INDEPENDENT SCIENTIFIC GROUP ON CATTLE TB

REPORT OF THE WORK OF THE GROUP & ITS PUBLISHED FINDINGS IN 2005

1 CHAIRMAN'S INTRODUCTION

- 1.1 Early last year the Independent Scientific Group on Cattle TB (ISG) published a wide-ranging and detailed report (Bourne et al, 2005) of its work up to the end of 2004, concentrating on the period from June 2001, when our previous substantive report (Bourne et al, 2001) was submitted to Ministers. We outlined in detail the holistic approach we adopted which has the aim of establishing an information structure to underpin the development of bovine tuberculosis (TB) control strategies, and also discussed the broad research programme needed to gain a better understanding of the epidemiology of TB in cattle and wildlife.
- 1.2 The Government is committed to policy making for disease control that is based on science. Over the last six years the ISG has been working effectively with Defra and other scientists in developing Defra's much-expanded TB research programme. Although there is still much to do, for the first time a TB science base is in place that is able to inform policy decisions. Defra can be proud of this achievement, as am I, of the ISG's contributions to a better understanding of the bovine TB complex.
- 1.3 The Randomised Badger Culling Trial (RBCT), one component of the research effort put in place by Defra and which we have directed since 1998, is now nearing completion; the badger culling programme has ended, and the final trial surveys are in progress. Detailed evaluation of the results will continue in 2006, during which time we will submit further interim reports to Ministers, and prepare papers for publication in peer reviewed scientific journals. We expect our final report, a full and substantive publication with our review of trial, and other related research, to be ready in 2007. Its publication will complete the Group's work. But, for the benefit of those attending our 3rd Open Meeting, we believe that it would be useful to produce a short report summarising the work of the Group in 2005.
- 1.4 This summary report up-dates the published information on the practical exercises, namely the RBCT and the Road Traffic Accident (RTA) and epidemiological surveys, which we have directed in 2005. In addition it highlights the scientific publications of the Group that have appeared and also fulfils the requirements of a public body, such as the ISG, to publish certain administrative data.
- 1.5 Some people may ask why this report has so much focus on the Group's publications and says relatively little about our "day to day" functions during 2005. For those who wish to know more detail about the latter, the agendas and summaries of the 11 meetings we held during the year are published on the ISG Web pages at http://defraweb/animalh/tb/isg/index.htm.

- 1.6 Much of our work in 2005 has involved the management of the RBCT and its associated surveys and research studies and, with the help of our much-valued Research Assistants, the assessment and further analyses of the huge amount of data the trial provides. These data are a key component in constructing the scientific base the Government requires to inform its policies in relation to bovine TB.
- 1.7 The strength of science is based on the long-established principle that findings are subjected to critical and independent peer review by qualified scientists, with findings judged to be sound then given prominence by publication in respected journals. It is only in this manner that the validity of claims of 'new knowledge' can become accepted in the wider community, and the ISG is working hard to ensure that, whenever possible our work appears in peer-reviewed published manuscripts. Most importantly this process ensures that the Government can genuinely claim to be basing future bovine TB policy decisions on sound science.

PROFESSOR JOHN BOURNE

REFERENCES QUOTED IN CHAIRMAN'S INTRODUCTION

- F. J. Bourne, C. A. Donnelly, D. R. Cox, G. Gettinby, J. P. McInerney, W. I. Morrison and R. Woodroffe. An epidemiological investigation into bovine tuberculosis: towards a science-based control strategy. Fourth Report of the Independent Scientific Group on Cattle TB. 2005, PB10138 Defra (London).
- F. J. Bourne, C. A. Donnelly, D. R. Cox, G. Gettinby, J. P. McInerney, W. I. Morrison and R. Woodroffe. An epidemiological investigation into bovine tuberculosis. Third Report of the Independent Scientific Group on Cattle TB. 2001, PB5801 Defra (London).

