BOVINE TUBERCULOSIS IN ENGLAND: TOWARDS ERADICATION

Final Report of the Bovine TB Advisory Group

Presented to the Minister for Farming and the Environment, and the Chief Veterinary Officer for Defra. 8 April 2009

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Annexes

(i) CHAIRMAN'S FOREWORD

The following pages draw together the conclusions and opinions of the Bovine TB Advisory Group since it was first convened in 2006. It represents the result of discussions with those closely engaged with tackling the bovine tuberculosis problem in cattle. Summaries of these discussions have been placed on the Defra website and give rise to the recommendations for changes members of the Group feel are necessary to make the control and ultimate eradication of bovine TB a reality.

The Group have had wide ranging responsibilities from playing a key role in obtaining stakeholder buy-in to TB control policies, constructively challenging Government and independently considering other issues it believed were of concern to the wider stakeholder community.

A clear theme throughout the Group's deliberations was the pressing need for Government to clarify its strategic goal for bovine TB and inject a necessary sense of urgency. In submitting advice to Lord Rooker (October 2007), then Minister for Food and Farming, we pressed for a clear steer on whether Government policy was to control or eradicate the disease. The establishment of the new Bovine TB Eradication Group for England would seem to have addressed this point, and we are pleased that a clear direction has been set in England, as has been done in Wales.

In summarising the work of the last two years or so I would like to put on record my sincere thanks to my colleagues in the Group for their consistently helpful and robust contributions. In addition I would like to acknowledge the willingness of all who have given so generously of their time to meet and discuss with us the difficult issues that this disease, its control and eventual eradication presents. Lastly, particular thanks must be given to our patient and helpful Defra secretariat whose persistent prompting and challenge added much to our efforts.

Peter Jinman
Chairman

(ii) OVERVIEW

There are some fundamental points that the Group would wish to make from the outset. Firstly, we were tasked with considering the role of bovine TB and cattle in terms of developing control policies in England while the Government decided what its policy should be on badger culling. This decision was ultimately taken by the Secretary of State who made the Government's position clear when he announced in July 2008 that Defra's policy is not to issue licences to farmers in England to cull badgers for TB control purposes. However, Government remain open to the possibility of revisiting this policy under exceptional circumstances, or if new scientific evidence were to become available.

With this decision came the birth of the new TB Eradication Group for England, to whom we extend our best wishes and hope that the following recommendations - gleaned from discussions with all parties involved in the bovine TB problem - may be of benefit in guiding their deliberations.

Bovine TB is a serious infectious disease where control and eradication gives rise to a major economic cost. We would emphasise the need to restore a sense of urgency when dealing with bovine TB and ensuring sufficient resources, both physical and financial, are available to tackle the disease efficiently and effectively. There is no magic bullet for the control and eventual eradication of TB from cattle in England. However, diseases have been eradicated from the UK even where there was an incomplete understanding of how transmission occurred e.g. rinderpest and rabies. The application of efficient testing and disease transmission reduction methods rigorously applied can successfully tackle TB. Given the infectious nature of this organism all attempts must be made to minimise the disease transmission risk and a consistent risk reduction approach must be used for all breakdowns.

A holistic multifaceted approach is needed with a combination of control measures. It is important to acknowledge that the goal of eradication can only be achieved over an extended timeframe and at substantial on-going cost. It is evident that any consideration of the timescale for control, let alone eradication of the disease, must be measured in terms of a minimum of 10 to 20 years. Any eradication policy must include measures for addressing the wildlife reservoir. Every effort must be made to stop the spread of bovine TB from existing endemic areas. Equally critical are rigorous measures to stamp out the disease where it occurs in new areas.

Efforts need to be made to dispel the myths and misconceptions that abound. We hope the document we recently produced - '*Bovine TB – The Facts'* – will be helpful in this respect (Annex D). It has become clear that the basic facts are not filtering out to those dealing with the disease on the ground – both the farming community and beyond. Who communicates the message is paramount and veterinary endorsement is key. This is particularly important in relation to science

and emerging research so as not to raise expectations unnecessarily amongst stakeholders. It is easy to lose sight of the importance of a committed multi-faceted approach for tackling this disease when faced with the promise of new developments e.g. badger vaccines. Although the latter provide the only viable option for dealing with the wildlife reservoir within the policy framework Government has currently set, they can only ever form part of a raft of measures necessary to control and eventually eradicate this disease.

The Group noted the work being done in Wales to develop an Eradication Programme. We would like to express our thanks to the former Wales TB Action Group for their invitation to observe their deliberations. We would express concern given the considerable expenditure currently being undertaken in Wales (Health Check Wales), that the high levels of TB on the English side of the border should not be allowed to detract from implementation of the Welsh plans. We would urge the Welsh Assembly and Defra to consider how both countries can cooperate in this region, thereby acting for mutual benefit. Disease does not respect borders and an alignment of policy across the different administrations must be beneficial to all countries.

It is clear from the various discussions with stakeholders that many involved with tackling bovine TB have become disheartened. In the absence of any perceptible progress and a decision not to cull badgers in England, many feel thwarted in their efforts to control this disease. Following this stalemate and with the agreement of industry representatives we convened a meeting in November 2008 to help progress issues such as the Badger Vaccine Deployment Project which were time critical and required industry input. We also focused on cattle control measures and how the long-term TB strategy might develop in light of engagement issues between industry and Government. Despite agreement that cattle controls needed to be looked at, it was clear that testing 'fatigue' was a serious issue in endemic areas where continuous testing showed little or no progress.

The overriding conclusion having spent a considerable amount of time cultivating stakeholders relationships and listening to a diverse range of views, is that clear leadership, both Government and industry, needs to be demonstrated and renewed vigour injected into TB control efforts if there is to be progress.

Finally, there is a need to acknowledge the human costs of this disease. TB has negative effects not only on the health of animals and trade but also the health and well-being of the herd owners involved. It has become apparent in discussions with industry that the stress of dealing with herd breakdowns, particularly in areas of repeated or extended breakdowns, has very real effects on individuals that extend beyond the immediate cost of the animals that are slaughtered. Some form of support (both business advice and direct financial support) is needed to help farmers to manage the impact of living under disease restrictions.

(iii) CONCLUSIONS

1. Bovine TB has been a difficult and demanding problem for many years. There are reasons for believing that it can be controlled and finally eradicated but this will require a long-term commitment by all stakeholders and take at least 20 years.

2. Very many who are involved in battling this disease are becoming disheartened with the lack of progress and with a widely held belief that the failure to tackle the wildlife reservoir undermines their efforts.

3. There is a need for strong and committed leadership (both Government and industry) to develop a clear consensus on tackling this disease. Renewed vigour needs to be injected into this long campaign and we welcome the establishment of the England TB Eradication Group.

4. Although control of the disease in cattle might be accomplished by cattle measures alone the time scale is long and the cost to the farming industry and the public purse will be considerable. There are not sufficient additional practical cattle controls which will result in the eradication of TB in the absence of measures to address infection in the wildlife reservoir.

5. The Secretary of State's decision has removed the option (preferred by many in the farming industry) of culling badgers in England. However, reducing the risk of transmission from the wildlife vector to cattle does not solely mean the culling of badgers, but encompasses all practical measures to break the cycle of transmission.

6. An injectable badger vaccine is due to be licensed by 2010 and an oral vaccine is expected by 2014 at the earliest. The practical widespread application of badger vaccines has the potential to contribute to eradication of bovine TB. However, it is likely to take several years before an effect in cattle is observed.

7. Vaccination of cattle is further away and will require the development of a test to differentiate vaccinated from unvaccinated cattle (DIVA) as well as a change in EU legislation before it can be used in the cattle population.

8. Given the current rate of spread of TB we are concerned there may be over-reliance on a future vaccination programme (cattle and badgers) - this should not negate the urgent need for measures to tackle the problem now.

9. The emphasis of the current TB testing programme (surveillance and control) appears to be unbalanced i.e. the same approach is used in both high risk and low risk areas.

10. Further measures aimed at stopping the spread of the disease will cause difficulties and costs to both the taxpayer and the farming industry. It is in the public interest and in line with the responsibility and cost sharing agenda that costs are shared.

1. KEY ISSUES

In summary, we propose that the Government's future strategy for the sustainable control of bovine TB in Great Britain take account of the following key issues. Our recommendations (R1 – R36) are highlighted under the relevant sections below.

1.1 Cattle Movements

Farming practices have evolved over time with farm amalgamation and expansion often leading to greater fragmentation and disease risks associated with the movement of cattle. Research at Warwick University has shown the spread of disease following the movement of animals in restocking farms following the Foot-and-Mouth (FMD) epidemic; the time required for disease to be spread can be rapid. The cattle industry relies on a considerable amount of cattle trade to function. However, there are currently many movements of cattle under schemes designed originally for the control of FMD which do not provide adequate safeguards against the spread of TB. The aim must be to render cattle movements safe whilst enabling trade to continue. Rules must be proportionate with regard to the level of risk.

Single Occupancy Authorities:
From the outset the Group questioned the role of Single Occupancy Authorities (SOAs) in the context of bovine TB. These premises were first licensed to allow the controlled movement of animals in the face of FMD. However, there are marked differences between the chronic bacterial disease of TB and the acute viral disease of FMD with regard particularly to transmission speed and mode, which in our view make the current use of SOAs inappropriate. Unfortunately they have continued to be licensed and used for movement of animals long after FMD controls have been lifted. The rules for SOAs are designed to create epidemiological units with stock proof boundaries, although spread over a number of land parcels. The problem arises in cattle moving from one land parcel to another where the two land parcels concerned have different TB testing regimes or more particularly when the cattle move from a higher frequency testing area to a lower frequency one. SOAs are exempt from pre-movement testing requirements and as such can be inappropriate in terms of TB, presenting a significant risk of disease spread.

We found it disappointing that faced with the evidence that cattle are clearly moving over long distances and between holdings with different testing frequencies without being tested, there has not been a greater effort to change the structure of these licences or impose stricter and more appropriate criteria for their application.

- **R1: The mixing of cattle from different sites under the aegis of an SOA does not sit well with risk related disease control. Whilst we welcome the pre-movement testing review we recommend that all**

new SOAs be licensed subject to a TB risk evaluation. SOAs should only be licensed for holdings of similar testing status e.g. 1 and 2 year or 3 and 4 yearly testing intervals.

Approved/Exempt Finishing Units:

Approved Finishing Units (AFUs) and Exempt Finishing Units (EFUs) can play a significant role in helping farmers to manage breakdowns. However, there is considerable confusion about the rules for setting up and running these units which may inhibit their wider uptake.

Subject to the appropriate controls, it is possible to allow the creation of AFUs for clear tested animals from herds placed under TB movement restrictions. This is to help alleviate the pressure on housing facilities and labour resources caused by long-standing TB restrictions. Surplus cattle from restricted herds can be sent to those units under licence for rearing and finishing before consignment to slaughter.

Cattle movements into AFUs are exempt from pre-movement testing. Movement to an AFU from TB2 restricted herds can only take place within 14 days of a negative tuberculin test. Unrestricted cattle are not required to have a tuberculin test prior to movement onto an AFU. Limiting the movement to within 14 days of a TB test places an unnecessary restriction, in that anyone seeking to move an animal 15 – 57 days after a test cannot do so nor can they have the animal tested because of the requirement for an interval of 60 days between tests. We therefore suggested this period could be safely extended from 14 to 60 days, thereby easing the entry criteria to AFUs and maintaining trade. As a result of our discussions it has been agreed in principle with Animal Health that this time period can be relaxed to bring it in line with the 60-day restriction on movements to approved slaughter markets for TB2 restricted cattle.

EFUs provide a route for beef producers to finish animals without the need to pre-movement test. Onward movements are restricted. EFUs must meet strict conditions designed to reduce the potential risk of disease spread from the premises and be approved by Animal Health.

A simplified and amalgamated AFU/EFU approval system based on ease of entry and good biosecurity would be an aid to those farms under severe financial and welfare stress. There is a marked need for such units and, where they have been established, their availability has been a lifeline for many livestock owners. The livestock industry remains dependent upon the ability to trade efficiently and the movement of animals must be considered in the context of this particular disease.

- **R2: We recommend the criteria governing AFUs/EFUs should be reviewed and if possible a simplified amalgamated model developed which is practical and meets the necessary biosecurity standards.**

- **R3: Government should work with industry to promote uptake of AFUs/EFUs.**

Shows:
At present, pre-movement testing is not required for animals to be transported to agricultural shows - provided that the animal is returned to the premises of origin or moved direct to slaughter. The mixing of animals at agricultural shows presents a TB risk.

- **R4: We recommend that the mixing of TB tested animals from parishes with different testing intervals at agricultural shows, and the exemption from pre-movement testing of such animals, be reviewed in terms of minimising disease risk.**

Risk-Based Trading:
The ability to trade and move animals is fundamental to the livestock industry but movements can carry considerable risks. The Group believes that further consideration should be given to risk-based trading although it is mindful of the difficulties that too rigorous enforcement of some of the ways in which this can be carried out e.g. zoning could affect the viability of cattle farming and markets. Whether there are enough livestock available to ensure that farms could only purchase from holdings of a similar or better TB status needs detailed investigation. In 1970 the State and Federal governments of Australia launched an eradication campaign which included movement controls based on risk assessment. Risk was assessed at the herd-level with risk-based trading allowed within and between regions (It should be noted that the wildlife reservoir of TB in Australia, the Asian water buffalo, was also addressed under this campaign). The idea is sound; it is another matter whether it is possible to implement such a system in England. We also recognise that herds with breeding animals are a higher risk for TB establishment. Therefore additional criteria may be required to allow trading between such herds e.g. post-movement testing.

- **R5: Further consideration needs to be given to Risk-Based Trading. We would favour an approach aimed at establishing categories based on testing interval and taking into account whether cattle are moving onto premises where there are breeding cattle.**

1.2 Testing Programme

Control or Eradication?
From our discussions we were not convinced there was sufficient clarity about the objective of the Government's current TB policy – particularly if it was aiming for control or eradication. The initial goal must be to control and reduce disease incidence. Prior to the establishment of the new Bovine TB Eradication Group for England we had encouraged Government to work with stakeholders to agree

clearer objectives, and to consider underpinning these with targets. The new group has been set up specifically to make recommendations to the Secretary of State on bovine TB and its eradication in England. This framework will provide much needed clarity although we would reiterate that clear targets should be developed in line with the group's work programme.

It is clear that the control and eventual eradication of bovine TB is going to take a long time. In assessing the cost/benefit balance of control measures, it is important that Government take a very long-term view: methods that may be very expensive in the short term may nevertheless result in economies when viewed over a longer timescale.

- **R6: Control and eradication of bovine TB will take years (at least 20 years). We therefore recommend Government use an extended timeframe when assessing the projected costs and benefits of controls.**

Testing Regime:

Routine herd testing and slaughter of infected cattle remains the key control mechanism for bovine TB. The Group is concerned that if testing is not carried out in a coordinated and timely way within areas, the maintenance of infection risk and potential for further spread will remain.

Given that most infectious diseases of livestock are controlled by testing around an outbreak and assuming the source has been traced, attention should be given to coordinating the testing of contiguous herds so that this can be achieved as a priority rather than leaving the choice of testing to a more random surveillance type approach. This is particularly important in areas where the disease has become endemic.

