ACM/981a

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

THE POSSIBLE HEALTH RISKS TO CONSUMERS OF MEAT AND DAIRY PRODUCTS FROM ANIMALS WITH EVIDENCE OF *Mycobacterium bovis* INFECTION

Introduction

1. The purpose of this paper is to:

- Highlight the changes in the regulations and disease incidence which have taken place in relation to *Mycobacterium bovis* infection in man and animals since the ACMSF last considered the issue in 2003.

- Seek the views of members on the level of protection afforded to consumers by current regulations relating to meat and milk from animals with evidence of infection.

2. The Committee assessed the health risks to consumers of meat from animals with evidence of *M. bovis* infection in 2001 and again in 2003. This paper focuses mainly on meat to enable members to review their initial risk assessment, which concluded that the risk, if any, from the consumption of meat is very low.

3. The risks to consumers from milk and dairy products, specifically those which have been made from unpasteurised milk, have not been considered in detail by the Committee. This paper does not aim to address this aspect thoroughly but proposes that these foods be addressed separately through the establishment of an ACMSF ad hoc group to advise the FSA.

Background

4. In September 2000, the Committee was asked to review the possible human health risks associated with the consumption of meat from cattle that had evidence of *M. bovis* infection. The Committee's views were also sought on the level of protection offered to human health by the legislation that was in force.

5. Members were reassured that a marked increase in bovine tuberculosis (bTB) in cattle had not been reflected in human cases of TB due to *M. bovis*. However, it was agreed that a Working Group would be set up to review the possible health risks associated with the consumption of meat from animals with evidence of *M. bovis* infection and to advise on the adequacy of control measures. The Working Group only considered GB data.

6. The Committee endorsed the Working Group's report and it was published in January 2002. In summary, it was concluded that the risk, if any, from the consumption of meat from animals with evidence of *M. bovis* infection, sold as fresh meat for human consumption following assessment by the Meat Hygiene Service in UK abattoirs, was very low. The controls in place at that time were considered adequate to protect public health. However, recommendations were made to improve hygiene practices in abattoirs and also in respect of options for reducing the risks to consumers still further. Prior to publication of the final report, the recommendations were addressed in an FSA Board paper in December 2001 (FSA 01/08/03) and the Board accepted those relating to changes in the legislation and meat inspection. More detail on the recommendations and actions taken to address them can be found in ACM/981b.

7. In September 2003, the ACMSF reviewed results from an FSA funded study to investigate whether *M. bovis* was present in the edible tissues of salvaged carcasses from cattle which had reacted positively to the tuberculin test. The Committee was asked whether the results of the survey might impact on the ACMSF's 2002 assessment of possible health risks to consumers. Key results of this study were that 4.5% (19 from 110) of cattle with no visible lesions yielded viable *M. bovis* from carcasses or edible offal lymph glands while 4% (1 from 25) of animals with a single visible lesion and 5.5% (1 from 18) of animals with two or more visible lesions also yielded viable *M. bovis* from the carcass or edible offal lymph glands. The Committee agreed that the results from the research did not alter the outcome of their 2002 risk assessment. However, they supported the Report's recommendation that enhanced surveillance of human *M. bovis* infection should be maintained to alert the FSA to any significant indications that eating meat from *M. bovis* infected cattle constituted a health risk.

8. An EFSA risk assessment adopted in 2003, which took account of the results of the FSA funded research, concluded that the risks to public health through the consumption of meat from TB reactor animals are very low and did not justify any changes to existing meat hygiene controls. In 2003, the Irish Food Safety Authority published their own risk assessment which also identified the public health risk as very low and did not result in recommendations for tighter controls on meat from TB reactor cattle. A second edition was published in 2008[1].

9. In October 2009, the FSA Board requested that the Agency review the potential risks to consumers of meat and milk from cattle with evidence o*f M. bovis* infection. The request was made as a number of years have passed since the ACMSF last considered the issue and in that time the incidence o*f M. bovis* in the UK cattle population has increased. The Board would like reassurance that the current controls on meat and dairy products are adequate to protect human health given this rise.

[1] Zoonotic Tuberculosis and Food Safety 2nd edition, Food Safety Authority of Ireland

10. To facilitate the Committee's consideration of the current controls, the FSA has prepared this paper in association with Defra, MHS and devolved administrations to bring members up to date on changes to bTB control measures on farm and in the slaughterhouse.

11. In 2002, the Committee concluded that there were no concerns in relation to milk and dairy products as the exposure pathway seemed well protected by the existing legislation and controls and the Working Group did not consider these foods. However, the FSA Board have particularly requested reassurance on the efficacy of pasteurisation and the controls in relation to milk and dairy products. It is therefore proposed that an ACMSF ad hoc group is established to advise the Agency further in relation to milk and dairy products, focusing specifically on those which have been made from unpasteurised milk.

Paper Outline

12. This paper will provide information on the changes in the regulations and disease incidence which have taken place in relation to *M. bovis* infection in man and animals under the following headings:

- Update on human *M. bovis* infection
- Update on *M. bovis* infection in cattle
    - Controls in Great Britain
    - Controls in Northern Ireland
    - Recent changes in Scotland
    - EU approved UK TB Eradication plan
- TB in non-bovine domestic species
- Control measures to prevent transmission of *M. bovis* to humans
    - Meat
    - Milk and dairy products
- Proposed ACMSF ad hoc Group

UPDATE ON HUMAN *M. BOVIS* INFECTION

13. The HPA and its partner agencies carry out a national surveillance programme for TB in humans and publish an annual report presenting data for the UK. A total of 8,655 cases of tuberculosis in humans were diagnosed in the UK in 2008, a rate of 14.1 per 100,000 population[2].

14. Disease caused by *M. bovis* and *M. tuberculosis* is clinically indistinguishable and can only be differentiated by laboratory methods. Of all bacteriologically confirmed human tuberculosis cases, approximately 0.5-1.0% are caused by *M. bovis*. There are approximately 30 cases of *M. bovis* tuberculosis disease in humans reported each year in the UK (Table 1). The overall trend has been stable or one of decline for the period 1994-2008, against a rising number and rate of TB due to *M. tuberculosis*.

Table 1: Number of *M. bovis* cases in the UK by country 1994-2008

Year	England	Northern Ireland	Scotland	Wales	United Kingdom
1994	29	5	13	2	49
1995	17	2	10	3	32
1996	29	4	3	1	37
1997	32	3	11	0	46
1998	24	0	11	5	40
1999	28	4	6	3	41
2000	19	0	10	0	29
2001	24	1	2	6	33
2002	17	0	1	1	19
2003	15	2	4	0	21
2004	14	2	4	1	21
2005	24	7	4	4	*39
2006	26	2	5	0	33
2007	23	1	1	2	28
2008	22	2	2	2	+29
Total	343	35	88	30	497

* The high number reported in this year was associated with a cluster of human to human transmission cases reported in the West Midlands
+ Includes one isolate where country was unknown
Source: *M. bovis* database 07/12/2009.
Prepared by: Health Protection Agency Centre for Infections. Last reviewed: 06/01/2010.

15. Most cases of human tuberculosis due to *M. bovis* occur in people born in the UK before 1960, suggesting reactivation of old infection that was acquired when bovine TB was more prevalent in the UK cattle population and when

[2] Annual report on tuberculosis surveillance in the UK 2009.

pasteurisation of milk and cattle testing programmes were not so widespread. About 20% of cases occur in non-UK born persons (suggesting infection contracted abroad). A small number of human cases attributed to direct contact with infected animals have also occurred (occupational exposure). There is no evidence that these infections have been acquired through recent consumption of contaminated meat or dairy products derived from *M. bovis* infected animals in the UK.

16. The HPA has concluded that since the proportion of human TB cases due to *M. bovis* continues to be very low, the epidemic in bovine and non-bovine animal species is not spilling significantly into the human population. However, in view of the recent increase in bovine TB in cattle, the HPA has undertaken in the future to investigate more closely those cases likely to have been infected in this country[3].

