First Report to the Rt Hon Dr Jack Cunningham MP from the Independent Scientific Group on Cattle TB - July 1998

Bovine TB: Towards a sustainable policy to control TB in cattle

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1.Background

Introduction and terms of reference

1.1 The Group formally came into being and began its work in February 1998. The full terms of reference given to the Group were:

To advise Ministers on implementation of the Krebs Report on bovine TB in cattle and badgers by:

- overseeing the design and analysis of the randomised trial to test the effectiveness of badger culling as a means of controlling bovine TB;
- regularly monitoring the progress of, and outputs from, the trial and assessing any important differences in results between the treatments;
- monitoring data on the *Mycobacterium bovis (M. bovis)* situation in areas and species outside the trial;
- reporting to Ministers on progress; and
- advising, as requested, on related issues.'

1.2 Our key task has been to advise on the design of the randomised trial recommended in the Krebs Report (sections 5.6 and 7.8) to ensure it is capable of giving robust results. However, we have been conscious from the outset that a key role of the Group is to recommend a combination of measures which, taken together, will provide information essential for the establishment of future policy. We have, therefore, considered the trial along with the other research recommended by Krebs.

1.3 Ministers have endorsed this wider remit for the Group. To fulfil this we have been closely involved in discussions with MAFF officials and the wider research community on the research requirements to address the issues surrounding TB in cattle and badgers. This first report focuses on the randomised trial but considers some of these wider issues.

Reviewing Krebs

1.4 In compiling this report, we have carefully considered the representations made to the Government in the wide scale consultation following publication of the Krebs Report. We have also, individually and as a Group, discussed the issues raised by the report with members of the research community, representatives from farming, veterinary, animal welfare and wildlife conservation organisations and with MAFF staff. Taking account of this wider input, we have critically reviewed the recommendations in the Krebs report. We align ourselves with the major findings of the Krebs review.

1.5 We think it worth reiterating Krebs' conclusion: ***The sum of evidence strongly supports the view that, in Britain, badgers are a significant source of infection in cattle'*** (Krebs Report 1997, page 6). However, as Krebs recognised, unambiguous quantitative scientific data are lacking.

Questions to be addressed

1.6 Having reviewed the evidence, we consider that the following key scientific questions must be addressed if a sustainable cattle TB control policy is to be implemented.

i. What is the quantitative contribution of badgers to TB infection in cattle and do the recommended proactive or reactive culling strategies result in a significant reduction in incidence of herd breakdowns?
ii. Might alternative badger control strategies, such as maintaining badger populations below a certain threshold, be used to control disease in cattle?

iii. Would these badger control strategies be cost effective?
iv. Can modifications be made to farm management practices that will reduce the transmission of *M. bovis* to cattle?
v. Could monitoring of badger population density and/or prevalence of infection in badgers be used to predict risk of infection in local cattle populations?

1.7 These key questions lead to other overlapping questions:

A Source of infection:

i. Is the badger the main source of *M. bovis* for infection of cattle?
ii. Do other wildlife species contribute to herd breakdowns either directly or by forming a source of infection for badgers?
iii. How significant is cattle-to-cattle transmission as a source of infection?

B Risk of infection:

i. Do different farming systems or farm management practices increase or reduce the risk of transmitting infection to cattle?
ii. Is the risk of herd breakdown related to factors such as:
   - badger population density
   - the prevalence of infection with *M. bovis* in badgers
   - the incidence of diseased badgers due to *M. bovis*
   - climate
   - geographical features?
iii. What factors influence the prevalence of infection with *M. bovis* in local badger populations, including:
   - population density
   - social group structure
   - climatic conditions?
iv. Do different genotypes of *M. bovis* present different risks?

1.8A further key question, which would be extremely difficult to answer relates to the route of transmission: if transmission of *M. bovis* from badgers to cattle occurs, is it by -

- direct contact
- aerosol as a consequence of close proximity
- contamination of pasture or other cattle feed.

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2. Objectives of the trial

2.1 The randomised trial and other research being put in place by MAFF will address all of the questions set out in section 1 above. Some of the critical questions above can only be addressed with the necessary rigour by a randomised scientific approach as recommended by the Krebs report and we, therefore, confirm our commitment to this.

2.2 The core aim of the trial is to present Ministers with a range of scientifically-based policy options which will be technically, environmentally, socially and economically acceptable. As well as careful scientific investigation, this will require assessments of, among other things, the environmental impact of these options, the financial effects for both farmers and the public purse, and the wider economic implications in terms of trade, change in national cattle testing regimes and human health.

2.3 It is essential that all the appropriate data are collected to permit such wide-ranging analyses. This is why the Group has, at an early stage, decided to commission a cost-benefit analysis of possible future policy options arising from the trial (see section 12 below).

2.4 The trial will, for the first time, allow comparison of two culling treatments with one of not culling, to assess the impact of each in reducing the number of herd breakdowns. It will also allow analysis of the relationship between badger population density and TB incidence in badgers and cattle and a multi-variate risk analysis covering factors such as husbandry and habitat. The trial will be applied under field conditions so any results can be extrapolated to national policy options.

2.5 Responses to the consultation on Krebs ranged from those who believed that large scale culling of badgers was the only way to control TB in cattle, to those who did not accept that badgers could transmit TB to cattle, and therefore believed that no culling of badgers could be justified. The evidence supports neither extreme; nor can we. The interests of animal health and welfare and, in addition, important considerations of public health, underline the need to develop an armoury of measures to combat TB in cattle and fully warrant the proposed randomised trial.

3. Practical issues, communications, and training

3.1 Possibilities of non-co-operation or interference with the trial have been widely raised by respondents to the Government's consultation exercise. This could result from three possible causes: landowners/occupiers unwilling to take part in the trial; illegal culling of badgers; and interference with MAFF culling operations.

3.2 In the absence of primary legislation, MAFF advise us that owners/occupiers may elect not to participate. While all feasible steps will be taken to ensure that individual failures to participate will not nullify the trial, nevertheless, non-compliance on a large scale would have serious consequences for the interpretation of the trial data.

3.3 If badger culling were effective in reducing TB incidence in cattle, illegal culling of badgers would reduce the difference in TB incidence between areas subject to culling and the no-culling areas within the trial, making it appear less effective than it really was. Thus, illegal culling of badgers would create difficulties because it would distort data from the trial and extend the time needed for the trial to generate conclusive results. Such action would not be in farming interests and we urge the Government and farming organisations to do everything possible to ensure that such action does not take place.

3.4 Interference with MAFF culling operations would also delay the availability of data and extend the period needed for the trial to furnish the necessary quantitative data. If badger culling were ineffective in reducing TB incidence in cattle, interference with culling would increase the time taken to reach this conclusion, requiring the culling of more badgers than necessary. Such interference would not therefore be in the interests of conservation or welfare groups. For these reasons, we hope that farming, conservation and welfare organisations will all encourage their members to support the trial and to comply with the treatments, ensuring that conclusions can be reached as rapidly as possible.

3.5 We recognise that there are important challenges in mounting a major trial of this type. However, we believe that these are not insuperable: with goodwill and an understanding and recognition, on all sides, of the problems and sensitivities involved, we believe that all the parties who have a genuine interest in animal health and welfare will accept and support the need for this work.

3.6 However, this will necessitate a major exercise to **explain** the trial to interested parties and to ensure, as far as possible, that those who are directly affected fully understand the need for their co-operation and the implications of non-co-operation. We understand that the Government is putting in place a wide-ranging communications strategy to address this imperative. We fully support the need for this.

3.7 The need for good communications extends not just to external audiences, but also to MAFF staff who will be directly involved in handling TB breakdowns and in the operation of the trial. It is essential that all staff who are involved in the implementation of the trial fully understand the issues, the actions being taken and their part in them.

3.8 Standard operating procedures will be drawn up to cover both implementation of the trial and the revised epidemiological questionnaire to be used to investigate all TB breakdowns. These are crucial to the success of the trial and will be regularly monitored and reviewed as the trial progresses. It is essential that all staff who will be involved in applying these procedures are properly trained. Monitoring and quality control, not just by MAFF managers, but also by independent assessors on behalf of the Group (see section 14 below) will also be essential to maintain a high level of data quality and hence confidence in the results of the trial.