- **R7: The TB testing regime needs to be conducted in a geographically and temporally coordinated way (aiming to cover all farms in a region within the same time period) both for surveillance and particularly when dealing with endemic and new area outbreaks.**

Testing Frequency:

The interval between tests has been the subject of much discussion. The adequacy of disease surveillance in low risk areas (based on 3 or 4 yearly testing parishes) was questioned by the ISG. They suggested modification of testing intervals to a maximum of 2 or 3 years, focused on individual farms rather than parishes as an alternative. Defra commissioned modelling of disease prediction trends to explore the effect of changing all 2 yearly testing parishes to annual testing, and all 3 and 4 yearly parishes to 2 yearly testing as well a six month and 2 yearly testing regime, in place of the current programme (1, 2, 3 and 4 yearly testing intervals). The modelling is at an early stage and some refinement is still required. However, initial indications suggest no great gain from increasing the

testing frequency in the most infected areas given that so many holdings are already under 60 day testing or contiguous premises testing. There may be a greater benefit from increased frequency in areas currently at 4 yearly testing and this should be further explored and the consequent likely costs evaluated.

The type of animal also needs to be considered when setting testing frequencies. Breeding animals can remain on-farm for a number of years whereas fattening animals have both a shorter lifespan and a consequent shorter time of residence on farm, being sent to slaughter usually within a number of months. Given the considerable length of time for which cattle infected with TB can remain actually or potentially infectious, the Group considers breeding animals present a greater transmission risk and the testing regime should reflect this.

- **R8: We have received conflicting views about the value of increased frequency of TB testing. This, and its application in a risk-based manner, need further investigation with particular reference to breeding animals.**

Designation of Testing Areas:

Whilst acknowledging the EU legislation within which this is prescribed (Directive 64/432), the adequacy of the designation of TB testing areas based on parishes was considered. The Group found that designation based on parishes was arbitrary and unsatisfactory from a disease control point of view. Parish boundaries may not coincide with epidemiologically significant factors. All other notifiable diseases are controlled by setting up surveillance zones around an outbreak.

Additionally, the nature of triggers for increasing testing frequency was discussed. Representation was made by Animal Health that consideration should be given to factors such as how long animals had been on a farm before rendering the whole parish as subject to a change in testing frequency. Indeed farmers had also expressed similar concerns. There is no doubt that because of the potential for rapid spread, rigorous measures need to be pursued but, in some cases, the effect on annual testing and pre-movement testing on other herds within the parish might be seen as disproportionate to the risk.

- **R9: We recommend consideration should be given to tackling TB breakdowns in an epidemiologically relevant manner in a true partnership approach e.g. livestock owner, local vets and Animal Health.**

1.3 Cattle Controls

We discussed a range of options with stakeholders for tightening cattle controls and we believe that a number of these merit more detailed examination.

Pre-movement Testing:
Pre-movement testing has figured frequently in discussions, with differing views being presented. Early on the Group was invited to consider and advise on the practical delivery and implementation of pre-movement testing policy. This was presented to Ministers and the CVO in 2007. The Group supported the pre-movement testing policy as a means of reducing the risk of TB spread through cattle movements but felt more time was needed to see the epidemiological impacts of the measure, ideally two years post introduction. We acknowledge the most recent FMD outbreak (2007) caused a delay in the review but are concerned this has impacted on progress in other areas dependent on the outcome of the pre-movement testing review e.g. SOAs. We note the undertaking from Government that the review will take place in 2009.

Farmers in areas clear of the disease have strong views on the necessity for maintaining pre-movement testing. They believe there is evidence the policy is working to control the spread of disease into new areas but are less certain of its effectiveness in high risk areas (1 and 2 yearly testing parishes). We look forward to the results of the important review of pre-movement testing.

There is currently no requirement for paperwork - establishing if pre-movement testing had been carried out on an individual animal – to follow that animal. This omission needs correcting. Because of this situation, in the trading of animals the receiving farmer was often unaware that animals had been tested and the consequence was unnecessary testing of some animals and the danger that others were not being tested. The industry had proposed that cattle passports should be marked to show when a test had been carried out. The Group were happy with this recommendation and are disappointed that this initiative has not yet been taken forward.

- **R10: We recommend the review of pre-movement testing be progressed as a matter of urgency.**

- **R11: Pre-movement testing records should travel with the animal and always be available to inform decisions about subsequent testing as well as animal and herd health biosecurity considerations on the receiving farm.**

Post-movement Testing:
The Group believe the greatest risk of wider disease spread is associated with cattle movements. The case for post-movement testing in England was discussed and we considered this measure more relevant to animals moving on to farms with breeding herds because of the potentially greater consequences of introduction of infection into such herds. Although industry did not believe there was enough confidence in the value of the pre-movement testing policy to justify introduction of post-movement testing, the requirement for animals to be post-movement tested when moving onto premises where breeding stock are kept in 3

and 4 yearly testing areas seems sensible. In terms of the greatest risk of disease spread to new areas, testing of all animals bought into herds in 3 and 4 yearly testing parishes from 1 and 2 yearly testing parishes is strongly encouraged.

- **R12: We recommend post-movement testing of animals brought on to holdings with breeding herds in three and four yearly testing parishes from one and two yearly testing parishes, with its use strongly encouraged for all other movements.**

Inconclusive Reactors:
A review of the inconclusive reactor (IR) testing policy was discussed with Defra officials. At present in Great Britain and Northern Ireland, IRs are allowed up to two skin re-tests following disclosure through skin testing. The only exception to this policy has been the persistent (twice) IRs in 1 and 2 yearly tested herds in GB, which since October 2006 have been gamma interferon blood tested in order to allow earlier removal of some animals. However, the current approach is not compliant with Annex B of Council Directive 64/432/EEC (as amended), which dictates that all standard IRs to the skin test must be immediately classed as reactors and slaughtered if they do not pass their first re-test. We note the recent decision by Wales and Scotland to comply fully with the Directive and believe this is consistent with an overall TB eradication strategy. An alignment of the GB position would have the benefit of removing the risk of disease earlier and farmers should be encouraged to get rid of 'at risk' animals as soon as possible by slaughter and compensation rather than trading on.

- **R13: We recommend Defra amend its current policy to fully comply with Council Directive 64/432/EEC (as amended) which states that all standard inconclusive reactors to the skin test must be slaughtered as reactors on failing their first re-test.**

1.4 Diagnostics

Gamma Interferon**:**
Council Directive 64/432/EEC (as amended) provides that Member States may deploy the gamma interferon blood test alongside the skin test to enhance the sensitivity of the diagnostic regime in order to enable detection of the maximum number of TB infected animals. The use of the gamma interferon test was welcomed as an additional means of more rapidly evaluating the extent of a TB breakdown. The fact that it shows up positively infected animals earlier could be a considerable advantage in determining the extent of infection. The test should be made more widely available – including for pre and post-movement testing, although we recognise there are current constraints in terms of cost, legal and logistical issues. This will improve the detection (and thus subsequent removal) of infected animals and will assist in the determination of the disease status of animals where the skin test gives an equivocal response. The Group is aware of

the lack of confidence in this test in some sectors of the industry. This is partly as a result of concerns over the specificity of the test i.e. lower than the skin test.

- **R14: We recommend Government explore wider use of the gamma interferon test e.g. pre and post-movement testing. This will require amendments to Council Directive 64/432 and we encourage negotiations at EU level.**

- **R15: We recommend continued investment in the development of the gamma interferon test to increase its specificity.**

Polymerase Chain Reaction:

Use of the polymerase chain reaction (PCR) technique for the determination of infection was mentioned frequently in discussions, particularly regarding the determination of infected badger setts. Although it is unlikely to have a role in this context (see below) it is clear this is a potentially useful diagnostic tool in some circumstances (detection of infection in live animals and at post-mortem) although the test has yet to be validated for use in the field. Whilst there is value in developing new techniques such as PCR we would caution against raising expectations unnecessarily. There are limitations in terms of using PCR and this message needs to be communicated more widely. The technique is not yet as sensitive, specific or reliable as conventional bacterial culture in detection of *M. bovis*, and whilst it may be possible for a PCR test to identify areas where the organism is present in the environment, it is currently not able to identify if the DNA detected is from *M. bovis* mycobacteria that are viable and infectious.

- **R16: We recommend continued investment in the development of PCR for the detection of viable *M. bovis* organisms as an aid to targeting biosecurity measures where a wildlife source is implicated.**

1.5 Wildlife Reservoir

Whilst it was not within the remit of the Group to advise on the role of badger culling in tackling cattle TB, the nature of the role of the badger in the epidemiology of bovine TB was a matter that could not be ignored and which impinged heavily on the debate around TB control. Given the undoubted role of the badger (as evidenced by the results of the RBCT) in the spread and perpetuation of TB in cattle, and in the absence of culling, tightened biosecurity and in the future vaccination, are the best options for control of TB transmission from badgers. It will therefore be vital to direct both effort and resources at those parts of the country where there is a clear indication of a significant wildlife risk. We recognise that some work to determine likely wildlife sources of infection is already undertaken for the management of current breakdowns. However, there is a need to develop criteria to aid the determination of the source of an outbreak

and using all epidemiological information gathered to inform individual herd management decisions.

In terms of other wild species we noted the results of studies on the prevalence of bovine TB in wild deer and their density in hotspot areas, and how this could pose a risk of *M. bovis* exposure to cattle. Though currently not considered a significant widespread TB risk to cattle, the situation should be closely monitored.

- **R17: We recommend that criteria be developed to help determine the origin of an individual herd breakdown and that this information is shared with all responsible for tackling the breakdown.**

- **R18: Improved surveillance of bovine TB in other wildlife species (including deer and wild boar) is required. Wild deer are not considered a significant widespread risk to cattle at present but this should be monitored.**

1.6 Vaccination

Both badger and cattle vaccines may play important roles in control and eventual eradication of the disease and we are pleased that development programmes are underway for both. The Group has spent considerable time assisting the Defra vaccines programme in its consideration of how vaccines could be used, cost effectiveness and potential delivery. We offered comments on Defra's policy options papers which were subsequently agreed and endorsed by stakeholders. It is important that the industry help take these forward but we caution against unrealistic expectations about rapid impact. These programmes are likely to take a considerable amount of time (some years, once introduced) to have a clearly observable effect. However that should not detract from the generally agreed benefit of having TB vaccines as an additional tool for the control of the disease.

A licensed injectable badger vaccine is likely to become available as early as 2010 and therefore it is most important that Government, industry and wildlife groups start now to work together to develop ways for its effective deployment. Whilst a licensed badger vaccine will not be available in an oral form for at least 5 years (earliest expected date 2014), vaccination provides a real opportunity to target bovine TB in the wildlife reservoir.

The development of a TB vaccine for cattle and its subsequent commercial production will take longer – the earliest estimate is 2016. A DIVA test would be required to differentiate between vaccinal and disease strains of TB if TB vaccination of cattle was used, but this would be subject to approval by the EU. The Group believes that cattle vaccination is likely to play a significant role in the longer-term but appreciates that currently vaccination of cattle against TB is prohibited and that its legal use will depend on negotiations at EU level. Defra

are currently assessing the process and likelihood of being able to address and remove these barriers.

- **R19: We recommend bovine TB vaccine development continue for both cattle and badgers.**

- **R20: We support the use of a cattle TB vaccine and recommend Government vigorously progress negotiations with the Commission on amending EU Council Directives 64/432 and 78/52 to allow the vaccination of cattle against TB, which is currently prohibited.**

- **R21: Government, industry and wildlife groups must work together to ensure effective deployment of licensed badger vaccines as they become available. We therefore urge all involved to engage positively with Defra in the development and delivery of the Injectable Badger Vaccine Deployment Project.**

1.7 Other Domestic Species

During the time we have been looking at control measures for cattle it has become evident that other domestic species e.g. new world camelids (alpacas and llamas) and pigs and goats, kept for pleasure or business, are becoming infected with bovine TB. We make particular mention of camelids around which there appears to be a paucity of legislation to individually identify animals, control their movements, undertake TB testing and deal with subsequent reactors. It is evident that the manner of testing for TB in camelids needs to be considered further; the skin test currently offers the best prospect of achieving a reasonable sensitivity whilst minimizing the rate of false positives, but is not validated for use in these species and is particularly difficult to undertake efficiently.

- **R22: We welcome the current review of TB controls for non-bovine species, and recommend a more effective test be developed and validated for use in camelids.**

1.8 Husbandry and Biosecurity

<u>On-Farm Biosecurity:</u>
Much has been made of the necessity for good biosecurity. The Group produced a report of its views and comments on the Husbandry Working Group's advice on husbandry best practice. The report was sent to the Husbandry Working Group and published on 22nd March 2007, and included views on promoting and disseminating the information. This valuable work should now be reconsidered in terms of cost to farmers adopting the various recommendations. The tailoring of biosecurity advice to particular TB outbreaks and farms is vital and the mechanism for doing so needs to be reviewed. The Welsh biosecurity work (Evaluation of the South West Wales Biosecurity Intensive Treatment Area -

Final Report) should be taken into account in any review and the practical benefits and costs of the techniques adopted in their intensive treatment areas analysed. The word *'biosecurity*' is seen as somewhat obscure and open to misinterpretation, and both veterinary surgeons and livestock farmers have found the discussion around some of the issues difficult. The Group advocate the use of the phrase 'disease risk reduction measures' as this conveys more clearly the aim of the particular change in behaviour required by the livestock keeper. We would stress the importance of ensuring that feed stores, cattle housing and feeding areas are made out of bounds to wildlife, especially badgers, as far as practicable.

It is good practice to have an isolation unit, for many reasons apart from TB control, and farms should endeavour to keep different risk groups apart from each other and the main herd e.g. through the isolation of newly moved-on stock. It is a statutory requirement to isolate reactors and inconclusive reactors from the rest of the herd. The increasing uptake of farm health planning is to be encouraged. This process details and consolidates the risk reduction measures specific to an individual farm/herd and farming system and provides an additional opportunity to ensure that TB specific measures are included in overall biosecurity.

- **R23: The Group endorse the advice produced by the Bovine TB Husbandry Working Group and encourage the adoption of measures to reduce risk. Each farm should have a tailored herd health plan.**

- **R24: Effective isolation units should be provided on every livestock holding.**

1.9 Implementation of Current Controls

Testing Process:
The testing process has in recent years been subject to review by Animal Health. The tightening of the audit process and the increased quality control is to be welcomed. The veterinary profession and livestock owners have stressed the dangers in undertaking TB testing of cattle and the requirement for proper handling facilities if testing is to be carried out safely is clear. The risk of injury is not only to the veterinary surgeon, farmer or farm staff, but also to the animals being tested. Ensuring operator safety will encourage improved efficiency both in the manner in which the test is carried out but also in terms of cost efficiency.

- **R25: We emphasise the need for cattle keepers to provide adequate handling facilities to ensure safe and effective TB testing.**

Reactor Removal:
The time delay between concluding the skin test at which a reactor animal is identified and its subsequent removal from the herd remains variable. Animal

Health has a target of 20 working days (from identification of positive animals) for removal of reactors. On average reactors in England are estimated to be removed within 16 working days but there are examples of it taking significantly longer. Any delay in reactor removal presents a risk of disease spread and sends a negative message to livestock owners - that of a lack of urgency. It is essential that reactors are immediately and effectively isolated on farm, and removed and taken for slaughter as quickly as possible. We appreciate that there are both practical issues and welfare considerations when isolating animals but where livestock owners are having such difficulties they should be encouraged to discuss their problems with Animal Health, thereby helping the prioritisation process and subsequent removal of reactor animals. We are very concerned that with the steady growth in numbers the facilities to deal with such reactor animals both in terms of the audit trail and available abattoir space is under considerable pressure. It is essential that all parties involved - livestock owner, veterinary surgeon and Animal Health - work together to facilitate rapid removal of reactors from farms.

