gap regarding the assumption made), the modelling is well informed by the field studies carried on at Woodchester park, so should not be too far removed from reality. The model implies that immigration is the most important mechanism for population recovery in a culled area and this has implications for the reintroduction and spread of bTB.

3.23 Nearly half of the badgers studied at Woodchester Park made temporary or permanent moves between social groups. There was a significant relationship between the annual proportion of badgers that moved and the incidence of disease in the population in the following year, such that years of high movement rates were followed by an increase in the number of new cases of disease detected in the population (Delahay *et al.*, 2003)**.**

3.24 The previously mentioned study by the University of Oxford (University of Oxford, 2005) also monitored the prevalence of bTB in badgers in the undisturbed populations and those perturbed by culling. Prevalence of bTB before culling was approximately 5% in the reactive area and 2% in the no-cull area. The study demonstrated an increase in the proportion of groups affected by bTB among social groups neighbouring reactively culled groups in the reactive area. New infections were predominantly found in female cubs, with relatively advanced disease and it was speculated that pseudo-vertical transmission may play an important role in bTB transmission within badger populations.

Badgers and the farm environment

3.25 Badgers are opportunistic, generalist foragers, with an omnivorous diet including cereals, fruits, invertebrates and small mammals. Whilst the eggs of ground nesting birds may form part of their diet, it has been shown that badgers do not decimate populations of ground nesting birds (Delahay and Hounsome, 2005). Likewise, badgers do not decimate hedgehog populations (Bright, 2004). However, fox and hedgehog numbers appeared to increase in proactive cull areas relative to control areas in the Randomised Badger Culling Trial (RBCT) (Defra, 2004b). A major part of the diet of badgers can be earthworms and they will search for them when they come to the surface at night. They will often seek them on pastures which brings them into indirect contact with grazing livestock.

3.26 Badgers use latrines for defecation away from the setts as their boundary demarcators. These can be accessible to grazing livestock. They also have established pathways around their territories, and where they cross, badgers are liable to urinate. These points can also be accessible to livestock. Hutchings *et al.* (2001) studied defecation and urination patterns of badgers at low density (mean +- SE across 4 social groups was 5.73 +- 0.735 badgers/km2) in south west England. Woodland was selected, and arable land avoided, for latrine sites. Pasture and built-up land was selected for single defecations not in pits whereas faeces in single pits were distributed randomly across habitat types. Faecal scent marks were strongly associated with the edge of pastoral fields rather than the middle. Urine was deposited randomly across habitat types but was concentrated at the linear features surrounding the main setts. Hutchings *et al.* (2002) compared the scent marking behaviour of badgers across a range of population densities in GB. Badgers placed greater proportions of faeces and urine at latrines with increasing population density, a change consistent with a shift from hinterland to boundary marking and suggesting that at low population densities, badgers distribute their faecal and urine scent marks in a more dispersed pattern.

3.27 Work at Warwick University has demonstrated a positive association between latrine density and cereal growing, including maize (Warwick University, 2003).

3.28 Philips *et al.* (2003) suggest that increased badger density in UK may have forced some badgers, particularly those in the terminal stages of disease, to seek refuge in farm buildings where there is food and shelter and that farmers may not be aware that badgers are frequenting their buildings. Roper *et al.* (2003) used radio telemetry and video surveillance to study farm visits by badgers on three farms. Badgers visited farm buildings, including cowsheds, feed sheds, barns, haystacks, slurry pits, cattle troughs and farmyards, in order to eat foods such as cattle cake and silage. Badgers defecated and urinated directly onto cattle feed and sometimes came into close direct contact with cattle.

3.29 Garnett *et al.* (2003) studied the ability of wild badgers to climb into cattle feed troughs set at different heights. At least 12 wild badgers climbed into a cattle feed trough set at heights above 80 cm (the recommended height in biosecurity guidelines for farmers). The maximum height climbed was 115 cm which is beyond the reach of calves and yearlings. They concluded that there is no trough height which is usable but completely excludes badgers.

3.30 The ecological niche of the badger coincides with the ideal environment for cattle farming, such that Delahay *et al.* (1998) comment, “Wherever we farm cattle, we may be incidentally farming badgers”. This brings badgers into close and protracted contact with pasture, where infectious excretions may become available to grazing cattle (Delahay *et al.*, 1998). However, badgers will normally avoid cattle where at all possible (Benham and Broom, 1989 cited by Nolan and Wilesmith, 1994).

Mycobacterium bovis *infection in the badger*

3.31 The badger is an ideal host for *M. bovis* infection (Gallagher and Clifton-Hadley, 2000, cited by Phillips *et al.*, 2003). Infected badgers excrete *M. bovis* in exhaled air, sputum, urine, faeces and pus. The behaviour of badgers to spend much of their time close together in a sett within a small air space assists the spread of a disease which is commonly disseminated by infected aerosol inhalation. The constant temperature and humidity in the sett may be favourable to prolonged survival of *M. bovis* and close proximity and confined airspace is conducive to transmission by the respiratory route. It is not surprising, therefore, that bTB is endemic in the British badger population. However, mortality in badgers caused by bTB is low. The badger is an ideal maintenance host because infected individuals can survive for relatively long periods and produce viable young, and infection appears to have no significant effects on population size or structure (Delahay *et al.*, 1998). One animal was shown to survive 3.5 year while excreting *M. bovis* (Little *et al.* 1982a) while up to one third of excretors survive for 12 months or more.

3.32 In some counties of GB, *M. bovis* infection in badgers has not been associated with bTB in cattle, which indicates that the infection can be maintained in the badger population without any other source of *M. bovis* (Nolan and Wilesmith, 1994).

3.33 According to Gallagher (2000), in GB, approximately 80% of infected badgers have no observed gross lesions at necropsy. Most infected badgers do not suffer from serious, or life threatening, disease and are able to continue their normal behaviour and breeding activities. There can be long periods of latency followed by reactivation of clinical disease. If infection occurs via a bite wound, there is more likelihood of progressive severe disease.

3.34 About 20 -25% of badgers removed from control areas are infected with *M. bovis* (Krebs *et al.* 1997) but in only a small proportion of these does the disease reach a fulminating stage in which the animals are excreting large amounts of the infectious agent (Gallagher, 1998, cited by Phillips *et al.*, 2003).

3.35 In advanced clinical disease, discharge of bacilli from bronchial pus, directly or swallowed and passed in faeces, as well as in urine, is enormous during the terminal stage of disease when immune reactions are overwhelmed. Gallagher (2000) terms such infected animals as “super-reactors” and states that they may live for possibly one or two months and are highly significant in the spread of infection to other species.

3.36 Gallagher (2000) also states that the finding that many badgers show an early containment reaction, resulting in arrested development of the disease, gives encouragement for the use of a vaccine.

3.37 Phillips *et al.*, 2003 (citing Gallagher *et al.* 1976) state that the badger kidney is a common site for *M. bovis* infection following haematogenous spread, with one study showing that almost 20% of badgers with gross lesions of bTB had infected kidneys. If this were so, one would expect a considerable excretion of *M. bovis* in the urine of infected badgers. However, Nolan and Wilesmith (1994), attempted isolation of *M. bovis* from seven tissue sites/pools in a study of 72 infected badgers. The results of their work are summarised in Table 1.

Table 1: Attempted isolation of *M. bovis* from seven tissue sites/pools in a study of 72 infected badgers (Nolan and Wilesmith, 1994)

Tissue site/pool	Total isolations
Retropharyngeal/submandibular lymph nodes	30
Lung/broncho-mediastinal lymph nodes	39
Liver	7
Spleen	7
Kidney	4
Axillary/prescapular/popliteal/inguinal lymph nodes	23
Mesenteric lymph nodes	16

Table based on Nolan and Wilesmith (1994)

3.38 The least number of isolations were from kidney (four) while 39 isolations (more than 50%) were from the lungs and associated lymph nodes. The results of their studies suggest that the respiratory tract is the most likely route of excretion of *M. bovis*.

3.39 There is evidence that bTB incidence in badgers is related to increased badger movement (Rogers *et al.*, 1998, cited by Wilkinson *et al*., 2005*)*. In the Woodchester Park study, Delahay *et al.*, 2003) bTB was studied in the badger population. Badger social group territories were determined annually by bait marking. Badgers were trapped four times yearly and individual badgers were trapped on average 2.5 times each year, tattooed, and their faeces, urine, tracheal aspirate, pus from abscesses and bite wound swabs were cultured for *M. bovis*. Their sera were tested by ELISA for *M. bovis* antibodies. Between 1978 and 1993, the badger population density in Woodchester Park increased from 7.8 per km^2 to 25.3 per km^2. Prevalence of infectious badgers fluctuated but bore no linear relationship to the increase in badger density. Rather, prevalence of infection fluctuated in an apparently cyclical pattern but has been maintained in the population at an estimated annual level of 12 to 19% from 1981 to 1995 (Delahay *et al.*, 1998).

3.40 In the Woodchester Park study, the most important route of transmission of infection between badgers was found to be respiratory, followed by infection through bite wounds. Respiratory tract infections are characterised by lesions in the lungs and associated lymph nodes, whereas infection through bite wounds are associated with discharging sinuses through the skin. Bite wounds and prevalence of infection are greatest in male badgers who are most involved in territorial and mating disputes in Spring (Delahay *et al.*, 1998).

3.41 In the Woodchester Park study, infection persisted for several years within certain groups, but was not significantly related to their demographic structure (group size, density, sex and age structure). However, Nolan and Wilesmith (1994) reported that there was an overall trend for increased prevalence with age but acquisition of infection occurred most frequently in young animals and this was considered to be due to “pseudo-vertical” transmission from infected sows to new-born offspring. They also noted that risk of transmission may be seasonal, coinciding with times of greatest badger activity in the Spring. Data from the RBCT analysed by Woodroffe *et al*. (2005a) showed a higher prevalence of infection in adults compared to cubs, and, in adults only, males were at a significantly higher risk of infection than females.

3.42 In social groups where bTB was endemic, about 10% of badgers remained uninfected. Also, transient seropositivity (by ELISA) was detected in some cubs during the first 6-8 months of their life, most of which remained culture negative for up to 5 years. These findings indicate that there was a proportion of the badger population at Woodchester Park that was resistant to infection with *M. bovis* and culling of such populations removes both susceptible and resistant animals.

3.43 In a study by Rogers *et al*. (2003) the score for prevalence and incidence of bTB in social groups was significantly and positively related to the number of occupied setts in a social group, such that the more occupied setts there were in a territory, the higher the bTB index of the group. Possibly the setts themselves contribute to the persistence of bTB within social groups, or badgers infected with bTB might show a different behaviour from uninfected badgers, making greater use of outlying setts.

Analytical Summary Box 4

It is not uncommon for organisms causing disease in domestic livestock to also have wildlife hosts. Unless such organisms are controlled in wildlife reservoirs, they can continue to cause disease in their domestic hosts, with welfare implications to livestock, economic and social consequences to their keepers and local, national and regional economic costs.

There is clear evidence that the badger population supports *M. bovis* in parts of the United Kingdom and the RoI. Many infected badgers show little clinical evidence of disease, neither do they excrete the organism. However, a small proportion become terminally ill and excrete *M. bovis*, principally from the respiratory tract, and also from infected wounds, in urine and in faeces.

The badger population of UK appears to have increased in the 1990's but stabilised since 2000. Badgers regulate their population according to the capacity of the environment through self-regulation of breeding. Badger density differs between GB and RoI.

Badgers live in loose social groups. Each group can use several setts and establishes and defends a territory. However, movement of badgers between social groups is not uncommon. There is movement of both males and females between groups. Following badger removal operations, it has been noted that there are increased movements, breeding activity and aggression within badger populations, the so-called "social perturbation" effect. While there is no correlation between badger density and prevalence of *M. bovis* infection, increased incidence of disease in badgers has been associated with increased movements within the badger population. For this reason it has been proposed that culling operations, through causing social perturbation, increase rather than diminish prevalence of bTB in the badger population.

Diagnostic tests in badgers

3.44 According to Nolan and Wilesmith (1994), the comparative skin test in badgers has poor sensitivity and is considered to be of no practical value. However, badgers vaccinated subcutaneously with *M. bovis* BCG produced no significant reaction to the Brock test but a significant reaction to the comparative skin test (Gormley *et al*., 2000).

3.45 The ‘gold standard’ for diagnosis of *M. bovis* infection in badgers is culture of the organism, while being specific, it may take six weeks. Also, Chambers *et al*. (2002) found that the majority of culture positive badgers excreted *M. bovis* intermittently over a study period. As a result, there was only a 27.5% chance of sampling a badger for culture when it was excreting. In contrast, a positive ELISA (Brock test) result correctly predicted 68.2% of badgers with a history of excreting *M. bovis*.

3.46 The Brock test is the most used diagnostic test for badgers. While the test is highly specific, sensitivity needs to be improved. Kampfer *et al*. (2003) developed a multi-antigen ELISA for enhanced diagnosis of tuberculosis in badgers. The test can improve on sensitivity or specificity of Brock test depending on cut-off value used.

3.47 In RoI, the Brock ELISA was used to measure humoral responses and the lymphocyte transformation assay (LTA) to detect cell-mediated responses to bTB in infected badgers. Of 36 badgers trapped in an endemic area, *post mortem* examination showed 7 of 36 (19.4%) affected, but when the Brock Test, LTA and *post mortem* results were combined, more than 60% showed evidence of exposure to *M. bovis* (Southey *et al*. 2000).

3.48 The first steps towards development of an IFN test for badgers in GB has been undertaken by Dalley *et al*. (2004) who are studying the cloning and sequencing of badger interferon gamma and its detection in badger lymphocytes. The IFN test is already in use on possums in New Zealand.