17. There is no longer universal BCG vaccination of children against TB. Vaccination is only offered to babies at birth who live in areas with high rates of TB or whose parents or grandparents were born in a country with a high prevalence of TB. Vaccination is 70 – 80% effective at preventing disease.

[3] Annual report on tuberculosis surveillance in the UK 2008.

UPDATE ON *M. BOVIS* INFECTION IN CATTLE

18. The following information on TB in cattle has been provided by Defra and devolved agriculture departments and updates the Committee on changes to TB control measures since 2002.

CONTROLS IN GREAT BRITAIN

19. The bTB control policy in force in GB when the ACMSF report was compiled in 2001 was known as the Five Point plan. This had been announced in 1998 by the then Ministry of Agriculture, Fisheries and Food (MAFF) to take forward the recommendations of the Krebs' report and revolved around the following five priorities:

- Protection of public health, improved liaison between MAFF and the Department of Health and better monitoring of cases of human *M. bovis* infection;

- Maintain, and where possible strengthen, the regime of regular testing and controls to minimise spread of the infection between cattle;

- Long term research leading to the development of a vaccine against M. bovis infections in badgers and cattle;

- Further research into epidemiology and pathogenesis of bTB to improve understanding of how it is transmitted; and

- Quantify the impact of badger culling on bTB herd incidence by completing the Randomised Badger Culling Trial (RBCT).

20. The control measures in cattle herds during this period were substantially the same as those applied in previous years. However, the national testing programme, and much field-based bTB research, was significantly disrupted for most of 2001 due to a major outbreak of Foot and Mouth Disease. This resulted in anomalous bTB statistics between 2001 and early 2003. Tuberculin testing did not fully resume until early 2002, by which time there was a backlog of some 27,000 overdue herd tests. It was not until April 2003 that the number of overdue tests reduced to pre-FMD levels. The much reduced testing programme led to a marked fall in the number of TB breakdowns and reactors detected in 2001, followed by a sharp increase in 2002 as tuberculin testing recovered. Since TB testing resumed (after the 2001/02 FMD outbreak) there has been a significant increase in the number of reactors and breakdowns – this is thought to have been caused by the cessation of routine testing and higher prevalence in cattle and badgers.

21. Key bTB statistics for GB are presented in Figures 1 to 3 below. Due to the impact of the suspension of tuberculin testing during most of 2001, data for that year are not comparable with other years. Likewise, data for 2002 are not comparable with other years because testing resources were concentrated on herds that had overdue tests because of the testing backlog caused by the FMD

outbreak. Year-end data for 2009 will not be compiled until late March 2010, although the indications are that the number (and incidence) of herd breakdowns, as well as the number of cattle slaughtered for bTB control reasons have declined in relation to 2008.

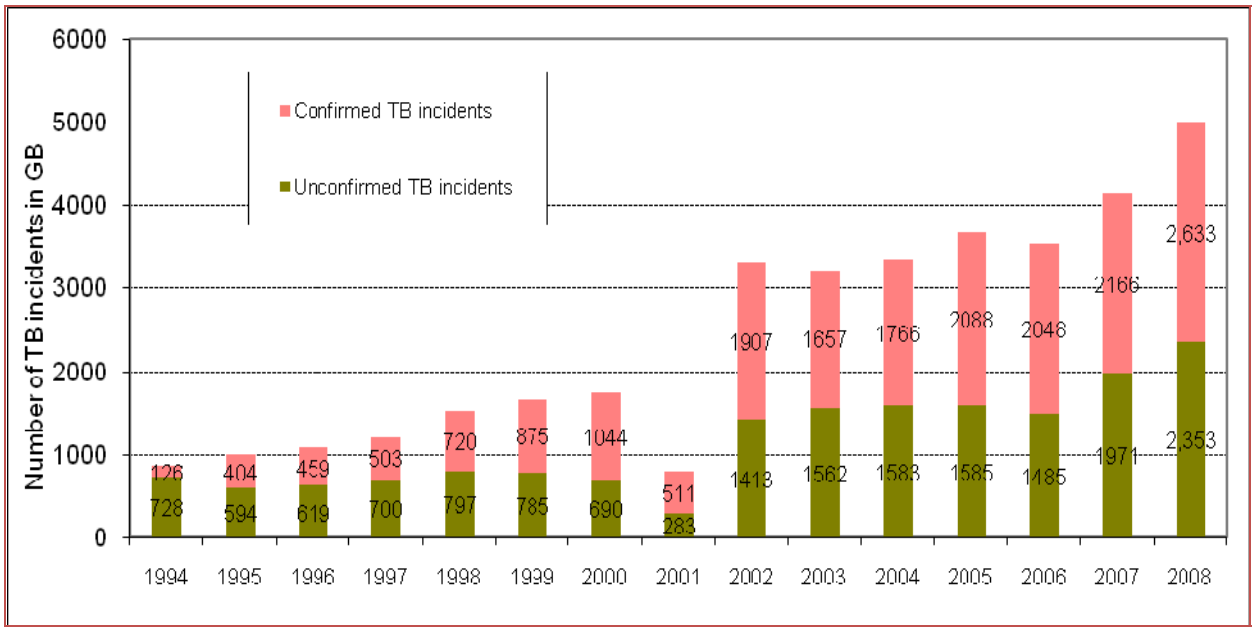

Figure 1 - Number of new bTB incidents (herd breakdowns) disclosed annually in GB (1994-2008) (source: Defra).

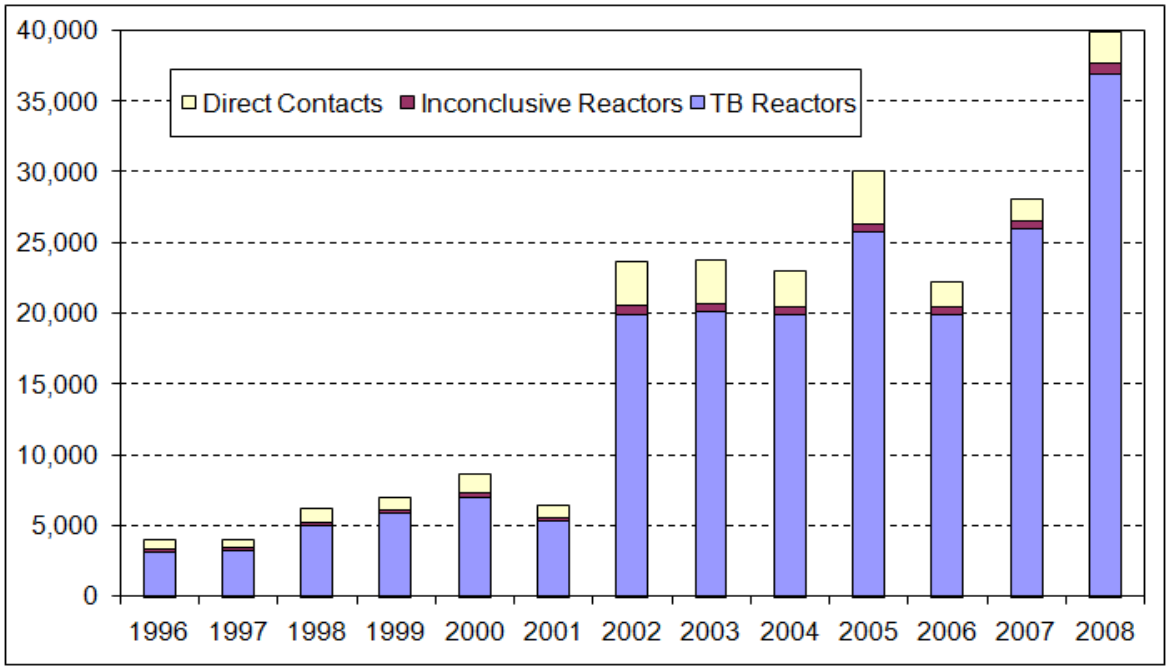

Figure 2 – Number of cattle slaughtered annually under the bTB control programme in GB (1996 – 2008) (source: Defra)