- **R26: It is essential that reactors are immediately and effectively isolated on farm and thereafter removed as rapidly as possible. Animal Health must be adequately resourced to meet this requirement.**

Tracings:
The speed at which tracings are carried out by Animal Health once a breakdown occurs was raised by farming and veterinary stakeholders. Animal Health have a target of 9 weeks to complete tracing action from the date of confirmation of a breakdown, for 80% of 'at risk' animals/ herds, giving priority to movements from high to low risk areas. Industry cited the cattle tracing system in the Republic of Ireland as being more effective and questioned whether a similar system could be developed for GB. In the absence of equivalent IT systems we sought views on speeding up tracings to reduce the risk of disease spread and provided advice to Animal Health to help improve communications to farmers with regard to the urgency of tracings.

The Group noted the difficulties that Animal Health had with their IT systems and the considerable limitations this placed on their ability to quickly and efficiently trace animals. The investment in new IT systems, under the Business Reform Programme, is to be welcomed but funding must be maintained so that new fit-for-purpose databases can be put in place. These new systems will also benefit customer information and contacts.

- **R27: It is a matter of urgency to speed up tracings where new breakdowns occur and so prevent further spread of disease.**

- **R28: There must be continued sufficient funding for the Animal Health Agency to upgrade and maintain fit-for-purpose IT systems.**

Field Epidemiology:
The investment in science relating to bovine TB is significant but we would express concern that the considerable extent of knowledge held by Animal Health Veterinary Officers (VOs) in the field is not being fully exploited and recorded. It may be possible to gather more information from breakdowns e.g. farm type, movement pattern, animal type, age and breed, to inform the testing programme and help target resources more effectively. The data captured by VOs in Animal Health Divisional Offices should be analysed for significant epidemiological patterns and where appropriate redirect activities to ensure useful data is collected.

- **R29: We recommend information held at Animal Health Offices be gathered and analysed for the purposes of informing central disease strategy planning and that Animal Health epidemiology expertise be developed to help with this process.**

TB Statistics:
A review of the statistical data collected for TB control is required. In June 2007, the ISG's Final Report recommended that Defra revise the current presentation of the national statistics so as to give an accurate indication of trends in TB incidence that are independent of changes in testing regime and publish the results in a way that allows regional comparisons. In addition, Defra currently publishes two sets of monthly TB statistics - these data need to be consolidated – and changes implemented to ensure that the data presented meet the current strategic planning requirements.

This work is closely linked to the ongoing developments of IT systems used by Animal Health and a coordinated approach is required. Defra are currently carrying out a TB statistics review and we await the results.

- **R30: We welcome the Defra review of TB statistical data and recommend that the information gathered is more effectively used to inform the TB testing programme in terms of surveillance and control.**

Coordination:
Coordination and collaboration between private veterinary practitioners, responsible for regular disease control on their client's farms (and who act as the local veterinary inspector carrying out TB tests in the majority of cases) and those responsible within Animal Health for following up on reported positive TB reactor tests, is crucial for the effective control of bovine TB. This will ensure each breakdown is tackled in the round with all relevant information shared.

The need to stamp out the disease when it appears in new areas of the country must be prioritised. The establishment of local TB control groups consisting of

farmers, veterinary practitioners, auctioneers and Animal Health representatives might well aid the speedy control of the disease and lead to a greater ownership of the disease problem.

Industry felt there was a lack of consistency across Animal Health offices in how breakdowns are dealt with, leading to confusion as to what exactly the rules are, and a concern that the variability in procedures in different regions was compounding the issue. One example cited was the determination of the fate of in-contact animals. This is affecting confidence in control measures and needs to be addressed.

- **R31: We recommend Animal Health involves the private vet - as part of the LVI duty - and the Animal Health VO responsible for an individual outbreak in meetings with the livestock keeper to design a disease risk reduction plan.**

- **R32: We recommend the establishment of local TB groups by the Animal Health Divisional Offices.**

- **R33: There needs to be consistency of approach across Animal Health in how it deals with TB breakdowns whilst respecting existing discretionary measures in terms of individual breakdowns.**

1.10 Communications

Throughout our discussions it has appeared that there are many misunderstandings about bovine TB. The fact that the skin test (and gamma interferon test) is a test for infection, not necessarily disease, has been a constant source of confusion. It seems the basic but crucial facts about bovine TB are not always reaching those affected by and dealing with the disease on the front line. The Group considered the most productive and efficient route to inform livestock keepers was by working with local veterinary practices. Whilst this would improve future communications there is a need to address current shortfalls in knowledge and general misunderstandings, and some changes in terminology could be beneficial. For example, it would be advisable to clarify in clear but consistent language that animals showing a positive reaction to the skin test are by international scientific agreement, considered to be infected. To this end the Group have worked with Defra policy and veterinary advisors to develop a document aimed at breaking the myths and misconceptions around bovine TB. The full document is published on the Defra website (also attached at Annex D). We hope this will be regularly updated as scientific understanding widens and to actively address any new myths and misunderstandings that may emerge.

- **R34: We recommend that ‘Bovine TB – The Facts’ be promoted to all stakeholders.**

1.11 Farmer Support

The Group noted the comments made to it concerning the social stress of the disease on livestock owners and the considerable amount of self-help farming communities have put in place. Whilst this is primarily a disease of animals the impact of the psychological stress that it places on farmers, their families, farm staff and indeed all who work with the affected animals should not be underestimated.

Extended or repeated breakdowns can cripple a business and there is a critical need for some form of financial support or business management advice to help bridge the gap until a herd has tested clear and animals can be traded. In these circumstances it is likely that insurance will either not be available or will be available only at considerable and often prohibitive cost, to cover consequential losses.

- **R35: We recommend an exploration of social support measures for farmers affected by TB breakdowns.**

- **R36: We recommend the Government explore the possibilities of helping farmers maintain viable businesses e.g. in terms of financial advice or direct financial support, in the face of a herd breakdown.**

2. BACKGROUND

2.1 TB Advisory Group

The Chairman, supported by a small number of members was appointed in July 2006 to advise Ministers and the Chief Veterinary Officer and play a leading role in Defra's engagement with interested organisations. Together they advise on the development of practical TB surveillance and control policies in England, working with interested organisations to secure their input whilst recognising the regional nature of the disease.

The TB Advisory Group have had wide ranging responsibilities as illustrated by the terms of reference (Annex A). In pursuing its objectives, the TB Advisory Group was encouraged to be creative and innovative in how it works and to maintain an overview rather than become process orientated. In essence, the TB Advisory Group's primary responsibility was to help deliver the aims of the Government strategic framework for the sustainable control of bovine TB in Great Britain by:

- advising on development and implementation of bovine TB control policies in England providing in particular a practical perspective;

- working with interested organisations to take account of wider views in developing your advice and also to help promote a shared understanding.

The TB Advisory Group have played a key role in tackling bovine TB by helping to obtain stakeholder buy-in to TB control policies, constructively challenging Government, and thereby working with Defra to develop more effective control measures. The TB Advisory Group have been asked to consider specific issues raised by Ministers and the CVO, but were also independently considered other issues it believed are of concern to the wider stakeholder community.

As well as building relationships with stakeholders, the TB Advisory Group has worked closely with the England Implementation Group (EIG) who oversee the implementation of the Animal Health and Welfare Strategy, as well as building links with Scotland and Wales to ensure a joined up approach.

More information, and the TB Advisory Group's previous advice to the department on husbandry best practice advice to farmers and pre-movement testing, can be found through the links below:

- Group advice to Defra Ministers and the CVO
- Meeting summaries and engagements

2.2 Membership

The former Chief Veterinary Officer for England, Debby Reynolds, appointed the members in October 2006. Brian Jennings (beef farmer from Devon), Bill Madders (dairy farmer from Stafford), James Kirkwood (animal welfare) and Andrew Cunningham (conservation, Institute of Zoology) all provide a balance across farming, veterinary, welfare and conservation expertise They all have good contacts and links within their respective industries which helped in their role working with stakeholders. Full roles and responsibilities can be found at Annex B.

2.3 Stakeholder Engagement

Since the Group was established they held a series of fact-finding meetings with interested stakeholders. These have been useful and constructive meetings, where members heard a broad range of views on controlling bovine TB in England and discussed the ISG's final report and its recommendations. The Group has met Professor John Bourne, representatives of Animal Health, representatives of the Husbandry Working Group and the Badger Trust with the RSCPA, representatives of the farming industry and veterinary profession. All stakeholders recognise the need to look closely at cattle controls and at ways of improving husbandry practices; the question of wildlife infection management remains difficult, but all recognise the need for a clear way forward.

The Group visited Ireland to hear more about their strategy for controlling bovine TB and attended the second Annual TB Conference for GB in 2007. Most recently, the Chairman presented at the BCVA Congress held in Ireland in November 2008. Links have been built with the England Implementation group (EIG), the former Wales TB Action Group and more recently the Science Advisory Body (established in January 2008) ensuring members are aware of the issues and wider views in taking forward bovine TB research.

ANNEX A

TERMS OF REFERENCE

1. The TB Advisory Group will play a key role in tackling bovine TB by helping to obtain stakeholder buy-in to TB control policies, constructively challenging Government, and thereby advising Defra on how to develop more effective control measures. The TB Advisory Group will be asked to consider specific issues raised by Ministers and the CVO, but would also be expected to independently consider other issues it believes are of concern to the wider stakeholder community.

2. The TB Advisory Group has been established to help deliver the aims of the *Government strategic framework for the sustainable control of bovine TB in Great Britain by:*

- *advising on development and implementation of bovine TB control policies in England providing in particular a practical perspective;*
- *working with interested organisations to take account of wider views in developing your advice and also to help promote a shared understanding ;*
- *responding to requests for advice from Ministers and the CVO, and identifying and advising on issues of concern to interested organisations.*

3. The Chair and members of the TB Advisory Group will serve in a personal capacity and will not represent any organisation with which they may be associated.

4. The TB Advisory Group will need to build links with a wide range of organisations, including the England Implementation Group and the Welsh TB Action Group.

5. The TB Advisory Group will need to take into account the remits of existing advisory and specialist groups established to advise Government on associated issues (such as the Independent Scientific Group (ISG) on Cattle TB, the Cattle Compensation Advisory Group and the bTB Husbandry Group) so as to avoid overlap and duplication of effort.

Chair

The Chair has particular responsibility for providing effective leadership on the issues above. In addition, the Chair is responsible for:

- ensuring that the TB Advisory Group meets at appropriate intervals, and that the minutes of meetings and any reports to the Minister accurately record the decisions taken and, where appropriate, the views of individual members;
- representing the views of the members to the general public; and
- ensuring that new members are briefed on appointment (and their training needs considered), and providing an assessment of their performance, on request, when members are considered for re-appointment to the TB Advisory Group or for appointment to some other public body.

Members

Members have collective responsibility for the operation of this body. They must:

- engage fully in collective consideration of the issues, taking account of the full range of relevant factors, including any guidance issued by Defra or its Ministers;
- ensure that the Freedom of Information Act and Environmental Impact Regulations are adhered to; agree an Annual Report; and make the proceedings of meetings available to the public;
- respond appropriately to complaints, if necessary with reference to Defra;
- ensure that the TB Advisory Group does not exceed its powers or functions; and
- respect the TB Advisory Group convention of working through collective agreement.

Communications between members and the Minister will generally be through the Chair except where the TB Advisory Group has agreed that an individual member should act on its behalf.

ANNEX B

ROLES AND RESPONSIBILITIES

The Chair has been appointed by Ministers for 3 years and is responsible for setting the vision for the Group. He will guide members in developing advice and recommendations on bTB, and present this to Ministers and the CVO. The Chair, who will also be responsible for managing the performance of the Group and its members, will act in a personal capacity, not as a representative for any other organisation of which he may be a member.

The Chair has particular responsibility for providing effective leadership and is also responsible for:

- ensuring that the Group does not exceed its powers or functions;
- ensuring that the Group meets at appropriate intervals, and that the minutes of meetings and any reports to Ministers and the CVO accurately record the views of the Group and where appropriate, the views of individual group members if they dissent from the consensus view;
- representing the views of the Group to the general public;
- ensuring that new Group members are briefed on appointment, to provide an assessment of their performance, on request, when members are considered for re-appointment to the Group.

All Members share collective responsibility for the operation of the Group and should:

- engage fully in collective consideration of the issues, taking account of the full range of relevant factors, including any guidance issued by the sponsor department or the responsible ministers;
- ensure that the Freedom of Information Act (including prompt responses to public requests for information) is adhered to;
- agree an annual report and respond appropriately to complaints, if necessary with reference to the sponsor departments;
- ensure that the Group does not exceed its powers or functions.

As with the Chair, members will act in a personal capacity, not as a representative for any other organisation of which they may be a member.

ANNEX C

SUMMARY OF RECOMMENDATIONS

- **R1**: The mixing of cattle from different sites under the aegis of an SOA does not sit well with risk related disease control. Whilst we welcome the pre-movement testing review we recommend that all new SOAs be licensed subject to a TB risk evaluation. SOAs should only be licensed for holdings of similar testing status e.g. 1 and 2 year or 3 and 4 yearly testing intervals.

- **R2**: We recommend the criteria governing AFUs/EFUs should be reviewed and if possible a simplified amalgamated model developed which is practical and meets the necessary biosecurity standards.

- **R3**: Government should work with industry to promote uptake of AFUs/EFUs.

- **R4**: We recommend that the mixing of TB tested animals from parishes with different testing intervals at agricultural shows, and the exemption from pre-movement testing of such animals, be reviewed in terms of minimising disease risk.

- **R5**: Further consideration needs to be given to Risk-Based Trading. We would favour an approach aimed at establishing categories based on testing interval and taking into account whether cattle are moving onto premises where there are breeding cattle.

- **R6**: Control and eradication of bovine TB will take years (at least 20 years). We therefore recommend Government use an extended timeframe when assessing the projected costs and benefits of controls.

- **R7**: The TB testing regime needs to be conducted in a geographically and temporally coordinated way (aiming to cover all farms in a region within the same time period) both for surveillance and particularly when dealing with endemic and new area outbreaks.

- **R8**: We have received conflicting views about the value of increased frequency of TB testing. This, and its application in a risk-based manner, need further investigation with particular reference to breeding animals.

- **R9**: We recommend consideration should be given to tackling TB breakdowns in an epidemiologically relevant manner in a true partnership approach e.g. livestock owner, local vets and Animal Health.

- **R10**: We recommend the review of pre-movement testing be progressed as a matter of urgency.

- **R11**: Pre-movement testing records should travel with the animal and always be available to inform decisions about subsequent testing as well as animal and herd health biosecurity considerations on the receiving farm.

- **R12**: We recommend post-movement testing of animals brought on to holdings with breeding herds in three and four yearly testing parishes from one and two yearly testing parishes, with its use strongly encouraged for all other movements.

- **R13**: We recommend Defra amend its current policy to fully comply with Council Directive 64/432/EEC (as amended) which states that all standard inconclusive reactors to the skin test must be slaughtered as reactors on failing their first re-test.

- **R14**: We recommend Government explore wider use of the gamma interferon test e.g. pre and post-movement testing. This will require amendments to Council Directive 64/432 and we encourage negotiations at EU level.

- **R15**: We recommend continued investment in the development of the gamma interferon test to increase its specificity.

- **R16**: We recommend continued investment in the development of PCR for the detection of viable *M. bovis* organisms as an aid to targeting biosecurity measures where a wildlife source is implicated.

- **R17**: We recommend that criteria be developed to help determine the origin of an individual herd breakdown and that this information is shared with all responsible for tackling the breakdown.

