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*Programmes for the eradication, control and monitoring of certain
animal diseases and zoonoses*

Eradication programme for Bovine Tuberculosis

United Kingdom

Approved* for 2013 by Commission Decision 2012/761/EU

* in accordance with Council Decision 2009/470/EC

UK BOVINE TB ERADICATION PLAN 2013

Standard requirements for the submission of national programmes for the eradication, control and monitoring of the animal diseases or zoonoses referred to in Article 1(a)¹

1. Identification of the programme

Member State: *United Kingdom*

Disease(s)²: *Bovine Tuberculosis*

Request of Union co-financing for³: *2013*

Reference of this document: *UK Bovine TB Eradication Plan 2013*

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Date of submission to the Commission: 14th September 2012

¹ In the case of the second and subsequent years of a multi-annual programme that has already been approved by a Commission Decision, only section 1, section 7 and section 8 need to be completed.

² One document per disease is used unless all measures of the programme on the target population are used for the monitoring, control and eradication of different diseases.

³ Indicate the year(s) for which co-financing is requested.

ANNEX I – ENGLAND ERADICATION PLAN

Standard requirements for the submission of national programmes for the eradication, control and monitoring of the animal diseases or zoonoses referred to in Article 1(a)⁴

1. Identification of the programme

Member State: *United Kingdom (England)*

Disease(s)⁵: *Bovine Tuberculosis*

Request of Union co-financing for⁶: *2013*

Reference of this document: *UK (England) Bovine TB Eradication Plan 2013*

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⁶ Indicate the year(s) for which co-financing is requested.

2. Historical data on the epidemiological evolution of the disease(s)⁷:

2.1 Bovine TB (bTB) is a chronic infectious disease and in the UK there is more than one maintenance reservoir with multiple routes of transmission. Current annual England spend on bTB controls is about £100m, of which compensation and testing make up the largest share.

2.2 Historically the long-term trend has been a worsening bTB situation in England resulting from a combination of both increasing overall incidence and spread of the disease to new geographical areas. Annual herd and animal incidence peaked in 2008 then fell in 2009 stabilising towards the second half of 2010 and increasing again in 2011. However, this increase was consistent with the additional testing effort made during 2011, which led to 2.0% more bTB herd tests and 1.9% more animal tests being completed than in the previous year (5.49 million in 2011 against 5.38 million individual tests in 2010). See section 2 of the Plan for more detail. The annual rate of increase in new breakdowns has slowed down since 2003 but bTB continues to be a problem, particularly in the South West and Midlands of England. Other parts of England are pretty much free of bTB with only sporadic breakdowns, generally associated with movements, which are dealt with quickly. We have a particular problem in that there is clear evidence that the sustained high disease incidence in the south-west and west of England is in part due to transmission of TB from badgers to cattle.

2.3 The efforts to eradicate bovine tuberculosis from Great Britain (GB) pre-date the first legal initiatives in this area at European Community (EC) level and were initially driven by public health concerns and the desire to increase the productivity and welfare of the national cattle herd. The voluntary herd schemes up to the 1950s were replaced by compulsory schemes. The **whole of GB became 'attested' on 1st October 1960** (i.e. each cattle herd was certified as being subject to regular tuberculin intradermal testing with immediate slaughter of any reactors). For the next two decades

⁷ A concise description is given including target population (species, number of herds and animals present and under the programme), the main measures (sampling and testing regimes, eradication measures used, qualification of herds and animals, vaccination schemes) and the main results (incidence, prevalence, qualification of herds and animals). The information is given for distinct periods if the measures were substantially modified. The information is documented by relevant summary epidemiological tables (in point 6) complemented by graphs or maps (to be attached).

there was a steady decline in the incidence of reactor cattle, clinical cases and infected herds detected and every year new counties would be designated bTB-free areas in which the herd testing frequency could be gradually relaxed to reflect the improved situation. Following the accession of the UK to the European Community (EC; later the European Union, EU) in 1973, British cattle producers were required to comply with the rules laid down in **Directive 64/432/EEC** (as amended), including certification of bTB testing of exported animals and official bTB freedom of herds.