2 RESEARCH PUBLICATIONS (2005)

2.1 RANDOMISED BADGER CULLING TRIAL

- 2.1.0 Four papers have been published in relation to aspects of the RBCT. We published our extended analysis of the reactive culling element of the trial and set out our initial analyses of the proactive element. There were also two papers on the welfare of badgers subjected to culling.
- 2.1.1 Firstly, in relation to the reactive element, we published a paper to update the initial publication (by Donnelly et al., 2003) on this strategy. This was "The impact of localised badger culling versus no culling on TB incidence in British cattle: a randomised trial" by Andrea M. Le Fevre, Christl A. Donnelly, D. R. Cox, F. John Bourne, Richard S. Clifton-Hadley, George Gettinby, W. Thomas Johnston, John P. McInerney, W. Ivan Morrison and Rosie Woodroffe and was published in October, at http://www.defra.gov.uk/animalh/tb/isg/pdf/lefevre1005.pdf. We concluded that

reactive culling as performed in the RBCT cannot contribute constructively to the control of bovine TB in Britain. The following is the published abstract of the paper:

Badger (*Meles meles*) culling has formed part of the British government's strategy to control cattle tuberculosis (TB) since the 1970s when *Mycobacterium bovis*, the etiological agent of bovine TB, was isolated in a badger carcass. Transmission between badgers and cattle has been demonstrated, but the dynamics remain unknown. The ongoing randomised badger culling trial, which began in 1998, was designed to compare two badger culling strategies, subject to welfare constraints, against a control and assess the impact of these strategies on cattle TB incidence.

Ten matched triplets, each consisting of three trial areas of approximately 100 square kilometres, were identified in areas of high TB incidence in cattle. Within a triplet, trial areas were randomly allocated to one of the two culling strategies or the control with no badger culling. Proactive culling aims to reduce badger densities to low levels across entire trial areas. Localised reactive culling was undertaken in response to the disclosure of TB in cattle herds. Analyses of data on TB incidence in cattle herds in the trial areas are undertaken every six months and will continue throughout the trial. The reactive treatment was suspended on 4 November 2003 based on a previous analysis; the current analysis uses an additional year of incidence data. Triplets were enrolled for an average of 3.6 years at the time of the current analysis. Log-linear regression was fitted to the incidence data and confidence intervals were adjusted for overdispersion.

There were 358 confirmed TB cattle disclosures in the control areas and 356 in the areas receiving localised reactive culling up to 22nd August 2004. After adjustment for covariates, localised reactive badger culling was associated with an estimated 25% increase in the number of cattle herds disclosing TB with 95% confidence interval (CI) 2.6 to 52% increase using the pre-specified time-scale (that is from the end of the initial proactive cull in each triplet). For comparison, the estimate based on the data from the end of the first reactive cull in each triplet was 21% with 95% CI: 1.0% decrease to 48% increase. This paper presents many previously unpublished extensions to these comparisons.

We conclude that reactive culling as performed in the randomised badger culling trial cannot contribute constructively to the control of bovine TB in Britain.

2.1.2 More recently, a paper presenting the interim findings from the proactive component of the RBCT has been published. Entitled "Positive and negative effects of widespread badger culling on cattle tuberculosis" by Christl A. Donnelly, Rosie Woodroffe, David R. Cox, F. John Bourne, Chris L. Cheeseman, Richard S. Clifton-Hadley, Gao Wei, George Gettinby, Peter Gilks, Helen Jenkins, W. Tom Johnston, Andrea M. Le Fevre, John P. McInerney and W. Ivan Morrison, it was published in Nature, 2005, doi.10.1038/nature04454. The paper and its contents can best be described as follows:

Diseases can be difficult to control where infection persists in wildlife populations. For three decades, European badgers have been culled by the UK government in a series of attempts to limit the spread of *Mycobacterium bovis*, the causative agent of bovine TB, to cattle. Despite these efforts, the incidence of TB in cattle has risen consistently, re-emerging as a primary concern for Britain's cattle industry. Recently, badger culling has attracted controversy because experimental studies have reached contrasting conclusions (albeit using different protocols), with

culled areas showing either markedly reduced or increased incidence of TB in cattle. Here we use data from a large-scale, randomised field experiment to help resolve these apparent differences. The paper concludes that on the basis of the analyses conducted at that time, the incidence of herd breakdowns has been 19% lower in proactive trial areas than in survey-only areas, and that analyses also revealed a 29% increase in cattle TB incidence on land neighbouring proactive areas, relative to land in survey-only areas.