- **R18**: Improved surveillance of bovine TB in other wildlife species (including deer and wild boar) is required. Wild deer are not considered a significant widespread risk to cattle at present but this should be monitored.

- **R19**: We recommend bovine TB vaccine development continue for both cattle and badgers.

- **R20**: We support the use of a cattle TB vaccine and recommend Government vigorously progress negotiations with the Commission on amending EU Council Directives 64/432 and 78/52 to allow the vaccination of cattle against TB, which is currently prohibited.

- **R21**: Government, industry and wildlife groups must work together to ensure effective deployment of licensed badger vaccines as they become available. We therefore urge all involved to engage positively with Defra in the development and delivery of the Injectable Badger Vaccine Deployment Project.

- **R22**: We welcome the current review of TB controls for non-bovine species, and recommend a more effective test be developed and validated for use in camelids.

- **R23**: The Group endorse the advice produced by the Bovine TB Husbandry Working Group and encourage the adoption of measures to reduce risk. Each farm should have a tailored herd health plan.

- **R24**: Effective isolation units should be provided on every livestock holding.

- **R25**: We emphasise the need for cattle keepers to provide adequate handling facilities to ensure safe and effective TB testing.

- **R26**: It is essential that reactors are immediately and effectively isolated on farm and thereafter removed as rapidly as possible. Animal Health must be adequately resourced to meet this requirement.

- **R27**: It is a matter of urgency to speed up tracings where new breakdowns occur and so prevent further spread of disease.

- **R28**: There must be continued sufficient funding for the Animal Health Agency to upgrade and maintain fit-for-purpose IT systems.

- **R29**: We recommend information held at Animal Health Offices be gathered and analysed for the purposes of informing central disease strategy planning and that Animal Health epidemiology expertise be developed to help with this process.

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- **R32**: We recommend the establishment of local TB groups by the Animal Health Divisional Offices.

- **R33**: There needs to be consistency of approach across Animal Health in how it deals with TB breakdowns whilst respecting existing discretionary measures in terms of individual breakdowns.

- **R34**: We recommend that 'Bovine TB – The Facts' be promoted to all stakeholders.

- **R35**: We recommend an exploration of social support measures for farmers affected by TB breakdowns.

- **R36**: We recommend the Government explore the possibilities of helping farmers maintain viable businesses e.g. in terms of financial advice or direct financial support, in the face of a herd breakdown.

ANNEX D

BOVINE TB – THE FACTS

TB TESTING

Q1. Is it true skin test positive animals that show no signs of diseased tissue at post-mortem examination (*known as NVL or no visible lesions*) have never had the infection?	**Background**: The specificity of a test can be defined as the proportion of truly non-infected animals in a screened population that are correctly identified as non-infected (i.e. "negative") by the test. The large percentage of reactors in which no visible lesions are detected at post-mortem examination (approximately 60%) is often cited as evidence of poor specificity of the comparative tuberculin skin test. However, this is not the case. Admittedly, no screening and diagnostic test is perfect (i.e. 100% sensitive and 100% specific), but the comparative tuberculin skin test used in the UK and Ireland has a specificity in excess of 99.9%. This means that only 1 in every 1000 (or more) truly non-infected cattle that are correctly tested will be expected to be misclassified as reactors (i.e. false positives).These genuine false positive reactors may be caused by non-specific tuberculin responses to the environmental mycobacteria that cattle are sometimes exposed to. The ease with which the typical lesions of bovine TB can be detected and the causative bacterium isolated from tissues depend upon the thoroughness of post-mortem inspection and the stage of *Mycobacterium bovis (M. bovis)* infection, being harder early in infection when most cattle are detected by the skin test. It is important to remember that the skin (and gamma interferon blood) tests are designed to detect an immune response to TB *infection* rather than the signs of *disease*. Because immune responses in TB infected cattle usually develop before visible signs of disease are evident to the vet or meat inspector, the percentage of test reactors without visible tuberculous lesions or positive cultures are not valid indicators of the false positive fraction for this test.
A1. The false positive rate for the skin test is very low (1 in 1000, see also question 2) and so it is very likely that any animal that tests positive is infected, regardless of whether this is confirmed at post -mortem.	
Q2. Is it true the skin test	**Background:** No diagnostic test, including the tuberculin skin test, is 100% accurate, but the current

only picks up half of all infections? **A2**. No. The current skin test for bovine TB is an effective test. It is the accepted standard laid down in both national and international legislation for determining the existence of infection in a cattle herd. Studies have shown that the test is on average 80% sensitive at standard interpretation rising to 93.5% sensitive at severe interpretation.	skin test is effective (and is the primary diagnostic test required under EU legislation). On the one hand, the comparative skin test used in the UK and Ireland can be expected to vary around approximately 80% detection rate of all the infected cattle in a herd at any one test (at standard interpretation, range 52-100%). On the other hand, reactions to the tuberculin test can sometimes be caused by exposure to other mycobacteria which do not cause bovine TB. When the skin test is applied to cattle without TB in Great Britain, there is a 1 in 1,000 chance that a non-infected animal will be wrongly classified as a reactor. The sensitivity of a test can be defined as the proportion of truly infected animals in a screened population (e.g. a herd) that are correctly identified as infected (i.e. "positive") by that test. In the case of most tests, sensitivity and specificity (see also question 1) are inversely related. In other words, as sensitivity is increased, specificity will be reduced and vice-versa, A compromise between the two must therefore be selected. It is important to understand that neither sensitivity nor specificity are fixed and the compromise between the two is selected according to the job that we want the test to do and the population in which we want it to do it. An example of changing (enhancing) the sensitivity of a screening test is the application of the severe interpretation of the skin test in those circumstances where we are certain that *M. bovis* infection is present in the herd being tested. Several studies from various countries have reported estimates of sensitivity for the comparative and other variants of the tuberculin skin test. Test sensitivity (and specificity) is independent of the prevalence of infection in the population and is frequently assumed to be constant across different populations. In practice, however, it can be influenced by a host of other factors including the test procedure, cut-off point for a positive result, tuberculin potency, the stage of infection in the host, other inter-current infections and prevalence of cross-reacting organisms in the locality. It is thus very difficult to quote a single sensitivity estimate for the comparative skin test that would apply to all herds in GB at all times. Studies evaluating the sensitivity of the test suggest that its sensitivity lies between 52% and 100%, with median values of 80% and 93.5% for standard and severe interpretations, respectively. In those studies that used the same concentrations of bovine and avian tuberculin and interpreted the comparative skin test results as in the current bovine TB control programme in UK, the estimated sensitivity lay between 75% and 95.5% at standard interpretation. In other words, a thoroughly performed comparative skin test can be expected to miss about 5 to 25 in every 100 infected cattle on a single round of testing, although this will vary from herd to herd. Furthermore, when infection has

	been detected in at least one animal in a herd, further rounds of testing will take place at 60 day intervals (and possibly using a severe interpretation) until no further reactors are identified, all of which will improve the initial sensitivity of the test.
Q3. Should skin test positive animals be kept because they have mounted an immune response to the disease and are therefore protected? **A3.** Very definitely not. Such animals are infected and can infect others.	**Background:** There is no scientific evidence to support this view which runs counter to one of the basic principles of control of bovine TB (and other contagious infectious diseases of animals). Where effective vaccination or treatment are not available (as in the case of bovine TB), early detection and removal of infected individuals before they become infectious to others is essential. The pathogeneses of bovine and human TB infections are not directly comparable. Nevertheless, the experimental findings suggest that a significant proportion of cattle infected with *M. bovis* could enter a state comparable to the latency defined for the majority of people infected with *M. tuberculosis*. This would explain, at least partially, why a large proportion of the skin (and gamma interferon) test reactors from herds with culture-confirmed bovine TB, are culture-negative and have no gross visible lesions. Many of these animals are likely to be carrying infection that is not detectable by the culture methods employed and that has the potential to re-emerge at a later date, especially when animals are stressed e.g. by movement to a new herd, high production demands etc. Such cattle, even if not infectious at the time of slaughter, might be so at a later stage if left in the herd. They should therefore be considered as potential disease transmitters that pose a threat to the disease security of the herd. Additionally, experimental models of drug-attenuated primary *M. bovis* infection in cattle have shown that simulated latent infection confers only a limited degree of protective immunity against subsequent re-challenge. Hence the need for regular herd testing and speedy removal of all skin (and gamma interferon) test reactors.
Q4. Is it true the skin test is a good herd screening test but a poor individual animal test for bovine TB? **A4.** The skin test is best used as a herd test but has value in controlling the spread of disease when used	**Background:** Any diagnostic test (not just the skin test) that is applied to individual animals for disease screening will have a better chance of detecting infected groups of animals (herds) than individual infected animals, because one only needs to find a single infected animal to declare a whole herd as infected. Therefore, the sensitivity of a test at the herd level will always be at least as high as its sensitivity at the individual animal level. Herd-level sensitivity (the probability that an infected herd is detected by a screening test) is a function of within-herd prevalence, the number of animals tested in the herd, the animal-level sensitivity of the test level and the minimum number of individual-animal positive test results required to designate a herd as infected (one, in the case of TB). Herd-level sensitivity will rapidly increase to its maximum level (100%) as the proportion of

as an individual animal test.	tested animals in the herd increases. This relationship holds true even if the within-herd disease prevalence is low to moderate. You are always going to be more likely to detect a herd with a 5% prevalence of infection than a herd in which only 1% of animals are infected. And that is regardless of whether you use skin testing, gamma interferon blood testing, post-mortem examination or culture to screen the herd.
Q5. Does tuberculin from different sources give different results?	**Background:** A VLA report analysing tuberculins produced between 1 January 2005 and 31 March 2007 by VLA and Lelystad can be found on the Defra website at: www.defra.gov.uk/animalh/tb/pdf/tuberculin-report.pdf. In August 2006, a report by Defra's Chief Veterinary Officer which looked at the apparent reduction in TB statistics included an assessment of the performance characteristics of the two tuberculins. The report, *CVO Statement on the reduction in the number of new TB incidents in GB* is available at: www.defra.gov.uk/animalh/tb/pdf/cvo-tbstatement.pdf . Sources of tuberculin The antigens currently used for the skin and gamma interferon tests are the so-called PPD tuberculins extracted from *M. bovis* and *M. avium*. In 1975, PPD production switched from cultures of *M. tuberculosis* to cultures of the AN5 strain of *M. bovis,* which was circulating in cattle in England around 1948. Among the 30,000 plus strains of *M. bovis* from GB that have been typed since the 1970s, none isolated have been recovered bearing the AN5 spoligotype pattern. This raises the possibility that AN5 might not be optimal for the detection of cattle infected by the *M. bovis* strains currently prevalent in GB. However, analysis by VLA researchers of the genome of *M. bovis* AN5 has shown that this strain has not suffered extensive gene deletions or lost any major antigens in the course of its extensive in vitro cultures, unlike the BCG vaccine strain. As part of a Defra-funded project (SE3220), VLA researchers identified through gene expression analyses 31 genes that were expressed at lower levels in *M. bovis* AN5, some of which encoded antigens. However, they concluded that it was unlikely that reduced expression of any of those genes would have significant effects on the potency of AN5 tuberculin. In conclusion, there is no significant evidence to suggest that the AN5 strain itself, its growth methods, or PPD production processes have impacted in an adverse way on the sensitivity of bovine tuberculin. The latest findings from project SE3220 (Garcia Pelayo *et al*., 2009) indicate that the differences observed between AN5 and field strains are likely to have only a marginal effect on the diagnostic accuracy of bovine PPD and continue to support the use of the AN5 strain as the universal source of
A5. Analysis has been carried out of the relative performance of both the VLA and Lelystad tuberculins and we are confident that both products are effective and reliable. Both are produced and assayed to the same standard, as part of the European Union licensing procedures.	

	bovine PPD tuberculin.
Q6. If animals test positive to bovine TB using the gamma interferon blood test but show no visible lesions, are they disease free?	**Background:** Failure to detect lesions of tuberculosis by post-mortem examination at the slaughterhouse, or to culture *M. bovis* in the laboratory, does not imply that a test reactor was not infected with bovine TB. Indeed, in the early stages of this disease it is not always possible to observe lesions during abattoir post-mortem examination, and, due to the fastidious nature of this organism, it is very difficult to isolate it from tissue samples without visible lesions.
A6. A positive gamma interferon result indicates the presence of replicating *M. bovis* organisms. There is evidence that they are more likely to be in the early stages of infection. Therefore, failure to find post-mortem evidence of disease does not mean that the animal in question was free of the infection.	
Q7. Negative culture results from the lab must mean no infection is present?	**Background:** The success of culture mainly depends on the presence or absence of visible lesions in the samples submitted to the culture laboratory. Due to the fastidious nature of this organism, it is very difficult to isolate it from tissue samples without visible lesions. The culture-positivity rate of samples collected from so-called NVL animals (without visible lesions) is very low (circa 5-6 %), whereas it is relatively high in VL (with visible lesions) animals where it is typically around 95-96%. Therefore, in the first instance, culture success depends on the quality of the abattoir inspection to detect lesioned animals. Whilst it is difficult to obtain precise figures on this aspect, particularly for GB, published data from Australia suggested that 'in a sample of cattle that were reactors to the tuberculin skin test, abattoir inspection failed to detect an estimated 47% of cattle with lesions' (Corner *et al.,* 1991). Whilst likely that the percentage of animals missed by meat inspection in GB may be lower, particularly when examining reactor animals, it is nevertheless indisputable that a substantial number of lesioned animals will be missed (because lesions are in organ systems that are not regularly examined, very small lesions, single lesions etc).
A7. No. Detection of *M. bovis* by culture is affected by many factors including the sampling process, with visibly lesioned animals giving a greater chance of detecting infection. Animals at early stages of disease	

and latently infected animals do not present with visible lesions at post-mortem and will result in some animals escaping detection.	
Q8. Does the gamma interferon test give a large percentage of false positives? **A8**. No. The risk of the gamma interferon test identifying a false positive animal is 3 in 100, this risk is further reduced when the test is applied in a herd known to be TB infected. It is a common misconception that, as 82% of gamma interferon test positive animals do not show post-mortem evidence of TB in the slaughter house or laboratory, they were "false positives". A failure to find post-mortem evidence of disease does not mean that the animal in question was free of infection.	**Background:** Scientific research has shown that the average specificity (accurate identification of uninfected animals) of the gamma interferon test is 97% - which is only slightly lower than the 99% plus for the skin test. Performance evaluation carried out in a number of countries shows that at the laboratory cut-offs used in GB the gamma interferon test has a sensitivity comparable to or marginally better than the skin test – between 73 and 100%, with a median value of about 87%. Scientific research has also shown that the two tests (gamma interferon and skin test) identify different populations of infected cattle. The gamma interferon test can identify infected animals at an earlier stage in the infection as well as infected cattle that simply fail to react to the skin test. An animal that reacts positively to the gamma interferon test and negatively to the skin test will not, in the vast majority of cases, be a false positive.
COMPROMISING FACTORS FOR TB TESTING	
Q9. Do animals with fluke show a stronger reaction	**Background:** A review of the veterinary literature on this topic provides somewhat conflicting evidence. On one hand, the cattle TB pathogenesis study conducted in GB (Defra project SE3013)