2.4 The Eurasian badger (*Meles meles*) was first identified as a possible wildlife reservoir of infection for cattle in the early 1970s in parts of the Southwest of England where a high incidence of bTB persisted despite enhanced herd control measures (bTB „hotspots’). A series of different strategies were developed throughout the 1970s, 80s and 90s to tackle this wildlife source of *M. bovis* in England and Wales (there is no evidence of such a reservoir in Scotland), along with further cattle-based measures. In 1979 the lowest bTB incidence was recorded in GB, with 0.49% of all herds tested having a reactor, which equated to 0.018% of all cattle tested.

2.5 However, the progressive reduction in bTB incidence stalled in the mid-1980s (Figure 1). Bovine TB herd incidence in the Southwest of England had remained about three times higher than in the rest of GB, despite the retention of an annual (and occasionally more frequent) tuberculin herd testing regime in those areas. Gassing (1975-1982) and „clean ring’ (1982-1986) strategies were used prior to an „interim’ badger culling strategy in place between 1986 and 1997, whereby badgers were removed only from farms where a bTB incident had been confirmed by culture of *M. bovis* and where, following investigation, it was thought that badgers were the most likely source.

2.6 In 2001, the national bTB testing programme, as well as most field-based bTB research projects, were severely disrupted due to a major outbreak of **Foot and Mouth Disease**, which led to anomalous bTB statistics from 2001 to early 2003. This led to a marked fall in the number of bTB breakdowns and reactors detected in 2001, followed by a sharp increase in 2002 as tuberculin herd testing resumed (Figure 1).

2.7 The **Krebs’ report** published in 1997 concluded that, “the sum of evidence strongly supports the view that, in Britain, badgers are a significant source of infection in cattle.” The main recommendation stemming from this review was to set up a controlled field experiment (the **Randomised Badger Culling Trial – ‘RBCT’**) overseen by the **Independent Scientific Group on cattle TB (ISG)** to quantify in a scientific way the impact of culling badgers on TB incidence in cattle. Immediately after the publication of the report in December 1997 the Government suspended all badger removal operations, pending the implementation of this trial.