3.9 In developing our advice on the conduct of the trial we have taken account of four key criteria: data quality, animal welfare, efficiency of implementation and cost. It is essential that we secure robust data: without this, the trial will not provide Ministers with the information necessary to evaluate future policy options. We have therefore recommended the approach that will produce the best results while minimising adverse impacts on badger welfare. This has implications for costs. We have therefore examined the consequences of scaling down the trial, and in some areas have identified cost saving approaches which would reduce the overall value of the trial, but which would not undermine the reliability of the results needed to underlie policy evaluations. Our recommended approach is intended to be cost-effective whilst maintaining the necessary scientific integrity.

3.10 The Group will continually monitor and review protocols and procedures in the light of experience gained from the trial.

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4. Identification of treatment areas

The treatments

4.1 The Krebs report recommended there should be three treatments:

1. **proactive culling**, where all badgers within the treatment area are culled;
2. **reactive culling**, where badgers from social groups associated with a breakdown are culled; and
3. **no culling.**

4.2 We have considered further how these three treatments would be applied in practice.

1. **Proactive culling** is self-explanatory. The target would be to cull as large a proportion of badgers resident within the treatment area as possible, and to prevent recolonisation by further culling on a regular basis.
2. **Reactive culling** will be triggered by a herd TB breakdown occurring within the treatment area. For this purpose, we do not recommend that any attempt is made to establish whether the breakdown should be attributed to badgers. The "trigger" point would be either visible lesions characteristic of TB found in the carcase of an animal which had reacted to the tuberculin test, or any animal from the herd giving a positive result for TB on laboratory culture.
3. The **no culling** treatment will constitute an experimental control, by which the effects of the culling treatments can be measured. We propose that surveying for badger activity should take place in the no-culling areas (see section 6), for this reason, we suggest that the term "survey only" is used, to distinguish this treatment from the rest of the country (outside the trial), where there will also be no culling.

We therefore confirm the Krebs recommendation that three treatments should be compared in the trial: reactive culling of social groups in response to breakdowns; proactive culling; and survey only with no culling.

The need for three treatments

4.3 In the light of particular concerns expressed by respondents to the consultation on Krebs about the implications of the proactive culling strategy, we have reviewed the need for this treatment to be trialled. Key concerns were the effect on badger populations and the appropriateness of trialling a treatment which was not perceived to be more widely applicable.

4.4 The precise effect of proactive culling on badger populations will not, of course, be known until we have hard data from the trial, although it has been suggested that the Krebs report has under-estimated the number of badgers which would be culled during the trial. We shall monitor this carefully.

4.5 We consider the inclusion of the proactive treatment to be essential for the following reasons: firstly, it will demonstrate the maximum effect that can be achieved by culling with methods considered acceptable on animal welfare grounds.

4.6 Secondly, the proactive treatment represents a management strategy that might form a component of future TB control policy. Given the current and potentially increased seriousness of the disease, both for animal and public health, we would recommend that no options be excluded at this stage: targeted proactive culling in very restricted circumstances might prove to be an effective management tool.

4.7 Thirdly, the proactive treatment will provide detailed data on the distribution, prevalence and disease severity of various strain types of *M. bovis* within badger populations which vary in density, habitat and history of past MAFF control. These data will provide important information on the epidemiology of TB in badgers, and the circumstances under which infection is (or is not) transmitted to cattle. Such data will be invaluable for the design of future management strategies.

4.8 We also consider a treatment based on reactive culling of badgers to be a vital component of the trial. It should be noted that the "reactive" treatment we propose differs from the "interim" strategy used by MAFF since 1986 in that it aims to remove all badgers that might have caused a breakdown by culling all badgers in social groups with access to the reactor land. The proactive and survey-only treatments provide benchmarks against which the cost-effectiveness - and thus future value - of reactive culling as a possible component of future policy can be measured.

4.9 Finally, the survey only treatment is vital to allow quantitative assessment of the extent to which the two culling treatments influence TB incidence in cattle. In the past, it has been impossible to assess the impact of badger culling because it has been implemented in all cases where herd TB breakdowns have been attributed to badgers. By including areas where no culling will be carried out, the trial will determine whether any changes in incidence in culled areas result from culling or simply reflect temporal changes due to other factors.

Number, size and shape of treatment areas

4.10 The Krebs Report recommended that the Group should determine the areas to be enrolled in the trial. It also recommended a sensitivity analysis to test the assumptions used in the illustrative approach to selection of areas set out in the report (Krebs report 1997, pages 90-93). This suggested that a minimum of 30 10 km by 10 km (100 km^2) squares, identified on the basis of the number of repeat or contiguous breakdowns experienced over a period, should be enrolled in the trial.

4.11 The Krebs report recommended that we examine the assumptions on which the size, number and location of the treatment areas were based; we have done this. We recommend that the total trial area should comprise 30 broadly circular treatment areas each of 100 km^2 . The use of circles of this size will minimise boundary effects and hence provide the maximum possible data suitable for analysis. It will also provide manageable areas for treatment to provide the necessary data within a reasonable timescale.

4.12 We consider that the circle thus provides the best shape for the initial identification of areas. However, in practice, the final treatment areas will not be perfect circles since boundaries of farms must be taken into account. Natural and man-made boundaries will also be taken into account to avoid edge effects and, specifically, to minimise the impact of each treatment area upon its neighbours. (See section 5 on boundary definition).

Grouping treatment areas and allocating treatments

4.13 We recommend that the treatment areas should be grouped into triplets (with each of the three areas within each triplet allocated to one of the three treatments) and that, where possible, proximity should be used as a criterion for establishing triplets. This will help to increase the similarities, in terms of terrain and badger density, of treatment areas within the same triplets. It will therefore increase the sensitivity of the trial to detect the effects of badger culling.

4.14 Thus, we expect three areas to be identified in the same locality to form a triplet. Within a triplet each of the three areas will be randomly allocated to one of the treatments. This will avoid the risk of bias in the assignment of the three treatments leading to systematic differences between them.

4.15 We also recommend that the random allocation of treatments to areas should be carried out at the latest possible time point and following the determination of boundaries and the first full survey (see sections 5 and 6). This is essential to avoid any bias in either compliance with the trial or determination of treatment boundaries.

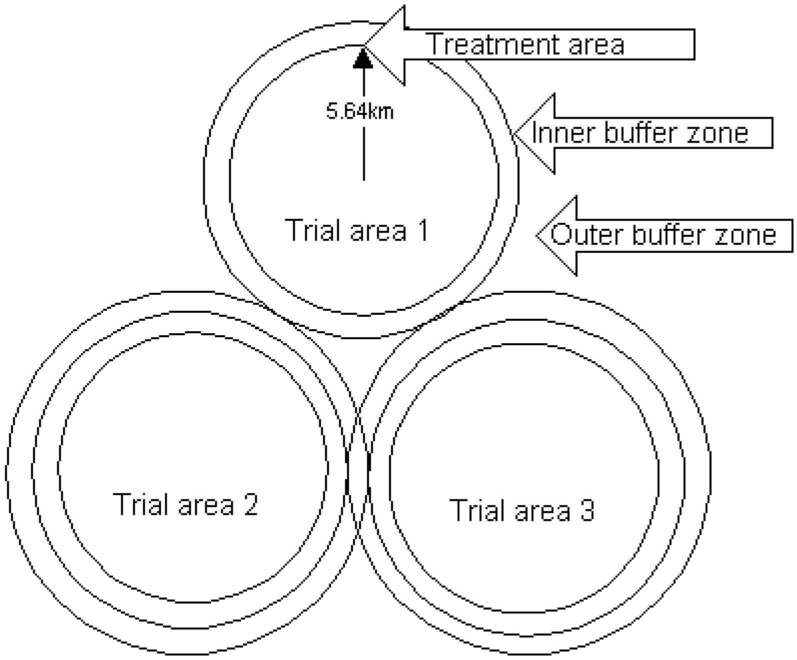
4.16 We recommend that the random allocation of treatments to areas should be witnessed by both MAFF and non-MAFF observers.

Buffer zones within triplets

4.17 Proximity of the three areas within a triplet is important. However, we have to balance the conflicting needs of maximising similarities between areas within a triplet and minimising the potential for the treatment applied in one area to interfere with the treatment in another area. We therefore recommend the use of buffer zones, where necessary, between the treatment areas within a triplet (and, by extension, between triplets). Buffer zones will only be required where there are no boundaries considered impassable to badgers (e.g. large rivers; sea etc. - see paragraph 5.4).