to the skin test and result in false positive reactions? **A9**. There is no conclusive evidence to support this. On the other hand fluke, through compromising immunity might make animals more susceptible to infection and/or might make infected animals less likely to react to the skin test (infected animals may therefore be missed).	reported that skin test reactors and contacts with antibodies to liver fluke (*Fasciola hepatica)* were less likely to show with evidence of *M. bovis* infection at post-mortem examination. The effect was most significant in dairy reactors. This finding could be explained by some husbandry practices associated with exposure to liver fluke that are also associated with a factor that retards pathogenesis of bovine TB. It is also possible that liver fluke infestation modulates the inflammatory response, reducing the positive predictive value of the skin test in infected animals. Liver fluke antigens are potent stimulators of T-helper (Th2) responses and prior or concurrent exposure to liver fluke antigens may modulate the cell-mediated response to tuberculin which is the basis for the skin test. On the other hand, *F. hepatica* infestations result in polarization of the host's immune response and generation of Th2 cell-mediated immune responses, which are known to inhibit the Th1 responses detected by the skin and gamma interferon test. In Ireland, Flynn *et al.* (2007) established an experimental model of co-infection of *F. hepatica* and *M. bovis* BCG to examine the impact of liver fluke infestation on correct diagnosis of TB in cattle. They found that the sensitivity of skin and gamma interferon tests was compromised in co-infected animals and that *F. hepatica* infection altered macrophage function. Their results raise the question of whether *F. hepatica* infection can affect the predictive capacity of tests for the diagnosis of bovine TB and possibly also influence susceptibility to bovine TB and other bacterial diseases. In summary, this is a hypothesis that merits further investigation.
Q10. Does the use of flukicide reduce the reaction to the skin test? **A10**. There is no evidence to support this.	**Background**: There is no known biological or pharmacological reason in principle why flukicides *per se* should interfere with the skin test. Farmers are advised not to give their animals *any* drugs (not just flukicides and other wormers) in the course a tuberculin skin test (see also question 9).
Q11. Is TB testing compromised by the presence of Johne's disease? **A11**. Yes. Exposure to Johne's disease can cause cross reactivity when using	**Background**: Johne's disease, caused by infection with the bacterium *Mycobacterium avium* subspecies *paratuberculosis* (abbreviated 'MAP') is a chronic and insidious disease of cattle and other ruminants which is believed to be endemic in the UK and many other countries worldwide. It is well known that exposure of cattle and other animals (including man) to MAP and environmental mycobacteria can cause cross reactivity to components of the bovine PPD tuberculin used in the skin and gamma interferon tests for bovine TB. In particular, this reduces the specificity of the single tuberculin skin test (in the neck or the caudal fold) in TB-free herds infected with (or vaccinated against) MAP.

the skin and gamma interferon tests for bovine TB.	In the UK and Ireland, however, responses to the test reagent avian-PPD are used alongside the bovine PPD tuberculin in the routine screening test for bovine TB to provide a comparative measure of cattle exposed to non-pathogenic environmental mycobacteria. Hence the higher specificity of the comparative skin test over the single test. The same principle applies to the Bovigam test, where optical density levels of gamma interferon released by white blood cells stimulated with avian tuberculin are subtracted from those measured in blood stimulated with bovine tuberculin. We have no direct data on the effect of (MAP) infection on the sensitivity of the comparative skin and gamma interferon tests for bovine TB in GB. Experimental studies in calves pre-sensitised with *M. avium* subspecies *avium* (a bacterium closely related to MAP) have shown that raised responses to avian tuberculin in the comparative skin and gamma interferon tests may mask the detection of *M. bovis* infection, even when the specific antigens (ESAT-6 and CFP-10) are employed (Howard et al. 2002, Hope et al. 2005). In Spain, Aranaz et al. (2006) studied a herd with both MAP and bovine TB infection that was followed up for 3.5 years. The comparative tuberculin skin test, gamma interferon assay and a serological test for MAP were used in parallel. Overall, the skin test detected 65.2% of all animals in the herd that were culture-positive for bovine TB and the gamma interferon test detected 69.6% of them**.** These percentages are in the lower part of the accepted normal range. Both the skin test and the gamma interferon test were able to detect bovine TB-infected animals in the first part of the trial, but the blood test was the only test able to detect such animals in the last three tests.
Q12. What is the TB implication of BVD infection in herds? **A12**. It is likely that any infective agent that suppresses an animal's immune response mechanism such as occurs in cattle when infected with BVD virus, will increase the likelihood of establishment and progression of any	**Background**: Bovine viral diarrhoea (BVD) is most common in young cattle (6-24 months old). Serologic surveys indicate that BVD virus is distributed worldwide and the virus is regarded as endemic in most parts of the world. A small experiment with five neonatal calves artificially infected with BVD virus and *M. bovis* BCG was carried out by Charleston *et al*. (2001). The results showed that infection of cattle with this virus could transiently reduce gamma interferon responses to *M. bovis* in the two weeks after BVD virus inoculation and resulted in a failure to identify tuberculous cattle. There is therefore some experimental proof of the principle that BVD virus infection could suppress the host's immune response against *M. bovis*, but it is far from clear that this is a significant issue in normal field conditions. BVD virus infection appears to be widespread in Australia, yet they have successfully eradicated bovine TB in their cattle.

additional disease such as TB. For instance, concurrent TB infection is frequently seen in people infected with human HIV (AIDS) infection, but there has been limited work to demonstrate a similar risk for cattle with BVD.	
Q13. If the skin test for bovine TB can be compromised by other mycobacteria (e.g. avium, microti), is the gamma interferon test compromised in the same way?	**Background:** *M. avium* is widespread in the environment and voles are the natural host of *M microti* . The use of comparative antigens increases the likelihood of a positive reaction being true (increased specificity). The gamma interferon test, like the skin test used in the UK and Ireland, is a comparative test and the risk of false positive reactors is reduced by the use, alongside bovine PPD, of avian PPD tuberculin which provides a measure of sensitisation by environmental mycobacteria (see also question 11).
A13. Yes. In cattle, false positive reactions to the gamma interferon test can sometimes be caused by exposure to mycobacteria other than *M. bovis*. However, this is minimised by a comparison of the reaction to avian and bovine PPDs (tuberculin) to try to discriminate between reactions due to environmental mycobacteria and *M. bovis*.	

TB IN CATTLE	
Q14. Is there is a large amount of undetected infection in cattle herds?	
A14. There is undoubtedly some undetected infection - no test is 100% accurate and not all animals are tested. Despite this, test and slaughter regimes based on the skin test have been successfully used in other countries to control bovine TB where there is no wildlife reservoir.	
Q15. Is it true a large proportion of cattle are never tested?	**Background:** Using CTS (Cattle Tracing System) data, a descriptive analysis of TB testing coverage in the cohort of the British cattle population that died in 2004 found that 71 to 85% of the cattle included in the analysis appeared not to have been TB tested in their lifetimes (Mitchell *et al*., Proceedings of the SVEPM annual conference 2006). However, this study included cattle that had lived through the FMD outbreak of 2001, when the TB testing programme was severely disrupted. The proportion was lower (65%) when the same analysis was re-run in 2007 on a more recent sample (~100,000 cattle that had died in 2006). Recent policy changes (such as pre-movement testing and zero tolerance of overdue TB tests) reduce the opportunities for high TB risk animals to go untested during their lifetimes. In addition to screening of cattle on farms by skin testing, supplementary passive TB surveillance by the Meat Hygiene Service takes place during the commercial slaughter of cattle. A substantial proportion of the national herd may never be screened for TB before slaughter. Many of these animals are fattening cattle in 3 and 4 yearly testing herds which, by definition, will not be tested (they are unlikely to live long enough) and are unlikely to represent a significant TB
A15. At present, 20% of parishes and 32% of herds in GB are tested every year (the proportion is higher in England and Wales). The frequency of TB herd tests (1-4 years) is determined by EU legislation, depending on the incidence of infected herds in a particular area. Herd testing frequencies are reviewed nationally on an	

annual basis and the proportion of herds and parishes annually tested has been increasing over the past few years.	transmission risk.
Q16. Do cattle become infectious only in the late stages of TB - once they have developed "open" lesions? **A16**. The evidence is that animals may become infectious – can pass on infection - very soon after they have themselves been infected (perhaps in days). This may be followed by periods when animals are less infectious with intermittent excretion of tubercle bacilli. These animals can eventually progress to clinical cases. Infected animals should be regarded as a risk to others.	**Background:** The concept of an "open" lung lesion is predominantly a term from human clinical practice, representing the situation where viable TB bacilli are demonstrated in respiratory secretions (i.e. sputum) during life. All cattle identified as TB reactors can pose an infection risk to other animals, regardless of whether or not lesions are found at post-mortem examination (PME). There is no way of knowing at PME of cattle whether lesions observed in any location were resulting in continuous or occasional shedding of bacteria in excretions or secretions while the animal was alive. Experimental data on pathogenesis of bovine TB indicate that shedding of *M. bovis* can occur at any stage of the infection process, but that there are phases of more frequent shedding during the early stages of infection, which are likely to be associated with an increased risk of transmission. The majority of TB lesions in cattle are located in the lymph nodes of the chest and head, with or without demonstrable lung tissue involvement. It is important to stress that the data collected at a cursory PME of reactors is not ideal to assess the status of a bovine animal as an *M. bovis* excretor. Any reactor with demonstrable signs of *M. bovis* infection is potentially infectious to other animals and any reactor, with or without TB lesions, is potentially infected, and may become infectious in due course. Whilst it is probably correct to say that all cattle with visible lesions in the lung parenchyma (with similar pathology perhaps to the so-called human "open cases") are a continuous or intermittent risk to other cattle and wildlife, it is not correct to imply that cattle without such lesions pose no such risk. The conditions under which an infected bovine becomes an effective disseminator of *M. bovis* are not well defined, although there is likely a gradation in the risk of excretion according to the distribution and severity of pathology. The possibility that nasal transmission of infection occurs during the early stages of infection cannot be excluded and it has been suggested that all cattle infected with *M. bovis* have the potential to shed bacilli at some stage during the infection (Neill *et al*., 1992). This has been shown to occur sporadically shortly after experimental infection at 20-30 and 80-90 days post inoculation (McCorry *et al*., 2005), but not yet in naturally infected field reactors (since the time of infection of these natural cases cannot be determined precisely).

Q17. Isn't it pointless to test calves for TB as this is a disease of adult cattle? **A17**. Cattle of all ages are susceptible to infection. TB has been successfully diagnosed by skin testing in animals less than 4 weeks of age. Young calves are also at risk through milk borne infection.	**Background:** Cattle of any age, including newborn calves, can succumb to *M. bovis* infection by the respiratory (airborne) or oral (milkborne) route. Congenital infection of unborn calves *in utero*, although possible, is considered extremely rare in GB and other countries with long-established test and slaughter regimes. Therefore, there is no reason, in principle, why young calves could not be tested for TB and, if infected, identified as test reactors, as it happens on occasions. However, there are two main reasons why calves under 42 days are excluded from the majority of TB tests: 1. First, it is unlikely for such young animals to be infected with *M. bovis*. In GB, the rate of skin test reactors increases steadily with age of the animal until it stabilises at about 24-30 months of age. Age in itself does not affect the susceptibility to infection but opportunities for exposure to the bacterium accumulate with time and, once infected, cattle are believed to remain sensitised to bovine tuberculin for the rest of their lives. Therefore, there is an age-dependent risk of contracting the infection (and thus becoming a test reactor). 2. Second, even if infected, not every calf undergoing skin testing in the first 42 days of life will be detected because it takes some time (usually a period of 3-6 weeks) to mount a detectable immune response to the skin test. So, whether or not an infected calf under 42 days of age is detected by the skin test will largely depend on how soon after birth it became infected and any individual variations in the ability to mount a delayed- type hypersensitivity response to tuberculin. Therefore, it is generally considered ineffective to TB test young calves, and this thinking is reflected in the rules for pre-movement and pre-export TB testing of cattle. However, in GB we have traditionally tested young calves in specific high risk situations, such as check tests of herds contiguous to a confirmed TB breakdown, or following disclosure of tuberculous cattle at routine meat inspection, or at short-interval tests of reactor herds.
Q18. Why are the genotypes (strains) of *M. bovis* geographically clustered in GB if the movement of cattle is the major cause of spread of disease?	**Background:** The most common *M. bovis* genotypes in GB show a highly aggregated distribution that is stable over time. This observation provides very strong empirical evidence that, in the high TB incidence areas of the country, wildlife reservoirs of this bacterium are involved in the persistence of infection in the more mobile cattle host. Non-random distribution of cattle movements could also, in very unusual circumstances, generate geographical localisation of genotypes. However, preliminary research indicates that cattle movement patterns are not compatible with single-genotype localised TB "hotspots". Thus the epidemic of bovine tuberculosis in GB may be seen as a series of local

Why not an even distribution of all spoligotypes or at the very least a spread in keeping with the major movements of cattle?	epidemics caused by different strains emerging in different areas of the country. Further modelling work is proceeding on this particular subject. Of course, each genotype of *M. bovis* is, on occasions, isolated outside its traditional core area ("home range") and many of the new TB breakdowns occurring in regions of traditionally low TB incidence can be traced back to movements of cattle from herds in the relevant core area, as was indeed the case during the restocking of herds in the North of England following the FMD outbreak of 2001. However, there is little evidence that cattle breakdowns detected outside the endemic TB areas are generating new "hotspots" of disease.
A18. Because most cattle movements are local. Only the main strains are quoted in figures and maps but clustering is shown and there is also some mixing which implies cattle movements are not the major cause of spread in endemic areas but are in low incidence areas.	
TRANSMISSION	
Q19. Does cattle to cattle contact only account for 1 - 2% of all TB cases?	**Background**: It is often very difficult to conclusively determine the precise cause of a TB breakdown in a cattle herd. However, in low bovine TB incidence areas, there is evidence that cattle to cattle transmission could be responsible for around 80% or more of cases. However, the situation is quite different in the high incidence areas of the country where 85% - 90% of all confirmed breakdowns occur. Some herds in these areas are also infected by purchased cattle (several studies have shown around 7% - 16%: Green *et al.,* 2008 and ISG), but wildlife is a major source of new herd infection and in many counties wildlife may be a more important source than cattle. It is impossible to put precise figures on these possible sources.
A19. No. The extent of cattle to cattle transmission varies depending on area and level of infection. There is no evidence to support this theory.	
Q20. Can cattle become infected by badgers and	**Background:** Transmission as a result of direct contact has received relatively little attention in the scientific literature because field observations suggest that badgers avoid grazing cattle. However

their infected excreta only when out at pasture? **A20.** No. There is an increasing body of evidence to suggest that badger visits to farmyards and buildings may pose a comparable disease transmission risk to that posed by contamination of grazing land.	there is an increasing body of evidence (Garnett *et al.,* 2002 (a &b); Daniels *et al* 2003; Roper *at al* 2003; CSL 2006) to suggest that badgers regularly forage in farm buildings such as feed stores and cattle sheds, where they consume and contaminate feed and may come into direct contact with cattle. A Defra funded study (project SE3029) aimed to investigate the extent of badger visits to farm buildings in TB hotspots in southwest England and to identify the reasons why these occur. The final report can be seen at www.defra.gov.uk/animalh/tb/research/projects.htm. Further work has been commissioned (Defra project SE3119) to assess the cost-effectiveness of farm husbandry manipulations to reduce risks associated with farmyard contact between badgers and cattle. This work will complete in 2009 and report in early 2010.
Q21. Do cattle regularly give TB to badgers? **A21.** With the routine testing of cattle and reactor removal the transmission of TB from cattle to badgers is a low risk, as cattle are unlikely to be shedding large amounts of TB organisms into the environment. This is only likely in uncontrolled cattle TB situations e.g. during FMD and pre-1930s when a dedicated testing and slaughter regime was not being carried out. The ISG reported an increase in prevalence in both cattle and badgers following the 2001 FMD epidemic.	**Background:** TB is endemic in the badger population and there is much evidence that it is self-sustaining in the absence of cattle TB. Evidence from the Defra Road Traffic Accident surveys in the 1980s show there are pockets of infection in badgers that at that time were not being transmitted and identified in co-located cattle. Studies of bovine TB in badgers at Woodchester Park have shown TB is maintained long-term in a stable badger population without cattle contact i.e. they are a natural self maintaining reservoir (Project SE3032: The long-term intensive ecological and epidemiological investigation of badger populations naturally infected with *Mycobacterium bovis* – Final Report; and SE3035: estimating badger density in RBCT proactive control areas). ISG findings (Woodroffe *et al.,* 2006) demonstrate indirectly that cattle may have transmitted TB to badgers. A suspension of TB controls in cattle during the epidemic of Foot and Mouth Disease, which substantially delayed the removal of TB infected cattle, was associated with a widespread increase in the prevalence of bovine TB in badgers in RBCT areas only. However, with the normal cattle TB control programme in place (testing and removal of reactor animals) the transmission of TB from cattle to badgers is a low risk, as cattle are unlikely to be shedding large amounts of TB organisms into the environment.
Q22. Can cattle that stray	

into a herd for a day cause a TB breakdown in that herd?	
A22. Generally accepted principles of disease transmission indicate that it is possible that infected, infectious cattle that stray into the herd can infect others almost immediately. Infection in these circumstances is a chance process and while transmission on the first day is possible, it is more likely the longer an infected animal is in contact with other cattle and If this contact is close or in confined spaces (as TB is primarily a respiratory disease). However, it is very difficult to ascribe date or source of infection in a long latent period disease such as bovine TB.	
Q23. Is the requirement for the isolation of reactors really necessary?	
A23. Reactor cattle are infected with *M. bovis* and thus infectious to other cattle.	