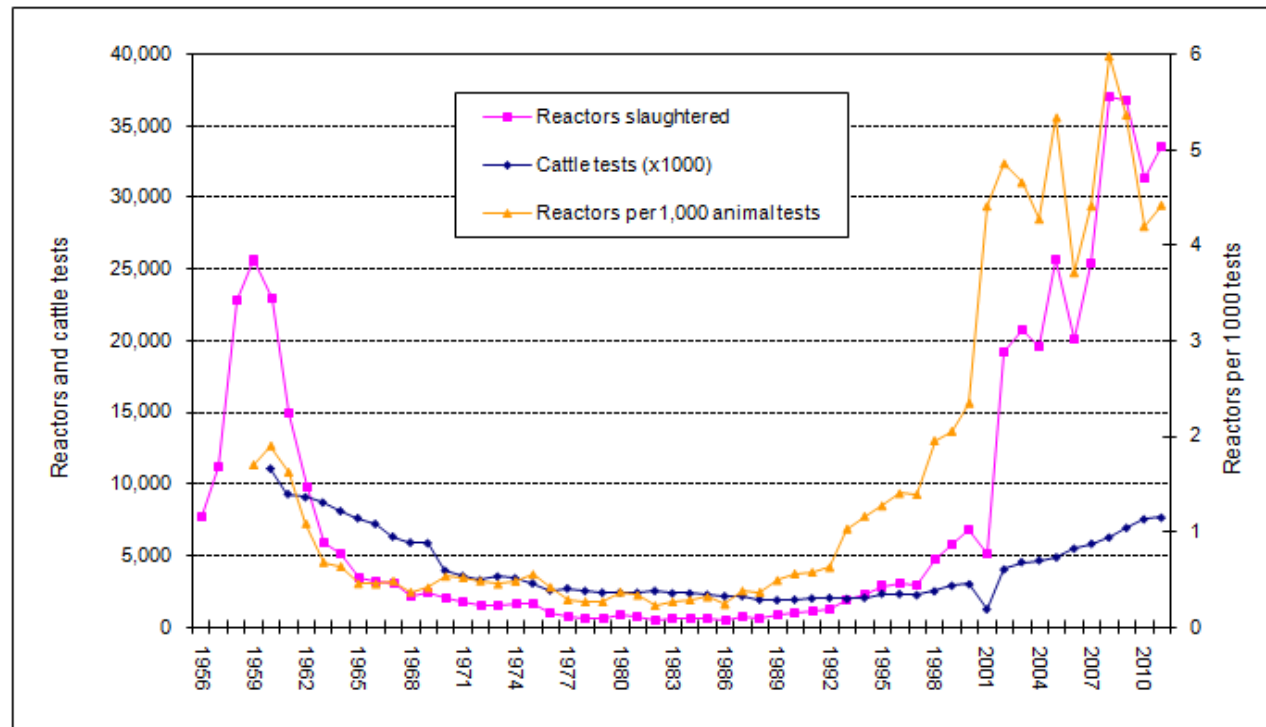


Figure 1 - Annual number and rate of bTB test reactors disclosed in GB between 1956 and 2011. The data series to 2006 consists of tuberculin skin test reactors only. From 2007 onwards the data also include interferon-gamma test reactors

2.8 The Final Report of the ISG published on 18 June 2007 included the findings of the RBCT. Evidence from the RBCT showed that at least 40% of cattle herd breakdowns in high incidence areas were caused by badgers. However the ISG concluded that badger culling (carried out in the way that was done in the RBCT) was unlikely to contribute positively, or cost effectively, to the control of bTB in Britain. It also concluded that there was substantial scope for improvement of control of the disease through the application of heightened control measures directly targeting cattle. Ongoing monitoring since the end of the RBCT has shown that the positive impacts on herd breakdowns within the culled areas were maintained for at least 6 years after culling stopped and that the negative effect on herd breakdowns in the surrounding areas had disappeared by 12-18 months after culling stopped. When bTB incidence figures from the period after culling are included, the benefits of proactive culling are greater than those observed during the trial itself.

Current epidemiological situation in England

2.9 Due to the replacement in September 2011 of AHVLA's legacy IT support system ("Vetnet") with a completely new system ("Sam") and some changes made in the methodology for the collation of bovine TB statistics in GB, the headline figures for 2011 in England shown in Table 1 and Figure 2 are not directly comparable to those of previous years. There was marked increase in new Officially TB Free status withdrawn (OTFW) breakdowns (from 2,025 to 2,555), partly due to the re-classification of new breakdowns initiated by routine slaughterhouse surveillance and by the additional herd testing coverage during 2011 (expansion of annual testing areas). However, the total number of newly infected herds (i.e. herds with OTF status suspended or withdrawn due to a new TB breakdown in the year) recorded during 2011 was less markedly up on 2010 (3,741 against 3,622). The slight increase in the number of new infected herds was expected given that in 2011 we carried out a record number of herd and animal tests. After a peak in 2008, the annual herd incidence of bovine TB (as a rate of new OTFW breakdown herds during the year for every 100 herd tests) appears to have stabilised and entered a gradually declining trend, which has continued in the first five months of 2012. It is nonetheless too early to determine whether this trend will be maintained in the longer term, since we have observed cyclical oscillations of the herd incidence in the recent past

2.10 The number of suspect cases of bTB in England initially identified during routine meat inspection of cattle carcasses in abattoirs (“slaughterhouse cases”) increased from 1,026 in 2010 to 1,330 in 2011. Approximately 70% of the suspect slaughterhouse cases notified in 2011 were confirmed by isolation of *Mycobacterium bovis* on culture. The proportion of new infected herds initially detected by routine meat inspection (slaughterhouse surveillance) has risen steadily over the last ten years to approximately 25% of all new OTFW breakdowns.

2.11 Although the annual rate of increase in the incidence of bTB breakdowns has slowed down since 2003 compared to the pre-FMD rate and it has actually fallen since the peak of 2008, bovine TB continues to be a serious problem in the South West and Midlands of England, where the infection is considered endemic in cattle herds and badgers. Herds in this part of England are tested annually and account for over 95% of all new OTFW breakdowns detected each year (Figures 3 and 4). Elsewhere in England, new TB breakdowns confirmed by PM examination and culture continue to be very sporadic and generally associated with the movements of infected cattle that escape detection by pre-movement testing. Sporadic incidental findings of *M. bovis* infection are also diagnosed in non-bovine domestic species, such as South American camelids, pigs, sheep, goats, captive deer herds, cats and, occasionally, dogs. *M. bovis* infections in those species almost invariably arise in parts of GB where there is an endemic high incidence of bTB in cattle and wildlife and are often due to infection with the locally prevalent molecular type of the bacterium.