4.18 We recommend that, where used, buffer zones should include an inner zone, 1 km wide, and an outer zone, also 1 km wide (see figure 1). The 1 km recommended width broadly reflects the diameter of the territory of one badger social group.

Figure 1 - Illustration of a triplet of treatment areas



4.19 Treatment areas may share outer buffer zones. However, inner buffer zones may not be shared.

4.20 Thus, in the absence of boundaries impassable to badgers, treatment areas within a triplet will be separated by a minimum of 3 km (representing two inner buffer zones and one outer zone). Similarly, each triplet will be separated by at least 3 km.

Locating the treatment areas

4.21 The impact of culling will be most easily detected in areas where the risk of herd breakdowns is high. In particular, the reactive strategy is likely to be most effective where the risk of recurrent and contiguous breakdowns is greatest. The Krebs Report suggested that trial areas might be selected on the basis of the number of repeat and contiguous breakdowns per 100 km^2 area over the most recent five year period. This took account of data up to the end of 1996.

4.22 Herd incidence data are now available for 1997. It is clear from these that incidence of the disease has continued to rise with particular continuing problems in the MAFF West region (comprising Cornwall, Devon, Somerset, Gloucestershire and Avon, Wiltshire, Dorset, Hereford and Worcester and Shropshire) and extension of the disease into the West Midlands (particularly Staffordshire).

4.23 We recommend that the most recent confirmed incidence data should be used to identify treatment areas. Since there is also a strong correlation between the number of repeat and contiguous breakdowns and the total number of breakdowns in an area, we conclude that it is sufficient merely to consider the most recent total confirmed breakdowns when selecting areas (see paragraph 4.26 below).

4.24 We have also reviewed the period over which incidence data should be considered. From our updated analysis, we recommend that data from the three most recent years are sufficient to establish the status of an area as an area of high incidence and so suitable for inclusion in the trial. We also recommend the additional criterion that there should be a continuing breakdown problem in the last calendar year before the survey year. Thus, an area which had had a breakdown problem in the past, but which had no breakdowns in the most recent year would not be a candidate for inclusion.

4.25 Having assessed with MAFF the resources required to enrol the full number of required areas into the trial, we conclude that these are insufficient to enable all ten triplets to be enrolled into the trial immediately. We therefore recommend that triplets should be identified on a rolling basis, taking account of the most recent breakdown data at the time each triplet is selected.

4.26 The revised criteria on breakdown data for inclusion in the trial will go some way towards meeting the concerns of farmers in the newer areas where incidence is increasing.

4.27 Ideally areas within a triplet would be identical in terms of a number of key factors such as: breakdown histories (recurrent, contiguous and total); numbers of holdings (dairy, beef and mixed); total surface areas; badger population density and number of cattle. However, such precise matching is not feasible in practice. Nor do we consider it essential.

4.28 Thus we recommend that areas which have had the highest incidence of TB in cattle over the most recent three years for which data are available at the time of selection and which have had breakdowns in the most recent of those years should be the prime candidates for enrolment into the trial. In addition, treatment areas within triplets should be balanced so that they have similar numbers of cattle holdings (a minimum of 50) and similar surface areas.

4.29 We have identified two triplets which we recommend should be enrolled immediately with the initial full survey and culling, where appropriate, undertaken in 1998. However, we recommend that fieldwork for the remaining 8 triplets should start in 1999. We recognise the severe logistical challenges of putting the remaining triplets in place by the end of 1999, but this is our recommendation. This is essential to ensure quantitative results are available as quickly as possible. Thereafter, we shall continue to keep TB breakdowns under review and shall recommend inclusion of new problem areas or new triplets into the trial, should this be necessary to meet the objectives of the trial, and where they meet the basic criteria.

5.Defining treatment area boundaries

5.1 Section 4 above outlines the key criteria for determining candidate treatment areas. The standard operating procedures for the trial will set out in detail the steps to be followed to draw the boundaries on maps so as finally to determine these. We envisage this initial process as desk based. There may be some scope for public access surveys, where members of the Wildlife Unit investigate a location as far as is possible using public rights of way. Such a survey might identify, for example, former pastures which have been converted to arable or woodland, or new housing developments. However, it is considered that this approach will not generally add much useful information. The boundaries thus established would subsequently be confirmed by the full initial survey (see section 6).

5.2 The Group will pass to MAFF the map references for the centre of each 100 km^2 candidate treatment area in a triplet and the total number of new confirmed breakdowns by area over the three year period taken into account for the purposes of selecting the area

5.3 A designated Wildlife Unit boundaries team, reporting to the National Trial Manager, will then plot these centres, together with the 100 km^2 circles on a map, adding details of all cattle holdings within the circle and within 2 km of it. Ideally this should be done on computer by means of a geographic information system (GIS). Known farm boundaries should then also be plotted.

5.4 The circle boundaries would then be adjusted to treatment area boundaries by reference to any natural features impassable to badgers.

These would include the sea and large rivers. These features, used as boundaries, would obviate the need for buffer zones. Other features, such as smaller rivers, might then be used as additional boundaries, but would need to have buffer zones adjoining.

5.5 There is no easy solution to the treatment of part-farms which fall within the boundaries with other separate parts falling outside the treatment area boundary. We recommend, therefore, that such part-farms should be included in the treatment area but that any other part or parts of the same farm which are geographically separate and which fall outside the boundary line should be excluded. However, links between farms in treatment areas with any land occupied outside the treatment area, and the nature of the link (e.g. livestock grazed there etc.) must be noted and confirmed at the time of the survey. Information from MAFF's animal health database (Vetnet) may be useful to identify such fragments in the first place; thereafter, following a herd TB breakdown, the epidemiological questionnaire will identify fragmented grazing land which will be mapped.

5.6 Another key issue raised during the consultation on Krebs concerns farms or other areas of land where the owner/occupier is not willing to co-operate with the trial. Where there are large, known special areas, such as nature reserves or sanctuaries which can readily be excluded from the trial by adjustments to boundaries, we suggest that this might be taken into account at the desk stage. We considered whether possible non-co-operation at a more local level should be taken into account in determining boundaries for the trial areas. On balance we would advise against this, since it might generate systematic biases in the areas.

5.7 We would expect to be consulted at the stage where the final boundaries of a treatment area have been established but before surveying has been commenced, to ensure that the criteria for determining boundaries had been applied properly, and that the members of each triplet had been properly matched.

6.Surveying the trial areas

6.1 Surveys are a crucial source of data for the randomised trial and are essential to measure relationships between badger density and TB incidence in cattle, both between and within the three different treatment areas. Our aim is to produce local estimates of badger density for each treatment area, and then to record changes in these estimates over the course of the trial.

6.2 In combination with the culling data collected in the proactive and reactive culling areas, and data generated by the recommended road traffic accident survey (see section 10), the survey data could be used to estimate local badger density, territory size and TB prevalence for the treatment areas. Such extensive data are not available elsewhere, but are essential to investigate the correlates of TB incidence in cattle.

Initial badger surveys

6.3 We see three core objectives for the initial surveys recommended: to provide baseline estimates of badger density; to locate setts for trapping; and to define the borders of removal areas.

6.4 These surveys will:

1. allow estimates of badger density to be included when comparing herd breakdown rates within and between treatment areas;
2. permit comparison of local badger density between breakdown farms and farms which do not experience breakdowns; and
3. iii. provide a baseline against which subsequent changes in badger populations can be measured, thus allowing analyses of the extent to which herd breakdown rates track changes in badger numbers.

6.5 In the culling areas of the trial, the initial survey will identify setts and other sites where badgers may be caught. It will thus permit rapid removal of badgers from proactive culling areas, and will also accelerate the location of setts for trapping following herd breakdowns in reactive removal areas.

6.6 Finally, by identifying badger social group territories, the survey will delineate the precise borders of removal areas from which badgers will be culled in the proactive areas. This will extend beyond the boundaries of the treatment area (identified by the desk exercise to delineate boundaries) to the extent necessary to cull entire social groups whose territories impinge on this area. Where reactive culls take place near the boundary of a treatment area, the same procedures will apply.

6.7 Surveying is labour intensive. For this reason we considered a range of survey options which might be applied to each triplet as it is enrolled into the trial. For the reasons set out in Appendix 1, we recommend that all treatment areas be subject to an initial survey, recording the location, size and activity of all badger setts, as well as other signs of badger activity (e.g. territorial latrines) within the treatment area and inner buffer zone. To facilitate delineation of social group territories, surveys will also need to cover parts of the outer buffer zone.