3.49 Dalley *et al*. (1999) describe the development of a comparative lymphocyte transformation assay (LTA) using bovine and avian tuberculin as antigen to detect cell mediated immunity. Compared with the existing Brock ELISA, sensitivity was greater (87.5% compared with 62.5%) the ELISA had greater specificity (100% compared with 84.6%). They considered that storing blood overnight might improve specificity of the LTA without losing sensitivity.

3.50 Attempts are being made to develop pen-side tests for badgers: Greenwald *et al*. (2003) have developed a multi antigen print immunoassay (MAPIA). This is a pen-side test which has sensitivity of 53% and specificity of 95%. The authors compared this with the Brock test which they found had a sensitivity of 47% and specificity of 89%.

3.51 The potential value of using a diagnostic test in live badgers, as an aid to targeting badger culling, has been explored, largely through the use of simulation modelling. This work is summarised in section 6.

Analytical Summary Box 5

Post mortem examination and culture is performed on badgers that are culled or killed in road accidents but is a lengthy procedure.

Culture of material from live badgers is unsatisfactory because infected animals excrete *M. bovis* only intermittently.

An ELISA (Brock) test correctly diagnoses less than 70% of infected badgers. Trap-side tests, where a result can be obtained at point of capture, are being developed and tested but as yet, as with the Brock test, there are problems of low sensitivity. There are potential opportunities to use ‘trap-side’ testing of badgers to improve targeting of badger culling as a method of bTB control.

Transmission of Mycobacterium bovis *from infected badgers to cattle*

3.52 In experimental conditions transmission has occurred from badgers to cattle (Little *et al*., 1982a). In two experiments, 3 and 9 calves were housed with 8 and 13 infected badgers, respectively, for 6 months in an enclosed pen, and were subsequently found to be positive tuberculin reactors and to have lesions in the retropharyngeal, pulmonary and bronchial lymph nodes. *M. bovis* was isolated from only the faeces not urine, pus or sputum, which together with anatomical evidences suggests that the organism was short-lived in the environment and was transmitted by droplet infection.

3.53 In UK cattle, risk of a herd becoming infected has been positively related to badger sett density (Wilesmith, 1983, cited by Phillips *et al.*, 2003). The badger population in UK is at its greatest density in south west England, where bTB prevalence is high (Krebs *et al*., 1997).

3.54 However, a study by Warwick University did not detect any relationship between badger density and bovine bTB incidence (Warwick University, 2003). In this study, badger setts and latrines were tested for *Mycobacterium* complex by PCR. Prevalence in setts was high (41%) and lower in latrines (12%). Per head of cattle, bTB incidence increased slightly with the proportion of sett samples that were PCR positive on the farm but there was no apparent relationship between bTB breakdown history of the farm and the proportion of positive setts or latrines on the farm.

3.55 There is currently a knowledge gap regarding the importance of *Mycobacterium* in the environment, but there is some work currently being done (information from Warwick University). Environmental load of bacteria may not be well correlated with the density of infected badgers, there being other important factors associated with the excretion behaviour of badgers (and cattle). This may limit the ability of badger culling, even targeted on infected badgers, to fully remove the infectious challenge in the environment.

3.56 In 1997, Hutchings and Harris (1997) wrote “the means by which bTB is passed from badgers to cattle remains unclear; pasture contamination with the urine, faeces and/or sputum of infectious badgers is believed to be the main route of transmission”. They studied the behaviour of grazing cattle to determine whether they avoided investigating and/or grazing pasture contaminated with badger excreta, and whether different farm management practices enhanced the potential for disease transmission. They found that cattle avoided active latrines until the sward length in the rest of the field was reduced, after which there was an increasing likelihood that active badger latrines would be grazed. Farm management practices that reduced the availability of long swards shortened the period of investigative behaviour and greatly enhanced the risk that cattle would graze active badger latrines. Cattle were more likely to graze pasture away from latrines that was contaminated either with badger urine or single faeces. Hutchings and Harris (1997) suggest that, because bacilli remain viable in the soil for up to 2 years, there is the potential for bacilli to accumulate at active badger latrines, and these could pose a significant risk to cattle, even when the latrine is no longer being used by badgers. Cattle readily grazed the lush sward at disused latrines, during which they could ingest contaminated soil; the amount of soil ingested increases as sward length decreases.

3.57 Hutchings and Harris (1999) carried out a study to quantify levels of investigative and grazing contacts between cattle and badger urine and faeces. They found that the levels of cattle contact with badger excreta are far higher than previously thought, suggesting that it is the probability of infection per given contact with infected badger excreta which has the greater influence on the probability of transmission and not the level of contact. They suggest that the infection probability per cattle contact with infected badger excreta is in all likelihood extremely low.

3.58 Others suggest that lesions in cattle associated with badger-related breakdowns strongly suggest that the primary route of infection is respiratory. An important part of the diet of badgers is earthworms, bringing badgers in close proximity to grazing cattle. While cattle avoid fresh badger latrines, badgers often urinate away from latrines, particularly where badger paths cross. Sputum, urine, faeces and purulent exudates from ruptured lymph node abscesses or bite wounds of infected badgers can all be implicated in contaminating pasture where cattle graze (Nolan and Wilesmith, 1994). *M. bovis* can persist in the environment for up to 11 months under optimal conditions. Sick badgers may enter farm buildings for easy access to food. In this connection, 64% of badgers found *in extremis* were infected by *M. bovis* (Delahay *et al*., 1998).

3.59 Nolan and Wilesmith (1994) consider that transmission of *M. bovis* from badgers to cattle is an infrequent event but has serious consequences for the control of bTB in cattle. In a case-control study of farms in NI, where farms were excluded on which bTB breakdown had already been ascribed to purchased infected cattle, an association between confirmed bTB breakdown and badgers was made in approximately 40% of case farms studied (Denny and Wilesmith, 1999). They point out that a significant proportion of purchased infected cattle may have been infected by a badger when in a previous herd.

3.60 Delahay *et al*. (2003), in their studies at Woodchester Park, found that 64% of badgers found dead or *in extremis* in farm buildings were infected with *M. bovis* while only 21% of RTA badgers found in the vicinity of Woodchester Park were positive. In another report, the prevalence of infection detected in RTA badgers at *post mortem* examination during 2000 -2003 inclusive was 20.5% (CSL, 2004a). This could be interpreted as suggesting that, assuming RTA's are a random sample of badgers (therefore ~20% represents a fair estimate of bTB prevalence in the general population where RTA data are collected), badgers found dead in farms are not random – i.e. there is a tendency for bTB-ill badgers to seek out farms buildings, as suggested by Phillips *et al.* (2003).

3.61 Scientists at the Department of Zoology, the University of Oxford conducted an investigation on the potential of ticks to transmit *M. bovis* from badgers to cattle (University of Oxford, 2001). They reached the conclusion that it is highly unlikely that British Ixodid ticks play a significant role in the transmission of *M. bovis* from badgers.

Analytical Summary Box 6

Badgers occupy an ecological niche that brings them into both direct and indirect contact with cattle.

M. bovis has been transmitted from badgers to cattle under experimental conditions. The observed behaviour of badgers shows that there is opportunity for this transmission to occur in field conditions. However, field studies have not been able to fully quantify the role of badgers in cattle bTB breakdowns.

Badgers territories often include fields where cattle graze which they visit to search for earthworms that are part of their diet. They often establish latrines in grazing areas and may also contaminate them with urine and discharges. More importantly (because bTB infection has been shown to occur more commonly when cattle are housed), studies have shown that badgers visit farm buildings to forage for food and diseased badgers may take up permanent residence in farm buildings. There is evidence of them contaminating areas to which cattle have access, including feed troughs. This behaviour provides an opportunity for infected badgers to transmit *M. bovis* to cattle. These risks can be mitigated by biosecurity measures to keep badgers out of farm buildings and grazing areas and to keep cattle away from areas contaminated by badgers.

The finding in a study in Gloucestershire that over half of badgers found dead or *in extremis* in farm buildings were infected with *M. bovis*, compared with only 21% infected of badgers in the same vicinity which had been killed by road accidents supports the proposal for biosecurity measures to keep badgers out of farm buildings.

Spatial association between disease in cattle and in badgers

Road Traffic Accident (RTA) Survey

3.62 The Krebs Report (Krebs *et al*.,1997) recommended a survey to collect badgers found dead on roadsides and to identify what proportion of these showed evidence of *M. bovis* infection. It was thought that this would allow an additional analysis of the link between herd breakdowns and the prevalence *M. bovis* infection in badgers over time and space.

3.63 It appears that RTAs are a plentiful source of badger *post mortem* material. Research by CSL has shown that of 207 badgers found dead in the Woodchester Park study area between 1978 – 93, 65% of them had died as a result of RTAs, 9% died from bTB, 9% from deliberate killing, 7% from starvation and 11% from unknown causes (Hansard, 2004b).

3.64 In order to validate RTA data, the ISG targeted the RTA into those areas in the RBCT and areas nearby with low breakdown rates, and areas with high, or increasing breakdown rates.

3.65 Seven counties were chosen: Cornwall, Devon, Gloucestershire, Herefordshire and Worcestershire were selected as high risk areas and Shropshire and Dorset selected as nearby counties with low breakdown rates (ISG, 2004).

3.66 The original target was to perform *post mortem* and cultural examinations on 1200 badgers per year, the work to be done by the SVS. Between the start of the RTA project in 2000 and June 2002 only 252 badgers had been processed. Problems again were caused by SVS preoccupation with CSF and FMD control. In June 2002, the responsibility for the collection of dead badgers was transferred to the CSL. Between June 2002 and June 2003, 1082 badger carcasses were collected from the seven counties where the trial was taking place (Godfray *et al.* 2004).

3.67 RTA data has been presented for the period 2002-2004 (ISG, 2005b). Culture results were obtained for 542 badgers in 2002, 718 in 2003 and 914 in 2004 – a total of 2174 badgers found dead by the road side. There was no significant change in overall prevalence of bTB in RTA cases between 2002 and 2004. Dorset and Shropshire had lowest prevalence in 2004 and 2003 respectively, followed by Devon (5% in 2003 and 7% in 2002). Highest prevalences were in Shropshire (27%) and Gloucestershire (26%) in 2002 and Herefordshire (28% in 2003). The animal health minister, Mr Ben Bradshaw commented that the results show no clear correlation between the levels of bTB in cattle and badgers (Anon., 2005).

3.68 In answer to a proposal by the NFU that the RTA survey should be extended to the whole of GB (NFU, 2005), the ISG commented that the RTA survey only provides informative data at county level. Initial findings are that increased skin testing of cattle in response to a bTB-positive RTA badger is no better at identifying new herd breakdowns than contiguous testing in response to a cattle herd breakdown. Growing evidence emphasises the need for a greater focus on reducing cattle-to-cattle transfer of infection (ISG, 2005b).

3.69 The National Federation of Badger Groups (NFBG) responded to the NFU's proposal by commenting that the costs are high and the benefits unproven of extending the RTA survey across England and Wales (NFBG, 2005).

3.70 In contrast to the results of RTA surveys in south west England, in a small survey of RTA badgers made in the Furness Peninsula of south west Cumbria in January 2004, in which 25 carcasses were examined (24 badgers + 1 deer), all were negative for *M. bovis* infection (Defra, 2004b).

Molecular epidemiology

3.71 Costello *et al*., (2000) studied the spatial distribution of RFLP types identified in *M. bovis* isolates from badgers (121) and cattle (86) in an area of 300 km^2 using a GIS database. The majority of isolates were represented by two RFLP types which were common to both species. There was a close correlation between the spatial distribution of RFLP types in badgers and cattle, which suggests that transmission of infection occurs between these species, (though cannot indicate the direction of transmission). In almost all instances where the same RFLP type was present in badgers and cattle in a locality, the sett from which the infected badger was culled was not present on the infected farm but was located some distance away. This distance typically varied from 200m to 2km.

3.72 Olea-Popelka *et al*., (2005) characterised the *M. bovis* isolates from the Four Areas Trial into RFLP types and looked for spatial relationships between the cattle, badgers and setts from which they had been isolated. Although cattle and badgers tended to have similar *M. bovis* strains within broad geographic areas, badger strains were not clustered strongly within an area. Infected setts did not have a clustered geographic distribution and were frequently infected with multiple RFLP types. Further, although badger and cattle strains cluster at an area level, there was no significant association between number of badgers with a given strain within 2 or 5 km of cattle herds and the risk of the same strain in these cattle.

3.73 The latter investigation of spatial relationships of RFLP types in RoI seems to indicate a considerable amount of movement in the badger population of RoI: i.e. if badgers are the source of infection on breakdown farms it seems that the infecting badgers have travelled from some distance away (>5km) to the breakdown farm. This either weakens the case for badger-to-cattle transmission accounting for a large proportion of herd breakdowns, or, suggests that the badger population in RoI in general is more perturbed than that in GB (perhaps due to long term badger culling of various forms).

3.74 Using data from the RBCT, Woodroffe *et al*., (2005a) investigated local spatial associations between *M. bovis* infection in cattle and badgers. *M. bovis* infections were locally clustered within both badger and cattle populations. They showed for the first time that *M. bovis* infections in badgers and cattle are spatially associated at a scale of 1-2km. Badgers and cattle infected with the same strain type (spoligotype) of *M. bovis* are particularly closely correlated. These observational data support the hypothesis that transmission occurs between the two host species; however, they cannot be used to evaluate the relative importance of badger-to-cattle and cattle-to-badger transmission. These results are in contrast to the results of spatial analysis of data from the Irish Four Areas Trial, targeted at the same issue (Olea-Popelka *et al*., 2005). This analysis found a lack of close spatial association between badgers and cattle infected with the same RFLP types of *M. bovis*.