Year (Jan-Dec)	Herd Statistics (1)					Animal Statistics (1)			
	Cattle herds registered at year end	Total herd tests	New TB herd breakdowns	New OTFW TB herd breakdowns	Herd incidence of new OTFW TB breakdowns (2)	Total cattle tested	Test reactors	Direct Contacts	Reactors per 1,000 tests
1998	77,135	24,756	1,226	630	2.5	1,989,428	4,102	724	2.1
1999	74,545	26,879	1,334	743	2.8	2,269,162	4,958	452	2.2
2000	72,006	25,890	1,423	894	3.5	2,309,183	6,029	951	2.6
2001	71,309	8,304	583	383	4.6	898,965	3,804	480	4.2
2002	68,674	30,799	2,622	1,543	5.0	3,058,048	15,482	2,381	5.1
2003	65,889	33,453	2,516	1,312	3.9	3,515,310	15,120	1,977	4.3
2004	63,639	32,298	2,612	1,423	4.4	3,513,306	15,093	1,862	4.3
2005	62,214	31,879	2,904	1,680	5.3	3,689,066	20,145	2,577	5.5
2006	61,133	36,310	2,721	1,594	4.4	4,131,849	14,585	1,061	3.5
2007	58,870	36,843	3,201	1,824	5.0	4,327,222	18,571	811	4.3
2008	58,465	37,940	3,765	2,165	5.7	4,645,263	26,070	929	5.6
2009	57,495	38,649	3,350	1,946	5.0	4,899,144	24,500	633	5.0
2010	56,867	41,519	3,622	2,025	4.9	5,471,752	24,213	471	4.4
2011	54,312	54,119	3,741	2,555	4.7	5,497,493	25,803	320	4.7
2012 (to 30 June)	54,082	35,497	2,005	1,340	3.8	3,110,148	13,098	102	4.2

(1) Data for 2011 and 2012 extracted from the new AHVLA IT system (Sam). Data for earlier years were derived from the old (VetNet) system

(2) This is an approximate incidence figure, calculated by dividing the new OTFW breakdowns by the total number of herd tests, multiplied by 100.

Note - In 2001, the TB testing and control programme was largely suspended due to the Foot and Mouth Disease (FMD) outbreak. When herd testing resumed in 2002, resources were concentrated on herds with overdue TB tests which would have had a longer period in which to contract the disease. Also the proportion of high risk herds tested post-FMD was greater than that prior to the outbreak. Consequently, the number of TB incidents since 2002 are not comparable to those in previous years.

Table 1 – Headline bTB statistics for England (1998-2012)