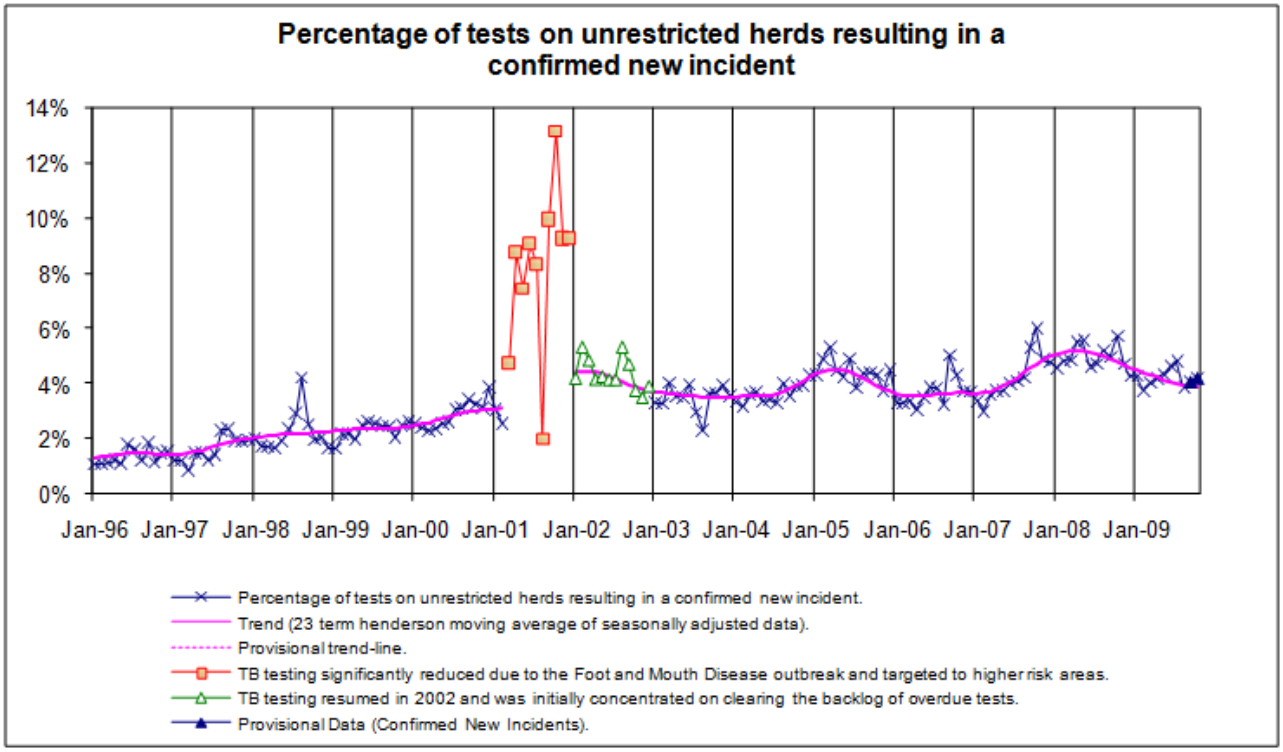

Figure 3 – Proportion of tests in unrestricted cattle herds in GB giving rise to a new bTB incident that was subsequently confirmed at post-mortem examination or by culture of *M. bovis* (source: Defra)

Additional control measures following 2001 FMD outbreak

22. In 2002, the Government introduced a package of additional control measures to mitigate the disease spread risks arising from the disrupted testing programme and the restocking of cattle premises in the wake of the FMD outbreak:

- Immediate movement restrictions on cattle herds in annual testing areas with an overdue 6 or 12 month check test;
- Phased movement restrictions on all other herds with overdue tuberculin tests;
- Promotion of private tuberculin testing;
- Annual testing of new and re-formed herds in the 3 years following restocking;
- Initiation of a field trial looking at the effectiveness of the gamma interferon (γ-IFN) blood test in reducing the duration of confirmed new TB breakdowns relative to the conventional approach of skin herd testing at 60 day intervals;
- New routes for licensed movements to slaughter of non-reactor cattle from TB-restricted premises (e.g. via approved finishing units and dedicated collections) introduced.

GB Strategic Framework

23. In March 2005, the GB Strategic Framework for the sustainable control of bovine TB was published. This recognised the importance of tailoring controls on a regional basis and that responsibility for policy is devolved. The GB Strategic Framework set out a 10-year vision for the development of a programme to control bovine TB with the express objectives of:

    - Slowing down and reversing the geographic spread of bTB into clean areas; and
    - Achieving a sustained reduction in incidence in high risk areas.

24. In working towards these objectives the Strategic Framework set out twelve goals including the need to: take a regional approach; work in partnership with stakeholders, in particular industry; ensure that cattle surveillance and controls are effective; base decisions on sound scientific evidence; and influence and comply with EU and international rules. A full list of these goals can be found at: http://www.defra.gov.uk/animalh/tb/strategy/goals.htm

Current position

25. Bovine TB remains the most serious endemic disease affecting the cattle industry in GB, particularly in the South West and Midlands of England and South and Mid-Wales (see Figures 4 and 5). Elsewhere in GB, sporadic bTB breakdowns are generally associated with the movements of infected cattle from high incidence regions.

26. The current bTB control programme is designed to detect *M. bovis* infection in the national cattle herd by routine testing of herds, slaughterhouse inspection of cattle carcases and targeted testing of herds and animals at risk (e.g. contiguous holdings, tracings and pre-movement testing). The cornerstone of the programme continues to be the routine tuberculin skin testing of cattle herds managed by Animal Health and performed according to a frequency dictated by the local incidence of bTB herd breakdowns. All test reactors and contacts are compulsorily removed with payment of compensation. Herds with test reactors and/or slaughterhouse cases undergo movement restrictions, short-interval testing and epidemiological investigations (including tracings), and occasional depopulation of severely infected units or groups of cattle.

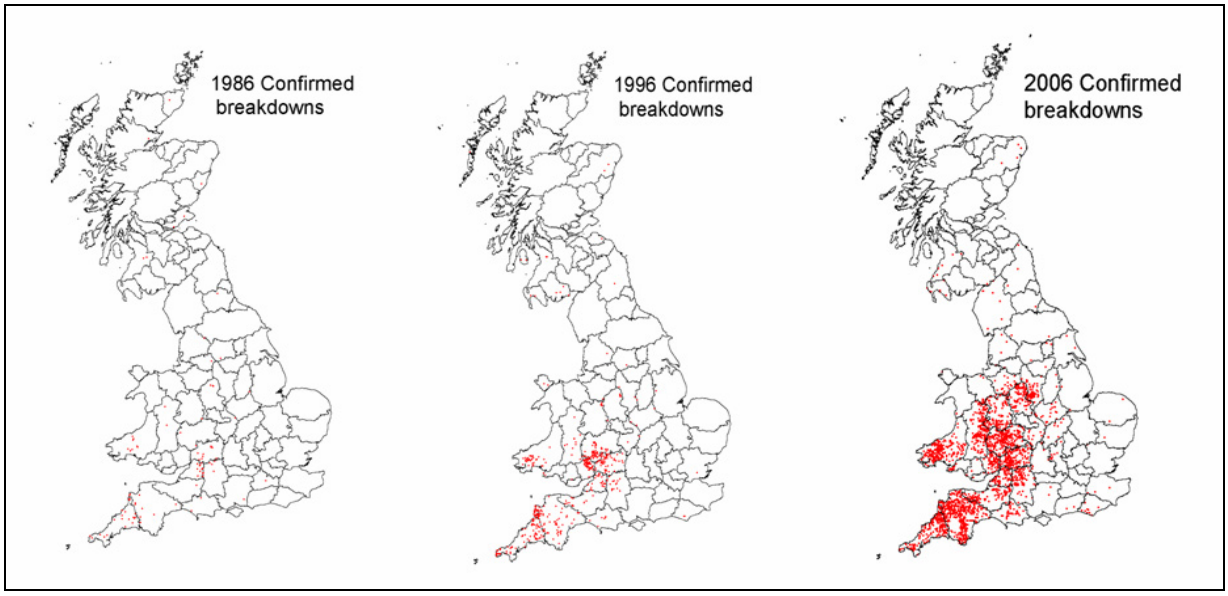

Figure 4 - Geographical distribution of all confirmed new bTB incidents identified in GB in 1986, 1996 and 2006 (source: VLA).