Development of bovine TB disease may take many months or years but transmission of infection may be immediate (see also question 22). Therefore the strict and immediate isolation of reactors is extremely important.	
INFECTED BADGERS / BADGER SETTS	
Q24. Can the badgers in a sett be proven to have TB by testing the soil and faeces? **A24**. No. Currently there is no validated test and even if one were available detection of *M. bovis* directly from badger excretions is difficult, largely because of the low levels and intermittent nature of excretion of *M. bovis* by infected animals.	**Background**: Polymerase chain reaction, or PCR, is a laboratory technique that can amplify an amount of genetic material (DNA) from a tiny sample to a large amount in just a few hours. The PCR technique can be used to detect the presence of DNA from the disease causing organism in animal tissues, cultures of the organism or the environment. In addition to the difficulties described above, detection of *M. bovis* using the PCR technique is also problematic because of the difficulty in extracting DNA from mycobacteria and the presence of components that slow down the PCR in clinical samples (so-called 'PCR inhibitors'). Between 2007 and 2010, £1.3 million will be invested in work to validate and optimise PCR assays that are aimed at allowing discrimination between *M. bovis* and other closely related species of mycobacteria in environmental samples including soil from badger setts. Whilst it may be possible to identify areas, such as badger setts, where the organism is present it would not be possible to identify individual animals that were infected or know definitely whether the DNA detected was from *M. bovis* mycobacteria that were viable and infectious. A study by Courtenay *et al.* (2006) found 100% of the main setts in Woodchester Park to test positive for *M. bovis* by PCR on soil samples, and in 16 of the 22 social groups at least one culture-positive badger was detected during the 32 months before environmental sampling. In the other 6 social groups no excreting badgers were detected, despite the presence of environmental *M. bovis* at the sett. However, the only clinical sampling methods currently available to us are insensitive and until the PCR test is fully validated it is not known whether the results included false positives (Courtenay et al 2008).

	Before any test can be considered for use in TB control policy it is essential that it is robust and fully validated, so that its sensitivity and specificity (i.e. its ability to detect true positive and negative results) are known. Careful consideration of how such a test could usefully be employed to replace, or be used in conjunction with, existing tests will also be needed once its performance has been assessed.
Q25. Isn't it relatively easy to identify TB infected badgers on the basis of appearance and behaviour? **A25**. No. It is quite impossible, as with cattle, to identify infected badgers on the basis of appearance and behaviour. Only in the very late stages of disease do animals show clinical signs and these are non-specific and may reflect diseases other than TB.	**Background:** TB infection is currently confirmed by culture of *M. bovis* from clinical samples or tissues in the laboratory. However, *M. bovis* grows very slowly so culture results can take 6 weeks to several months to come through. Tests on clinical samples are insensitive compared to post-mortem examination and this itself is only reasonably sensitive if carried out in detail and visible lesions are then cultured. A more rapid test is needed to detect *M. bovis* both in cattle tissues and in live badgers or badger setts. With the available limited blood test (the Brock test) having to be repeated three times at intervals on individual animals, it is impractical and verging on the impossible to confidently distinguish between healthy and bovine TB infected badgers. The sensitivity of the Brock test based on validated data is 54%, with the lower 95% confidence limit being 49%. If applied three times, the overall sensitivity is therefore 87-90%. So put simply, even if you repeat the test three consecutive times, there is still a 1 in 10 chance that you will be releasing a TB positive animal. There are several tests which are more sensitive but they are not trap-side. Currently there is no sensitive and reliable field diagnostic test for bovine TB in live badgers. Bovine TB is difficult to diagnose in individuals of any species. Most of the tests (clinical signs, blood tests, skin tests, culture, histopathology, PCR and post-mortem examination) are less sensitive and less specific when testing individual animals than is ideal and rely on testing large numbers of individuals as a group (cattle herd or badger social group) in order to increase the sensitivity to acceptable levels.
Q26. Is it easy to identify TB infected setts? **A26**. No. It is impossible to identify infected setts without the capture of animals from that sett and detailed diagnostic tests.	**Background**: Whilst it may be possible to identify areas where the *M. bovis* organism is present (by testing soil or faeces around setts) it would not be possible to identify individual animals that were infected or know definitely whether the DNA detected was from *M. bovis* mycobacteria that were viable and infectious. There is currently no validated test for use in the field. A study by Courtenay et al (2006) found 100% of the main setts in Woodchester Park to test positive for *M. bovis* by PCR on soil samples, and in 16 of the 22 social groups at least one culture-positive badger was detected during the 32 months before environmental sampling. In the other 6 social groups no excreting badgers were detected, despite the presence of environmental *M. bovis* at the sett. However, the only

	clinical sampling methods currently available to us are insensitive and until the PCR test is fully validated it is not known whether the results included false positives (Courtenay et al 2008). See also question 24.
RESISTANCE / SUSCEPTIBILITY	
Q27. Are some cattle breeds more resistant to bovine TB than others? **A27**. There is anecdotal evidence pointing to genetic variation for resistance of cattle to infection of *M. bovis*. However this has not been properly quantified in the cattle population in the UK and it remains a possibility that such genetic variation exists.	**Background**: Genetic variation may be expressed in resistance to infection, in the response to the diagnostic tests, or both. Defra funded a study (SE:3040) to test these hypotheses and the findings are due to be published shortly. Benham (1985) found no evidence of breed differences in susceptibility to *M. bovis* infection in the UK.
Q28. Do family lines within the same breed have different levels of susceptibility? **A28**. There is no evidence to either support or dismiss this theory.	**Background**: There is anecdotal evidence that certain familial lines of cattle show particular susceptibility to bovine tuberculosis. Petukhov (1981) investigated two cattle farms with 2742 animals in Latvia, where 23% were infected, and noted that some families had 80% of its members infected, whereas others had none. If significant variation exists between familial lines this would not be surprising. In experimental animals, strains of disease resistant and susceptible mice and rabbits have long been recognised and utilised for research purposes. In humans both racial and ethnic variation in susceptibility to tuberculosis has been recognised (O'Reilly and Daborn, 1995). Hypothetically, many mechanisms of non-specific immunity may be effective in eliminating a low dose *M. bovis* challenge. Mechanisms under genetic influence might be the chemical nature of the bronchial mucus, the efficiency of the muco-ciliary escalator, the number of active non-specific macrophages in the lungs and the destructive efficiency of those macrophages' lysosomal enzymes. Other genetically controlled factors influencing susceptibility to bovine tuberculosis may be

	behavioural. For example, the animals grazing habits with respect to avoidance of excretory products may be under genetic influence. The amount of social behaviour that might facilitate cattle-to-cattle transmission, or investigatory behaviour towards badgers or their excreta, may also be under genetic influence. Specific mechanisms of immunity will almost certainly be genetically influenced (Phillips 2000).
BADGERS AND BOVINE TB	
Q29. Are 60% of badgers in 'Hot Spot' areas infected with TB? **A29**. It is not known for certain. Not all badger populations in GB have been tested for bovine TB. However, evidence of *Mycobacterium bovis* infection was found in all Randomised Badger Culling Trial (RBCT) areas.	**Background:** The results of Defra's Road Traffic Accident survey, carried out in Cornwall, Devon, Dorset, Gloucestershire, Herefordshire, Shropshire and Worcestershire between 2002 and 2005, showed badger populations in all of the counties sampled were affected by bovine TB to some degree. On average *M. bovis* was detected in 15% of badger carcasses i.e. around one in seven. This is similar to that recorded in proactively culled badgers in the RBCT during the same time period (16.6%). An extended post-mortem examination carried out on a sample of 205 RBCT badgers revealed substantially more infected animals (Crawshaw *et al.,* 2008), approximately double (33%), than did standard post-mortem examination. Therefore, these prevalence values are likely to be under-estimates. This represents a high prevalence of infection.
Q30. How much cattle TB is caused by badgers? **A30.** One of the conclusions the ISG reached at an early stage was that it was not possible to quantify the relative importance of badgers (and cattle) in transmitting infection. However, it was reported by the iSG at their final open	**Background**: The RBCT has shown that culling badgers leads to a decrease of about 23% in cattle herd breakdowns in the culled areas, with a trend to a stronger effect (about 40%) in the central areas (Donnelly *et al.,* 2007). The question of how much bovine TB in cattle is caused by badgers has not been answered accurately through the RBCT as culling could not be conducted with 100% efficacy. It is unlikely that it will be possible to quantify the relative contribution each species make.

meeting that results from the RBCT showed at least 40% was due to badgers.	
Q31. Do badgers infected with TB suffer?	
A31. Infected badgers are able to reproduce and raise young successfully and live for several years. However, based on knowledge of the pathology and extrapolation from the disease in other species, there is evidence that indicates that the disease will have a progressively increasing negative effect on the physical well-being of the badger. This has been documented at Woodchester Park (Clifton-Hadley *et al*., 1993).	
Q32. Will TB in badgers die out if disease is controlled in cattle?	**Background**: Understanding host status is important for determining the role badgers play in perpetuating the disease amongst their own population. A spillover host is one in which the disease agent can persist in the population for a time (i.e. there is some transmission, but it is not self-sustaining), but will die out without an external source of infection. Extensive research has shown that badgers are capable of maintaining infection in the absence of outside infection (e.g. cattle) and therefore act as maintenance hosts. It is not known for certain but evidence from the Defra Road Traffic Accident surveys in the 1980s show there are pockets of infection in badgers that at that time were not being transmitted and identified in co-located cattle.
A32. We don't know for certain. Modelling suggests that if disease in cattle is reduced then disease in badgers will also be reduced. On the other hand, there is	

evidence that TB is a self-sustaining infection within the badger population and once introduced, the infection persists within that species without the need for input from other infected species such as cattle.	During the outbreak of Foot and Mouth Disease in 2001, the majority of cattle TB testing was halted. This provided an opportunity for infected cattle to spread TB to other cattle and, potentially, to badgers. The prevalence of infection in adult badgers increased substantially and a weaker trend was observed in badger cubs across all seven proactive trial areas. A similar pattern in road-killed badgers from the seven counties in which the trial areas were situated confirms that this was not driven by culling itself (Woodroffe *et al*.,2006). As the ISG noted, this suggests that cattle to badger transmission may be an important factor in TB dynamics and that cattle controls may influence the chances of reinfection of badgers through their effect on cattle-to-badger transmission.
Q33. Are there many more badgers in England and Wales now than in the 1990s? **A33**. This is not known for certain. A national survey in the 1980s estimated that the overall badger population was about 250,000 (Cresswell *et al*., 1990). Following repeated surveys in the 1990s estimates of the national badger population were published (Wilson *et al*., 1997) indicating a likely increase between the two main studies, when it was estimated at around 300,000. It should be noted that the data are more than ten years out of date. Additionally, the methods used in these surveys	**Background**: Between November 2005 and December 2006 research (Defra Project WM0310 & WM0311) was undertaken on behalf of Defra to provide an estimate of population densities of badgers in selected habitats in regions of south-west England which have a high incidence of bovine TB. These estimates, representing indices of overall abundance, serve as a baseline against which any future changes in population densities can be assessed. - WM0311: Using distance analysis, the mean densities of badgers foraging in open pasture (autumn 2006) were estimated to be: Cornwall 2.9 badgers per km^{-2} (95% confidence limits: 2.1–4.0); Devon 4.3 per km^{-2} (3.2–5.7); Gloucestershire 3.3 per km^{-2} (2.4–4.6); Herefordshire 1.5 per km^{-2} (1.0–2.4). - WM0310: Using distance analysis, the mean densities of badgers foraging in open pasture (spring 2006) were estimated to be: Cornwall 4.5 badgers per km^{-2} (95% confidence limits: 3.2 – 6.5); Devon 4.1 badgers km^{-2} (3.0 – 5.6); Gloucestershire 4.4 badgers km^{-2} (3.2 – 6.1); Herefordshire 3.9 badgers km^{-2} (2.9 – 5.4). The densities recorded in the hotspot surveys illustrate the inherent variability of badger abundance across regions within GB - a variability which is equally applicable at a local level – and the difficulty in estimating overall numbers of badgers.

differed so it is not possible to directly compare the results of these surveys.	
BADGER CULLING	
Q34. Was the risk of perturbation and subsequent effects sustained after proactive culling in the RBCT had stopped? **A34**. Initially this appears to be true - the borderline significant trend for the beneficial effect to increase over time from the start of culling that was reported in the ISG final report is shown to continue and appears to be increasing for at least the two years since proactive culling in the RBCT stopped. Further studies are underway to monitor if this effect continues.	**Background**: The ongoing analysis on the impact of proactive badger culling following the cessation of annual culls was updated in January and August 2008. The analysis concludes that the effect on reducing cattle herd incidence inside the proactively culled areas has continued more than one year after culling stopped (i.e. from summer and autumn 2006 and reports a reduction of 54% (95% CI: 39% to 66% lower) in confirmed herd incidence during this time period. This is based on sufficient data to make it statistically robust. The deleterious effect on cattle herd incidence initially seen after culling in the 2 km ring outside the culled area is reported to be no longer apparent over this timescale. The authors conclude that the borderline significant trend for the beneficial effect to increase over time from the start of culling that was reported in the ISG final report is thus shown to continue and appears to be increasing for at least the two years since proactive culling in the RBCT stopped (Jenkins *et al.,* 2008). These results affect the main figures in the ISG's Final Report by increasing the overall beneficial effect on cattle herd incidence since culling started from the 23% in the ISG Final Report to about 30% and is statistically significant. The overall deleterious effect is estimated to have fallen from the 24.5% reported by the ISG in June 2007 to around 12% and is now statistically non-significant (subject to further studies commissioned by Defra). The cost benefit analysis of culling will change once more data becomes available, however the issues around practicality of coordinated sustained culling over a wide area would remain. This evidence was taken into account when the Minister made the decision on culling in July 2008.
Q35. Did the results of the RBCT demonstrate that reactive badger culling has no role in bovine TB control in GB?	**Background**: There has been some debate around the biological plausibility of timing and locations of culls and association with herd breakdowns (Godfray 2004; King 2007). Further examination of the spatial and temporal trends in cattle data associated with the RBCT was the subject of a research call advertised at the end of 2007. Five research projects were commissioned this year to further analyse the RBCT dataset to examine this issue.