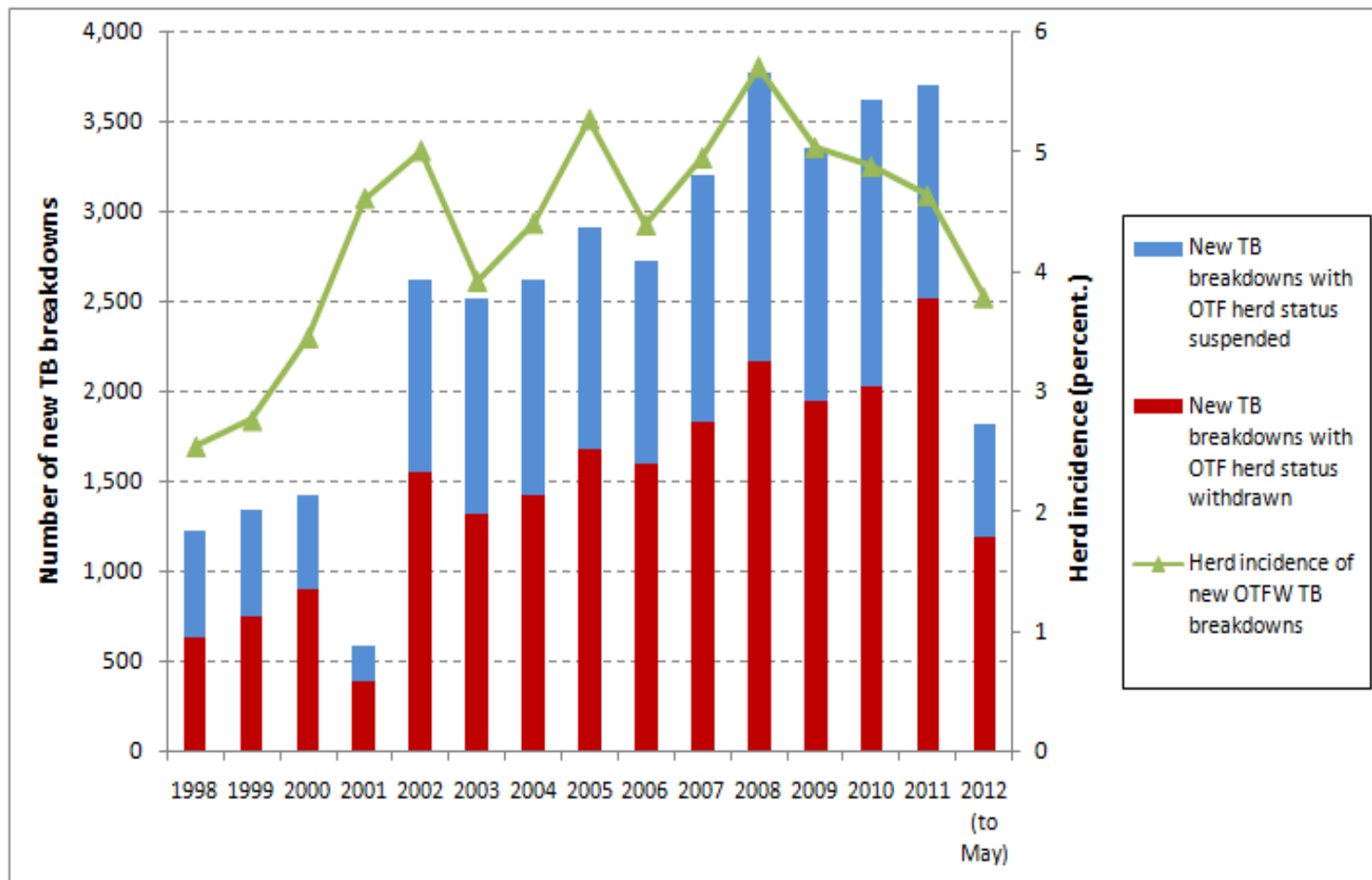


Figure 2 – Annual number and herd incidence of new TB breakdowns in England (January 1998 to May 2012)