Analytical Summary Box 7

In England, a close spatial association has been demonstrated between the strains of *M. bovis* (typed by spoligotype) found in badgers and the strains found in neighbouring infected cattle (1-2km). This is strong supporting evidence that transmission occurs between the two species. This is in agreement with results of spatial analysis of *M. bovis* (by RFLP type) in RoI presented in 2000. More recently, a spatial analysis of strains of *M. bovis* (RFLP types) in RoI was not able to show a significant spatial association of RFLP types between badgers and cattle, neither were RFLP types clustered within the badger population. The results indicated that there is a lot more movement within the badger population in RoI than there is in GB. This may indicate a general difference in behaviour between British and Irish badgers, or that the badger population of RoI suffers more social perturbation than that in GB, perhaps due to the higher frequency of badger removal operations.

Mycobacterium bovis a*ssociations with wildlife other than the badger*

3.75 A large sample of the wild animals found on a farm in south Dorset were trapped and examined for *M. bovis* following discovery of widespread infection in cattle and badgers. *M. bovis* was isolated from the lymph nodes of two of 90 rats and one of seven foxes but no lesions of bTB were observed. It was concluded that the badger was the only species of wild mammal which was a reservoir of *M. bovis* in this area (Little *et al*., 1982b).

3.76 Delahay *et al*. (2002), reporting on work conducted at the Central Science Laboratory (CSL) and the Veterinary Laboratory Agency (VLA), concluded that the weight of evidence from studies does not appear to support the existence of a significant self-maintaining reservoir of infection in any wild mammal in the UK apart from the badger.

3.77 Although deer are carriers of *M. bovis* their presence was not a significant risk factor in an epidemiological survey in NI though it was concluded that more detailed research would be advisable before it is confirmed that deer do not play a role (Denny and Wilesmith, 1999).

3.78 In GB, all species of deer are, like the badger, increasing in numbers and their distribution ranges are extending, with the possibility that they may become important reservoir hosts in future. Rats and foxes can carry *M. bovis* infection but do not show progressive disease and are unlikely to pass on infection (Phillips *et al*., 2003).

3.79 In a study conducted by scientists at the Department of Zoology, the University of Oxford (University of Oxford, 2004) the risk to cattle from *M. bovis* infection in wildlife species other than badgers was investigated. The study was conducted on eight case farms where bTB breakdowns had occurred and on four control farms. Wild life, including badgers but excluding deer, and cats and dogs were examined for *M. bovis* infection. The species, and percentage, identified as infected with *M. bovis* are shown in Table 2.

Table 2: The species of wildlife examined, and the percentage found positive, for *M. bovis* infection by the Oxford University group.

Species	number tested	%
Bank vole	1307	0.2
Wood mouse	1338	0.2
Common shrew	272	0.3
Badger	43	7.0

Table based on University of Oxford (2004)

3.80 All but one of the isolates obtained from small mammals were of spoligotype SB0267. This spoligotype has never been isolated from cattle in GB and it is suggested that this is a spoligotype which has adapted to small mammals.

3.81 One bank vole had the same spoligotype of bTB as that isolated from badgers and cattle at the same farm. The authors suggest the possibility of bank voles participating in the epidemiology of bTB and indicate that although prevalence of infection in small mammals is low, they are extremely numerous, with their biomass in the British countryside being approximately two thirds that of badgers.

3.82 More recently, an investigation of the risk to cattle from wildlife species other than badgers in areas of high herd breakdown risk was made by scientists at the CSL (CSL, 2004a). Table 3 shows the number of species of wildlife examined and the percentages of them that were infected with *M. bovis.*

Table 3: The species of wildlife examined, and the percentage found positive, for *M. bovis* infection by the CSL group.

Species	number tested	%
Muntjac	58	5.2
Fallow deer	504	4.4
Polecat	24	4.2
Stoat	78	3.9
Fox	756	3.2
Yellow necked mouse	36	2.8
Common shrew	41	2.4
Field vole	67	1.5
Roe deer	888	1.0
Red deer	196	1.0
Wood mouse	333	0.6
Grey squirrel	450	0.4

Table based on CSL (2004a)

3.83 In fallow, red and roe deer, the principal sites of infection were in the lungs and associated lymph nodes, consistent with infection by inhalation and the potential for onward transmission.

3.84 The spoligotype of each *M. bovis* isolate was identified and common *M. bovis* spoligotypes were isolated from a variety of wild mammal species which indicates inter-species transmission. Comparison with cattle and badgers showed a similar frequency of occurrence of spoligotypes with that found in wild mammals. Type 17 was the most common spoligotype, though four other types were also identified.

3.85 Information on prevalence of infection, pathology, and ecology, density and distribution of wild mammals was integrated in a qualitative risk assessment for the likelihood of transmission to cattle. The lowest risk was presented by grey squirrels, with intermediate levels of risk associated with small mammals, fox, stoat, polecat, muntjac and roe deer, and the highest risks being posed by red and fallow deer. Fallow deer however exhibited the highest frequency of cases with generalised TB, are more widespread across SW England than red deer and more likely to be found in grasslands frequented by cattle. This indicates a potential risk of disease transmission to cattle which is relatively high in comparison to the other species surveyed. However, none of the estimates of *M. bovis* prevalence for wild mammals in this study approach those observed in badgers. For example, in the vicinity of Woodchester Park, the prevalence of infection detected in RTA badgers at *post mortem* examination during 2000 -2003 inclusive was 20.5%. In addition, badgers are known to excrete potentially large numbers of bacilli and to forage on pasture and in buildings used by cattle. Nevertheless, deer have been implicated in the transmission of bTB to cattle, and in particular localities, especially when their population density is high, they could pose a significant risk. In this context, it is noted that there are rapidly expanding numbers and distribution of deer in southern England.

Wildlife and feral hosts in other countries

3.86 In other countries different species are associated with reservoirs of *M. bovis* infection. In New Zealand, the brush tail possum is an important feral reservoir of infection for cattle (Skinner *et al.*, 2000). While the possum is the principal feral reservoir of bTB, the disease has also been demonstrated in feral ferrets, though infection of the latter is not thought to be of epidemiological importance (Caley and Hone, 2000), and in deer. Wild deer in New Zealand are considered to be spillover hosts for bTB that mostly become infected through interactions with possums. Control of wild deer density is probably, therefore, not an essential component of a bTB eradication programme, but might usefully hasten elimination of the disease (Nugent and Whitford, 2000). More recently, *M. bovis* infection has been demonstrated in wild pigs in New Zealand. According to Nugent and Byrom (2005), sporadic outbreaks of bTB continue to occur in wildlife and livestock distant from known sources of infection, or in areas with too few wild animals to sustain the disease. Although wild pigs and ferrets are generally regarded as spill-over hosts of bTB, there is increasing suspicion that they play some role in sustaining and spreading the disease in these areas of unlikely occurrence: pigs and ferrets may play a central role in spreading bTB via three- or four-species chains (possums-pigs-ferrets/possums-livestock).

3.87 The possum is not a native species but has been introduced from Australia where it does not act as a reservoir for bTB and its numbers are controlled in an ecological balance. In New Zealand, however, the species is subject to less ecological control and it has multiplied, is spreading spatially and become a reservoir for bTB infection. Terminally ill tuberculous possums infect cattle. In possums, bTB is a respiratory infection, but clinical signs of infection are palpable abscessation of superficial lymph nodes, and sinuses draining from these abscesses (Skinner *et al.*, 2000).

3.88 New wildlife reservoirs are emerging:

- In South Africa, *M. bovis* infection was first diagnosed in the African buffalo in Kruger National Park in 1990. Over the past 15 years, the disease has spread northwards leaving only the most northern buffalo herds unaffected. The disease is spilling over into other wildlife hosts (including lions) but, as yet, not into domestic animals (Michel *et al.*, 2005);
- *Mycobacterium bovis* infection has recently emerged in Swedish deer (Wahlström and Englund, 2005) and has been recognised for 10 years in white-tailed deer in Michigan, USA (O'Brien *et al.*, 2005);
- In France, since 2001, *M. bovis* infections have been discovered accidentally in wild ungulates in Normandy, Corsica and Burgundy. In 2001 -2002, in the Norman "Brotonne forest" there was an apparent prevalence of bTB of 28% in wild boars and 14% in red deer (Boschiroli and Hars, 2005).

3.89 As yet undiscovered wildlife reservoirs may exist. For example, in the Kafue Basin, Zambia, prevalence of bTB in pastoralist cattle appears to increase with increasing level of contact with wildlife (Munyeme *et al.*, 2005).

Analytical Summary Box 8

bTB infection has been shown to occur in many wildlife species in UK, although prevalences are generally much lower than found in badgers. Though currently infected with lower prevalence than the badger, wild deer, notably fallow deer in south west England, are increasing in numbers and range and could be an alternative reservoir of infection, posing a potential risk to cattle because of the relatively high probability of contact between deer and cattle. In other countries, *M. bovis* exploits other wildlife/feral reservoir hosts, notably the possum in New Zealand and in South Africa it has recently adopted the African Buffalo as a reservoir host.

Studies of bTB infection in wildlife in GB have mostly concentrated on the badger. In view of the dynamics of population change of wildlife species and the ability of *M. bovis* to exploit different hosts, studies of bTB in wildlife hosts other than the badger, particularly fallow deer, should continue in UK.

4. *Mycobacterium bovis* control: controlling a disease with a wildlife reservoir

4.1 Strategies used to minimise disease in domestic animals with wildlife or feral reservoirs have been:

- separation, for example separating the African buffalo from domestic cattle in southern Africa to protect them from SAT types of Foot-and-mouth disease;
- immunisation, for example vaccinating the red fox population in some countries of Europe through distribution of an oral vaccine against rabies, and;
- wildlife population control, for example, in the case of *M. bovis*, to date, most activities have been directed towards elimination or reduction of the population of the wildlife or feral host.

Australia

4.2 Australia provides an example of elimination of the feral host. In Australia, the feral reservoir (water buffalo) was confined to one area of the country and provided a source of bTB infection for cattle, though over much of the country bovine bTB was largely or solely driven by cattle-to-cattle transmission. Control measures involved elimination of feral water buffalo, but it took a further 30 years of tuberculin testing of cattle with slaughter of reactors, complemented by rigidly policed and enforced cattle movement controls, and full farmer support, before bTB was finally eliminated from the national herd (NFBG, 2005; ISG, 2005b).

New Zealand

4.3 Corner *et al.* (2000) describe how population reduction by trapping (snaring) and baiting possums is used to control the spread of bTB from possums to cattle. This programme is costly, requiring continuous support and, by itself, does not reliably eradicate bTB. *Mycobacterium bovis* infection in wild possum populations is clustered both in time and space, and simple population reduction alone cannot be expected to achieve eradication. Vaccination is considered to be a potential complementary control tool and efforts are being made to develop a vaccine for possums against bTB using BCG as the live antigen. For field application it is anticipated that vaccination will follow an initial population reduction programme and will be on going to ensure adequate cover of the extant population and vaccination of any immigrants (Corner *et al.*, 2000). As a result of a multi-faceted, science-based programme, consisting of test and slaughter and movement control (zoning) in the cattle population, and culling possums, a deteriorating tuberculosis problem in cattle and deer in new Zealand has been halted over the last decade (Ryan *et al.*, 2005).

Republic of Ireland

4.4 Bovine tuberculosis has been an on-going problem in RoI for many years and there has been a national bTB eradication programme since 1954 leading to a considerable reduction in the prevalence of the disease by the mid 1960s. At this point, control was focussed on cattle farming and attention was being given to quality control of the programme, biosecurity and testing standards, mandatory pre-movement testing, cattle identification and traceability, strategic disease control measures in areas of high prevalence and enhanced data analysis through the introduction of computerisation. Despite these efforts, progress towards bTB eradication had stalled, though prevalence in cattle has subsequently remained low (More, 2005; More and Good, 2005).

4.5 In view of the disappointing progress, a major initiative was undertaken in 1988, primarily to limit cattle-to-cattle transmission, with the launch of the Eradication of Animal Diseases Board (ERAD), an executive agency to oversee the management of the eradication programme. Over the following four years, a more intensive programme of tuberculin testing was implemented through a refined programme management system. A reactor collection service, improved compensation, random sample testing of herds by government veterinarians, continuation of a pre-movement test, improved control of dealers, depopulation of problem herds, improved cattle identification and testing of cattle at factories and markets and extended restrictions of breakdown herds were introduced. Specialised epidemiological research and a bTB investigation unit were established, together with a bTB farm advisory service and a farmer awareness campaign covering issues such as disease-proof fencing, cleansing and disinfection, improved *post-mortem* procedures during factory surveillance, establishment of badger research and control services and improved control of fomites. However, despite these intensive measures and a substantial investment of financial and human resources, no substantive progress was observed: disease problems continued despite comprehensive measures to limit cattle-to-cattle transmission (More, 2005).

4.6 From 1992, the results of epidemiological research started to influence Irish policy with regard to bTB control. While brought-in cattle were identified as an important cause of herd breakdowns, there was generally little evidence of transmission from each primary case and substantial breakdowns were not common, despite very close contact during winter housing. As a result of mandatory annual testing and early and ongoing removal of infected animals, there is limited opportunity for Irish cattle to become infectious (that is, capable of transmitting infection) prior to detection. This is supported by field evidence, where breakdowns involving a single reactor accounted for between 38.3 and 44.4% of all breakdowns each year during 1987 – 1997 in RoI (O'Keeffe and Crowley, 1995 cited by More, 2005).

Skin testing

4.7 O'Grady *et al.* (2000) reported that approximately 50% of herds which disclose skin test reactors in RoI contain only one reactor. They suggest that a proportion of these singleton reactors may not have been infected with *M. bovis*, and may have given a positive reaction to the skin test due to sensitisation to environmental mycobacteria. However, approximately one third of singleton reactors showed lesions at abattoir examination, which is similar to the lesion rate in multiple reactor herds, and suggests that there are not many false positives among singleton reactors.