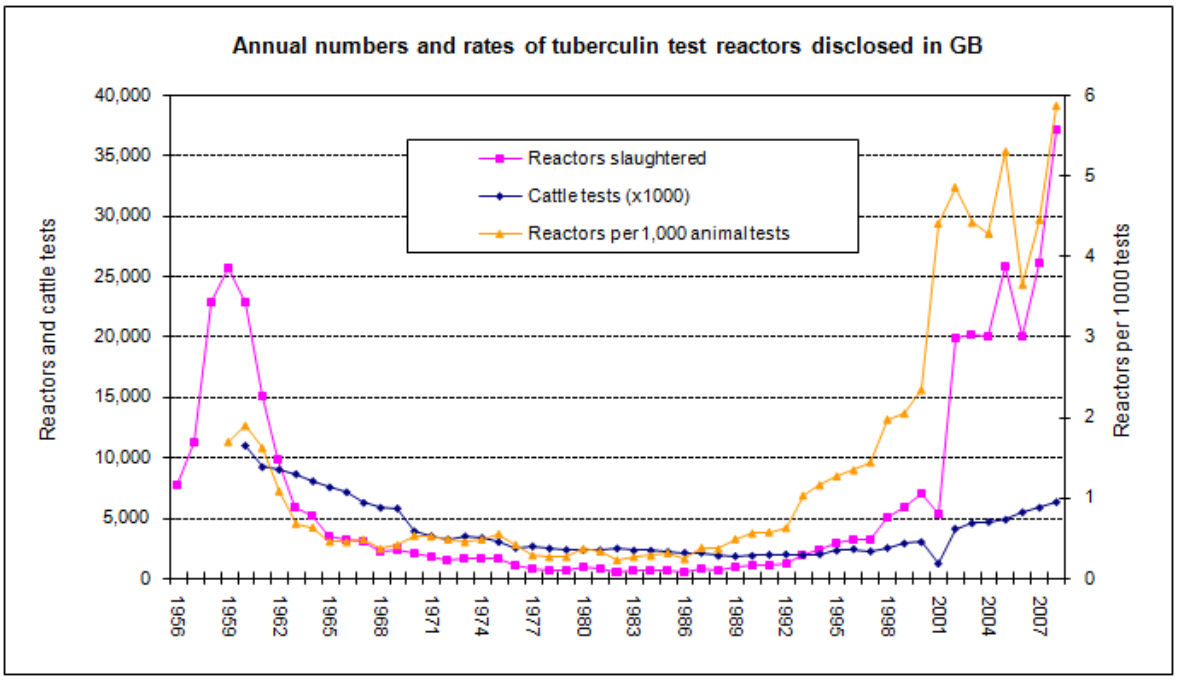

Figure 5 - Number of tuberculin reactors and animal tests (and rate of tuberculin test reactors per 1000 cattle tests) disclosed annually in GB (1956-2008) (source: CVO annual reports, Defra).

27. The majority of cattle slaughtered for bTB control purposes (i.e. those fit for human consumption) undergo post-mortem examination at licensed abattoirs and carcases are judged as to their fitness for human consumption in accordance with EU food hygiene regulations (Regulation (EC) 854/2004, Annex I). A representative sample of reactors from each affected herd also undergo fresh

tissue sampling for mycobacterial culture and molecular typing of *M. bovis* isolates at VLA as an aid to on-farm outbreak investigations.

28. The proportion of test reactors slaughtered in GB with demonstrable evidence of *M. bovis* infection at post-mortem examination (i.e. visible lesions or no visible lesions but positive culture results) continues to change over time. In the latter years it has fluctuated between 30% and 40%, compared with 50-60% during the 1990s and 2000 (i.e. the years of data used to inform the ACMSF risk assessment) (Figure 6).

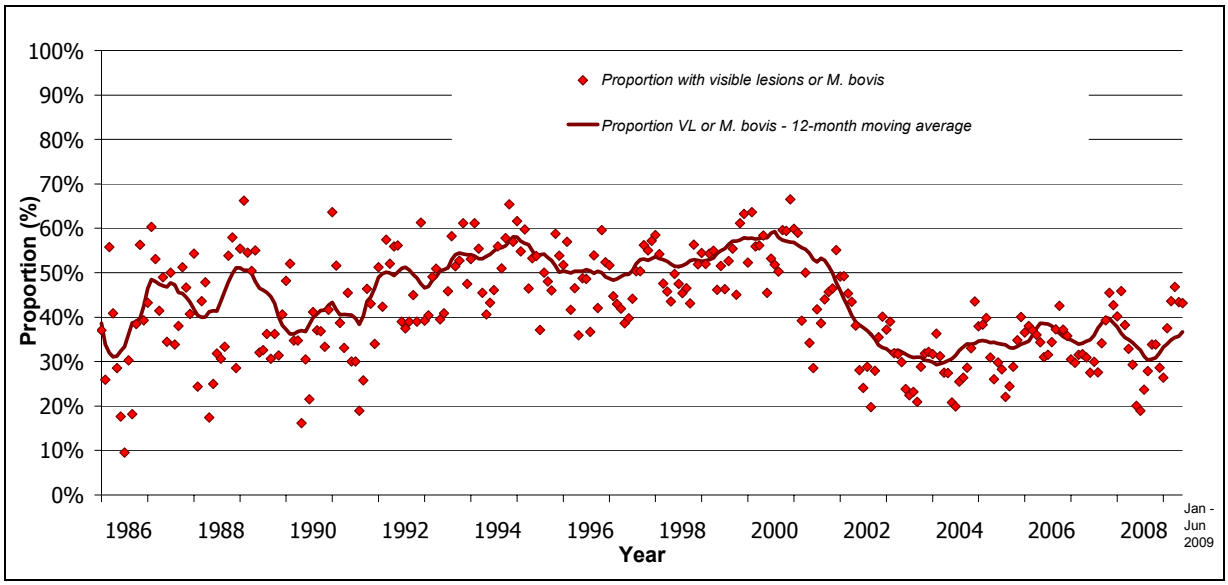

Figure 6 - Overall "confirmation rate" (proportion of VL and NVL-*M.bovis* positive) for reactor cattle removed by Animal Health in GB per month, between January 1986 and June 2009. The mean reactor confirmation rate in the period July 08 - June 09 was 34% (s.d. 9.0%) (source: VLA).

29. This active, on-farm bTB surveillance regime is supplemented by routine meat inspection of non-reactor cattle at commercial slaughter by the Meat Hygiene Service. In 2008 the MHS submitted to VLA tissue samples from 1,153 cattle carcases presenting with suspect bTB lesions at routine slaughter, of which 828 (72%) yielded *M. bovis* on culture. These so-called 'slaughterhouse cases' account, on average, for approximately 10% of total new bTB incidents and 17% of new confirmed bTB incidents detected in cattle herds in GB every year, although as expected, this proportion is much higher in the 4-yearly tested herds (Figure 7).