2.1.3 The first of two papers on badger welfare, entitled "Welfare of badgers (*Meles meles*) subjected to culling: Patterns of trap-related injury" by R. Woodroffe, F. J. Bourne, D. R. Cox, C. A. Donnelly, G. Gettinby, J. P. McInerney and W. I. Morrison was published in <u>Animal Welfare</u>, 2005, 14, 11-17. The following extract from the paper describes its content:

As part of a far-reaching evaluation of the effectiveness and acceptability of badger culling as a TB control measure, this paper assesses one aspect of the welfare of badger populations subjected to culling: the risk of badgers confined to cage traps prior to despatch becoming injured as a result of rubbing or biting on the cage. In a large-scale field trial, 88% of badgers received no detectable injuries as a result of being confined in a trap. Of those that were injured, 72% received only minor skin abrasions. A minority (1.8% of the total) acquired damage to the teeth or jaws that may have caused serious pain. Although trap rounds were commenced in the early morning, badgers were no more likely to sustain injuries when they remained in traps until later in the day. Coating of cage traps, intended to give the wire mesh a smoother surface, was associated with a reduction in the incidence of minor skin abrasions, although it may have slightly increase the frequency of less common but more serious abrasions. Modification of the door design reduced tooth damage. Traps will be further modified if appropriate. However, all aspects of the conduct of trapping operations must balance badger welfare with concerns for the health and safety of field staff.

2.1.4 The second badger welfare paper related to breeding females was entitled "Welfare of badgers (*Meles meles*) subjected to culling: Development and evaluation of a closed season" by authors R. Woodroffe, F. J. Bourne, C. L. Cheeseman, C. A. Donnelly, D. R. Cox, G. Gettinby, J. P. McInerney and W. I. Morrison and it was published in <u>Animal Welfare</u>, 2005, 14, 19-25. Here, too, this extract best describes the paper:

As part of a far-reaching evaluation of the effectiveness and acceptability of badger culling as a TB control measure, this paper assesses one aspect of the welfare of badger populations subjected to culling: the killing of breeding females, which risks leaving their unweaned cubs to starve in the den. To avoid this possibility, a three-month closed season was adopted, running from 1st February to 30th April, based on the best available estimates of the timing of birth and weaning in British badgers. During May 1999-2003, when a total of 4705 adult badgers were culled, field teams failed to capture 12 unweaned litters when their mothers were despatched. In 31 other cases, lactating females were culled but litters of almost-weaned cubs were also caught and despatched at the some dens, usually within a day of capture of the mother. The number of unweaned cubs missed by culling teams - estimated at approximately nine per year on average - was dramatically lower than that projected by a badger welfare lobby group. Our data suggest that the dosed season is effective in reducing the suffering of unweaned cubs in badger

populations subject to culling, and we recommend that this measure be maintained should badger culling form a component of any future TB control policy.

2.2 GENERAL ANALYSIS

- 2.2.0 The ISG has also been involved in the preparation and publication of three papers which perhaps can best be considered under a "general analysis" heading.
- 2.2.1 The first considered the geographical associations between TB infection in badgers and cattle, the paper being entitled "Spatial association of *Mycobacterium bovis* infection in cattle and badgers *Meles meles*" by R. Woodroffe, C. A. Donnelly, W. T. Johnston, F. J. Bourne, C. L. Cheeseman, R. S. Clifton-Hadley, D. R. Cox, G. Gettinby, R. G. Hewinson, A. M. Le Fevre, J. P. McInerney and W. I. Morrison and was published in Journal of Applied Ecology, 2005, 42, 852-862. The abstract says:

Control of zoonotic disease is difficult to achieve when populations of multiple hosts, particularly wildlife, become persistently infected. Bovine tuberculosis (TB) is one such disease: its causative agent, *Mycobacterium bovis*, infects cattle, humans and multiple wildlife species including European badgers *Meles meles*.