4.8 It should also be noted that the reported sensitivity of the comparative skin test is around 70-80% (WHO, 1994; Monaghan *et al.*, 1994). Therefore 20-30% of infected cattle will fail to react. The possibility that herds with singleton reactors actually contain other infected cattle is quite high and should not be forgotten.

4.9 All cattle are skin tested annually in RoI but imperfect sensitivity of the test has been acknowledged as a constraint to disease eradication in RoI. Evaluation of an

ELISA test and the IFN test has been undertaken. The sensitivity and specificity of the ELISA test was too low for use as a routine herd test. Although the IFN test is considered unsuitable as a screening test, when the skin test and the gamma interferon test are used together the sensitivity of the testing system approaches 97%. The tests are used together when testing herds which break down frequently and where the removal of as many infected animals as possible is a priority (Gormley *et al.*, 2003).

4.10 Prior to April 1996 pre-movement testing formed part of national disease control. Cattle can now be moved without a pre-movement test provided they have passed a tuberculin test in the previous 12 months. However, a cost benefit analysis is currently being undertaken with regard to the possibility of re-introducing pre-movement testing (More and Good, 2005).

Herd depopulation

4.11 Herd depopulation is rarely undertaken now because it has been demonstrated that, following a herd breakdown, depopulated herds do not have a longer period of disease freedom to a later herd breakdown than herds that were not depopulated (More and Good, 2005).

Abattoir surveillance

4.12 In RoI, the visible lesion rate (VLR) (the number of animals deemed reactor at a herd test where a tuberculous lesion was subsequently detected at veterinary inspection in the abattoir) has been progressively falling (from 40% in 1988 to 28.3% in 2004). However, in RoI, while VLR is associated with size of tuberculin test skin reaction, there is considerable variation in VLRs reported between factories where cattle are slaughtered (Frankena *et al.*, 2005) indicating that there are differences in the ability to detect visible lesions between slaughtering factories.

4.13 Only 2.2% of breakdowns had a lesion detected at factory inspection but no reactor and in 85% of these herds no reactors were identified at subsequent herd testing.

Herd level risk factors

4.14 Farm location is an important factor affecting the risk of a bTB breakdown in RoI: 50% of all skin test reactors have been located in 20% of the land area of RoI.

4.15 Olea-Popelka *et al.* (2004) carried out a retrospective cohort study of Irish cattle herds to investigate possible predictors of the hazard of a future bTB breakdown in a herd. In the study, the exposed group was made up of farms that had breakdowns in 1995 and the non-exposed group were farms that had not had breakdowns. Farms in the exposed group were at increased risk, both following singleton and multiple animal breakdowns. However, singleton breakdowns are of lesser risk of a future herd breakdown than breakdowns with more reactors: hazard of a future breakdown increases with breakdown severity (measured by the number of reactors). The hazard of a future bTB breakdown also increased directly with number of cattle in the herd, a positive history of previous bTB in the herd, and the local herd prevalence of bTB. The presence of confirmed bTB lesions in reactor cattle was not predictive of the future breakdown hazard when the effects of other factors were controlled. 38.4% of breakdowns are associated with a single reactor, with or without lesions at *post mortem* examination.

Role of badgers in the epidemiology of bTB in the Republic of Ireland

4.16 In RoI, evidence had been building of the potential role of badgers in prevalence of bTB. Evidence included (More and Good, 2005).

- isolation of *M. bovis* from badgers;
- recognition that badgers are highly susceptible to *M. bovis* infection with bTB being endemic in the badger population with a prevalence approaching 50% in a recent survey (in contrast, the apparent incidence of infection in cattle during 2002 was 0.4% - 29,162 bovine reactors from a population of approximately 7 million cattle);
- an association between badger density and the incidence of bTB in cattle in Galway;
- identification of identical strains of *M. bovis* in local cattle and wildlife, including deer and badgers, using both non-molecular and molecular methods and, most importantly;
- ongoing disease problems despite intensive disease control efforts aimed at early detection and prevention of cattle-to-cattle transmission.

4.17 In RoI, there is close proximity between badgers and cattle, given the preference of badgers in RoI to locate setts in hedgerows, rather than in woods, as in UK (University College Dublin, 2004).

4.18 However, proof was lacking of badger-to-cattle transmission: it was not possible to determine whether coincident disease (with identical strains) in local badgers and cattle is a consequence of badgers infecting cattle, vice versa, or co-infection from an independent source. Projects were implemented in order to clarify the role of badgers in infection of cattle with bTB (see the 'East Offaly' and 'Four Areas' Trials, below).

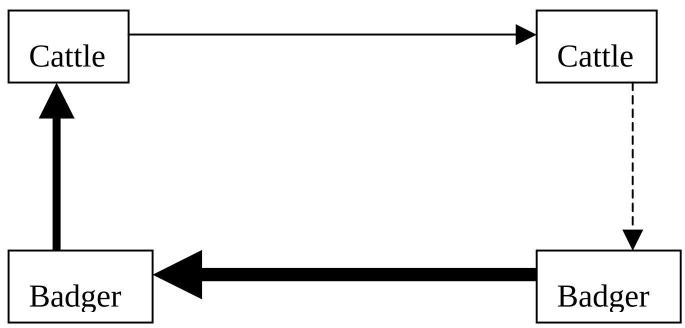
4.19 Among badgers in RoI, there is within-sett clustering of infection which is suggestive of close contact, either direct or indirect (Olea-Popelka *et al.*, 2003).

4.20 Because respiratory lesions are common whereas skin wounds are not, it is believed that aerosol is the main mechanism of badger-to-badger transmission.

4.21 Cattle to cattle transmission is small because the mean bTB prevalence in Irish cattle (reactors to the skin test) during 2002 was 0.4% (More, 2005) compared with nearly 50% in Irish badgers in the areas where badgers were trapped during the Four Areas Trial (see below).

4.22 It is suggested by More (2005) that spread of *M. bovis* between badgers and cattle is according to the diagram below (where the thickness of the arrow indicates the level of transmission) in that there is much transmission between badgers, some transmission from badger-to-cattle, less transmission between cattle, and doubtful whether there is any transmission from cattle to badgers:

Figure 1: Diagrammatic representation of transmission of bTB among badgers and cattle in RoI



4.23 It is worth noting that badger-to-badger transmission is believed to occur mostly within setts and social groups, unless the population is perturbed, therefore maintaining the disease in a locality. The spread from badgers to cattle leads to cattle herd breakdowns in that same locality. Cattle-to-cattle transmission, though less common, can be important if it involves cattle movements, as this can spread disease over longer distances.

4.24 The respiratory route is considered to be the most common route of excretion by badgers and cattle, and in both species, the respiratory route, rather than ingestion is thought to be the most important route of entry. When badgers share the same airspace transmission is most likely to occur between them. As in GB, there is evidence of badgers frequenting cattle housing without farmers being aware of their presence.

Current development of Republic of Ireland bTB control policy

4.25 In the short term, there is a national programme to cull badgers when and where they are implicated in on-farm breakdowns of bTB. These activities are focused in areas of higher disease prevalence. In these areas, badger removal will form the basis of temporary disease control (by minimising contact between cattle and infected badgers), and will also provide potential locations for vaccination trials and (later) usage. In the longer term, Ireland is committed to the development of an effective badger vaccine and the implementation of a strategic programme of badger vaccination, with the aim to reduce the transmission of *M. bovis* between infected badgers and susceptible cattle. The Government of RoI intends to make full use of modern information technology and data management in its bTB control programme. Data management systems in use in RoI include:

- Animal Health Computer System (AHCS);
- Cattle Movement Monitoring System (CMMS) since Jan 2000;
- Bovine Tagging and Registration System;
- Reactor Herd Management System (RHMS) – trace-back and trace-forward.
- Herd finder GIS system is accessible to assist with field investigation of bTB breakdowns.

Great Britain and Northern Ireland

4.26 Since most of this review is focussed on information pertaining to GB and sometimes NI, only a brief summary of bTB control policy is given here, as background. The current and possible future arrangements of the cattle testing and slaughter policy are presented.

4.27 The cattle test and slaughter policy remains a major part of the UK control policy and is the policy of the EU as laid down in Council Directive 64/432/ EEC. In 1975 the specificity of the test was improved when Weybridge human purified protein derivative of tuberculin (PPD) was replaced by Weybridge bovine PPD.

4.28 In GB, unlike in RoI where skin testing is performed on all cattle annually, skin testing is performed at one, two, three, or four year intervals. Counties in which the average herd incidence of confirmed bTB breakdowns has not exceeded 0.1% since 1998 are on a four year interval (in 2004 this applied to 74% of parishes and 61% of cattle herds). Otherwise, testing frequency is set on a parish by parish basis. The SVS Divisional Veterinary Managers are able to increase testing frequency over and above the baseline testing frequency prescribed by the EU Directive. Sixteen percent of parishes and 26% of herds, mostly in south west England and south Wales, are on a 1-year testing frequency. At the end of 2004 there were 2,739 overdue herd tests across GB. This situation has been addressed as since 16 February 2005 cattle herds are placed under movement restrictions if their routine test has not been completed by its due date (Defra, 2004b). Routine testing intervals will be reviewed annually (Defra, 2005). Stricter control of testing was introduced in NI in November 2004. Tighter controls included ensuring any herd test was completed before the “due by” date and subsequently preventing moves, even to slaughter, in herds with overdue tests. Since November 2004, there has been a 40% drop in number of herd breakdowns and a 45% drop in individual reactor numbers in NI. It is perhaps reasonable to suggest that stricter testing has influenced this trend, although a number of other factors probably also played a part. It should also be noted that the incidence has been decreasing in NI since early to mid 2003. It will be interesting to see how long the trend continues and if other factors, such as the reservoir of disease in the badger population, prevents further progress.

4.29 Currently, an independently chaired stakeholder group is developing a proposal for a new statutory requirement for pre-movement testing of cattle in GB on the basis that costs will be shared with the farmer, though ideally a more sensitive test than skin test is needed for this. A separate stakeholder group has been established in Scotland to develop proposals for post-movement testing, in addition to pre-movement testing (Defra, 2005). Recommendations in the report on proposals for a new statutory requirement for pre-movement testing, developed by independently chaired stakeholder group, are being considered. Defra aims to introduce pre-movement testing in England as quickly as possible.

4.30 The Welsh Assembly Government are working towards implementing pre-movement testing regime compatible with that proposed for England.

4.31 On 6 September 2005, the Scottish Executive Environment and Rural Affairs Department announced the introduction, from 23 September 2005, of compulsory pre and post movement testing requirements for Scotland.

Analytical Summary Box 9

Lessons from other countries:

Australia provides a good example of eradication of bTB through co-ordinated control activities. There was a reservoir of infection in feral water buffalo. This was easily eliminated as the animals were confined to a small area. However, it took a further 30 years of tuberculin and IFN testing of cattle with slaughter of infected herds, complemented by rigidly policed and enforced cattle movement controls, and full farmer support, before bTB was finally eliminated from the national herd.

In New Zealand, the feral possum population is an important reservoir host for *M. bovis* and a possum culling programme is part of the bTB control strategy. However, it is expected that population reduction will not achieve eradication of *M. bovis* from the possum population and efforts are being directed towards the development of an oral vaccine for delivery to possums, and for cattle, test and slaughter with movement controls, which includes zoning (restriction of movement between ‘hot-spot’ zones and clean zones.

In the RoI, like GB and NI, the badger has been implicated in the spread of *M. bovis* to cattle. Following intensive control measures, including annual skin testing of cattle with removal of reactors and movement control, bTB has been reduced to a low prevalence in cattle in the RoI (only 0.4% of tested cattle reacted to the skin test in 2002). However, trials of badger culling have been undertaken, and badger removal operations are now part of RoI bTB control policy. But, in the long term, the RoI is committed to the development of a badger vaccine to control the disease in its wildlife reservoir.

In GB, where the frequency of herd testing with the tuberculin skin test is determined by previous information on presence of bTB, herd testing is not being used optimally as a bTB surveillance tool, compared, for example, to its use on an annual basis in RoI and NI. In NI, following very strict application of an annual skin testing regime, giving no opportunities to delay herd tests and testing herds contiguous to breakdown herds, the number of herd breakdowns has reduced by 40%. It is perhaps reasonable to suggest that stricter testing has influenced this trend, although a number of other factors probably also played a part. It should also be noted that the incidence has been decreasing in NI since early to mid 2003.

5. Recent trials to investigate the role of the badger in the epidemiology of bovine tuberculosis and the effect of different badger culling strategies on the incidence of the disease in cattle herds

5.1 It is recognised that *M. bovis* infected badgers play a role in the epidemiology of bTB in cattle (Krebs *et al.*, 1997). Attempts have, and are being, made to quantify that risk and test strategies aimed at reducing the risk. Trials have been focussed on badger culling strategies. Trials have been completed in RoI and are currently still ongoing in GB. The work that has been done, the results that have been achieved, and conclusions that have been drawn, are summarised below.

Field trials carried out in the Republic of Ireland

East Offaly Trial

5.2 Definitive evidence was sought for involvement of badgers in infection of cattle and the East Offaly Trial was conducted from 1989 to 1995 (Eves, 1999). More and Barrett (2004) provide a summary of this trial. This involved the proactive removal of badgers from a central inner Project area (528 km^2) and outer Buffer zone (210 km^2), but not from the surrounding Control area (1456 km^2) where badger disturbance was minimal. A total of 1,264 badgers (an average of 0.34 badgers/km^2/year with 12% bTB disease prevalence based on lesion detection at *post mortem*, were removed from the Project area during the 7-year study period, with a removal intensity during the first two years of the study (when 71% of badgers were captured) of 0.85 badgers/km^2/year. Based on multivariable analyses, there was a significantly lower proportion of new confirmed bTB herd restrictions among cattle in the Project area as compared to the Control area. This effect has continued to the present day with the rate of herd restrictions within the Project area generally remaining at approximately one-third of the national average. This despite the 'doughnut' design with potential for continuing migration of badgers from the Control to the Project area.