A35. Reactive, localised culling was stopped in November 2003 as results from the reactively culled areas showed an associated increase in new TB incidents of 22% (95% CI 2.5-45.3% higher) measured from the start of the proactive cull (or 18.9%, 95% CI 5.4% lower – 49.5% higher if measured from the start of the reactive cull) throughout the whole of the reactively culled areas. This led the ISG to conclude that it is highly unlikely that reactive culling, as carried out in the RBCT, could contribute other than negatively to future TB control strategies. The ISG hypothesised that the increase in disease was caused by perturbation of the badger population - culling disturbed territorial behaviour (increased ranging) which thereby increases contact rates between badgers and between badgers and cattle (ISG 2007).	

VACCINES

Q36. Badger vaccine will not be ready for several years? **A36**. An injectable badger vaccine is expected to be fully licensed in spring 2010. The earliest projected date for the availability of an oral badger vaccine is 2014.	**Background**: Vaccine development has been a priority for a number of years in line with the recommendations in the 1997 Krebs Report. There are currently six Defra research projects underway. Details of all on-going and completed research projects are available on the Defra website at http://www.defra.gov.uk/science/default.htm and http://www.defra.gov.uk/animalh/tb/research/projects.htm respectively. Badger vaccines are further progressed than those for cattle - a three and a half year vaccine field trial to gather safety data and assess efficacy of injectable Bacille Calmette-Guerin (BCG - the human TB vaccine) in badgers, and a project developing oral bait formulations of BCG are underway. An injectable badger vaccine will be the first product from the vaccine research programme. Whilst an injectable vaccine is not regarded as suitable for widespread use, stakeholders have agreed that a small scale project to demonstrate the principle of vaccination could be beneficial. An injectable badger vaccine will be used in a Defra funded vaccine deployment project to assess the viability of injectable vaccination and to support the long-term goal of oral vaccination.
Q37. Isn't it pointless to start a badger vaccination programme before infected badgers are removed? **A37**. No, there is a good case for starting a vaccination programme even though a proportion of animals are infected. The key objective is to reduce transmission risks – between badgers and from badgers to cattle. Although desirable, there is no need to vaccinate all badgers or stop them becoming infected to have an impact on transmission.	**Background**: Although vaccination of infected animals is unlikely to have an effect on these, nor will it be harmful. It is impractical and verging on the impossible to confidently separate healthy badgers from bovine TB infected badgers (see also questions 24 - 26). The BCG vaccine will reduce the risk of uninfected badgers becoming infected but would not offer protection to already infected badgers, nor will it harm them. Even if infected badgers were present in the population at time of vaccination, one would still expect the disease pressure on cattle to reduce over time as infected badgers die off naturally. The typical life-span of a badger in between 3-5 years. Other advantages of starting a badger vaccination programme now are to build farmer confidence in the long term contribution badger vaccination can make to tackling bovine TB and to provide valuable information which can help us move towards the long term goal of an oral badger vaccine, before it is available.

Q38. Will cattle vaccine ever be allowed, due to international trade regulations? **A38**. The Government is currently investigating the scope and potential timetable for making changes to EU trade regulations which would allow vaccination of cattle against bovine TB.	**Background**: Vaccines based on BCG will potentially make cattle react to the current tuberculin skin test as if they were infected with *M. bovis*. Without a test to differentiate infected from vaccinated animals (a 'DIVA') cattle from vaccinated herds would be indistinguishable from infected animals and would lose their Officially Tuberculosis Free (OTF) status and would be required to be slaughtered as reactors. Significant changes are required to EU legislation to allow the use of a DIVA test. A cattle vaccine in conjunction with a reliable, EU accepted DIVA test is not expected to be available for at least 8 years. The work by the Veterinary Laboratories Agency on developing a DIVA test has shown some initial promise based on experimentally infected animals. Work is ongoing to validate the test in the field. There is evidence to suggest the Commission would be open to persuasion in the use of vaccines. In particular, the Commission has agreed funding under Framework Agreement 7 for diagnostic and cattle and badger vaccine research. Also the EU Animal Health Strategy for the European Union (2007-2013) mentions the EU moving to a more flexible approach to vaccination. This is in the context of controlling exotic disease outbreaks but again demonstrates the Commission's changing views on vaccination.
Q39. Is vaccination the 'magic bullet' for TB control? **A39**. No. Vaccines can only ever contribute to the control of bovine TB where, as for many other disease control strategies, it is a combination of control measures that is most likely to be successful.	**Background**: Vaccines for a chronic granulomatous disease such as TB do not work as well as for more acute infections such as leptospirosis due to the nature of the immune response and course of disease in the host. Vaccines will not provide a single answer to the problem of bovine TB. However modelling suggests that they may make an important contribution when used as part of a raft of control measures. The lead candidate vaccines in both cattle and badgers are based on BCG. While BCG vaccination has shown promise in both cattle and badgers, efficacy is unlikely to exceed 80% and may be substantially lower. This does not mean that vaccines are of no use for the control of bovine TB - for badgers in particular as any level of efficacy in reducing transmission will have a positive benefit.
OTHER SPECIES	
Q40. Are other wild mammals a TB risk to cattle?	**Background**: While small numbers of many mammalian species such as rats have been shown to able to be infected with bovine TB (Krebs 1997, Defra project SE:3010) most are spillover hosts and

A40. The greatest TB risk to cattle in wild mammals is from badgers which are the main wildlife host.	there is no evidence that they can transmit the infection to other species or even maintain infection in their own populations. The reasons for this are usually immunological or behavioural (e.g. they do not develop progressive disease, are solitary species or not in contact with other susceptible species). Previous research undertaken by the Central Science Laboratory and Oxford University (2005) has shown that the only wild mammalian species which act as reservoirs of bovine tuberculosis and thus are a risk to cattle are badgers and some species of deer (see also question 41). Other species may be infected with TB but are end hosts (i.e. do not transmit the disease further).
Q41. Are wild deer as much a risk to cattle as badgers? **A41**. Wild deer in GB are generally considered a sentinel or 'spillover' host of infection in cattle rather than the source of disease in cattle. Overall TB prevalence in wild deer is low and the ecology and behaviour of wild deer makes it unlikely that they would have any close direct contact with cattle. The key results of a Quantitative Risk Assessment (CSL 2008) indicate that deer are likely to pose less of a TB risk to cattle than badgers throughout most of Southwest England and Wales.	**Background:** Quantitative Risk Assessments commissioned by Defra (CSL 2005) demonstrated that the risk of cattle infection from deer is only likely to be significant if the prevalence of TB infection in deer is high. The indication from research is that the overall prevalence of TB infection in deer (wild, park and farmed) is not high and is estimated to be generally less than 5%.The ecology and behaviour of wild deer makes it unlikely that they would have any close direct contact with cattle. More information about this research can be found on Defra's website at: www.defra.gov.uk/animalh/tb/research/projects.htm Defra subsequently commissioned a wild deer density and disease prevalence study the results of which were published in November 2008. The study shows that on public forest estate land in the Southwest Peninsula, bovine TB is present at a very low level (less than 1%, except in one area where it is present at 3.8% in fallow deer); in the Cotswolds high prevalences were found in two of the three areas sampled (15.9% and 8.1%), particularly in fallow deer; and in all areas surveyed, fallow deer were the species most likely to have the highest level of infection with *M. bovis* (Defra 2008). On their own, these data cannot predict the role that deer may play in the current epidemic of bovine TB in cattle; however, it does provide essential, previously missing data for use in ecological disease models for this purpose. Results from the density and prevalence surveys were subsequently used to inform a Quantitative Risk Assessment (CSL 2008) to determine the risk of *M. bovis* infection posed to cattle from wild deer. The findings of the QRA indicate that wild deer do not currently pose a significant TB risk to cattle. Under current conditions of low to moderate density and bovine TB prevalence the majority of infected wild deer populations in Southwest England and Wales are most likely to act as spillover hosts of *M. bovis*. More detailed information about this research can be found on Defra's website at: www.defra.gov.uk/animalh/tb/index.htm

	It is known that close contact of animals can help spread bovine TB, so any measures which help avoid this could be beneficial. Maintaining lower deer densities is one option of avoiding close contact. Whilst culling is one option that could be considered, it is not the only possible way of avoiding close contact in high numbers. Wild deer do pose a significant risk to cattle in other countries, especially when the deer in question occur at high densities (for references see Wilsmore & Taylor, 2008). Since 1994, the state of Michigan, USA has recognized a problem with *M. bovis* in wild white-tailed deer. Strategies for eradication of bovine TB from Michigan wildlife focus on reducing deer population densities to biological carrying capacity and reducing artificial congregation of deer by restriction or elimination of baiting and feeding. While much work remains, substantial progress has been made towards eradication of TB from Michigan wildlife.
Q42. Are pigs a dead-end host of *M. bovis*? **A42**. Currently pigs are considered spillover hosts in Great Britain.	**Background**: Historically, and in most countries including GB, domestic and feral pigs are regarded as incidental spillover hosts of *M. bovis,* which become infected through direct or indirect contact with infected cattle, badgers or deer, their carcases and excreta. The evidence from Australia, New Zealand and the USA indicates that pigs become infected only when the prevalence of infection in the natural hosts is relatively high and pig populations cannot sustain the infection in the absence of infected cattle or a wildlife maintenance host i.e. the incidence of infection in pigs wanes as it is eradicated from the cattle population. However, more recent pathological and molecular epidemiological evidence has emerged in Spain suggesting that wild boar and semi-feral pigs could be acting as maintenance hosts of *M. bovis* in parts of that country, particularly where the population densities are kept at artificially high levels. In GB we are likely to continue to observe sporadic incidents of porcine TB due to *M. bovis* infection, on farms where pigs and cattle are raised together and in outdoor breeding-fattening units in those regions where bovine TB is endemic. *M. bovis* has not yet been reported in the very small British feral pig population.
TB CONTROL / ERADICATION	
Q43. Can TB be eradicated from cattle through extra cattle measures without	**Background:** EU member states and Australia, that have successfully eradicated bovine TB in their cattle have done so without the presence of a wildlife host of the disease. Other countries where the disease is present in wildlife have succeeded in controlling the disease in cattle with varying success

addressing the wildlife reservoir? **A43**. In September 2005, the Wilsmore review concluded that the international evidence shows clearly that bovine TB in cattle cannot be eradicated by cattle controls alone when there is a secondary reservoir of infection from wildlife. Thus, on the basis of this evidence, some form of intervention in the wildlife domain is necessary if bovine TB in cattle is to be eradicated. The ISG concluded that the elimination of infection in high risk areas can only be achieved in the very long-term and that this problem is a consequence not only of the failure to remove all infected cattle on some farms, but also reintroduction of infection from wildlife (see also question 32).	by tackling the wildlife population. In New Zealand, a deteriorating bovine TB problem in cattle and deer has been halted and then reversed over the last decade. *M. bovis* infection in both wild and domestic animal populations has been controlled. This has been achieved by applying a concerted, resource intensive multi-faceted science-based programme including the wildlife reservoir. Reducing that reservoir of infection by removal of possums dramatically reduced the incidence of cattle TB (Tweddle & Livingstone,1994). The ISG used a simple model (Cox et al, 2005) to summarise the TB epidemic in two species, cattle and badgers, either being capable of infecting the other. The implication from this model is that the current TB epidemic can be controlled by either increasing testing frequency, by using a diagnostic method which increases effective testing sensitivity, or by a combination of both. However the epidemic will be reduced by these means only where it is driven by infection from cattle to cattle. On the other hand, the Government's former Chief Scientific Advisor, Sir David King noted in his report that badgers are a clear source of infection for cattle and that TB control will require interventions that reduce the prevalence of disease in both cattle and wildlife. It is likely that the value for each transmission route (cattle / badger) varies from one region of GB to another, in which case the contribution of badger removal to TB control will also vary. However, it is clear that any badger measures must be applied alongside continued cattle controls if the best results are to be achieved
Q44. Can tuberculin testing and slaughter of cattle eradicate the disease in cattle?	**Background**: The systematic application of tuberculin skin testing and slaughter programmes over extended periods, along with other cattle controls, has eradicated bovine TB from most industrialised countries where cattle are the sole maintenance host of infection. Examples of this are: Australia, the majority of the 50 states in the USA, most provinces and territories of Canada and 11 of 27 EU Member States.

A44. Yes - where there is no transmission from wildlife to cattle.	
Q45. Did the gamma interferon test make a significant contribution to the eradication of bovine TB in Australia? **A45**. The gamma interferon test was introduced into the programme at a late stage and did not make a significant contribution.	**Background**: The gamma interferon assay was not routinely applied in the eradication of bovine TB from Australia (Eradication of Bovine TB from Australia; key management and technical aspects. CSL Veterinary Ltd, Cousins *et al.,* 1998) The gamma interferon test was used in the latter stages only and by the time the test was developed most of the residual infection was located in extensive herds in Northern Australia remote from diagnostic labs. The main control measures used in the eradication scheme were the tuberculin skin test (single caudal fold test) used in repeat herd testing and in most cases in the later stages, disease was eradicated by depopulation. Movement and trade restrictions were imposed on infected herds and areas, slaughter out of the feral buffalo reservoir and use of radio tracked Judas cows to locate stragglers in extensive grazing areas. Incentivised slaughterhouse monitoring for TB lesions was also used. The eradication scheme was run by Government in partnership with the cattle industry with clear strategic aims signed up to by all involved.
Q46. Is pre-movement testing a waste of time and money? **A46**. No. Pre-movement testing helps to reduce the risk of spreading bovine TB through cattle movements, especially to areas that are currently free of disease.	**Background**: Cattle to cattle transmission is a serious cause of disease spread which is substantiated by scientific evidence (see www.defra.gov.uk/animalh/tb/pdf/prmt-litreview.pdf). Ascertaining the disease status of an animal prior to movement using the tuberculin skin test and only permitting movement of those that test clear (i.e. disease is not detected) will reduce the number of cattle with bovine TB that are moved within the country and in turn the risk of disease spread. New TB incidents are being prevented by pre-movement tests and infection is being picked up earlier in high risk herds Furthermore, the obligation to carry out pre-movement tests discourages what was common practice of moving cattle prior to a routine herd surveillance test, so fewer cattle should be escaping Government funded routine surveillance tests.
Q47. Isn't TB in cattle just an economic problem - not an animal health one? **A47**. The Government's strategy for controlling bovine TB is to work with stakeholders to reduce the	B**ackground**: Bovine TB is GB's biggest endemic animal health issue, costing the taxpayer around £80 million in 2007/08 (surveillance, research, testing and compensation). Despite recent increases in cattle herd breakdowns this has not been mirrored by an increase of bovine TB infection in humans. The introduction of milk pasteurisation (1930s) and systematic culling of cattle that react to a skin test has virtually eliminated *M. bovis* infection in humans in the UK. Cases of human TB caused by *M. bovi*s do occur occasionally in the UK and elsewhere, but the majority are attributable to reactivation of latent infection in older people or infection contracted abroad. The current risk posed by bovine TB to human health in the UK is very low. The overwhelming cost of bovine TB to society is

economic impact of the disease whilst maintaining public health protection and animal health and welfare.	directly attributable to the cost of controlling the disease in cattle and associated research. As long as infection is detected at an early stage - as it is almost always under the current testing regime - very few animals are affected by the clinical disease. In the absence of significant transmission to humans the question has been raised whether controlling bovine TB should be justified only in economic terms of reducing losses in animal productivity (Torgerson & Torgerson, 2008).
Q48. Does a badger vaccine against bovine TB offer the best prospect of eradicating TB in the UK? **A48**. Yes – when used in conjunction with cattle control measures. Bovine TB is unlikely to be eradicated from the UK unless the secondary wildlife reservoir is addressed and badger vaccines currently offer the best prospect for tackling this (see also question 43).	**Background**: Although the development of vaccines would provide a significant contribution to the control of bovine TB, it must be noted that it will not provide a single answer to the problem but would need to be used in conjunction with other control measures. This is because vaccination is not 100% effective in terms of protection so would need to form part of a package of measures. The use of badger vaccination as another tool is supported by the ISG (and Godfray) which concluded that use of a vaccine for badgers that might reduce transmission of infection and the risk of infection of cattle, thus providing another control option.
Q49. Is the UK an OTF country? **A49**. No, the UK is not an OTF country. EU Council Directive 64/432/EEC provides for Member States to determine officially TB free (OTF) status on a country, region, or herd basis. Because of the incidence of	**Background**: An OTF herd is one where, i) all animals (over 6 weeks old) are being routinely tested in accordance with the correct intervals for the herd; and ii) in infected herds where all the bovine animals have reacted negatively to at least two consecutive routine tests. Where a positive reaction is detected or suspicion of TB is found at routine meat inspection of slaughtered cattle, the herd will cease to be regarded as TB free for a period and will have to undertake a series of herd tests. EU Council Directive 64/432/EEC defines an officially TB free (OTF) country or region as one in which the percentage of herds with confirmed TB breakdowns has not exceeded 0.1% per year and at least 99.9% of its herds have achieved OTF status each year for six consecutive years. Because of the herd incidence of bovine TB, no country/region of the UK (England, Northern Ireland, Scotland or Wales) is currently (or has ever been) designated as OTF by the European Commission. However, most herds in UK are considered OTF at any particular time and so are able to trade freely and