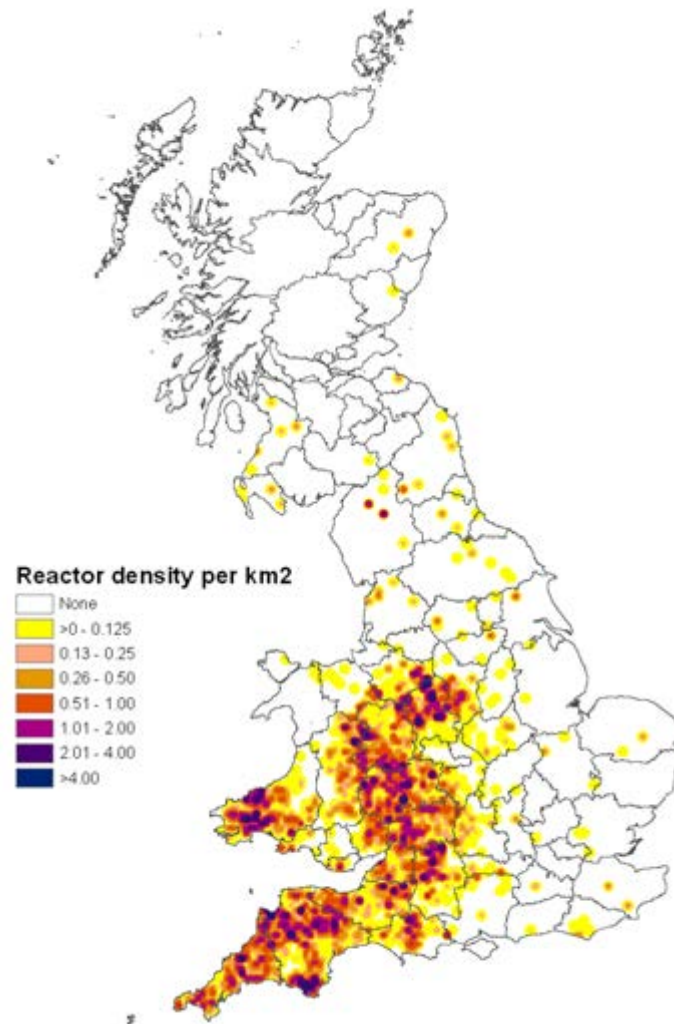


Figure 3 - Density of skin test, IFN-gamma test reactors and slaughterhouse cases per km² removed between July 2010 and June 2011 in OTFW incidents

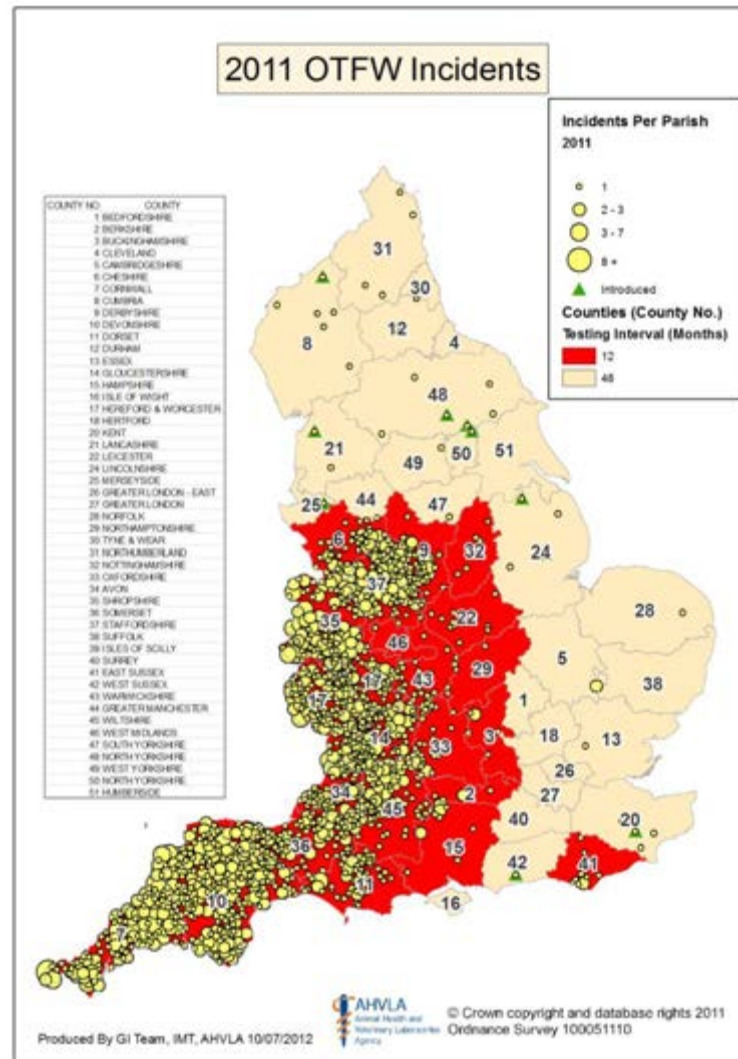


Figure 4 - Geographic distribution of new OTFW TB herd breakdowns identified in England during 2011, mapped onto the proposed herd testing interval areas for 2013