Four Areas Trial

5.3 The results and conclusions of the Four Areas Trial reported below are taken from the official report (University College Dublin, 2004) and from Griffin *et al.* (2005).

5.4 The Four Areas Trial sought to build on the East Offaly Trial and to determine the effect of badger removal at a number of sites representing a wider range of farming environments. The study was conducted from September 1997 to August 2002 in purposively selected, matched[1] Removal and Reference areas (average area of 245.1 km^2 in counties Cork, Donegal, Kilkenny and Monaghan. Total size of Removal and Reference areas was 1961 km^2 and over 5,000 setts were identified. Badger removal (2-3 times per year) was intensive and proactive in the Removal areas throughout the study period (removal intensity of 0.57 badgers/km^2/ year during the first two years of the study), but reactive (in response to major outbreaks in cattle) in

[1] Matched for disease prevalence, natural geographical boundaries, livestock density, herd size, farm enterprise type, disease prevalence and geographical features.

the Reference areas where removal intensity during the equivalent period was 0.07 badgers/km^2/year. 2,360 (19.5% tuberculous) badgers were removed from Removal and Buffer areas, 258 (26.1% tuberculous) were removed from Reference areas. In the Reference areas, badgers were removed only following severe outbreaks of bTB involving four or more reactors. Farmer compliance with the programme was very good: only one farmer refused to allow his holding to be surveyed and there was failure to capture badgers at only 13 setts.

5.5 There was a significant difference between Removal and Reference areas in all four areas in both the probability of, and the time to, a confirmed herd restriction due to bTB. In the final year of the study the odds ratios (comparing the likelihood of a confirmed herd restriction in Removal areas with Reference areas) were 0.25 in Cork, 0.04 in Donegal, 0.26 in Kilkenny and 0.43 in Monaghan. These results, together with their confidence intervals, are shown in Table 4.

Table 4: Odds of a confirmed herd restriction in the Removal as compared to the Reference area.

Cork	0.25 (95% C.I. 0.07-0.88) on average 4x more likely in Reference area
Donegal	0.04 (95% C.I. 0.00-0.27) on average 25x more likely in Reference area
Kilkenny	0.26 (95% C.I. 0.08-0.79) on average, 3.8x more likely in Reference area
Monaghan	0.43 (95% C.I. 0.22-0.84) on average, 2.3x more likely in Reference area

5.6 In the Removal areas, 193 (11.7% of herds in the Removal areas) were the subject of a confirmed restriction on at least one occasion during the study period. In the Reference areas, 393 (26.7% of all herds in Reference areas) were the subject of a confirmed restriction on at least one occasion during the study period.

5.7 There was no significant change in the hazard of a confirmed herd restriction in any of the Reference areas between the pre-study and study periods (i.e. no effect of reactive culling).

5.8 If cattle-to-cattle transmission were still common in RoI, differences in disease incidence between the Removal and Reference areas would not have been as marked.

Conclusions that have been drawn from these field studies

5.9 A policy of badger removal from areas where bTB breakdowns are common in the cattle population reduces the risk of further breakdowns;

5.10 There was no evidence from these studies linking reactive badger removal with any increase in herd breakdowns.

Comments and criticisms that have been made regarding the trials that have been conducted in the Republic of Ireland on control of badgers and the Irish bTB control policy

5.11 The Four Areas Trial provides strong evidence that badgers have a role in propagating bTB in cattle (Godfray *et al.* 2005; ISG, 2005c). With regard to the question of the effectiveness of badger culling, the most that could be concluded is that virtual elimination of badgers over a substantial area and maintained over time is likely to have a beneficial effect on the incidence of bTB in cattle (ISG, 2005c).

5.12 The culling procedure, which involves use of snares two to four times per year and continues through the badger breeding season, is very different from that considered implementable in UK (ISG, 2005c). The RBCT in GB remains the only trial with the potential to provide information regarding the effectiveness of a less draconian badger cull which it is thought possible to implement in GB.

5.13 In the East Offaly and Four Areas Trials there was no experimental control area (no cull), therefore there is no way of deducing whether there was or was not a significant increase in levels of bTB in cattle in response to reactive culling (as has been demonstrated in GB) since there was nothing with which the data can be compared.

5.14 Reports and publications on the Four Areas Trial ignore published evidence on the perturbation affect on badgers produced by culling programmes.

5.15 In the Four Areas Trial, the Removal and Reference areas were selected using "purposive" sampling. It is suggested that the results may be widely applicable across RoI given knowledge of differences in farming systems, badger population densities and badger sett locations. None of these variables were included within the models presented so these statements cannot be justified. The purposive sampling procedure chose higher than normal prevalence areas for removal: these areas could have simply been at the peak of random temporal variation in prevalence, therefore 'due for a decrease', in which case the decrease observed may not have been a result of badger removal (Godfray *et al.*, 2005)

5.16 Information available suggests that the density of badgers in the four areas had been significantly reduced before the Four Areas Trial began. Overall density of badgers in GB and RoI appears to be very different. In the Four Areas Trial, badger removal intensity during the first two years in the study's Removal areas averaged 0.57 badgers per km^2 (this with a very intensive removal strategy involving frequent setting of snares). For the first year of the Random Badger Culling Trial (RBCT) 3.13 badgers per km^2 were removed from the proactive cull areas (this with an acknowledged less intensive removal strategy than in RoI, involving less frequent setting of baited traps). Surveys in RoI (Smal, 1993 cited by Phillips *et al.* 2003) have suggested that there should have been more badgers in RoI: the inference is there must have been considerable culling activity before the trial commenced. If there had been considerable culling activity in the years before the trial then the badger populations could have been perturbed. Given that the removal areas were purposively chosen to be areas where physical features could prevent badger recolonisation, it could be that the effect of perturbation was systematically less in the removal areas compared with the reference areas, biasing the trial in favour of the observed result. On the other hand, it could be argued that the cull in the Removal areas was not 100% - therefore, there could be left behind a small, but rapidly multiplying, very perturbed population?

5.17 Quantitative assessment of the benefit accruing in the RoI study is made difficult in that the impact varies significantly in the four counties studied and the impacts of limited culling in the Reference areas is unclear although these are claimed to be negligible (ISG, 2005c). Professor Simon More comments: "the culling in the Reference areas was at a very low level: to qualify for badger culling in the Reference areas a farmer had to have at least four reactors to the skin test and the breakdown had to be considered by epidemiological assessment as due to badgers. This was a more severe standard for culling than in the rest of the country where only one reactor is needed for epidemiological assessment and culling where badgers are implicated.

Farmers in Reference areas were not prepared to participate if culling of badgers was completely abandoned during the trial period".

5.18 Assignment of a separate DVO and team to each of the four areas, despite having central co-ordination, introduces the possibility of experimental error.

5.19 With almost complete co-operation with culling and seemingly low badger density, coupled with the capture method, the effects described are associated with virtual total badger elimination from Removal areas and buffer zones. The situation the RBCT faces is very different (ISG, 2005c):

- Farmer co-operation is lower;
- Higher initial badger densities make it difficult to cull and maintain low numbers;
- A political decision taken at the start of RBCT that, in accordance with the Bern Convention, bTB control policies would not include elimination of badgers from large tracts of the country;
- Badger welfare must be considered.

5.20 Because of the differences in design, implementation and setting, the results of the RoI study do not allow the impact of the proactive RBCT strategy to be predicted (ISG, 2005c).

5.21 In the report of the Four Areas Trial by Griffin *et al.* (2005), arguments are presented in the manuscript which suggest that proactive culling provides a useful management tool, yet paradoxically, the authors conclude that widespread badger culling does not offer a viable strategy for bTB control.

5.22 Professor Simon More commented: "the culling programme has a projected cut-off date and will cease when an effective oral vaccine is mobilised. A BCG oral vaccine is ready for field trials".

Randomised Badger Culling Trial in Great Britain

5.23 The Krebs report (Krebs *et al.*, 1997), recommended that MAFF should set up an experiment to quantify the impact of culling badgers on the prevalence of bTB in cattle. The report proposed that the experiment, in which farmers should play a role, should involve three treatments: proactive culling of badgers, reactive culling following the identification of bTB in cattle and no culling. Both of the culling policies should include lactating sows. The report further recommended that the experiment is conducted in a minimum of 30 10 km by 10 km highest risk areas ('hot-spots'). The experiment should be overseen and analysed by an independent Expert Group who will finally determine the precise areas to be included, assigning equal numbers of hot-spots randomly to each of the three treatments. For the remainder of the country, the Report recommended that no further badger culling is carried out.

5.24 In response to the report, MAFF set up an Independent Scientific Group on Cattle TB (ISG). The ISG set up the Randomised Badger Culling Trial (RBCT) to address the recommendations of the Krebs report to assess the effectiveness of proactive and reactive badger culling to control bTB in cattle with the intention of providing Government advice on future control policy options.

5.25 The culling methods and procedures employed had to take account of the practical difficulties of field work, landowner permission, and the public sensitivities concerning badger welfare. While this placed restrictions on trial design and implementation, it means that the methods used closely approximate how culling as a policy could be implemented in practice (ISG, 2004).

5.26 To avoid killing breeding female badgers with unweaned cubs which may starve in the sett, a closed season for culling was adopted from 1 Feb to 30 April. During May 1999 to 2003, when 4,705 badgers were culled, field teams failed to capture 12 un-weaned litters when their mothers were killed. In 31 other cases, lactating females were culled but litters of almost weaned cubs were also caught and killed at the same setts, usually within a day of capture of the mother. The number of unweaned cubs missed by culling teams was estimated at nine per year on average (Woodroffe *et al.*, 2005b).

5.27 Unlike the culling trials in RoI where snaring was used, only cage trapping was used in the RBCT to catch badgers for culling. After cage trapping, 88% of badgers received no detectable injuries. Of those that were injured, 72% received only minor skin abrasions. A minority (1.8% of the total) acquired damage to teeth or jaws that may have caused serious pain. Modifications to traps were made to make them less damaging (Woodroffe *et al.*, 2005c).

Design of the Trial

5.28 The trial involved three experimental regimes:

(i) proactive culling;

(ii) localised reactive culling, and;

(iii) no badger culling, referred to as 'survey only'.

5.29 The RBCT study commenced in 1998 and was designed to continue for five years.

Proactive culling

5.30 The objectives of proactive culling are to reduce badger densities to low levels across entire trial areas and to maintain low density by further culling on a regular basis within constraints imposed by issues of animal welfare.

Reactive culling

5.31 Reactive culling is initiated in response to confirmed bTB cattle herd breakdowns and subject to similar welfare concerns. Culling was undertaken across badger social groups occupying home ranges that overlapped the area used by reactor cattle.

Survey-only areas

5.32 Survey-only areas receive no badger culling but are subject to regular field surveys to record signs of badger activity and interference with setts.

5.33 Thirty trial areas, each of approximately 100 square kilometres, were selected as ten matched groups and labelled for identification purposes as triplets A,B,C,…..J. The three treatments were then allocated to areas within each triplet, each triplet being regarded as becoming active after the completion of its initial proactive cull. A security constraint prevented the random allocation of treatments in triplet I, but treatments were randomly allocated in all other triplets. Many aspects of the trial have been subjected to independent audit (ISG, 2004).

5.34 Two main developments have affected the course of the RBCT: firstly, restrictions on field activities as a result of the Foot-and-Mouth disease (FMD) epidemic suspended all trial operations over the 2001 culling year, from May 2001 to January 2002; secondly, the reactive component of the RBCT was suspended by Defra on 4 November 2003 (ISG, 2004). Other delays, including training and mobilising skilled staff have resulted in the RBCT being two years behind schedule (Godfray *et al.*, 2004). Currently, the predicted end point of the RBCT is mid-2006 (ISG, 2004).

Results of the reactive cull trial

5.35 The reactive cull trial was suspended because ISG presented interim results to Defra and produced a publication that showed, rather than producing a positive effect with regard to time between bTB breakdowns, it was estimated to lead to a 27% increase in herd infections (confidence limits from a 2% decrease to a 65% increase) (Donnelly *et al.*, 2003).

5.36 Two hundred and eighty two herd breakdowns had been notified by the time the reactive cull was suspended. From these, 179 had been subjected to a reactive cull. The remaining 103 (approximately 36%) were not culled because of lack or consent (6%), reporting an ineligible notification (6%), abandonment due to delays associated with FMD (4%) and notifications being due for culling at the time of the abandonment of the trial (20%). The reactive culling strategy was delayed because, before any field preparations for reactive culling could commence, breakdowns had to be confirmed by laboratory culture of *M. bovis* or the presence of visible bTB lesions. These inevitable delays are a feature of a reactive strategy, and the ISG argue that the RBCT is therefore a fair trial of the effects of policies as they would actually be implemented.