TB here, UK is not designated as an OTF country. However, most herds in UK are (at any particular time) OTF and so able to trade freely.	export live cattle to other EU Member States, provided that those animals have received a tuberculin skin test with negative results in the 30 days before the date of export.
PUBLIC HEALTH	
Q50. What is the public health risk of TB in cattle and other species in the UK?	**Background**: In developed countries TB in humans arises principally from infection with *M. tuberculosis*, which is generally transmitted from person to person through the air by sneezing or coughing. *M. bovis* infections in humans are rare. In the 1930/1940's large numbers of people were infected with TB. At that time it is estimated that approximately 2,500 deaths a year and 50,000 cases of illness in humans were due to *M. bovis* infections. *M. bovis* infections in animals are transmissible to humans through inhalation of infectious aerosols, ingestion of unpasteurised dairy products or, less commonly, by contact with broken skin. The risk to the general public has decreased significantly due to an extensive cattle testing and slaughter programme, almost universal pasteurisation of the drinking milk supply and veterinary inspection of cattle carcasses at slaughterhouses. The HPA (through the local CCDC) closely monitor human cases of TB caused by the *M. bovis* infection in the UK (and related bodies in Wales, Scotland and Northern Ireland). The numbers of cases identified remain consistently low, at less than 50 new cases a year. This represents between 0.5% and 1% of the approximately 8,000 culture positive cases of human TB diagnosed in the UK every year. This relative incidence of human *M. bovis* infection in the UK is in line with that of other industrialised countries with long standing bovine TB eradication schemes. The disease can in most cases be successfully treated with antibiotics. Provisional data show 31 cases, in Great Britain, of bovine TB in humans in 2006, and 27 cases in 2007. This is similar to the situation reported in the vast majority of developed countries.
A50. For the majority of the population, the risk of people contracting TB from cattle in Great Britain is considered very low. At present, less than 1% of all confirmed cases of TB in humans are due to infection with *M. bovis*. The majority of these cases are considered to be due to reactivation of latent disease contracted before widespread milk pasteurisation or from infection contracted abroad. Somewhat greater risk in some occupations where there is direct exposure to infected animals.	

Q51. Does raw milk give you immunity against bovine TB? **A51**. No. Unless milk is pasteurised it is possible that it could be a source of infection.	**Background:** Zoonotic TB was formerly a far more common disease in the UK human population, usually transmitted to man by consumption of raw cows' milk. *M. bovis*, the bacterium that causes bovine TB, is killed by normal pasteurisation. Disease due to human *M. bovis* infection usually occurs as a result of reactivation of previously acquired infection in older patients, in whom drinking unpasteurised milk in the past is the probable source of infection, or as a result of infections acquired overseas by immigrants to GB (SE3017). Since 1990, only one case has been documented in the UK of confirmed, indigenous human *M. bovis* infection recently acquired from an animal source. Cattle herds that produce cow's milk for sale raw in England and Wales i.e. unpasteurised, are subject to more regular bovine TB tests than other herds, which should reduce the risk that infectious cattle are present in the herd. No unpasteurised milk is sold in Scotland. The EU's consolidated Food Hygiene Regulations (in effect from 2006) consolidate legislation relating to milk. Milk (raw or pasteurised) from any animal showing a positive reaction to a TB test cannot be used for human consumption. Milk from the rest of the herd may continue to be sold for human consumption in England and Wales but only if it is heat-treated.
Q52. Are TB infected camelids (llamas and alpacas) a significant public health risk? **A52**. There is a low risk to the public in general but many owners of these animals are not aware of the zoonotic risks associated. Camelids are not regularly tested for TB compared to cattle. Educating owners and making them aware is something that needs to be taken forward by both industry and Government.	**Background:** Bovine TB is not a major health problem with camelids in comparison to cattle, but these species do occasionally develop the disease. Although reports of infection in their natural habitat in South America are few, cases have been diagnosed in llamas and alpacas in New Zealand, the USA and in Great Britain. *M. bovis* infections in camelids, as in other mammals, are zoonoses (i.e. infections that are naturally transmissible between animals and humans). One of the potential mechanisms of transmission between camelids and man could be through aerosols generated if an infectious camelid "spits" while being handled by a person. Owners and keepers of these animals need to be aware of the associated public health risks (which are not negligible). Camelids are spillover hosts to *M. bovis* and the prevalence of infection in these species is low compared to cattle and badgers in the traditionally endemic TB areas of GB.

HUSBANDRY AND BIOSECURITY	
Q53. Will supplementing cattle feed with trace elements and/or selenium prevent a TB outbreak?	**Background:** Much of the soil in the UK is deficient in one or more minerals, and deficiencies of copper, selenium, cobalt and iodine can occur in farmed animals. Mineral supplements for cattle are desirable to help alleviate this, where it occurs. Some evidence also exists that trace element deficiencies can result in impaired immune responses.
A53. No. Whether or not there is a possible relationship between trace element supplementation and decreased susceptibility to infectious diseases such as bovine TB has yet to be proved. Deficiencies of trace elements should be corrected as a matter of good husbandry practice.	The association between *Mycobacterium bovis* infection and trace elements such as selenium, copper and vitamin B12 status of cattle was investigated as part of the Defra funded project "Pathogenesis and diagnosis of tuberculosis in cattle – complementary field studies" (project SE3013). The report concluded that lower selenium status might increase susceptibility to *M. bovis* infection and there might be an association with copper. However, given the design of the study and the evidence that the action of some micro-nutrients can be substantially influenced by the levels of others it was not possible to conclude that the associations observed were factors in the incidence of bovine TB in cattle. The full report can be downloaded from Defra's TB web pages at; http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=9317. Case-control studies TB99 and CCS2005, carried out as part of the Randomised Badger Culling Trial which ran from 1998 to 2006, also attempted to identify risk factors associated with TB herd breakdowns. Whilst it was not possible to identify specific risk factors which if addressed would confidently result in reduced transmission of disease to and from cattle, the study did support the application of broad principles of biosecurity which includes taking greater care with feeding practices and providing cattle with a balanced nutritional diet. Whilst occasionally a clear cause and effect relationship can be demonstrated by epidemiological studies, in most cases the situation is more complex and the research tells us what factors are important concerning a specific question or a theoretical level of risk associated with a particular event, behaviour or contact. This said, the need for further research to investigate the relationship between trace element deficiency and susceptibility to TB is being considered by the Defra TB Science Advisory Body.
Q54. Do cattle only become infected by badgers through close	**Background**: We know transmission of bovine TB occurs from cattle to cattle; from badgers to cattle and cattle to badgers; and badger to badger. There are practical steps farmers can take to reduce the risk of transmission from badgers to cattle. Adopting husbandry best practice on farm to minimise, as

contact? Close the barn doors, put up electric fencing around silage clamps and you will resolve the problem...	far as possible, the risk of contact between cattle and badgers is advisable to reduce the risk of experiencing a herd breakdown. Defra has produced advice on husbandry and biosecurity best practice in partnership with the Bovine TB Husbandry Working Group. The advice includes details of low cost measures: www.defra.gov.uk/animalh/tb/abouttb/protect.htm The Husbandry Group did not think it would be practical to fence off entire farms, however fencing off specific fields or buildings could be useful in some cases. Research is currently being carried out into the cost and practicality of husbandry measures to reduce both indirect and direct contact of badgers with cattle (SE3119).
A54. TB is mainly a respiratory disease, caught by breathing in the bacteria and direct transmission can occur through, for example, nose to nose contact. However, there is also evidence that indirect transmission is possible, for example through contact with infected saliva, urine, droppings, pus from TB abscesses etc. It is difficult to identify the relative importance of each route of transmission of the disease and for this reason emphasis should be put on efforts to reduce the risk of cattle and badgers coming into both direct and indirect contact.	
Q55. Does growing maize increase the risk of a TB breakdown in your herd?	
A55. There is anecdotal evidence that badgers are	

attracted to maize and maize silage and in areas where maize is grown it often forms a major part of their diet, but there is no evidence to suggest that reducing the amount of maize / changing from maize to grass silage can reduce bovine TB to an extent that would justify what would be significant changes to farm management practices.	
Q56. Does ensiling kill the TB bacterium? **A56**. Research by VLA from 1999-2000 (Project SE3022) has shown that the ensiling process does, with time (6-12 weeks), kill the *M. bovis* bacterium. As with the effect of all such processes on bacterial survival, the longer that the organism is exposed to the hostile acidic conditions in silage, the higher the proportion that will be killed or rendered non-viable (McCaskey and Wang, 1985).	**Background:** The objective of project SE3022 was to investigate the ability of *M. bovis* to survive the ensiling process undergone when grass is conserved for winter feeding to cattle. The increasing incidence of *M. bovis* infection in cattle has resulted in considerable debate over the routes by which cattle may be infected. It has been suggested that contamination of grass with *M. bovis*, for example by badgers urinating on the pasture, and subsequent ensiling and feeding to cattle is a possible route of infection. Due to the pathogenic nature of *M. bovis* and the risk of infection to man and animals it is not possible to carry out such studies using farm scale silage making. Therefore, a laboratory scale version was developed to replicate the farm process and investigate whether this was a possible source of mycobacteria for cattle. An experiment was designed in which a laboratory scale version of the ensiling process was developed to take account of the safety issues arising from the use of a human pathogen, at the same time allowing investigation of the ability of *M. bovis* to survive the ensiling process. *M. bovis* was recovered for twenty four hours from inoculated grass undergoing the ensiling process. *M. bovis* was not recovered from grass that had undergone the ensiling process for periods of 6 and 12 weeks. However, the results must be qualified by finding that recovery of *M. bovis* from the 24 hour control was at a very low level compared to that of the inoculate used to prepare the grass sample. This indicates that the sensitivity of the recovery process requires further investigation to determine if the findings are real or a result of the low sensitivity of the recovery method.
Q57. Do iron rich soils cause bovine TB in cattle?	**Background:** A theory has been proposed that *M. bovis* bacteria survives and proliferates in iron rich soils thereby causing TB outbreaks in hotspot areas of the country where old mine spoils are known to exist. It is claimed that previous scientific research (Johnson-Ifearulundu and Kaneene, 1997)

A57. No. Iron rich soils have not been shown to have a causal role in bovine TB.	supports this theory. The results of these studies where lime was spread on farms in Michigan suffering from high rates of mycobacterium infection, concluded that lime treatment (which reduces iron availability) had reduced infection of cattle after a three year period had passed. However, the studies were designed to look at the paratuberculosis strain of mycobacterium, not bovine TB, and as such are not scientifically rigorous enough to support this theory for bovine TB.
Q58. Is there a risk from spreading slurry on land used by cattle?	**Background**: Slurry has the potential to spread bovine TB via two routes: ingestion (via the pharynx and gut) and respiratory (via the lungs); however, in order to do this, the slurry must first contain viable *M. bovis* organisms in sufficient quantity and/or be presented as an infectious aerosol. For slurry to be a source of infection for bovine tuberculosis, at least one animal in the herd must be shedding *M. bovis* in faeces, urine or coughed-up sputum. In the areas where bovine TB is most prevalent, annual testing reduces the likelihood of cattle having time to develop these lesions before they are detected and slaughtered. The infected slurry must contain (i) an infectious dose of (ii) viable *M. bovis* and these must (iii) come into effective contact with at least one (iv) susceptible animal via the respiratory system or the gut. In order to do this, it must survive storage and the environment, either on or in the ground, or in the air as an aerosol – slurry spreading techniques commonly used produce small droplets rather than aerosols and these fall out of suspension in the air within a few hundred metres. These droplets are not small enough to enter bronchi and would have to be swallowed to reach a site of infection, which requires a far higher dose. Very small droplets (true aerosols) which are small enough to enter bronchi are very hostile to bacterial survival and bacteria are less likely to survive to transmit disease.
A58. Yes - slurry has the potential to spread bovine TB but this is highly unlikely under the conditions existing in the UK as a result of current cattle controls. The risk is mitigated by the dilution effect of slurry , the pH and the storage process, plus spreading on land and exposure of organisms to the environment.	
Q59. Is cleansing and disinfection (C&D) of buildings/yards used by reactor cattle a waste of time?	
A59. TB infected cattle can shed *M. bovis* bacteria in faeces, urine and in coughed-up sputum. C&D is a key part of TB risk reduction and in the control	

of other infectious diseases.	
Q60. Are newly calved cows more prone to give a false positive reaction to a TB test?	**Background**: A paper by Buddle *et al.* (1994) looked at TB in pregnant cows after experimental, intratracheal, *M. bovis* infection. To quote the abstract directly: 'Pregnancy did not appear to affect the susceptibility to *M. bovis* infection, and immune responses of the cattle in this group at the end of the study were similar to those in the high dose non-pregnant group '. In short, in this research project, the test responses were not significantly different between pregnant and non-pregnant cows (certainly not higher in the pregnant ones shortly due to calve). It is important that all potentially affected animals are removed from the herd once TB is diagnosed. Any other approach would risk leaving infected animals in the herd to spread the disease, thus perpetuating the problem and, ultimately, resulting in the need to remove a greater number of animals at a later stage. Positive reactors to a gamma interferon test are infected and therefore must be removed from the herd for disease control reasons.
A.60. The suggestion that heavily pregnant or newly calved animals are prone to react positively to the gamma interferon test is not supported by scientific evidence.	