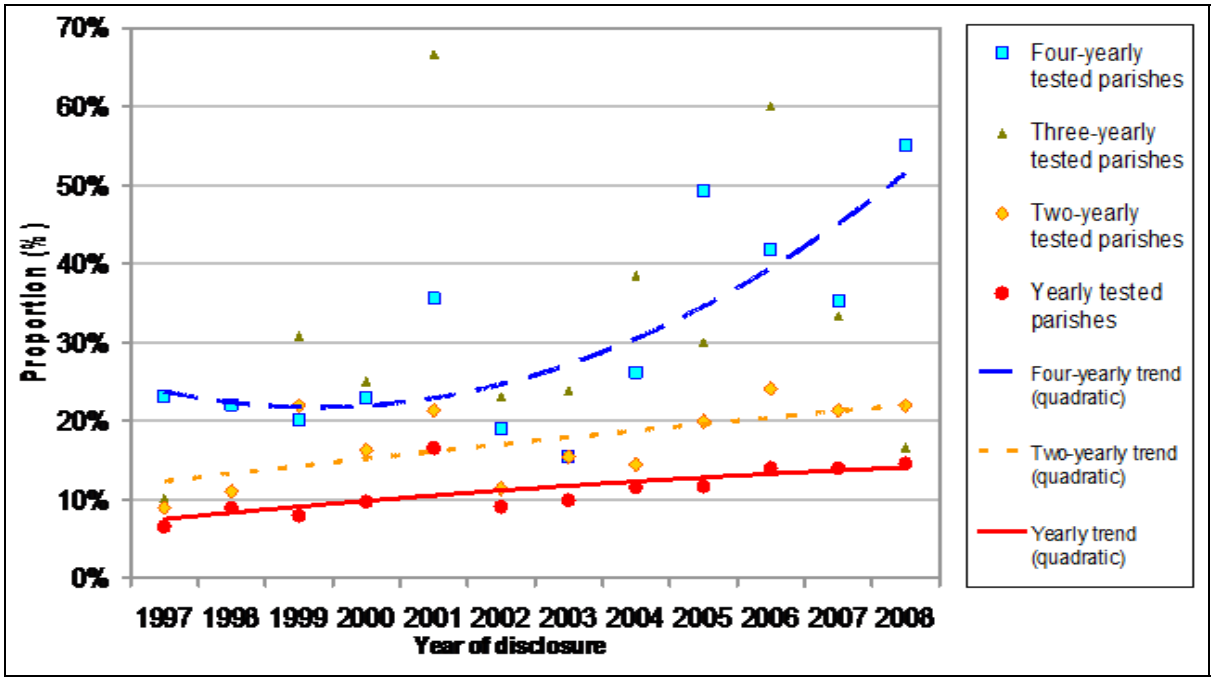

Figure 7 - Proportion of all confirmed new bTB incidents initiated by slaughterhouse cases between January 1997 and December 2008, by testing interval (source: VLA)

30. In response to the worsening bTB situation over the last decade, a number of specific enhancements to this programme have been introduced. The first raft of new measures were announced in the 2004 as part of the public consultation on the new Strategic Framework, and included:

- **Annual review of routine TB testing intervals**. This has resulted in year-on-year increases in the proportion of herds annually tested and the total number of herds and animals tested (Figure 8).
- Implementation of a new **'potential hot spots' policy** for enhanced bTB surveillance arrangements in a 3 km radius around new confirmed breakdowns, that are not readily attributable to infected cattle movements, in 3 and 4 yearly testing areas;
- More rigorous bTB testing schedules introduced for new and re-formed cattle herds (including annual testing for 3 years after restocking);
- Herd movement restrictions and suspension of OTF status as soon as a TB test becomes overdue (**'zero tolerance'** regime);
- Staggered testing (in 2, 3 and 4 yearly testing parishes);

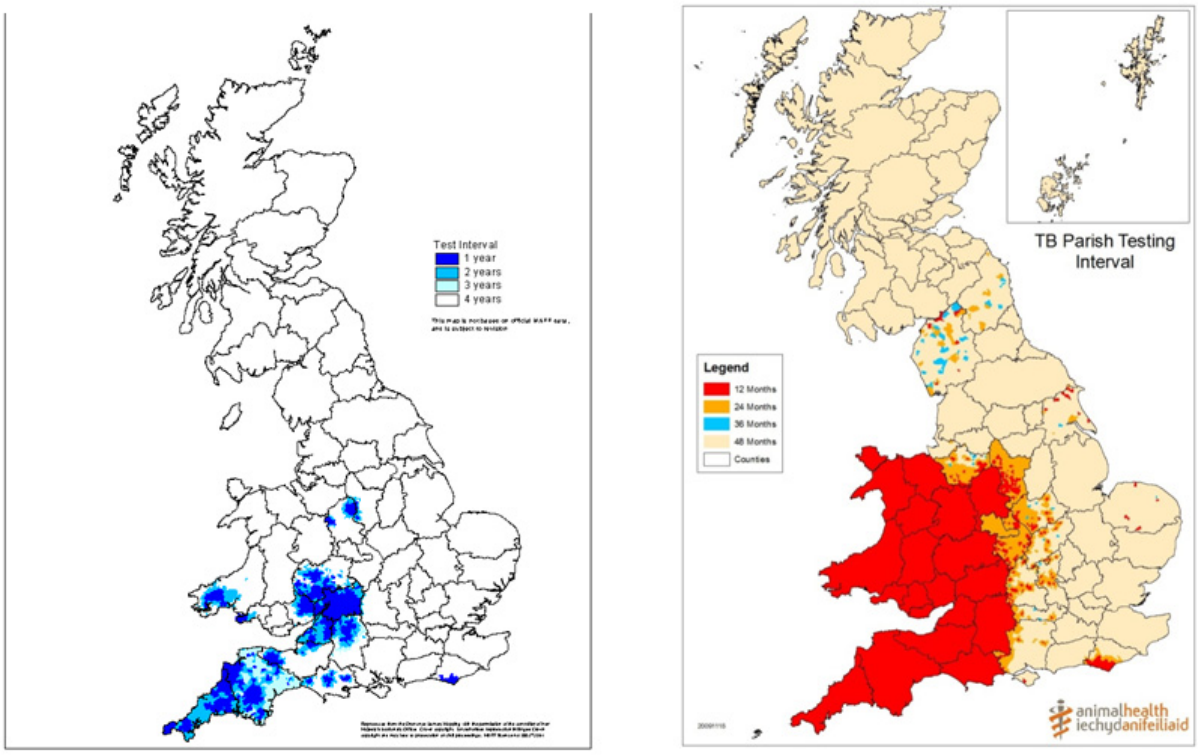

Figure 8 – Routine herd bTB testing frequencies in GB in 2000 (left) and 2010 (right). The maps illustrate the expansion of annual testing areas in the last 10 years, but please note the different colour schemes representing the four testing frequencies on both maps.

31. Additionally, compulsory pre-movement tuberculin skin testing of cattle was introduced in Scotland in September 2005 (alongside statutory post-movement testing), England (March 2006) and Wales (May 2006). This is targeted at movements of cattle from herds in the higher incidence areas (1 and 2 yearly testing), except for cattle sent to slaughter (directly or via a dedicated slaughter gathering). There are other types of exemption (e.g. for cattle under 42 days of age).

32. Between 1 March 2006 and 30 November 2009, 1,785 reactors were identified in 1,005 herds through dedicated pre-movement tests in England and Wales. A further 2,799 inconclusive reactors (IRs) were also identified. These figures are an underestimate of the impact of the policy since they do not take into account the benefits of herd owners utilising Government funded routine TB surveillance tests as pre-movement tests, or IRs identified by pre-movement testing which are reactors when retested. Infection is also being picked up earlier in high risk herds.

33. The pre-movement testing policy in England is currently under review. The review will gather information on the impacts, costs and benefits of pre-movement testing and make recommendations for policy changes that enhance the disease control framework and minimise any negative impacts on the livestock sector. Any recommendations from the review will be implemented from 2010.