In Britain, from 1974 to 1998 various strategies for the control of cattle TB involved culling badgers in the immediate vicinity of TB-affected herds. However, patterns of association between cattle and badgers had not been investigated at a local scale.

Using data from the Randomised Badger Culling Trial, we investigated local geographical associations between *M. bovis* infection in badgers and cattle.

Mycobacterium bovis infections were locally clustered within both badger and cattle populations.

We show, for the first time, that *M. bovis* infections in badgers and cattle are spatially associated at a scale of 1–2 km. Badgers and cattle infected with the same strain type 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.

The close associations between *M. bovis* infections in cattle and badgers suggest that localised badger culling could reasonably be expected to reduce the risks of cattle TB infection; however, experimental culls have found no such beneficial effects over the time-scale on which they were tested. This demonstrates the difficulty of predicting the outcome of management interventions, and reinforces the need for well-designed empirical assessments of future control strategies.

2.2.2 The second paper "Simple model for tuberculosis in cattle and badgers" by D. R. Cox, Christl A. Donnelly, F. John Bourne, George Gettinby, John P. McInerney, W. Ivan Morrison, and Rosie Woodroffe was published in <u>Proceedings of the National Academy of Science, USA</u>, 2005. 10.1073/pnas.0509003102. This paper is freely available to all at: http://www.pnas.org/cgi/content/full/102/49/17588.

- 2.2.2.1 As an aid to the study of bovine TB, the paper developed a simple model of an epidemic involving two species, cattle and badgers, where each species may infect the other. In the paper the proportion of animals affected is assumed relatively small so that the usual non-linear aspects of epidemic theory are avoided. The model is used to study the long-run and transient effect on cattle of culling badgers and the effect of a period without routine testing for TB, such as occurred during the 2001 epidemic of foot-and-mouth disease in Great Britain. Finally, by examining the changes in cattle TB over the last 15 years, and with some other working assumptions, it is estimated that the net reproduction number of the epidemic is approximately 1.1 (note: "net reproduction number" is a statistical term; conditions for epidemic growth are that this number exceeds *one*).
- 2.2.2.2 The paper shows that although the net reproduction number is clearly above <u>one</u>, it is sufficiently close to <u>one</u> that relatively modest improvements either in TB test performance or TB testing frequency would be sufficient to bring an epidemic under control, but under the highly idealised assumptions made in the model.
- 2.2.2.3 The implications for controlling the disease are discussed.
- 2.2.3 There was also a paper "Effects of culling on badger (*Meles meles*) spatial organisation: implications for the control of bovine TB" by R. Woodroffe, C. A. Donnelly, D. R. Cox, F. J. Bourne, C. L. Cheeseman, R. J. Delahay, G. Gettinby, J. P. McInerney and W. I. Morrison which was published in <u>J Applied Ecology</u>, 2005, 42, 852; doi 10.1111/j1365-2664.2005.01081.x
- 2.2.3.1. This paper describes a study when badger home ranges were mapped by feeding colour-marked baits at badger dens and measuring the area in which colour-marked faeces were observed. The study areas had been subjected to different levels of badger culling since 1998.
- 2.2.3.2. The study demonstrated that culling badgers profoundly alters the spatial organisation of those badgers not culled and this has the capability to influence contact rates between cattle and badgers where culls occur and on near-by land.
- 2.2.3.4 These results may offer an explanation why localised badger culling appears to have failed to control cattle TB.