6.8 The initial survey will maximise the information available on badger population density prior to the implementation of badger removals, and hence the explanatory power of the trial.

6.9 Sett surveys provide only limited data on badger density, since they cannot take into account local variation in badger group size, or past disturbance of the badger population. Nevertheless, at present they represent the only available technique for estimating badger numbers over large areas. Furthermore, the proactive cull will provide measures of actual badger density in surveyed areas. These data can be used to calibrate estimates made for other treatment areas, perhaps in combination with information about local landscape characteristics.

6.10 We have recommended that all treatment areas should be surveyed fully as they are enrolled into the trial. We further recommend that these surveys should be carried out concurrently in the three treatment areas of each triplet. This will ensure the consistency of the data.

6.11 Surveys in all trial areas must cover the treatment area (i.e. the area defined by the desk exercise to delineate boundaries) and inner buffer zones.

6.12 The extent to which surveying is needed within the outer buffer area will depend on the local distribution of setts. This must therefore be determined on the ground by the Wildlife Unit, in accordance with the guidelines set out in the standard operating procedures. In addition, in the reactive and proactive treatment areas only, parts of the outer buffer zones may need to be surveyed where this is necessary to determine the precise outer' boundaries of social groups whose inner' boundaries (i.e. those closest to the centre of the treatment area) extend into the treatment area.

6.13 Estimating badger social group density and delineating territory borders both require that main setts be identified. In many cases, main setts can be recognised on the basis of their size and activity, but the absolute size and activity of main setts varies locally. Surveys must therefore collect data on the location, size and activity of all setts.

6.14 A questionnaire is being prepared for use in surveys of setts and field signs. This will ask the surveyor for a subjective opinion as to whether each sett is a main sett. The standard operating procedure will provide criteria on which this decision can be based. This opinion will be used in conjunction with the objective data to reach a final conclusion on the identification of main setts. The surveyor is not asked to classify setts into other categories (i.e. as annex, subsidiary or outlier setts).

6.15 Accurate data on locations of setts and field signs would ultimately best be achieved by equipping survey teams with global positioning system equipment provided that 10m resolution is possible. These data could then readily be entered into a GIS.

6.16 The detailed procedures for executing surveys, including obtaining permission, and systematic surveying techniques (e.g. walking both sides of every field boundary; using about 100 m transects for surveying open moorland and narrower transects for woodland etc.) will be set out in a standard operating procedure.

6.17 The boundaries of badger territories will be established by the use of Dirichlet tessellations and field signs.

6.18 We recommend that bait-marking should be retained as an option to resolve borders **only** where:

1. it is necessary to define the edges of removal areas under either proactive or reactive culling; **and**
2. where other methods have failed to resolve the locations of territory borders; **and**
3. where badgers have not been heavily disturbed (e.g. by recent MAFF removal operations); **and**
4. iv. in spring and autumn, when badger territorial activity is high.

In practice, bait-marking would be used very rarely under these criteria.

Subsequent surveys

6.19 Repeat surveys are essential:

1. i. to provide up-to-date estimates of badger density that can be incorporated into analyses of herd breakdown rates;
2. ii. to determine the extent to which herd breakdown rates track changes in badger numbers;
3. iii. to determine the rate at which badgers recolonise cleared areas; and
4. iv. to measure the impact of culling (including illegal culling) upon badger populations.

6.20 To ensure that data from repeat surveys are comparable with data collected in the course of initial surveys, it is important that the same methodology should be used. Moreover, surveyors should not be provided with the results of previous surveys, which might influence the number of setts located in the course of repeat surveys.

6.21 To provide the data outlined in 6.19, we recommend that repeat surveys should be carried out in years 3 and 5 following the initial survey. We do not expect that it will be necessary completely to re-survey trial areas: it should be possible to collect the necessary data by re-surveying a smaller study area within each treatment area.

6.22 Areas allocated to the proactive treatment will also be re-surveyed to locate setts where further culling is necessary to maintain clearance of badgers. This is discussed at paragraph 7.2 below.

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7. Culling procedures

7.1 The procedures for badger culling operations must balance efficiency of removal with considerations of animal welfare and cost. Culling has different objectives under the two culling treatments recommended in the Krebs report. In proactive treatment areas, the aim is to remove as large a proportion as possible of badgers resident within the treatment area, and to prevent recolonisation by further culling on a regular basis. In the reactive treatment areas, the aim is to remove as large a proportion as possible of badgers which might be associated with the breakdown, by culling all badgers within social groups using the farm (or the reactor land if it can be rigorously identified). As indicated below, it may not always be possible fully to meet these objectives given limitations imposed by capture methods. Culling in reactive areas will begin following surveying and once culling has been completed in the proactive area of the triplet.

7.2 No capture method can be guaranteed to be totally effective (see paragraphs 7.4 and 7.7 below). It is therefore likely that a small number of badgers will remain following clearance and it will be impossible to distinguish these from immigrant badgers which subsequently move in. This is not important in the proactive treatment areas where the aim is to maintain as high a clearance of badgers as possible. We therefore recommend that, in these areas, all setts should be revisited 5 to 9 months after the initial removal and annually thereafter. Repeat removals should be carried out at all setts showing signs of badger activity.

7.3 However, the aim of the reactive strategy is to remove only badgers associated with the breakdown and not to capture immigrant badgers. We therefore recommend that no repeat removals are carried out in these areas.

Capture Methods

7.4 No capture method is perfect. Cage trapping, the most commonly used method for badgers, has the major problem that all badger populations contain a proportion of badgers that are reluctant to enter cage traps. Anecdotal evidence suggests that this proportion is higher in populations which have been subject to previous removals or other disturbance.

7.5 Trapping success is also strongly influenced by season and weather conditions, with efficiency greatly reduced in winter and in wet weather. This problem can be overcome, to some extent, by extending the period of trapping. However, the probability of capturing non-target immigrants in reactive areas increases as trapping periods are extended (see paragraphs 7.2 and 7.3).

7.6 Given the problems of trap-shyness and seasonal and local variations in trapping efficiency, the Krebs report suggested that the use of snaring should be considered as an alternative to cage trapping, taking account of efficacy, cost and welfare considerations. Snaring is one of the issues which has caused most concern in the consultation on the Krebs Report. We have therefore weighed the arguments for and against it very carefully.

7.7 Snaring has considerable potential advantages: most importantly, in skilled hands, snares achieve higher capture efficiency than cage traps alone. Informal estimates suggest that snaring, combined with cage trapping, could allow 90-100% capture, compared with up to 80% for cage trapping alone. Snaring would be most likely to improve capture efficiency in winter and in highly disturbed populations, where the efficiency of cage trapping is known to be low. In addition, snares are cheap to build. They are also light and easily transported. Their efficiency, and the fact that no baiting is needed means that removal may be achieved more quickly, thus reducing staff costs.

7.8 Against these advantages we must balance the considerable potential disadvantages of snaring. Its poor public image arises from two particular concerns: first that they may be stressful or damaging to badgers; and secondly that they may capture non-target species.

7.9 Some types of snare do undoubtedly have welfare drawbacks. Public perception of snaring appears to be based largely on evidence arising from the misuse of snaring. There have been some very unfortunate incidents (including ones where snares have been used as a method of killing wild animals) which show that the misuse of snares can lead to appalling injuries. However, the Krebs report envisaged using snares only as a capture method, with snares frequently checked and any badgers captured then humanely destroyed. There are currently no data to enable assessment of the welfare implications of snaring carried out under these conditions. Nor are there any data to enable a proper assessment of the risk snares pose to non-target species, although limited MAFF experience in the past suggests this risk is small.

7.10 There are other factors which also need to be balanced against the advantages of snaring: the use of snares would place an additional training need on Wildlife Unit staff. Moreover, the need to ensure that snares were properly monitored and regularly checked would increase the need to work at night. This would entail additional costs, mitigating the savings mentioned at paragraph 7.7, and raise concerns in terms of health and safety of staff.

7.11 Anecdotal evidence suggests that, properly carried out by trained operators, snaring may pose no greater welfare cost to badgers than trapping.

However, given the strength of public feeling on this issue, that does not seem to us to be a sufficiently firm basis to recommend its use. We are unable, therefore, to recommend it as a capture method on the basis of evidence currently available. However, it is important to recognise that not using snaring may necessitate extending the trial, possibly both in time and in the number of treatment areas which would have to be included, in order to obtain unambiguous data.