Gamma interferon (γ-IFN) blood test

34. Although the single intradermal comparative cervical tuberculin test remains the primary screening method for bTB in cattle herds, the ancillary gamma interferon (γ-IFN) blood test has been used in the field since 2002 in certain scenarios. Between 2002 and 2006 this was mainly within the context of (i) a randomised field trial of selected herds with confirmed M. bovis infection (2002 – 2005) to evaluate its effectiveness in resolving TB breakdowns compared with repeat skin testing alone, and (ii) an ad hoc basis in other herds (generally with severe or persistent confirmed M. bovis infection) that did not qualify for that trial. Since October 2006 this in vitro test has been formally adopted in the legislation and in Animal Health procedures as an adjunct to the skin test in certain prescribed scenarios, primarily for enhanced sensitivity of the bTB testing regime in cattle herds with culture-confirmed M. bovis infection. Between October 2006 and December 2009, 77,919 animals underwent γ-IFN blood testing, of which 10,489 (13.5%) gave a positive result and were slaughtered as reactors.

Inconclusive reactors

35. The long-standing policy whereby inconclusive reactors (IRs) to the skin test were allowed up to two retests before being removed as reactors was also reviewed in late 2008 and 2009. On 1st March 2009, Scotland and Wales adopted a single retest policy on IRs, both in bTB breakdown and non-breakdown situations. England followed suit on 1 January 2010, bringing the treatment of IRs in GB in line with the requirements of Directive 64/432/EEC, i.e. IRs are now removed as reactors if they fail to resolve at their first re-test. Defra have estimated (based on current disease trends) that this change in policy will result in the identification of an additional 900 reactor animals and approximately 370 new herd bTB incidents in England in the first few a years of its implementation.

CONTROLS IN NORTHERN IRELAND

36. Although NI is subject to the same legislative requirements as the rest of the UK, disease control has always been devolved and the position in NI has distinctive features from GB, both in terms of disease and in terms of control measures. All herds are now designated Officially Tuberculosis Free (OTF), Suspended (OTS) or Withdrawn (OTW) at all times. These designations indicate the herd trading status for EU purposes.

37. Herd incidence of bTB in NI peaked in 2001/2002 at about 10%, has declined to about 5.5% and remained at this level for the past two years (see Fig 9). Whilst there are areas with higher herd incidence, the disease is less geographically demarcated than in GB.

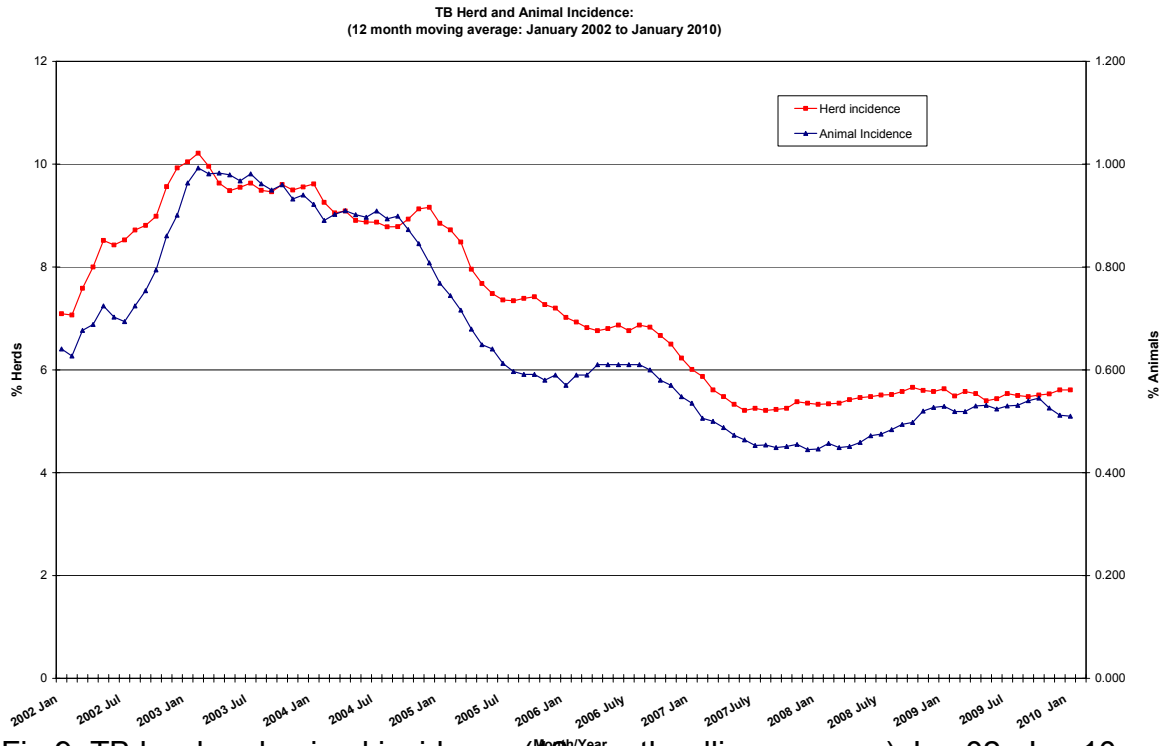

Fig 9: TB herd and animal incidence (12 month rolling average) Jan 02- Jan 10

38. Surveillance is through a twin approach - live animal and abattoir based – and both are fully under the competence of DARD. Disease information, test results information and movement control are effected through the Animal and Public Health Information System (APHIS). This is a live database coordinating all the elements required for disease control.

39. Live animal surveillance, controlled by DARD, is primarily based on the comparative intradermal skin test, supplemented where required by ancillary gamma interferon (γ-IFN) blood test. Routine surveillance requires a herd test within 1 year. However just under 30% of herds in NI undergo more frequent testing as a result of epidemiological investigations. From 2004, live animal movement control restrictions are automatically placed on herds that do not complete a herd test within this time. Failure to test cattle within 13 months attracts a further restriction on movement to slaughter.

40. All reactors disclosed by live surveillance are compulsorily removed and compensation paid. Movement restrictions are applied and epidemiological investigation and tracing is undertaken. Depopulation may occur where considered necessary for disease control. Reactors are removed by DARD and slaughtered in one contracted abattoir.

41. Although the single intradermal comparative cervical tuberculin test remains the primary screening method for bovine TB in cattle herds, the γ-IFN blood test has been used in the field in Northern Ireland since 2004.

    - Between July 2004 and June 2006, it was used in a field trial of centrally selected TB breakdown herds with a chronic history of confirmed *M. bovis* infection during the 2 calendar years preceding selection.

- In early 2007, gamma interferon testing was offered on an ad hoc basis in locally selected breakdown herds throughout NI (generally with history of confirmed *M. bovis* infection) without offer of purchase of all γ-IFN positive animals.
- Since July 2007, this assay has been available in centrally selected breakdown herds as an adjunct to the skin test in certain prescribed scenarios, primarily for enhanced sensitivity of the bTB testing regime in cattle herds with culture-confirmed *M. bovis* infection. Herds are recruited locally and participation is voluntary, as is surrender of any γ-IFN positive non intradermal reactors, with compensation at full market value.

42. Between January 2007 and December 2009, 37,024 animals underwent γ-IFN blood testing, of which 2734 (7.4%) gave a positive result. This is out of a total cattle test population of about 1.6 million. Of these 2134 (5.8% of total tested) were not intradermal reactors and 1386 (64.9%) of these were voluntarily slaughtered.

43. Blanket pre-movement testing is not applied in NI as it is not considered appropriate given the epidemiology of the disease and the control measures already in place. Since 2008, further restrictions to live market are placed upon animals that have had not been tested within 15 months. These restrictions may be removed by pre-movement testing of the animal. Removal of inconclusive reactors that do not give a negative result at first retest was implemented from 1 January 2010 and is expected to result in approximately another 300 herd incidents per annum.