5.37 The first reported preliminary analysis of reactive cull data (Donnelly *et al.*, 2003) was conducted as if the reactive culling treatment began at the time of the proactive cull in the triplet, i.e. the breakdown incidence in the reactive cull areas that is compared with the incidence in the survey only areas was calculated by counting all breakdowns since the ‘triplet live date’ (the date of the end of the first proactive cull in the triplet). But 80% of reactive cull operations took place after April 2002 (i.e. after the FMD epidemic in 2001) and of the 282 herd breakdowns counted in the reactive cull areas by the time the reactive cull was suspended, 130 occurred before a reactive cull had been carried out in the respective triplet. It was therefore argued that only the incidence of breakdowns in the reactive areas counted after reactive culling had started would truly reflect any possible effect of reactive culling (Godfray *et al.* 2004). Further analyses of confirmed breakdowns have subsequently been conducted based on herd breakdowns up to 15 February 2004 (ISG, 2004) and beyond (ISG paper in preparation). These analyses include alternative definitions of time period under study (ISG, 2004), for example pre- and post-FMD and pre- and post- the date of the first reactive cull in a triplet. The results of these subsequent analyses are broadly supportive of the original findings (Donnelly *et al.*, 2003). Comparing incidence for the whole period from ‘live date’ to 15 February 2004, the reactive treatment was associated with an estimated increase of 28% in confirmed herd breakdowns (overdispersion-adjusted 95% confidence interval: 1.1% to 62% increase) compared to the no-culling survey-only areas. The analyses for different observation periods gave the following results (ISG, 2004):

- Before the first reactive cull in a triplet (total observation period of 11.9 triplet years) the estimate is a 30% increase in breakdown incidence associated with the reactive areas. As a result of the short observation time the confidence intervals of this estimate are very wide (95% CI from 13% decrease to 99% increase).
- After the first reactive cull (total observation period of 19.2 triplet years – but including the time from cessation of reactive culling in November 2003 to 15 February 2004) the effect associated with the reactive areas is an estimated 26.2% increase in breakdown incidence. Because the observation time is longer, the confidence intervals of this estimate are narrower (95%CI from 1.3% decrease to 61% increase).

5.38 The ISG interpret the results as "convincing evidence that reactive culling of badgers does not offer a beneficial effect" (on cattle TB) and that there is "substantial, though not overwhelming evidence of an adverse effect of the reactive strategy" (ISG, 2004).

5.39 Whilst the first part of the above statement can be quite clearly supported by the lack of any reduction in breakdown incidence (both between the no-cull and reactive cull areas and when comparing the periods before and after the start of reactive culling in the reactive cull area alone), the case for a detrimental effect (that led to the suspension of this aspect of the RBCT following the reporting of the preliminary analysis) is weakened by the subsequent analyses.

5.40 Referring to the result for the period before the first reactive cull, the ISG say "although the point estimate was non-zero, the CI includes zero so there was not a significant increase in herd breakdowns before treatment had commenced." The fact that the confidence interval for the effect after the reactive culling began ranges from only just below zero appears to be taken as (weak) evidence that there was an increase in herd breakdowns after treatment had commenced – i.e. something changed after reactive culling started. However, an alternative interpretation could be that the only real difference between the situation before and after reactive culling started in the reactive areas is that the increased incidence of breakdowns was not STATISTICALLY significant before (because observation time was short) but was closer to STATISTICAL significance after (because observation time was longer). In other words, nothing may have changed BIOLOGICALLY after reactive culling started –i.e. for some reason the reactive areas had a higher incidence of breakdowns than no-cull areas, even before reactive culling started and the start of reactive culling did not change this (the size of the estimated difference did not change much). This would undermine the argument that reactive culling had a detrimental affect. It may also lend some support to claims that inherent and systematic differences existed between no-cull areas and reactive areas (despite the randomised allocation of treatments to areas in each triplet) may have biased the trial and undermined the ability of the trial to show any positive effect of reactive culling.

5.41 In their 4th report, the ISG (2004) indicate the possibility that an increase in cattle bTB breakdowns in response to reactive culling could be caused by social perturbation in the badger population, but they caution that the processes involved are complex. The study carried out by Oxford University, on the effect of reactive culling in one of the triplets (E) on the badger population (University of Oxford, 2005) shows that the effect of reactive culling could be to 'stir up' disease in badgers, but others have argued that it would take some time for this to result in a noticeable increase in cattle herd breakdowns. Although the perturbation effect on the badger population and possible subsequent spread of bTB between social groups could be rapid, when account is taken of the fact that 80% of reactive cull operations in the RBCT took place after April 2002, they question whether an effect on cattle herd breakdowns could have followed so soon after, bearing in mind the period between infection and demonstration of reactors by annual skin testing or appearance of visible lesions at slaughter). On the other hand, it should now be recognised that the subsequent analysis includes analysis of herd breakdown incidence up to February 2004 (2 years after the start of reactive culling), so it might be argued that enough time has now elapsed for any effect of perturbation in the badger populations to have impacted on cattle herd breakdowns.

5.42 Sayers *et al.* (2005) have also made an analysis of the RBCT reactive cull data which indicates a beneficial effect of reactive culling for the breakdown farm triggering the cull. It must be stressed that their analysis is quite a different approach to that used by the ISG. Sayers *et al*. (2005) do not compare breakdown incidence between reactive cull areas and survey only areas. Instead, they looked at individual farms in the reactive areas only (thus avoiding any biases that may have been introduced by the allocation of treatments to the different areas). A survival analysis was carried out in which the population for the analysis consisted of the herds within the reactive trial core areas which experienced a confirmed bTB breakdown after the 'live' date and before 21/3/05 (307 farms and a total of 415 breakdowns). Survival analysis techniques were used to model the time period to a herd's next breakdown (if any) using several explanatory variables. Among the candidate explanatory variables was a variable describing application of the reactive cull in response to the breakdown using three categories:

- no badger cull took place, or if it did, no badgers were trapped (304 breakdowns);
- badgers were trapped and all were culture negative for bTB (54 breakdowns);
- badgers were trapped and at least one was bTB culture positive (57 breakdowns).

5.43 Several variables were significant in the final multivariable model. Survival time varied significantly between triplets and survival time was shorter for bigger herds and for herds with higher numbers of 'historic' breakdowns. With regard to badger culling, the model, accounting for the effects of triplet, herd size and breakdown history, also showed a significant effect of reactive culling. There was a significantly reduced hazard (that is a lower risk of further breakdown) when badgers were trapped that were culture negative for bTB (hazard ratio 0.54 with 95% confidence interval 0.33 – 0.89). The hazard was also reduced by a lesser amount when at least one bTB culture positive badger was trapped (hazard ratio 0.76 with 95% confidence interval 0.47-1.22).

5.44 These results indicate a benefit to the breakdown farms where reactive badger culling was carried out and removed badgers; i.e. breakdown farms where badgers were culled tended to survive longer before suffering a repeat breakdown than those where no badgers were trapped. This seems contrary to the ISG finding that reactive culling does not reduce breakdown incidence. One possibility is that whilst the breakdown herds are somewhat protected from repeat breakdown by badger removal, the reactive culling activity may lead to increased risk of infection to surrounding farms (leading to the area-wide lack of effect indicated by the ISG analysis). To provide further insight into this a further analysis is planned (to be completed in the next month or so) that will look at the possible effect of badger culling on the risk of breakdown faced by farms contiguous to the farms triggering a badger cull.

5.45 To summarise, the reactive cull component of the RBCT may still be open to differing interpretation. In fact, it may never be possible to 'prove' the veracity of one interpretation over another, given the unavoidable issues of lack of control inherent in field trials. Some issues will certainly be difficult to resolve given that no further field data are ever likely to be available. Good field evidence appears to be emerging for perturbation of badger populations in response to limited culling activity and there is some evidence that this can lead to increased spread of bTB between badger social groups. There is less certain field evidence that this then leads to more widespread cattle herd breakdowns in the vicinity, but this would be a logical extension. Conversely, there is some evidence that individual farms may face lower risk of bTB following a reactive badger cull. In simplistic language one might suggest that, whilst individual breakdown farms may see a medium-term benefit in terms of a longer time before re-infection (the result found by Sayers *et al.*, 2005), reactive culling, by stirring up the badger population leading to spread of bTB between social groups, has the end result of spreading an unchanged amount of cattle disease more evenly among all the cattle farms in the wider area (the result of the ISG analyses).

Results of the proactive cull trial

5.46 The ISG has been urged to release interim results of the proactive trial (Godfray *et al.*, 2004) but present reasonable arguments why this should not be done (ISG, 2004). The only indications of the proactive trial results that are in the public domain to date are in a Defra press release of November 4th 2003 (referred to by Godfray *et al.*, 2004), which says "the data for these areas do not yet yield statistically significant results", and the 4th report of the ISG (ISG, 2004), which states, "the results on the effect of the proactive treatment remain inconclusive". The ISG forecast, based on statistical calculations, that the trial will have run for long enough to draw useful conclusions from the results by mid-2006 (ISG, 2004), but the calculations carried out for the review of the trials by Godfray *et al.* (2004) suggest a later date, perhaps as late as 2008.

5.47 We have not had any privileged access to the interim results of the proactive trial and therefore cannot comment further.

5.48 Godfray *et al.* (2004) have posed the question - what is the RBCT set up to answer? They refer back to the Krebs Report (Krebs *et al.*, 1997) and emphasise the need to establish the quantitative contribution of badgers to the cattle bTB problem. They note that Krebs talked about achieving near total elimination of badgers in trial areas. However, the ISG (ISG, 2004) stresses that the experiment is a trial of viable policy options in field conditions and treatments must be politically, economically, socially and practically sustainable.

5.49 With the experience of the RBCT, in UK, near total elimination of badgers from large areas has been unachievable. This is in contrast to the situation in RoI.

Analytical Summary Box 10

Recent trials in RoI have concluded that widescale culling of badgers can lead to a reduction in cattle herd breakdowns. But there are serious issues that limit generalisation of this result to GB, and also issues of practicality in the GB situation.

In RoI, culling badgers was first shown to be an effective strategy through the East Offaly Trial in which a beneficial effect of culling badgers on bTB herd breakdowns was demonstrated. This was followed by the Four Areas Trial to demonstrate the effect of badger removal at a number of sites representing a wider range of farming environments. Again, a decrease in herd breakdowns was observed in the areas where badgers were proactively culled, compared to reference areas where there was limited reactive culling. Criticisms of these trials have been that there have been no control areas for comparison where no culling took place and purposive, rather than random selection of trial sites was made which could have introduced bias; perturbation of the badger populations through culling was neither considered nor discussed. It has also been pointed out that the results of these trials cannot predict effects of culling in the British situation because of differences of ecology and behaviour between Irish and British badgers and because the culling methodology adopted in RoI could not be applied in GB. In RoI, despite the results of the East Offaly and Four Areas Trials, government policy is to replace culling by vaccination of badgers as soon as an efficient vaccine is developed.

In GB, at the instigation of the Krebs Report, an Independent Scientific Group on Cattle TB (ISG) was set up to study the role of badgers in bTB and they devised the Randomised Badger Culling Trial to test policies of proactive and reactive badger culling. In this trial, sites have been selected and distributed randomly and proactive and reactive cull sites are compared with control sites where no culling takes place. The trial commenced in 1998 and was designed to continue for five years. However, activities in the field were delayed, particularly by the FMD epidemic in 2001. Consequently, in order to produce a conclusive result, the trial is now due to finish in 2006.

In 2003, the ISG presented surprising interim results of the reactive badger cull component of the RBCT. Rather than producing a positive effect, i.e. a reduction in incidence of bTB breakdowns of herds in the reactive cull area, it was estimated to lead to an increased incidence in herd infections (with wide confidence limits). As a result, the reactive cull component of the RBCT was abandoned. Others argued that the reactive cull data was analysed too soon for any changes in herd breakdown rate to be attributed to badger culling, bearing in mind the time needed between transmission of disease to cattle and disclosure of infection through testing or clinical disease. However, further analysis of data collected beyond the time of abandonment of the reactive culling, presented in the most recent report of the ISG, appears to confirm the lack of a reduction effect of reactive badger culling on herd breakdown rate.

It has been suggested that the adverse effect of reactive badger culling described could be due to the 'social perturbation' effect which has been observed following culling exercises, leading to spread of bTB in the badger population and more opportunities for *M. bovis* to spread to cattle.

In a survival analysis of reactive cull data which looked at individual farms in the reactive areas only, survival time to a herd's next breakdown was calculated for farms where, amongst other variables, (a) no badgers were culled (mostly because the trial was halted before the cull could be implemented), (b) badgers were culled but were bTB culture negative, and (c) badgers were culled and at least one was culture positive. Several variables were significant in the final multivariable model: survival time was shorter for larger herd size and for herds with higher numbers of previous breakdowns. With regard to reactive culling, there was significantly increased survival time in herds associated with culled badgers that were culture negative, and significantly increased survival time (though to a lesser degree) in herds associated with culled badgers, some of which were culture positive, when compared to herds where no badgers were culled. These results appear to contradict those of the first reactive cull analysis where reactive cull areas were compared with no cull areas. One might suggest that, whilst individual breakdown farms may see a medium-term benefit in terms of a longer time before re-infection (the result found in the second analysis), reactive culling, leading to perturbation of the badger population and spread of bTB between social groups, has the end result of spreading disease more evenly among all the cattle farms in the wider area (result of the ISG analyses).

With regard to the results of the proactive cull compared to the no cull areas, results will not be available until after the trial is concluded in 2006. There appears to be some concern that the trial may not reveal statistically significant differences between proactive cull and no cull areas. However, that in itself would be a conclusive result, provided the trial has collected sufficient data to demonstrate a significant difference if one had existed of sufficient size to be important.

6. Some results from computer simulation modelling of bTB control strategies

6.1 Smith *et al.* (1997) used a simulation model of bTB in a badger population to explore ways in which live testing of trapped badgers could be usefully incorporated into bTB control activities. They concluded that the use of an 'ideal test' (i.e. having 100% sensitivity), so that only infected badgers are removed when trapped, could lead to eradication of disease without population extinction. However, they comment that the sensitivity of the then current ELISA was 40.7% (Clifton-Hadley *et al.*, 1995).

6.2 Woodroffe *et al.* (1999) described the constraints imposed by live test sensitivity on attempts to control tuberculosis in cattle by removing infected badgers. They refer to, and use data from, a MAFF field trial in which badgers were trapped and tested with an ELISA test. If one or more badgers from a sett were positive, the whole sett was culled. The sensitivity of the test is 41% and the authors carry out mathematical modelling to show that the probability of identifying an infected sett, if prevalence is 30% is only 24-37% when around 2 badgers are tested per sett (field data). If testing is evaluated at the level of social group (several setts) then just over 3 badgers per group were sampled, but the probability of identifying an infected group is still only 43-62%. Even if all badgers in a group are sampled (average size 10) the chance of correctly identifying infected groups becomes 80%. The authors conclude that the low sensitivity of the live test is such a severe constraint that any feasible adjustment to the testing protocol would fail to produce a satisfactory level of detection.