7.12 Given the imperfections of trapping as a capture method, and the possible implications that this may have for the length and scope of the trial, we recommend that MAFF should urgently investigate other humane capture methods, such as leg cuffs, and should also make an urgent assessment of the actual welfare implications of snaring carried out in accordance with proper guidelines. If an alternative humane capture method can be identified or developed, we recommend its subsequent use within the trial should be considered.

7.13 In the meantime, we recommend that using trapping alone will provide an acceptable, albeit imperfect, capture method for the trial. The detailed procedures for trapping will be set out in the standard operating procedures. We anticipate that the minimum trapping period is likely to be 14 consecutive nights. We recognise that this will require weekend working by MAFF staff, which may be unwelcome to some and which will inevitably increase costs. However, we consider this as critical in order to optimise trapping efficacy.

Lactating Females

7.14 Many of those who responded to the consultation exercise expressed serious concern about the welfare implications of removing lactating females with dependent cubs underground. In recognition of the welfare cost of leaving dependent cubs underground to starve, past control strategies have sought to release females thought by field teams to show evidence of lactation.

7.15 Despite these concerns, both the Krebs and Dunnet reports recommended that lactating females should be removed for three main reasons.

1. Releasing lactating females limits the efficiency of badger removals.

2. Mother-to-cub transmission is believed to be important in the maintenance of infection within badger populations. Releasing lactating females may therefore involve a high probability that infection will not be eradicated from the local badger population.
3. Partial removal of social groups is likely to entail social perturbation which might increase transmission of infection between social groups.

7.16 While accepting these concerns as valid, we have considered very carefully the extent to which the welfare cost is indeed justified by the need to ensure that the trial operates effectively. We conclude that a limited, three month, closed season for culling would meet the major welfare concerns about dependent cubs underground without unacceptably jeopardising the trial with its wider welfare objectives.

7.17 We considered a range of options to seek to meet the welfare concerns. However, it is important to recognise at the outset that although culling strategies may seek to greatly reduce the number of lactating females killed, none can avoid it entirely.

7.18 One possibility considered was the continuation of the strategy which applied under the interim and clean ring operations: these strategies permitted trapping at all times of year; but lactating females were released when they were identified. However, lactating females may constitute a substantial proportion of the population at some times of the year and may not necessarily have dependent cubs underground. Most importantly, this option entails partial removal of social groups. We therefore consider it unacceptable because it would seriously compromise the integrity of the underlying strategy. For similar reasons, we also consider the option of suspending culling whenever a lactating female is identified as unacceptable.

7.19 Although dates of birth and weaning vary, the majority of cubs are born in February and weaned in May. We therefore recommend that a closed season for culling from 1 February to 30 April be applied in the proactive and reactive treatment areas. This will avoid taking badgers at the time when it is most likely that there will be dependent cubs underground and hence meet the major welfare concern.

7.20Some respondents favoured a six months closed season from 1 January to 30 This would virtually eliminate the chances of capturing females with dependent cubs (whether underground, or above ground and so readily captured). However, such a long closed period would not offer any substantial welfare gain but would severely limit the rate at which removals could be carried out. This would probably considerably prolong the trial. In the reactive areas it would lengthen unacceptably the interval between detection of infection in cattle and the start of a badger culling operation. We do not therefore consider the disadvantages of this option to be outweighed or justified by the welfare considerations.

7.21We consider that a closed season would not cause problems for the efficacy of the proactive strategy as regards the initial cull. We also considered whether a closed season should apply to repeat culls of recolonising badgers in proactive areas. If these culls take place at regular intervals, ecological evidence suggests that only a small proportion of immigrant badgers in a disturbed population would be breeding. The welfare gain is therefore smaller. However, since this can be achieved without compromising the proactive strategy, we recommend that the same closed season should be applied for repeat culls.

7.22A closed season potentially has a greater impact on the efficacy of the reactive strategy. The long delay frequently experienced between the confirmation of disease in cattle and the start of a badger removal operation was a major criticism of the "interim" strategy. MAFF evidence suggests that, provided the targets set out in paragraph 7.24 are adhered to, there would be no appreciable increased risk of further breakdown either at the breakdown farm or at contiguous farms. However, we consider that the likelihood of detecting a significant treatment effect will be greater if culling commences as soon as possible after the breakdown has been confirmed.

7.23There are inherent variations in the speed at which culling can be commenced in the reactive treatment areas. These result from the time needed to make a firm diagnosis of infection in cattle, the time needed for surveying and the time needed to put a culling operation in place. To avoid adding further delay we considered not testing cattle in the three month period prior to the culling close season, but rejected this on the grounds of practicality. Although a closed season from 1 February to 30 April will delay the reactive response to some positive herd tests carried out in the winter, we are confident that the scientific rigour of the trial can be maintained.

7.24The logistics of responding in May to a backlog of herd breakdowns will need to be addressed by MAFF in determining work priorities. We recommend that, in any event, the maximum gap between confirmation of the breakdown triggering a reactive cull and the start of culling should in no case be longer than six months and, in the majority of cases should be no more than a few weeks. It is essential that MAFF ensures sufficient resources are available to meet these targets.

8.Protocol for post-mortem of badgers and cattle

8.1The primary objective of laboratory procedures concerning cattle and badgers from the trial areas is to determine the presence or absence of *M. bovis.* A secondary objective is to describe the severity of disease and quantify the organisms that affected animals are excreting.

8.2Current MAFF procedures to detect infection have been considered and these will be adopted as the main basis for TB detection in cattle and badgers. In cattle, surveillance depends on post-mortem examination at abattoirs and on the tuberculin test, which will be conducted annually in the trial area.

8.3Animals which are reactors or inconclusive reactors to the annual tuberculin test or animals which are epidemiologically linked to them, and other cattle leaving farms for slaughter, will be subject to post-mortem inspection by the Official Veterinary Surgeon, according to standard Meat Inspection Procedures. Where lesions are found, these will be recorded and sampled by a Veterinary Officer. In the case of reactors where lesions are not found, a standard selection of lymph nodes will be sampled. This material will be examined for *M. bovis* using culture. Isolates will be subject to molecular typing by polymerase chain reaction (PCR) to determine the spoligotype.

8.4Badgers which are caught in trial areas, and any badger carcases collected in the road traffic accident survey, will be submitted for laboratory examination which will include visual external inspection and inspection of viscera and lymph nodes, recording of lesions and collection of material from these and selected lymph nodes. All badgers caught would be measured, weighed and classified as to their age group (i.e. cub, yearling, adult).

8.5A summary of the procedures is in Appendix 2.

8.6Aspects of the current procedure for cattle have evolved separately from those for badgers. For example, lymph nodes from cattle are frozen before culture whereas those from badgers are pooled in a transport medium and not frozen. We will adopt the existing procedure for the trial. However, these must be standardised and where refinements can be made these will be introduced if they represent an improvement in optimising *M. bovis* detection. Such revisions will be piloted on samples of material during the trial.

8.7It is probable that some molecular methods, for example those which will discriminate further between strains of *M. bovis,* will be developed during the trial. Tissues and isolates should be retained so that they can be subject to these new approaches. Additionally, tissue material should be collected to provide an opportunity for DNA typing of badgers.

8.8We do not expect the continued submission of material from cattle in the trial area to represent a change from existing arrangements in MAFF. However, for badgers we anticipate significant peaks of requirements for pathology and culture over at least the first two years, as proactive culls are undertaken. This will necessitate storage of some material to even out the peaks and troughs and may require MAFF to find extra laboratory capacity at certain times. Urgent assessment of the impact of storage on the viability of *M. bovis* is needed.

8.9A method is needed to estimate the numbers of *M. bovis* excreted by badgers. A robust method of scoring lesions in the badger, particularly in the lung and kidney, will be considered and incorporated to give a semi-quantitative indication of disease in culled animals. This may assist in determining the severity of disease.

8.10There is an urgent requirement for a test to detect infection with *M. bovis* in live badgers in order to determine TB prevalence. A satisfactory immunological test using blood samples is likely to provide the basis for this. Blood should be collected from culled badgers to facilitate development and validation of such a test.

8.11The presence of *M. bovis* in species other than cattle and badgers will be addressed in proposals from prospective research contractors. It will be essential that any methods used are standardised and conform to MAFF's laboratory procedures.