44. During 2008, there were 1,066 animals detected with suspect TB lesions at routine slaughter with 638 (60%) confirmed through the culture of *M. bovis*. This is out of a total cattle test population of about 1.6 million. Of the 1,412 herds with confirmed bTB infection during 2008, 335 herds (23.7%) had TB confirmed through animals with lesions at routine slaughter only.

RECENT CHANGES IN SCOTLAND

45. On 8 September 2009 the European Commission granted Scotland officially bovine tuberculosis free (OTF) status, reflecting the low and stable incidence of bTB in Scottish herds. Given the ongoing risk of bTB incursions from neighbouring countries, and as the majority of recently disclosed new confirmed incidents in Scotland have been found in cattle introduced from neighbouring countries, controls on movements of cattle into Scotland remain in place to protect this regional OTF status. These are mainly in the form of statutory pre- and post-movement tuberculin skin testing for live cattle imported from England, Wales, Northern Ireland and the Republic of Ireland.

46. Whilst routine skin testing is not required in an OTF country or region, the Scottish Government has decided to retain the current four-yearly testing regime of Scottish cattle herds during a six-year transitional period. Other routine bTB surveillance measures will continue in Scotland as follows:

    - abattoir surveillance through meat inspection

- reporting of suspect clinical cases
- source and spread tracing of breakdowns
- gamma interferon testing for all new confirmed breakdowns
- laboratory surveillance and statutory requirement to notify isolations of *M. bovis* from mammals, carcases and environmental samples.

EUROPEAN COMMISSION APPROVED UK TB ERADICATION PLAN

47. In November 2009, the Commission formally agreed the UK bovine TB Eradication Plan for 2010 which sets out our current programme for the surveillance, control and eradication of TB in cattle in the UK. It also acts as an application for European Union (EU) funding to support certain TB measures - the Commission have committed up to €10 million in 2010 towards compensation and testing costs.

TB Eradication Group for England

48. In working towards the eradication of bTB, the Government is committed to working with key stakeholders. The TB Eradication Group for England was established in November 2008 and is made up of representatives from Defra (including the Government's Chief Veterinary Officer), Animal Health, the farming industry and the private veterinary profession. This Group has been tasked with reviewing the strategy and recommending improved measures for the control and eradication of bTB in England. They have identified a number of priority issues including optimisation of the frequency and targeting of bTB testing in the surveillance regime, options for reducing the risk from animal movements, and management of the wildlife risk including vaccination and reviewing new scientific evidence.

TB Eradication Programme for Wales

49. Under "One Wales: A progressive agenda for the government of Wales" there is a commitment to 'vigorously pursue a programme of bovine TB eradication' in Wales. This commitment is being delivered through the TB Eradication Programme for Wales. The Programme has already introduced a number of changes including annual and pre-movement bTB testing of all herds in Wales following the completion of the 'TB Health Check Wales' (an initiative to skin test all cattle herds in Wales between October 2008 and December 2010), changes to the IR policy in line with Directive 64/432/EEC (as outlined above) and will be looking to introduce further measures in the Principality.

50. The TB Eradication Programme for Wales is comprehensive, using all means possible to tackle the problem. The Welsh Assembly Government takes the view that in order to achieve its aim of eradicating bTB it has to tackle the disease in cattle and badgers and is, therefore, establishing a pilot area in a small part of west Wales, where a limited badger removal project will take place alongside stricter cattle disease control measures.

51. The Programme also recognises that the incidence of bTB differs across Wales. In order to address the disease at a local level three Regional Eradication Delivery Boards have been set up across Wales. These Boards are made up of a range of stakeholders with a practical involvement in bTB including local farmers, private veterinarians and local authority officials. In North Wales, for example, where bTB levels are fairly low it is important to take measures to clear bTB from herds and stop new infection coming in.

TB IN NON-BOVINE DOMESTIC SPECIES

52. The following information on TB in non-bovine domestic species (i.e. goats, sheep pigs) has been provided by Defra and devolved agriculture departments and updates the Committee on changes to TB control measures since 2002.

Great Britain

53. The TB control framework for non-bovine domestic species was tightened up in February 2006 with a revision to the TB Orders for England, Wales and Scotland. Since February 2006, animal keepers, meat inspectors and veterinarians have been legally required to notify Animal Health (AH) of any suspect tuberculous lesions identified at post-mortem examination of any farmed or pet mammal. The revised Orders also introduced a statutory obligation to report to VLA Weybridge all *M. bovis* isolates from tissues and clinical samples taken from any mammals except humans.

54. Annual numbers of non-bovine, meat-producing domestic animals disclosed as having TB caused by *M. bovis* infection are published on Defra's bovine TB website (and updated on a quarterly basis) at:

    http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/tb-otherspecies.pdf

55. It is difficult to establish what proportion of the increasing number of reported cases has arisen as a result of better surveillance and awareness of TB in non-bovine hosts and how much is due to a higher risk of spillover from infectious cattle and badgers. In some years the figures are somewhat biased by the disclosure of large numbers of infected animals on a small number of farms or by the results of follow up TB testing conducted by AH (e.g. to control an outbreak of caprine TB in a series of small goat holdings in 2008) . Nevertheless, they show that meat inspectors and VLA regional laboratories continue to identify a low number of tuberculous goat, pig, and sheep carcases year on year. These sporadic TB incidents in non-bovine domestic species arise almost invariably in areas of England and Wales sustaining an endemic high incidence of cattle TB breakdowns.

56. When a culture-confirmed episode of *M. bovis* infection is disclosed in farmed animals other than cattle, movement restrictions are immediately applied on the herd/flock of origin and a veterinary risk assessment of the premises is carried out by AH. As with all confirmed incidents of *M. bovis* in cattle, AH will also

inform the Consultant in Communicable Disease Control of the Local Health Protection Unit. Movement restrictions are usually lifted only once the affected herd or epidemiological group have been removed and slaughtered and after any tuberculin skin testing has been completed with satisfactory results, i.e. no reactor animals left on the premises. Ante-mortem TB testing of these species and removal of test reactors is voluntary.

Northern Ireland

57. Bovine TB in other species is notifiable in NI. No action is taken in respect of movement restriction, disease control or testing and compensation in these species outside the risk they pose to bovines. If they are considered significant in a bovine episode, restrictions on movements and disease control measures are placed on the cattle herd as required.

CONTROL MEASURES TO PREVENT TRANSMISSION OF *M. BOVIS* TO HUMANS

MEAT

58. The following has been provided by the MHS and DARD and updates the Committee on changes to inspection arrangements since 2002.

Controls in Great Britain

Ante Mortem Inspection

59. Ante-mortem inspection requirements are contained in Regulation (EC) 854/2004, which replaces the Fresh Meat (Hygiene and Inspection) Regulations 1995, as amended, in place at the time when the ACMSF carried out their risk assessment in 2001. Inspection of animals intended for human consumption must be performed by the Official Veterinarian (OV) at the slaughterhouse within 24 hours of arrival and less than 24 hours before slaughter.

60. The regulations also allow that ante-mortem inspection may be carried out at the holding of provenance rather than in the slaughterhouse if this is carried out by an OV or an Approved Veterinarian and the results of the inspection and documentary checks are communicated to official staff at the slaughterhouse. However this option has very rarely been taken up.

61. The EC regulations have introduced the new requirement that abattoir operators request their suppliers to provide food safety information (Food Chain Information or FCI) about their animals and act upon this information. The official veterinarian must check this information and take account of this when doing the ante-mortem and post-mortem inspections. This has been implemented in a staged approach for different species and the need of FCI for cattle came into force in January 2010.

62. The Competent Authority (FSA) has to provide guidance on the minimum elements of FCI. This, for cattle, includes the need for producers to declare

whether their holding is under movement restrictions due to bTB. AH have also introduced a requirement for all cattle destined for slaughter from bTB restricted herds to be identified by means of an orange stripe along the back of the animal, irrespective of the bTB status of individual animals.