6.3 Smith *et al.* (2001) used a further extension of the earlier model, using an extensive database of population and epidemiological parameters derived from Woodchester Park to examine badger culling policies in which a live test was used to identify social groups to be culled. The results can be summarised as follows:

- proactive culling (testing all badger groups once a year and culling if any positive) was the most successful strategy – in terms of reducing cattle herd breakdowns – the reduction was greatest and occurred over a few years;
- there was no effect of increasing trapping efficacy over 80%;
- doubling the number of badgers caught and tested from 2 to 4 doubled the effect on bTB control;
- the effectiveness increased if test sensitivity was increased, but no further benefit above 70% sensitivity (this will depend on the prevalence of bTB in an infected group and the number trapped and tested).

6.4 The model of Smith *et al.* (2001) continues to be developed. The addition of a 'cattle layer' allows badger control strategies, which are implemented in reaction to individual cattle herd breakdowns, to be simulated. More recently the model has been integrated with a cost-benefit spreadsheet model in order to estimate the overall cost, or benefit, of any badger control strategy in one or two simple steps. Preliminary results from this integrated modelling exercise have been made public (CSL, 2004b) but the authors of the report emphasise that these results should not be used in policy decision support. They comment, "… note that the results are also preliminary and may change as the models and parameter inputs are adjusted in the future." The model that produced the preliminary results contains several important assumptions and is subject to considerable, and potentially important, data uncertainty. For example, simulations were carried out at different levels of (hypothetical) badger bTB prevalence and in scenarios that either included or did not include a social perturbation effect. The authors also point out that, "The model assumes, simplistically, that each badger social group maps to one cattle herd…". There are several other simplifying assumptions, as is necessary in any modelling exercise, that must lead to caution when relating these preliminary results to real-life decisions. One result that appears to be of dramatic importance is that the modelled effect of badger culling on cattle herd breakdowns is highly dependent on whether perturbation effects are modelled or not.

Analytical Summary Box 11

Results of modelling have shown that testing badger groups annually, and conducting a badger removal operation on those groups with positive animals, could be a successful strategy in terms of reducing cattle herd breakdowns, but a test sensitivity greater than that currently available is required.

Modelling is a potentially valuable tool in policy decision support but care must always be taken regarding data uncertainty and assumptions in models.

7. Vaccine development

7.1 Worldwide, there are many efforts being made to develop vaccines against tuberculosis in humans, domestic animals and wildlife. In UK**,** Defra is estimated to be five years into a 15 year programme to develop a cattle vaccine. With regard to badgers, Defra is waiting for the results of the RBCT to assist it to decide on the resources it should put into development of badger vaccines (Hewinson, 2005), meanwhile Defra is continuing to fund collaborative research into the development of vaccines for both cattle and badgers.

7.2 In RoI, Government is committed to the development of an effective badger vaccine and the implementation of a strategic programme of badger vaccination, with the aim to reduce the transmission of *M. bovis* between infected badgers and susceptible cattle (More, 2005).

7.3 Development of a vaccine against *M. bovis* has concentrated in all species on use of BCG strain for antigen for two reasons:

- Although originally developed for vaccination of humans against TB, BCG is made of a live, weakened strain of *M. bovis*, therefore, BCG has the capability of generating protective immune responses to *M. bovis* in other species;
- BCG has passed safety tests and been licensed for human use and the strain is manufactured commercially according to GMP standards. Therefore, a licence for its use in wildlife or cattle should be relatively easy to achieve.

Cattle

7.4 As well as BCG vaccine development, DNA, protein sub-unit vaccination, vaccination with live viral vectors as well as heterologous prime boost scenarios for cattle vaccination are being studied at VLA, together with development of diagnostic reagents which distinguish between BCG vaccine and infection with *M. bovis* (Vordermeier *et al.*, 2004).

7.5 Subunit vaccines can be designed to allow continued use of the tuberculin test to discriminate between vaccinated cattle and those infected with *M. bovis* (Vordermeier *et al.*, 2000).

Badgers

7.6 Gormley *et al.* (2000) vaccinated badgers subcutaneously with a BCG vaccine. It produced no significant reaction to the Brock test but there was a significant reaction to the comparative skin test.

7.7 Southey *et al.* (2001) measured the immunological responses of a group of badgers vaccinated subcutaneously with low doses of *M. bovis* BCG *in vitro* and compared with non-vaccinated control animals over a period of 42 weeks. Peripheral blood mononuclear cells from badgers which had received repeated booster injections of BCG proliferated in response to culture with bovine PPD. The proliferation was significantly greater than that seen in the non-vaccinated control group. In contrast, the proliferative response of peripheral blood mononuclear cells from vaccinated badgers to avian PPD declined relative to the control group. The authors interpret these results as demonstrating that repeated vaccination of badgers with *M. bovis* BCG induced a population of T-lymphocytes responsive to specific antigens in bovine

PPD. No animals at any stage showed seroconversion to the Brock test, consistent with the tuberculosis-free status of the badgers under study.

7.8 In GB a parentally delivered BCG vaccine is to be field tested to gain safety and efficacy data. The antigen used for the vaccine will be a commercially produced BCG, licensed for human use, which meets GMP standards. Up to 500 (at least 300 - 400) badgers will be cage trapped, sampled and marked for identification. The samples will be subjected to a variety of tests, including an IFN test, Brock test, a trap-side test and culture. More than half of the trapped badgers will be vaccinated and in order to gain data on safety of the vaccine, a proportion of them will be held for 24 hours while their body temperature is monitored using constant monitoring devices. Then they will be released and attempts will be made to recapture them two weeks later with the expectation that at least 12 – 20 will be recaptured. They will be re-sampled and tested and checked for any adverse reactions at the site of vaccination. As well as blood, samples will include tracheal aspirates, urine, faeces and swabs of any bite wounds. The results of this field study will be used to inform further development of badger vaccines, including oral vaccines, and to provide Defra with information needed to consider vaccination as a strategy to control bTB in wildlife. The trial will continue for three to four years.

7.9 In RoI, a BCG oral vaccine for badgers is ready for field trials (More, 2005). This oral formulation is not yet standardised or manufactured to GMP standards. As such, unless further work is undertaken on safety and efficacy and it is produced to GMP standards in order to licence the vaccine for use in badgers, the possibility of its use may be limited to emergency or research situations.

Other wildlife

7.10 Much work has been done in New Zealand on development of a vaccine for possums.

7.11 Corner *et al.* (2000) conducted a field study in an area of New Zealand where bTB in possums was endemic to determine the efficacy of BCG vaccine and the practicability of vaccinating wild possums. BCG vaccination showed high efficacy for protecting possums against bTB under conditions of natural challenge. Although not suitable for broad scale application, vaccination of hand held possums by aerosol and conjunctival routes induced strong immunological responses.

7.12 During the study, bTB disappeared from the resident possum population. This may be attributable to a combination of vaccination and a halving of the possum population. For field application they anticipate that vaccination would follow an initial population reduction programme and would be on-going to ensure adequate cover of the extant population and vaccination of any immigrants.

7.13 To improve the efficacy of BCG vaccination against bTB in possums, Skinner *et al.* (2000) tried two approaches: first, BCG was combined with heat killed *Mycobacterium vaccae*; second, prior to vaccination by the intra-gastric route, stomach acidity was reduced by administration of a drug to treat gastric ulcers. Both approaches enhanced the efficacy of BCG vaccination against a subsequent challenge with *M. bovis.*

7.14 Buddle *et al.* (2000) found that vaccination with attenuated *M. bovis* strains protects possums against aerosol challenge. This result has prompted them to search for additional avirulent mutants of *M. bovis* that will induce greater protection than BCG and be useful for control of bTB in the possum.

7.15 Currently, a field study similar to the one in badgers in RoI is planned in New Zealand in which an oral preparation of BCG vaccine will be tested.

Analytical Summary Box 12

The results of this review indicate that all countries with a bTB problem where there is a wildlife/feral reservoir are interested in development of a vaccine, particularly for use in the wildlife/feral reservoir. In this respect, it is important that Defra is continuing to fund collaborative research into the development of vaccines for both cattle and badgers.

In wildlife, work in New Zealand and RoI is focussed on development of a live BCG vaccine to be delivered orally. In GB, efforts have now also been directed towards producing a BCG vaccine and a field test has been planned for a parentally delivered BCG vaccine in badgers. This vaccine is derived from a commercially produced BCG, licensed for human use and meeting Good Manufacturing Practice (GMP) standards. With this background, it should be easier to eventually license the product for field use.

8. Evidence for and against, and areas of uncertainty, in relation to culling badgers as a bTB control policy

The numbers in the table margins refer to the paragraph number in the review where each item of evidence is presented.

	Evidence for		Areas of uncertainty		Evidence against
3.2	In 1971 bTB caused by *M. bovis* was first identified in badgers in Britain in Gloucestershire by Muirhead *et al.* (1974). Since that time, a higher prevalence of bTB in cattle in south west England has been associated with the disease in badgers.	2.2	The short-term gains are far greater from controlling cattle movement than from killing badgers (Defra 2004a).	3.18	*Perturbation effect* Badger movements and home ranges have been observed to increase following culling, and such perturbation has been associated with a disruption in territorial boundaries lasting several years (Tuyttens *et al.*, 2000a).
3.2	Experiments conducted at CVL, Weybridge showed that badgers experimentally infected with a bovine isolate of *M. bovis* developed lesions and excreted the organism for up to 1,305 days and passed on the infection to healthy badgers and calves (Little *et al.*, 1982a).	2.3	Case farms that ascribed infection as brought in by purchased cattle were excluded from this analysis. In the remaining farms there were two main associations with bTB breakdowns: presence of badgers (approximately 40%); contiguous neighbours who had had confirmed bTB breakdowns (approximately 40%). The aetiological fraction for neighbouring cattle with confirmed bTB of 40% implies that the spread of bTB from herd to herd, across farm boundaries, may play a significant role in the epidemiology of bTB, at least in Northern Ireland (Denny and Wilesmith (1999).	3.19	*Perturbation effect* Tuyttens *et al.* (2000b) described recovery after a badger removal operation (BRO) at North Nibley, Gloucestershire and compared it with two nearby high density undisturbed populations (Wytham Woods and Woodchester Park). Badgers moved between social groups more at North Nibley than in the other study areas, particularly in the immediate aftermath of the BRO….the population took only 3 years to recover to its (already lowered) pre-removal density.

	Evidence for		Areas of uncertainty		Evidence against
3.26	A major part of the diet of badgers can be earthworms and they will search for them when they come to the surface at night. They will often seek them on pastures which brings them into indirect contact with grazing livestock. Badgers use latrines for defecation away from the setts as their boundary demarcators. These can be accessible to grazing livestock. They also have established pathways around their territories, and where they cross, badgers are liable to urinate. These points can also be accessible to livestock (Hutchings *et al.*, 2001; 2002).	2.5	Factors relating to the existence of previous infection in cattle and the management of cattle and badgers are all linked to the incidence of the infection-but those related specifically to the management of cattle are of overriding importance in determining the scale of the problem. They suggest that improvements to the procedure for testing and managing bTB in cattle, reductions in cattle stocking density, a greater human input in herd management and more-carefully targeted badger culling all might contribute to reducing the incidence and/or number of herd breakdowns (White and Benhin, 2004).	3.21 & 3.24	*Perturbation effect* In a field study of perturbation conducted by University of Oxford, badgers in two areas of the RBCT were studied: a reactive treatment area (where local badgers had been culled following a bTB breakdown in cattle) and a control (no-cull) area where no culling had taken place. After culling, an increased number of females were found to be reproductively active in the reactive treatment area compared to the control area, the reactive treatment area and neighbouring social groups increased their territorial overlap with adjacent groups with increased and overlapping home ranges and dispersal. Overlapping increased from 0.8 to 2.7 animals after culling. Aggression increased in the reactive treatment area social groups and neighbouring groups following culling, with higher rates of bite wounding. Prevalence of bTB in badger groups surrounding reactively culled groups increased. (University of Oxford, 2005).
3.28	Philips *et al.* (2003) suggest that increased badger density in UK may have forced some badgers, particularly those in the terminal stages of disease, to seek refuge in farm buildings where there is food and shelter and that farmers may not be aware that badgers are frequenting their buildings.	2.4	In their analysis of data from veterinary field investigation reports of bTB herd breakdowns in NI they suggest that 25% are due to purchase of diseased cattle, 47% to local spread from diseased cattle and 2.5% were attributed to wild life sources with a further 24% where the source could not be established (Menzies and Neill, 2000).	3.39	*Perturbation effect* There is evidence that bTB incidence in badgers is related to increased badger movement (Rogers *et al.*, 1998, cited by Wilkinson *et al.,* 2005).