9.Epidemiology questionnaire

9.1An epidemiological investigation will be required on farms which experience TB in cattle during the trial to facilitate the analysis of risk factors and the detailed analysis of factors affecting incidence.

9.2A new questionnaire is under development and will have to be piloted before use in the trial. It will need to classify the breakdown according to herd location, composition and when the breakdown began. It will determine the evidence for previous TB and the risk of residual infection in the herd. Following a TB breakdown, some information on risk factors which may have predisposed cattle to TB over the last 12 months will be considered. All data must be gathered objectively; on badgers this must include the method used to survey setts for the trial, in addition to an interview with the herd owner.

9.3The scope of the epidemiology questionnaire is set out in Appendix 4

9.4Work is also in hand to develop studies comparing breakdown farms with others where no breakdown has occurred. The epidemiology questionnaire will also be completed for these farms. We expect to be advising further on this work and on the development of the epidemiology questionnaire following wide consultation.

10.Disease in badgers

10.1 Precise estimates of prevalence of disease in badgers will be obtained from proactive areas. We require information from other areas. Such information is needed to establish the extent to which disease status of badger populations contributes to the risk of transmission to cattle. We have considered several methods by which this could be obtained, and set out our views on them below.

Selective culling

10.2We accept that a properly organised and sufficiently large random sample of badgers trapped, killed and subjected to post-mortem examination and laboratory culture, would give a reliable and robust estimate of disease prevalence in the sampled population. No other method can provide this information to the same degree of accuracy on very small spatial scales. However, the number of badgers that would have to be killed in order to provide this information would be high, especially where disease prevalence is low. We do not consider that this is acceptable and have therefore rejected this approach.

Collecting samples from latrines

10.3This technique would have the advantage that no disturbance of badger populations would be necessary. However, the techniques currently available for identifying *M. bovis* from badger faeces samples are not sufficiently reliable. In addition, relatively few infected badgers excrete organisms in their faeces and it is in any case not possible at present to relate the presence of organisms in badger faeces to disease prevalence in the badger population. Whilst this might have some value in detecting the presence of infection, it is unlikely to yield useful information in relation to the trial.

Sampling of live badgers

10.4The ELISA blood test which has been validated for use in live badgers is not sufficiently sensitive to provide reliable estimates of TB prevalence among badgers. The test has been found to be more effective (but still unacceptably insensitive) in determining presence of the infection at social group level. We recommend that further research should be directed to developing more sensitive live tests (probably based on detection of cellular immune responses) to determine infection of badgers (see also paragraph 8.10).

Road traffic accident survey

10.5The Krebs report recommended a limited reintroduction of road traffic accident surveying as part of a programme to establish the prevalence of TB in badgers. Post-mortem examination and laboratory culture of such badgers will provide a good indication of disease in the badgers sampled. With the co-operation of the public and the agencies responsible for roads in reporting the locations of roadside carcases, the data collected on disease prevalence in badgers will be used initially to estimate regional prevalence and later as sample sizes increase to estimate local prevalence.

10.6We propose that, initially, a road traffic accident survey is designed to cover the counties of Cornwall, Devon, Gloucester, Herefordshire, Worcestershire, Shropshire and Dorset. These include areas with a high cattle TB incidence and also neighbouring areas which currently have low levels of TB. They are also all areas with a relatively high badger population density. Some road traffic accident surveying has been undertaken in most of these counties over recent years, but we recommend that a new formal campaign be instigated to coincide with the launch of the randomised trial.

11.Other wildlife

11.1*M. bovis* is a zoonotic infection with a wide host range. In Great Britain the badger is an important reservoir host with widespread infection. Previous work suggests that other susceptible species, including man, are spill-over hosts in which infection is not self-maintaining. Nevertheless, it is possible that these other species could act as a source of infection for cattle and badgers. Thus any attempt to manage the disease should take full account of the role of other potential hosts.

11.2We recommend that the data collected during the trial should include information on other potential wildlife sources of the disease. This should include accurate estimates of population density and disease dynamics.

12.Economic evaluation of policy options

12.1The Group has co-opted an economist who will undertake an economic appraisal of the options which emerge from the scientific study. This appraisal will take the form of cost-benefit analyses of possible badger culling regimes defined on the basis of experience with the proactive, reactive and survey only areas in the trial.

12.2For this purpose data will need to be collected covering the output losses and costs (to farmers and to MAFF) of breakdowns in cattle herds and of the current frequent-testing regimes applied in selected farms in the triplets, as well as estimates of the possible wider costs in terms of trade restrictions and human health risks if TB incidence in cattle were to rise further. The avoidance of such costs represents the economic benefit that would be gained from a successful disease control strategy.

12.3Against this have to be set the resource costs of the alternative badger culling policies to estimate the overall net economic merits and provide information to guide the choice of any such intervention. The economic appraisal can be conducted to assess the net benefits of badger control to farmers, to the regional agricultural economy, to the public purse and to the overall national economy, and the balance of interests between these different standpoints needs to be made clear in the selection of any policy.

13.Testing frequency for cattle

13.1The frequency of routine tuberculin testing of cattle in Great Britain is based on EU rules. Testing frequency decreases with the incidence of disease, with the minimum of 4-yearly testing applying if the annual incidence of herd breakdowns is 0.1% or less. Because the trial will take place in those parts of the country which are worst affected by the disease, it is inevitable that most herds in the trial will be on more frequent testing, many being tested annually. Markedly different testing frequencies would be a complicating factor in the analysis of the results of the trial and, since the majority of herd outbreaks are disclosed by routine testing, the numbers disclosed in any given period will be influenced by testing frequency. We therefore recommend that, so long as Ministers are satisfied there are no legal obstacles, all herds within the trial should be subject to annual routine tuberculin testing.

13.2We propose that testing in trial areas is done approximately annually and that it is, as far as practicable, more evenly spread throughout the year to reduce the proportion of tests undertaken in the winter (some reactive culls resulting from tests carried out during this period would be delayed because of the closed season for badger culling - see paragraph 7.23).

14.Auditing arrangements

14.1The reliability of the conclusions to be drawn from the evaluation of the trial results will depend critically on the trial being properly conducted. We therefore consider it essential that audit arrangements are put in place.

14.2A MAFF internal audit is needed to check that staff closely follow the standard operating procedures at every stage of the trial, in identifying treatment areas, in survey and culling work, and in laboratories. This will be for MAFF managers to put into place as part of normal quality management.

14.3In addition, we would put in place an external audit to check how efficient the culling is within the limitations imposed. We recommend that in areas to be selected at random, an independent check of badger activity should be carried out immediately after the end of a culling operation and before it is likely that substantial recolonisation has occurred. We further recommend that the approach taken to this external audit should be kept under review, both in the light of experience gained during the audit of the first triplets to be completed, and as results flow from new research.

14.4It is finally recommended that an audit external to MAFF of data quality and completeness should be done some months after the trial is commenced.

15.Environmental impact of badger removal

15.1Proactive culling involves removal of a species, which is potentially ecologically important, over relatively large areas. In assessing badger culling as a future strategy for TB management, we therefore recognise a need to quantify its environmental impact. A preliminary study has been undertaken, and the Executive Summary of a report presented to us is attached at Appendix 5. The full report is available from MAFF.

16.Collateral research

16.1The publication Animal Health and Welfare Research Requirements (1999-2000) MAFF, March 1998 outlines TB research requirements.

16.2We wish to record that we identify the following research areas as the highest priority and would hope that sufficient resources are directed to these areas to ensure that objectives can be met in a prescribed time frame

- risk analysis

- molecular epidemiology

- cattle immunology and vaccine development

- methods to estimate badger populations.

16.3The Group also advise that it is important to ensure that opportunities are taken to maximise the information gathered by the randomised trial by identifying other ancillary research that could be undertaken by scientists involved, for example, in badger ecology, physiology and behaviour.

16.4Exploiting this opportunity will add value to the trial and will be considered in detail by the Group as a future priority agenda item.

17.Randomisation

17.1There is a real risk of bias if the treatment to be applied to any particular trial area is known earlier than is absolutely necessary. Knowledge of the treatment is likely to influence the decisions of landowners/occupiers as to whether or not to agree to take part in the trial. If the treatment is known at the time of the preliminary surveying, this could influence the intensity of the survey. Thus we recommend that the random allocation of treatments should not take place until after the preliminary surveys have been completed.

18.Data confidentiality

18.1Careful management of key data arising from the trial is necessary for a number of reasons, as set out below.