2.3 TB99 EPIDEMIOLOGICAL SURVEY ANALYSIS

- 2.3.1 Finally, we published a paper "Herd level risk factors associated with TB breakdowns prior to the 2001 UK foot and mouth disease epidemic among cattle herds in England" by W. Thomas Johnston, George Gettinby, David .R. Cox, Christl A. Donnelly, F. John Bourne, Richard S. Clifton-Hadley, Andrea M. Le Fevre, John P. McInerney, Andy Mitchell, W. Ivan Morrison and Rosie Woodroffe which appeared in Biology Letters, 2005, 1, 53-6. This contained the first case-control results from the 6-year TB99 survey.
- 2.3.2 A case-control study of the factors associated with the risk of a bovine tuberculosis (TB) breakdown in cattle herds was undertaken within the randomised

badger culling trial (RBCT). TB breakdowns occurring prior to the 2001 foot-and-mouth disease epidemic in three RBCT triplets were eligible to be cases; controls were selected from the same RBCT area. Data from 151 case farms and 117 control farms were analysed using logistic regression. The results suggested that the strongest factors associated with an increased TB risk were movement of cattle onto the farm from markets or farm sales, operating a farm over multiple premises and the use of either covered yard or 'other' housing types. Spreading artificial fertilisers or farmyard manure on grazing land were both associated with decreased risk. These first case—control results will be followed by similar analyses as more data become available.

2.3.3 Analysis of TB99 data from 2001 to 2004 (when the survey was ended) has continued during 2005 and additional results will be presented at the 3rd Open Meeting.

2.4 REVIEW ARTICLE

- 2.4.1 In 2005, one review article was also published:
- 2.4.1.1 Bovine Tuberculosis Towards a Science Based Control Strategy by F. J Bourne, C. A. Donnelly, D. R. Cox, G. Gettinby, J. P. McInerney, W. I. Morrison and R. Woodroffe in <u>Science in Parliament</u>, 62 (1), 25-28, 2005.

3 ADDITIONAL TB SURVEYS

3.0 There are two other major areas of work that merit a mention.

3.1 CCS2005 EPIDEMIOLOGICAL SURVEY

- 3.1.1 The TB99 survey was subject to two independent audits in 2004 and recommendations were made for a substantial revision to provide a new, simpler and much shorter form for use in 2005. The new questionnaire format made use of existing databases to improve accuracy and consistency and required considerably less information to be collected at the farm level. The 2005 survey, known as CCS2005 (i.e. 'Case Control Survey 2005'), used the simplified questionnaire and was restricted to four areas of GB, namely Carlisle, Carmarthen, Stafford and Taunton. This provided continued collection of risk factor information from a sample of triplets during the final stages of the RBCT and should provide valuable information from outside the triplets.
- 3.1.2 So far, when this report was written, 315 case forms and 603 control forms had been completed and the survey was progressing extremely well. The ISG are presently analysing the results of the survey.

3.2 RTA SURVEY

3.2.1 The Group published its analysis of the 2002 to 2004 Road Traffic Accident (RTA) data at http://www.defra.gov.uk/animalh/tb/publications/index.htm; overall, one

in seven badger carcasses retrieved in Cornwall, Devon, Dorset, Gloucestershire, Herefordshire, Shropshire and Worcestershire, and subject to post mortem, were found positive for bovine tuberculosis. The analysis contained maps of the locations of the carcasses.

3.2.2 The RTA survey continued in 2005 and so far, when this report was written, 1281 carcasses had been collected and 1063 post mortems carried out. The Group intends to publish a report on the data next July. 2005 was the last year of this survey.