63. Both the FCI and the orange stripe alert the OV that animals have come from bTB restricted herds, even when the individual animals may not be compulsorily slaughtered by AH (i.e. non-reactor or contact cattle can be transported to the abattoir under a general licence issued by AH).

64. In addition to the above, any animal compulsorily submitted for slaughter by AH as a "reactor", "inconclusive reactor" or "direct contact" will be sent to the abattoir with a movement licence TB24. This also applies to inconclusive reactor animals voluntarily sent for slaughter by the keeper.

Post Mortem Inspection

65. Suspect bTB animals slaughtered as part of disease control are normally batched and slaughtered on previously agreed days. They should ideally be slaughtered either last in the day, before the full cleaning and disinfection of the slaughter line, or slaughtered and dressed in a dedicated room in the abattoir. They may also be slaughtered at other times provided that the slaughter hall is cleaned and disinfected before processing other animals. These instructions have been incorporated to the MHS Manual of Official Controls (MOC)[4] .

66. Post-mortem meat inspection requirements are also provided in Regulation (EC) 854/2004. The legislation provides for partial or total seizure and subsequent disposal is required for parts deemed unfit for human consumption.

67. In contrast with previous legislation, there are no additionally prescribed post-mortem inspection requirements for the examination of carcases where bTB is suspected.

68. Notwithstanding this, bTB suspect cattle (whether sent for slaughter with a TB24 movement licence or found to have suspect TB lesions during post-mortem inspection) a higher level of inspection is applied as per guidelines agreed with Defra and AH. These are based on the additional inspection requirements in former domestic legislation.

Judgement of Tuberculosis at Post Mortem Inspection

69. In accordance with (EC) 854/2004, Annex I, Section IV, Chapter IX, E all meat from animals in which post-mortem inspection has revealed localised tuberculous lesions in a number of organs or a number of areas of the carcase is declared unfit for human consumption. However, when a tuberculous lesion has been found in the lymph nodes of only one organ or part of the carcase, only the affected organ or part of the carcase and the associated lymph nodes need to be declared unfit for human consumption. These legislative requirements have been incorporated into the MOC.

[4] This implements recommendation 6: that suspect animals are either slaughtered last in the day, before the full cleaning and disinfection of the slaughter line, or are slaughtered in a dedicated room in the abattoir.

70. In Great Britain, there are three possible actions by the MHS in relation to reactor carcases and suspect slaughterhouse cases of bTB encountered during commercial slaughter of non-restricted cattle:

    - Pass the carcass and offal if MHS staff are certain that there is no evidence of TB;
    - Partial seizure, with the remainder going forward as fresh meat if the MHS consider it to be a localised infection of TB;
    - Total seizure of carcase and offal as unfit for human consumption if the MHS officers consider it a generalised infection of TB.

71. Where an animal is found to have a tuberculous-like lesion at routine post-mortem meat inspection ('slaughterhouse cases'), the MOC requires that the carcase and offal be placed in the detained area before further detailed inspection and before any samples are collected.

72. The final judgement as to the fitness for human consumption of carcasses and offal is a matter for the OV. AH, with the assistance of the MHS, is responsible for arranging the collection of relevant samples and subsequent submission to the laboratory for analysis.

73. Following trials during 2009, AH and the MHS are now introducing significant changes to the procedures for the collection of samples of bTB suspect cattle. New data collection systems being developed will permit electronic recording of the type of lesions found and the decision about the fitness of carcases and will link these to the results of the VLA laboratory analysis. These new arrangements will be gradually introduced to England and Wales during 2010.

Controls in Northern Ireland

74. Meat inspection of all routinely slaughtered bovines remains under the direct control through in house inspection by DARD staff. All post mortem examination information for bTB is entered onto APHIS and is immediately available for field officers. Further laboratory investigation as appropriate is undertaken by AFBI and reported through APHIS. All culture positive reactors are variable number tandem repeat (VNTR) typed and this information is available for epidemiological decision making.

MILK AND DAIRY PRODUCTS

Cows' and buffaloes' milk

75. Regulation (EC) 853/2004 requires that raw cows and buffaloes milk shall come from animals belonging to a herd which is officially tuberculosis free (OTF). If OTF status is lost (i.e. when Animal Health or DARD issue movement restrictions on a herd following disclosure of tuberculin test reactors, etc.) then milk from the reactor animals is not permitted to go for human consumption and milk from the non-reactor animals in the herd must be pasteurised. The minimum pasteurisation time/temperature stipulated in the legislation (72°C for 15s) destroys *M. bovis*, therefore pasteurisation provides a safeguard to consumers of milk and dairy products, provided it is properly carried out. The majority of raw milk entering the food supply chain in the UK is pasteurised. There are no known sales of raw cows' drinking milk direct to the consumer in N. Ireland and sales in Scotland have been banned since 1983.

76. For cattle herds in England and Wales whose milk is sold as raw drinking milk direct to the consumer, it is Defra policy to require them to be TB tested annually. If officially TB free (OTF) status is lost then sales of raw drinking milk must cease until it is regained. Fewer than 100 retailers of raw cows' drinking milk now exist in England and Wales, compared to several hundred in 2001. Milk is only allowed to be sold direct to consumers at the farm gate or in a farmhouse catering operation, through milk roundsmen or at farmers markets. All such milk must carry the health warning 'This milk has not been heat treated and may therefore contain organisms harmful to health'. In Wales, the warning also highlights the risks to vulnerable groups. Sales of raw drinking milk and cream from any species are banned in Scotland. Northern Ireland has similar controls to England and Wales but there are no known sales.

77. Regular tuberculin testing of dairy herds and rapid removal of tuberculin reactors means that clinical cases of bTB and udder TB lesions are now rare. However, there remains a risk from unpasteurised milk or dairy products derived from animals which become infected and develop lesions between the routine tuberculin tests.

78. In cases where herds providing milk to raw milk cheesemakers lose their TB free status, the local food authority will carry out a risk assessment on the public health implications for any products made prior to the loss of status and any control measures necessary. This assessment is undertaken locally with the Consultant in Communicable Disease Control (CCDC) and Animal Health. Guidance issued to Local Authorities by the FSA sets out detailed information on the factors to take into account when making such a risk assessment e.g. the TB history of the herd, the number of reactors found, whether the reactors were milk producing animals and tissue culture results[5]. The FSA are currently funding a project (end date autumn 2010) to investigate the survival of *M.*

[5] Food Law Practice Guidance (England) ANNEX 8, APPENDIX 1: Guidance to Food Authorities in England on Officially Tuberculosis Free Status and Dairy Hygiene Legislation

bovis in raw milk cheeses, the results of which should help inform any future risk assessments.

79. Advice on the investigation and management of potential human contacts is included in guidance issued to CCDCs and Chief EHOs by the National Institute of Clinical Excellence. Screening is generally recommended only in the case of those less than 16 years old who have not been vaccinated and who may have consumed unpasteurised milk or dairy products from affected animals with proven or possible udder infection.

Sheep and goats' milk

80. The legislative requirements in Regulation (EC) 853/2004 for species other than cows and buffaloes which are susceptible to TB are less clear and work is ongoing to clarify the testing requirements. However, the legislation requires that raw milk from sheep and goats must come from herds which are regularly checked for this disease under a control plan that the competent authority has approved. In addition, if goats are kept with cows, such goats must be inspected and tested for TB when *M. bovis* infection is found in a co-located cattle herd.

PROPOSED ACMSF AD HOC GROUP

81. In order to progress this matter without further delay, members are asked to agree in principle to the setting up of an ad hoc group to consider in more detail the risks of *M. bovis* from milk and milk products. Suggested terms of reference are:

"To review the possible health risks associated with consumption of milk and dairy products from animals with evidence of *M. bovis* infection, specifically those which have been made from unpasteurised milk, and to advise on the adequacy of current control measures."

March 2010