18.2We recognise that much of the data collected in the trial will be of considerable general interest and that it is essential that such data are ultimately made widely available for alternative analyses, discussion and interpretation, in particular through the scientific literature in the usual way. However, we consider it very likely that premature release of primary data on breakdowns could jeopardise the viability of the whole investigation by undermining compliance with the regimes proposed. It is highly likely that in the initial phases when there have been only small numbers of breakdowns the data may appear to suggest conclusions not confirmed when there are more data collected over a longer time frame. Merely issuing warnings against over-interpretation would, we believe, be ineffective in the present context. Therefore, we consider it essential that the primary data affecting the comparison of treatments are kept strictly confidential until the Group advise that reasonably firm conclusions can be drawn and have reported to Ministers accordingly.

18.3The number of people with full access to the data should be strictly limited. We propose that only three people should have full access: one member of the Group, one member of MAFF staff (preferably not from the Animal Health and Veterinary Group) and one statistician/epidemiologist independent of both MAFF and the Group. Others within MAFF and the Group would have access to data on a "need to know" basis.

18.4Because the data relate to individual farmers, it is essential that personal and commercial information is not released. This is of course a normal duty upon MAFF in collecting information about farms generally and we do not consider that the Group has the remit to advise further on this.

18.5The above considerations should not mean that no information about the trial will be made available more widely on a preliminary basis. Indeed, we fully support the view expressed in the Krebs report, that data should be made available at the earliest opportunity, on advice from the Group, and consider that this axiom should apply in relation to the randomised trial.

19.Statistical analysis

19.1It is inevitable that the data to be collected during the course of the trial will be voluminous. We envisage that the analysis will progress on four main fronts, as set out in Appendix 3.

19.2The first interim analysis would take place after a total of 100 herd breakdowns have been confirmed within the trial, or after 12 months from the completion of culling in the proactive areas of the first two triplets, whichever is the sooner. Further interim analyses will then be undertaken about every six months. Analyses of TB incidence in cattle will be presented to the Group with treatments coded a, b and c, in order to maintain data confidentiality, as set out in paragraph 18.4.

20.Public health implications

20.1Many cases of clinical TB in humans are treated without bacteriological proof so it is possible that some cases of *M. bovis* remain undiagnosed.

20.2Human isolates of *M. bovis* are identified by the Public Health Laboratory Service (PHLS) Mycobacterium Reference Unit (MRU) and Regional Centres for Mycobacteriology. The number of cultures of human *M. bovis* is small (approximately 30 to 40 a year). Nevertheless, *M. bovis* may be more difficult to culture in the primary laboratory than *M. tuberculosis,* by the methods currently employed, so that organisms may not be cultured and, consequently, would not be available for referral to PHLS reference services and included in their data.

20.3The trial offers a unique opportunity to apply new molecular techniques to evaluate transmission between man and animals. We recommend that the Government should consider a targeted study, based on the first two triplets, to enhance surveillance for *M. bovis* in people.

APPENDIX 1 Options for initial surveys within trial areas

Approach	**Proactive removal areas**	**Reactive removal areas**	**"Survey only" areas**
Minimal	Initial survey of setts across the entire treatment area, inner buffer zone and, to the extent necessary, outer buffer zone. Initial survey of field signs in buffer zones to define the edges of the removal area.	No initial survey	No initial survey
Median	Initial survey of setts across the entire treatment area, inner buffer zone and, to the extent necessary, outer buffer zone.	Initial survey of setts only	Initial survey of setts only

	Initial survey of field signs in buffer zones to define the edges of the removal area.		
Intensive	Initial survey of setts and field signs, across the entire treatment area, inner buffer zone and, to the extent necessary, outer buffer zone.	Initial survey of setts and field signs, across the entire treatment area, inner buffer zone and, to the extent necessary, outer buffer zone.	Initial survey of setts and field signs, across the entire treatment area and inner buffer zone

1.The **minimal survey** provides the minimum data required to complete the trial, allowing a comparison of cattle herd breakdowns under different strategies of badger removal. This option would be least costly but would not represent value for money since it would:

- prevent comparison of badger density between removal areas within and between triplets, severely limiting the power of the trial to explain local variation in herd breakdown rates; and
- make no attempt to measure farmers' compliance in survey only areas, and maintain no MAFF presence on farms that were allocated to this treatment.

2.The **median survey** would demand more resources because of the more widespread surveying, but is preferable because it would:

- provide baseline estimates of local badger density at the start of the trial, dramatically increasing the potential of the trial to investigate variation in herd breakdown rates within and between triplets;
- ensure MAFF presence on farms allocated to the survey only treatment, increasing farmers' sense of involvement with the trial; and
- provide an opportunity to measure compliance with the no-culling treatment.

3.The **intensive survey** would require most resources, but the marginal increase in cost over the median survey would be very small. This is because survey teams would simply collect extra data on field signs as they searched for setts. This survey would provide the most complete and reliable estimates of local variation in badger density, and would be of immense value in the analysis of TB risk in cattle.

4.Given the overall aims of the trial, we recommend that the intensive survey represents the optimal initial survey approach.

APPENDIX 2

PATHOLOGY AND MICROBIOLOGY PROCEDURES

Purpose	Procedure
A. CATTLE	
Detect lesions at slaughter (all cattle)	Visual inspection by Official Veterinary Surgeon (OVS) to find lesions
	Veterinary Officer (VO) examines carcase
Detect lesions at slaughter (TB suspects -reactors, inconclusive reactors, dangerous contacts)	Visual inspection by OVS to find lesions
	VO examines carcases
Sample collection	a) Visible Lesion reactor herds - *lesions*
	b) Non-Visible Lesion reactor herds - *pool of lymph nodes*

Lesion type	Record of size and position (TB50)
Sample submission	Packaging, numbers, frozen or thawed
Sample preparation	Tissues received at Central Veterinary Laboratory (CVL), dissected, prepared for examination (histology, ZN, culture)
Detect *M. bovis* at CVL	Sowing of LJ, 7H11 and Stonebrinks
	Examination of cultures
Report	Results reported by CVL
Molecular type	Spoligotyping

B. BADGER

Carcase submission from the trial	Bagging, labelling (WLU9) and submission to MAFF laboratory
Carcase receipt from the trial	Distribution of samples and forms

Other carcases (road traffic accident)	Collection and submission
Lesion type	Necropsy examination
Detect *M. bovis* at CVL	Sowing of cultures Examination of cultures
Detect *M. bovis* at Veterinary Investigation Centre	Cultural examination
Molecular type	Spoligotyping

APPENDIX 3STATISTICAL ANALYSES

Statistical findings will be interpreted by the Group with the identity of treatment groups remaining blinded until firm conclusions are reached. The main aspects of the analysis are set out below.

1.Primary incidence analysis

The primary analysis will be the comparison of the incidence of TB in cattle in the three treatment groups, initially on an intent-to-treat basis (i.e. all farms regardless of their co-operation with the trial will be included in the analysis). Incidence rates will be computed and analysed both on a per head of cattle and per farm basis. It is anticipated that the incidence of new herd breakdowns arising from routine tuberculin testing and from slaughterhouse detection will be differentiated and separate analyses will be undertaken.

2.Secondary incidence analysis

An analysis on a farm basis will be made to assess the factors, including aspects of badger activity, but other features too, that discriminate between farms having a breakdown and those which do not. Where appropriate, the analyses will allow for spatial correlation between nearby farms.

3.Additional analyses

Other important analyses include:

i. The robustness of estimates of treatment effects will be examined through the adjustment of herd-specific attributes including herd type, herd size and husbandry practices.

ii. Any spatial association between breakdowns in cattle herds, both historical and during the course of the trial, and prevalence in badgers will be investigated.

iii. The effects of treatment compliance on herd outbreak incidence will be examined.

4.Data quality

Throughout the trial, the integrity of the data collection will be assessed to ensure data quality. Operational problems will be addressed.

APPENDIX 4TB EPIDEMIOLOGICAL INVESTIGATION

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	Contamination		
11.	Other	-	manuscript report
		-	preliminary conclusions
12.	Laboratory results		

APPENDIX 5 AN ASSESSMENT OF THE POTENTIAL IMPACT OF THE LARGE-SCALE REMOVAL OF BADGERS MELES MELES

Executive Summary of a report by Dr P Robertson, Central Science Laboratory

1 A literature review has been carried out on the diet, impact on prey species, parasites, diseases, economic damage and legal status of the badger in the

United Kingdom. Recognised experts on badgers and their main dietary items were also consulted. These sources have been used to assess the potential impact of removing badgers on other wildlife species. No published studies of the effects of badger removal on other species were found.