4 PREVIOUS PUBLICATIONS

- F. J. Bourne, C. A. Donnelly, D. R. Cox, G. Gettinby, J. P. McInerney, W. I. Morrison and R. Woodroffe. Towards a sustainable policy to control TB in cattle A scientific initiative. First Report of the Independent Scientific Group on Cattle TB. 1998, PB3881, MAFF (London).
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- R. Woodroffe, F. J. Bourne, C. A. Donnelly, D. R. Cox, G. Gettinby, J.P. McInerney and W.I. Morrison. Towards a sustainable policy to control TB in cattle. Conservation and Conflict: Mammals and Farming in Britain, London: Linnean Society. Eds. F. Tattersal and W. Manley. 142-151, 2003.
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- F. J. Bourne, C. A. Donnelly, D. R. Cox, G. Gettinby, J. P. McInerney, W. I. Morrison and R. Woodroffe. An epidemiological investigation into bovine tuberculosis: towards a science-based control strategy. Fourth Report of the Independent Scientific Group on Cattle TB. 2005, PB10138 Defra (London).

JANUARY 2006

Appendix 1.

Numbers of badgers culled in the RBCT up to the end of 2004 and in 2005.

Years	Number culled		
1998-2004	9756		
2005	1201		
TOTAL	10957		

Total number of non-target species caught, found dead, despatched or released in the RBCT up to the end of 2004 and in 2005.

Years	Caught	Found dead	Despatched	Released
1998-2004	1879	59	56	1764
2005	220	5	6	209
TOTAL	2099	64	62	1973

Appendix 2.

Appendix E of the ISG's 4^{th} Report (Bourne et al, 2005) summarised the position, as at the end of 2004, of RBCT audits. In the following table the position of published reports is up-dated to the end of 2005:

REPORT	AUDITOR	REPORT DATE	REF NO	SUMMARY OF FINDINGS / COMMENT
Humaneness of despatch procedures (4 th audit)	James Anderson	October 2005	PB 11329	The Department made a response and accepted recommendations on archiving of training material and production of a training video and an acceptance of a past minor change in the SOP, but not a recommendation to modify it to reflect more strongly that accuracy is more important than speed in shooting a badger.
Statistical aspects of the RBCT for 2004/5	Denis Mollison	December 2005	-	Report, without Defra response, published on Defra Website.

Appendix 3.

SECOND OPEN MEETING

The Independent Scientific Group on Cattle TB (ISG) met for the 75th time at 1 Great George Street in London on 17 November 2004, this meeting being the second that the Group had conducted in public. Following advance publicity, Members were pleased to welcome representatives from 19, mainly farming, organisations together with 39 individuals.

The audience heard Professor Christl Donnelly give a talk entitled "Presentation of analysis of the Randomised Badger Culling Trial data", Professor Ivan Morrison spoke on "Pathogenesis of TB in cattle" and Professor Gettinby gave a presentation entitled "TB99 Farm Survey".

The audience participated in a Question and Answer session during which a range of issues was discussed such as Reactive badger culling, biosecurity measures, genetic susceptibility to TB and the specificity of the gamma interferon test. Informal discussions also took place over lunch and provided attendees with the opportunity to ask further questions.

The Chairman thanked those present for attending the meeting and said he hoped it had demonstrated the broad-spectrum scientific approach taken by the ISG to advise on the control of bovine tuberculosis.

Appendix 4.

REGISTER OF MEMBERS INTERESTS (CHANGES SINCE 2004)

Professor Christl Donnelly

Current main employment is as Professor of Statistical Epidemiology in the Department of Infectious Disease Epidemiology, Faculty of Medicine, Imperial College London.

Principal investigator of a Defra-funded research grant for epidemiological / statistical research assistants analysing data on bovine TB in cattle and badgers, in association with the ISG.

Joint contractor on a grant: "Transmission dynamics and control of foot and mouth disease" sponsored by the Biotechnology and Biological Sciences Research Council (BBSRC) and Defra.

Professor George Gettinby

Research contracts held in the area of sea lice epidemiology on salmon farms funded by Defra, and endopthalmitis in cataract patients, funded by the European Society of Cataract and Refractive Surgeons.

Past member of the Defra Veterinary Fellowship Review Panel and the UK Veterinary Products Committee.

Scientific adviser to Waltham Centre for Pet Nutrition, Novartis, Intervet, Merial US, Organon Medical Research Laboratories and David Begg & Associates.