	Evidence for		Areas of uncertainty		Evidence against
3.28	Roper *et al.* (2003) used radio telemetry and video surveillance to study farm visits by badgers on three farms. Badgers visited farm buildings, including cowsheds, feed sheds, barns, haystacks, slurry pits, cattle troughs and farmyards, in order to eat foods such as cattle cake and silage. Badgers defecated and urinated directly onto cattle feed and sometimes came into close direct contact with cattle.	3.22	Wilkinson *et al.* (2005) describe a spatial model of bTB in the badger and its transmission to cattle which was used to determine whether changes in movement and social behaviour following culling could increase the incidence of bTB in cattle. The model included density-dependence and local dispersal to give realistic rates of population recovery. Under the assumption that disease transmission between neighbouring social groups becomes equivalent to within-group transmission following culling, the model showed an increase in bTB incidence in cattle. It is important to highlight that this is a model-based result, not from real life, the modelling is well informed by the field studies carried on at Woodchester Park. The model implies that immigration is the most important mechanism for population recovery in a culled area and this has implications for the reintroduction and spread of bTB.	3.30	Badgers will normally avoid cattle where at all possible (Benham and Broom, 1989 cited by Nolan and Wilesmith, 1994).
3.29	Garnett *et al.* (2003) studied the ability of wild badgers to climb into cattle feed troughs set at different heights. At least 12 wild badgers climbed into a cattle feed trough set at heights above 80 cm (the recommended height in biosecurity guidelines for farmers). The maximum height climbed was 115 cm which is beyond the reach of calves and yearlings. They concluded that there is no trough height which is usable but completely excludes badgers.	5.41	In their 4th report, the ISG (2004) indicate the possibility that an increase in cattle bTB breakdowns in response to reactive culling could be caused by social perturbation in the badger population, but they caution that the processes involved are complex.	3.39	Prevalence of infectious badgers fluctuated but bore no linear relationship to the increase in badger density. (Delahay *et al.,* 1998).

	Evidence for		Areas of uncertainty		Evidence against
3.30	The ecological niche of the badger coincides with the ideal environment for cattle farming. This brings badgers into close and protracted contact with pasture, where infectious excretions may become available to grazing cattle (Delahay *et al.*, 1998).	6.3	Smith *et al.* (2001) used a model and an extensive database of population and epidemiological parameters derived from Woodchester Park to examine badger culling policies in which a live test was used to identify social groups to be culled. The results can be summarised as follows: - proactive culling (testing all badger groups once a year and culling if any positive) was the most successful strategy – in terms of reducing cattle herd breakdowns - the reduction was greater and occurred over a few years; - there was no effect of increasing trapping efficacy over 80%; - doubling the number of badgers caught and tested from 2 to 4 doubled the effect on bTB control; - the effectiveness increased if test sensitivity was increased, but no further benefit above 70% sensitivity (this will depend on the prevalence of bTB in an infected group and the number trapped and tested).	3.39 & 3.23	There is evidence that bTB incidence in badgers is related to badger movement (Rogers *et al.*, 1998, cited by Wilkinson *et al.*, 2005). There was a significant relationship between the annual proportion of badgers that moved and the incidence of disease in the population in the following year, such that years of high movement rates were followed by an increase in the number of new cases of disease detected in the population (Delahay *et al.*, 2003).
3.31	The badger is an ideal host for *M. bovis* infection (Gallagher and Clifton-Hadley, 2000).	3.72	Olea-Popelka *et al.* (2005) characterised the *M. bovis* isolates from the Four Areas Trial in Ireland into RFLP types and looked for spatial relationships between the cattle, badgers and setts from which they had been isolated. Although cattle and badgers tended to have similar *M. bovis* strains within broad geographic areas, there was no significant association between number of badgers with a given strain within 2 or 5 km of cattle herds and the risk of the same strain in these cattle.	3.54	A study by Warwick University did not detect any relationship between badger density and bovine bTB incidence (Warwick University, 2003). Badger setts and latrines were tested for *Mycobacterium* complex by PCR. Prevalence in setts was high (41%) and lower in latrines (12%). Per head of cattle, bTB incidence increased slightly with the proportion of sett samples that were PCR positive on the farm but there was no apparent relationship between bTB breakdown history of the farm and the proportion of positive setts or latrines on the farm.

	Evidence for		Areas of uncertainty		Evidence against
3.31	The badger is an ideal maintenance host because infected individuals can survive for relatively long periods and produce viable young, and infection appears to have no significant effects on population size or structure (Delahay *et al.*, 1998).	3.85	Fallow deer exhibited the highest frequency of cases with generalised bTB, and are more widespread across south west England than red deer and more likely to be found in grasslands frequented by cattle. This indicates a potential risk of disease transmission to cattle which is relatively high in comparison to the other species surveyed (CSL, 2004a).	3.55	Environmental load of bacteria is not well correlated with density of infected badgers, there being other important factors associated with the excretion behaviour of badgers (and cattle). This may limit the ability of badger culling, even targeted on infected badgers, to fully remove the infectious challenge in the environment.
3.32	In some counties of Britain, *M. bovis* infection in badgers has not been associated with bTB in cattle, which indicates that the infection can be maintained in the badger population without any other source of *M. bovis* (Nolan and Wilesmith, 1994).	4.2	In Australia, the feral reservoir (water buffalo) was confined to one area of the country and provided a source of bTB infection for cattle, though over much of the country bovine bTB was largely or solely driven by cattle to cattle transmission. Control measures involved elimination of feral water buffalo, but it took a further 30 years of tuberculin testing of cattle with slaughter of reactors, complemented by rigidly policed and enforced cattle movement controls, and full farmer support, before bTB was finally eliminated from the national herd (ISG, 2005a).	5.35	*RBCT* The reactive cull trial was suspended because ISG interim results showed, rather than producing a beneficial effect with regard to time between bTB breakdowns, it was estimated to lead to a 27% increase in herd infections (confidence limits from a 2% decrease to a 65% increase) (Donnelly *et al.*, 2003).
3.53	In UK cattle, risk of a herd becoming infected is positively related to badger sett density (Wilesmith, 1983, cited by Phillips *et al.,* 2003).	4.3	In New Zealand, Corner *et al.* (2000) describe how population reduction by trapping (snaring) and baiting possums is used to control the spread of bTB from possums to cattle. This programme is costly, requiring continuous support and, by itself, does not reliably eradicate bTB.		

	Evidence for		Areas of uncertainty		Evidence against
3.53	The badger population in UK is at its greatest density in south west England, where bTB prevalence is high (Krebs *et al.*, 1997).	5.12	*RoI Four Areas Trials* The culling procedure, which involved use of snares two to four times per year and continued through the badger breeding season, is very different from that considered implementable in UK (ISG 2005c).		
3.58	Sick badgers may enter farm buildings for easy access to food. In this connection, 64% of badgers found *in extremis* were infected by *M. bovis* (Delahay *et al.*, 1998).	5.46	*RBCT* As yet, the Trial has not been able to demonstrate a significant difference between the proactive cull and no cull areas (ISG, 2004).		
3.71	Costello *et al.* (2000) studied the spatial distribution of RFLP types identified in *M. bovis* isolates from badgers (121) and cattle (86) in an area of 300 km^2 in Ireland using a GIS database. There was a close correlation between the spatial distribution of RFLP types in badgers and cattle, which suggests that transmission of infection occurs between these species.				
3.74	Using data from the RBCT, Woodroffe *et al.* (2005a) investigated local spatial associations between *M. bovis* infection in cattle and badgers. *M. bovis* infections were locally clustered within both badger and cattle populations. *M. bovis* infections in badgers and cattle were spatially associated at a scale of 1-2km. Badgers and cattle infected with the same strain type (spoligotype) of *M. bovis* were particularly closely correlated. These observational data support the hypothesis that transmission occurs between the two host species.				

	Evidence for		Areas of uncertainty		Evidence against
3.76	Delahay *et al.* (2002), reporting on work conducted at the CSL and the VLA, concluded that the weight of evidence from studies does not appear to support the existence of a significant self-maintaining reservoir of *M. bovis* infection in any wild mammal in the UK apart from the badger.				
4.16	In RoI, evidence had been building of the potential role of badgers in prevalence of bTB. Evidence included: - isolation of *M. bovis* from badgers; - recognition that badgers are highly susceptible to *M. bovis* infection with bTB being endemic in the badger population with a prevalence approaching 50% in a recent survey (in contrast, the apparent incidence of infection in cattle during 2002 was 0.4%; - an association between badger density and the incidence of bTB in cattle in Galway; - identification of identical strains of *M. bovis* in local cattle and wildlife, including deer and badgers, using both non-molecular and molecular methods and, most importantly; - on-going disease problems despite intensive disease control efforts aimed at early detection and prevention of cattle-to-cattle transmission. (University College Dublin, 2004).				
5.2	*RoI East Offaly Badger Culling Trial* Based on multivariable analyses, there was a significantly lower proportion of new confirmed bTB herd restrictions among cattle in the Project (cull) Area as compared to the Control Area. This effect has continued to the present day with the rate of herd restrictions within the Project Area generally remaining at approximately one-third of the national average (More and Barrett, 2004).				

	Evidence for		Areas of uncertainty		Evidence against
5.4	*RoI Four Areas Trial* There was a significant difference between Removal (proactive cull) and Reference (limited reactive cull) areas in all four areas in both the probability of, and the time to, a confirmed herd restriction due to bTB. In the final year of the study the odds ratios (comparing the likelihood of a confirmed herd restriction in Removal areas with Reference areas) were 0.25 in Cork, 0.04 in Donegal, 0.26 in Kilkenny and 0.43 in Monaghan (University College Dublin, 2004).				
5.42 & 5.43	*RBCT* In a survival analysis of reactive cull data which looked at individual farms in the reactive areas only, survival time to a herd's next breakdown was calculated for farms where (a) no badger cull took place (mostly because the trial was halted before the cull could be implemented), (b) badgers were culled but were bTB culture negative, and (c) badgers were culled and at least one was culture positive. There was significantly increased survival time in herds associated with culled badgers that were culture negative, and significantly increased survival time (though to a lesser degree) in herds associated with culled badgers, some of which were culture positive, when compared to herds where no badger culling had taken place (Sayers *et al.,* 2005).				

9. Conclusion

9.1 The summary table in section 8 of this review shows strong evidence that the badger population of Britain can provide a reservoir of infection for *M. bovis*. There is also good evidence for indirect contact between badgers and cattle and contamination of fields and cattle housing and feed stores and troughs by excreta and discharges from infected badgers. Molecular studies also reveal that cattle and badgers in the same vicinity share *M. bovis* strains, indicating that there is exchange of infection between them.

9.2 Control strategies which include a culling policy have been tested in other countries, and in RoI two trials have demonstrated a reduction in bTB breakdowns in herds in areas where badgers have been removed. However, since the Krebs Report (1997), studies of badger culling exercises in Britain have so far failed to provide any clear indication that culling badgers, either reactively or proactively, has a useful effect on the incidence of herd breakdowns. On the contrary, there is evidence that prevalence of bTB in the badger population is not related to density of badgers and culling them leads to ‘social perturbation’. This can result in increased movements of badgers with further dissemination of the disease in the badger population which may lead to more, rather than less, herd breakdowns. This remains an area of uncertainty because models have indicated that in Britain, a reduction in herd breakdowns should follow badger culling exercises.

9.3 The summary table also shows evidence for transmission from herd to herd not involving badgers, both locally and over long distances. This, together with experiences from other countries, emphasises the need for effective and comprehensive control measures within the cattle population. Because a culling policy, as it can be implemented in Britain, has not yet been demonstrated to be effective, it is important that research into other strategies, such as separation of badgers from cattle through biosecurity measures, and vaccination of the badger population should be continued.

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Annex: Terms of Reference

Terms of Reference for a review of the international evidence for an interrelationship between cattle and wildlife in the transmission of bovine TB.

Background to the problem

Bovine TB is a growing problem in Great Britain. Over recent years we have seen year on year increase in cattle culled of around 18% and costs to the Government of £88.2m in 2004. Farmers and others, including vets, are very concerned about our inability to control this rising epidemic using present methods of cattle testing and culling. There is an urgent need to re-examine our bovine TB control policies.

Sir John Krebs carried out a comprehensive study of bovine TB in cattle and badgers and reported in 1997 (the "Krebs Report": Bovine Tuberculosis in Cattle and Badgers; MAFF Publications). He and his Group established that there was very strong qualitative evidence for a link between cattle and badgers in the transmission of bovine tuberculosis. He recommended that a complex replicated experiment be set up to establish the quantitative relationship in disease transfer between cattle and badgers. This experiment, known as the Randomised Badger Culling Trial (RBCT) was commissioned in 1998, and is due to cease and finally report in 2006.

A number of confounding factors have affected the trial since its inception and we now have to deal with the possibility that it will not yield evidence of a quantified link between cattle and badgers in the transference of the disease.

Current indications are that disease incidence and associated costs will increase and we must take some action in the near future. Thus urgent expert analysis of the bovine TB evidence base is being sought to establish the confidence with which we can pursue new policies if the RBCT fails to produce conclusive results.

Lessons learned

Experience from Australia shows that elimination of a wildlife host needed to be followed up by a long and extensive programme of cattle testing, slaughter, movement control and public awareness campaigns before bTB was eventually eradicated.

Population reduction of possums does not by itself reliably control bTB in cattle in New Zealand.

Terms of Reference

To review the recent (post Krebs, 1997) published research and available grey literature from UK and Eire on bovine TB to identify advances in knowledge:

of the interactions between cattle and badgers in disease transmission

and to identify the evidence for and against, and areas of uncertainty, in relation to culling badgers as a bovine TB control policy

Process

This review has to be carried out to a very short deadline. We ask that you send your synthesis report to the Chief Scientific Adviser by 8th **September**. The report will be independently peer reviewed before being used to inform the Chief Scientific Adviser's advice to policy colleagues and Ministers.

Confidentiality

Data Protection Act 1998. In line with Defra's policy on openness and transparency, your name will normally appear on the report as a matter of course. You should be aware that we may be required to disclose your report in response to a request, including under the Environmental Information Regulations, the Code of Practice on Access to Government Information and the Freedom of Information Act 2000. We would as far as practicable, seek to consult with you if such a request were received.

Conflicts of interest

All reviewers are asked to declare any personal interests (including relevant interests of close family and household members) and non-personal (for example, those relating to university departments for which a reviewer may be responsible) interests which they feel might conflict with their responsibilities as a reviewer of this project, or which may be *perceived* (by a reasonable member of the public) to influence their judgement. Note that reviewers are asked to declare both financial and non-financial interests.