2 Badgers are widespread and sometimes common animals in the United Kingdom. Following legal protection their numbers have increased. Badgers are omnivorous, feeding on a wide range of prey, and have no natural predators in the United Kingdom.

3 Studies of badger diet in the United Kingdom have utilised faecal or stomach analysis. These studies usually classify items into broad groups; typically earthworms, insects, mammals, birds, amphibians, reptiles, cereals and fruit. Earthworms are the dominant component of the diet. Insects, cereals and fruits are seasonally important. Birds and mammals appear regularly in the diet but as a relatively minor component. Reptiles and amphibians are occasional items.

4 Badger distribution and density in the United Kingdom is thought to be heavily influenced by the availability of earthworms, their major dietary component. They are also opportunist predators, utilising a wide range of alternative food. The availability of these other food sources is thought to be of lesser importance in determining badger abundance.

5 Badger impacts on other species were reviewed by examining the literature on causes of mortality from studies of other species in the United Kingdom, but including key studies from other parts of Europe. It was thought unlikely that badgers had any serious impact on earthworm or most insect populations. Anecdotal reports suggest that predation of wasp and bumblebee colonies may be significant in certain circumstances. Predation by badgers was thought to be only a minor cause of mortality for small mammals, rats, hares and adult birds in the United Kingdom. Badger predation on hedgehogs appears significant and studies suggest hedgehogs may be excluded from many areas by the presence of badgers. Badger predation on young rabbits is frequently mentioned in anecdotal reports although few rabbit studies were found to quantify this cause of mortality in the United Kingdom. Badger predation of ground nesting birds, their eggs or young may be significant for some species. In the absence of predation these highlighted species may demonstrate reduced rates of mortality which may lead to increases in

numbers. Other species may also alter their status but the existing literature provides no evidence on which to base conclusions.

6 Literature on competition between badgers and other mammalian predators was examined. While these predators may respond to increases in prey and the availability of disused setts in the absence of badgers, no evidence was available to suggest direct competition between species, with the exception of badgers and hedgehogs.

7 isuse of setts following badger removal may affect their use by invertebrates and other commensal species. There may be vegetation changes in areas currently frequented by badgers in the absence of trampling, digging, soil nutrification and seed deposition in badger faeces.

8 Badger parasite and disease occurrence in the United Kingdom was reviewed. Badgers play a role in the transmission of bovine tuberculosis and the effects of badger removal on TB incidence in cattle is a key topic for future research but outside the remit of this report. With the exception of tuberculosis, the literature suggests that badgers do not currently form a significant reservoir of other diseases transmissible to humans, wildlife or livestock in the United Kingdom.

9 Badgers can conflict with a number of human interests through digging, predation and foraging behaviour. Recent surveys of badger damage are reviewed. Damage from these sources would be reduced by badger removal.

10 Badgers and their active setts are covered by The Protection of Badgers Act (1992). Badger removal from an area will, as a consequence, make the setts inactive and therefore no longer protected by legislation. It is possible that there will be an increase in sett disturbance by those wishing to deter badgers in future. There may also be an increase in the use of certain legal techniques for fox control, such as snaring, if badgers are reduced in abundance and less likely to be caught as a non-target species.

APPENDIX 6 MEMBERSHIP OF THE INDEPENDENT SCIENTIFIC GROUP ON CATTLE TB

Professor John Bourne MRCVS CBE (Chairman) - a former Professor of Veterinary Medecine at the University of Bristol (1980 - 1988), a former Director of the Institute for Animal Health (1988 - 1997) and Professor of Animal Health at Bristol since 1988.

Dr Christl Donnelly (Deputy chairman) - a research statistician at the Wellcome Trust Centre for the Epidemiology of Infectious Disease at the University of Oxford; a specialist in infectious disease modelling.

Sir David Cox FBA, FRS - Honorary Fellow of Nuffield College, University of Oxford since 1994; a statistician with considerable experience in developing and applying statistical methods of analysis and design.

Professor George Gettinby FRSE - Professor in the Department of Statistics and Modelling Science at the University of Strathclyde; an applied statistician and modeller and a specialist in experiment design for the evaluation of veterinary products.

Professor Ivan Morrison FRSE - Head of the Division of Immunology and Pathology at the Compton Laboratory of the Institute for Animal Health. A veterinarian and specialist in bovine immunology and disease pathogenesis with practical experience of field experiments.

Dr Rosie Woodroffe - a research fellow at Gonville & Caius College, University of Cambridge, based in the Department of Zoology; a specialist in wildlife disease and badger ecology and behaviour.

- **Professor John McInerney OBE, FRSA** - Glanely Professor of Agricultural Policy and Director of the Agricultural Economics Unit at the University of Exeter.
- **Co-opted member**

GLOSSARY

BAIT-MARKING

a means of establishing badger social group territories: coloured plastic chips are placed in palatable food at sett entrances using a different colour at each main sett; particular colours of chips found in faeces at different latrines, usually situated at territory boundaries, are then recorded.

BREAKDOWN

MAFF define a breakdown as occurring when one or more reactors are revealed by the tuberculin skin test or when disease is suspected in either live cattle showing clinical disease or in carcases with lesions at post-mortem examination.

BUFFER ZONE

an area separating different treatment areas and different triplets. There are inner and outer buffer zones; these are explained in paragraphs 4.17 to 4.20. Data on the incidence of TB in cattle in the buffer zones will not be included in the main analysis of the trial.

CLEAN RING STRATEGY

strategy applied from 1982 to 1986, in which infected and uninfected social groups of badgers (determined by bait-marking) were removed until a clean ring' of uninfected social groups was removed.

CONFIRMED BREAKDOWN

a herd breakdown where the disease has been confirmed in one or more animals, usually reactors, by detection of lesions at post-mortem and/or through culture of *M. bovis*.

ELISA TEST

a test used to detect antibodies or antigens, by measuring their binding to antigens or antibodies absorbed on plastic wells, by visualising colour changes caused by enzymes reacting in the test solution.

EPIDEMIOLOGY

the study of the distribution and dynamics of disease in populations. Its purpose is to identify factors which determine the occurrence of disease, and to provide a basis for intervention programmes. Epidemiological methods are also used to assess the variance, severity and magnitude of disease and related risks.

GENOTYPE

DNA fingerprint.

INCIDENCE

the rate at which new cases of infection arise in a population.

INTERIM STRATEGY

strategy applied from 1986 to 1997, in which badgers were removed from a limited area (the reactor land or, if this could not be identified, the entire farm suffering the herd breakdown).

LESION

a pathological change in organs or tissues produced by TB or other causes of disease.

MYCOBACTERIUM

a family of related bacteria characterised by a lipid-rich waxy coat that results in acid fast staining, which include species that cause TB.

PREVALENCE

the proportion of the population infected at a particular time.

RANDOMISED TRIAL

technique for comparing treatments in which specific treatments are allocated to trial areas by physical randomising device in order to avoid allocation biases and to ensure comparability.

REACTOR

animal which gives a positive result (i.e. reacts') to the tuberculin skin test.

REACTOR LAND

the land used by a herd with reactors and on which TB may therefore have been contracted.

SETT

burrow system which badgers use for shelter and breeding.

SOCIAL GROUP

group of badgers (averaging six to eight in a group, although a maximum of 25 has been recorded) occupying one or more setts within a well defined territory from which badgers of other social groups would be excluded.

SPOLIGOTYPE

a particular DNA typing profile of a bacterial strain identified by a molecular typing technique called spoligotyping.

SPOLIGOTYPING

spacer-oligonucleotide typing (a molecular typing technique).

STRAIN

isolate of a bacterial species which is differentiated from other isolates of the same species by particular characteristics.

TREATMENT

term used to refer to the relevant treatment, i.e. proactive culling, reactive culling or survey only, which will be applied in the trial areas. Each triplet has three trial areas and each trial area will be subject to one of the three treatments.

TRIPLET

group of three trial areas, each subject to a different treatment. Within each triplet, one area will be allocated to proactive culling, one to reactive culling and one to survey only.

TUBERCULIN

a sterile, protein extract derived from the tubercle bacterium and used to diagnose TB in cattle by skin testing (also known as Purified Protein Derivative or PPD).