Changes introduced in 2012

Changes to TB surveillance

2.12 From the 1st January 2012, we implemented the annual review of testing frequencies. The core annual testing area was expanded in Cheshire, West Midlands and Warwickshire and there was also a widening in some areas of the two year testing buffer separating the core annual testing area from the low TB incidence (background four-yearly testing) areas of the East and North of England. In doing this the two year testing buffer and background four year testing areas were brought in line with the requirements of EU legislation (Directive 64/432/EEC (as amended)). In 2012, the annual testing area in England was set on a county level basis. Additional areas in some counties adjoining the core annually tested area were placed on more frequent annual testing on the basis of local veterinary risk assessments. The size of the two-yearly buffer area was also determined through a veterinary risk assessment of the level of risk in this area, although some areas of higher risk within this buffer were placed on annual testing. The same also applied in the four-yearly tested area for areas of higher risk based on historic incidence after an assessment at the county level was made.

Movement controls

2.13 The case for tightening movement controls was highlighted by both the FVO audit of September 2011 and the Task Force visit in March 2012. We have made a number of enhancements to our cattle movement controls since the FVO mission, in line with our responses to its recommendations. These measures are set out in the following table (table 2):

TABLE 2 - ENHANCEMENTS TO CATTLE MOVEMENT TB CONTROLS INTRODUCED IN ENGLAND DURING 2012

Date of policy change	Detail of the change
27 January	Prohibition to bring cattle into OTFW herds until the first post-breakdown disclosure test has been completed (and any reactors removed). Derogation from the general rule of no re-stocking until clear official test allowed only in cases where this is supported by a veterinary risk assessment.
1 July*	Removal of the 30-day herd residence exemption for domestic pre-movement tests – which theoretically could have enabled untested cattle from unrestricted herds to move from farm to farm indefinitely i.e. if the animal were held on each farm for less than 30 days.
1 July*	Removal of the testing exemption for movements between premises in higher TB risk Sole Occupancy Authorities (SOAs)** i.e. those that include premises in higher and lower TB risk areas.
1 July*	Removal of the testing exemption for movements to agricultural shows where cattle are housed or remain on the showground for more than 24 hours.
1 July	No applications for new SOAs, or for additional land to be added to existing SOAs accepted.
1 July	No applications for new Cattle Tracing System*** links (CTS links) for premises in different TB risk areas accepted. The approval of existing higher TB risk CTS links will be rescinded as/when they reach their renewal date n.b. for CTS links with no renewal date (these are in the minority) authorities are contacting the operators individually and rescinding the links.

* These changes relate to exempted movements from Defra's pre-movement testing policy – under this policy cattle moved from OTF herds subject to 1 or 2 year routine TB testing must have had a clear TB test within the 60 days preceding a movement off the farm.

** Sole Occupancy Authorities have been approved by AHVLA since 2003. They are a group of premises under the same farm management and control.

*** Cattle Tracing System Links – in some circumstances one CPH can be linked to another, with no requirement to report movements between the links. Allowed, for example, when a farmer shares facilities with another farmer or where land is rented for summer grazing.

Changes to compensation rules

2.14 The following new changes to Defra's table valuation based cattle compensation system also came into force on 1st July 2012:

- Reduced compensation payments for any bTB reactors or contacts disclosed at tests that are overdue by more than 60 days.
- The dairy calved animals categories (pedigree and non-pedigree stock) were split into two age bands: up to 7 years, and over 7 years. This addresses the concern raised by FVO inspectors that older, less productive cattle were being compensated at the same level as younger stock.
- Introduction of a new category for young pedigree beef animals (aged 0-6 months)

Changes to compliance and enforcement procedures

2.15 In April 2012, Defra published a set of priorities for compliance and enforcement action in England in 2012/13. Funding has been provided to look at specific projects involving Local Authorities. We will also be reviewing the current penalties structure with a view to strengthening this.

- Breakdown reporting to Local Authorities and milk producers was improved in April. A daily report is now distributed electronically to inform of new breakdowns in dairy herds to tighten dairy hygiene controls and ensure that milk from TB reactor herds is pasteurised.
- Introduction of new procedures for cleansing and disinfection of infected holdings have been in place since January 2012, so that a declaration signed by the herd owner is required before OTF status can be restored. Since May 2012, enhanced on-farm audit procedures have been in place to verify that cleansing and disinfection has taken place and with the correct disinfectants.

3. **Description of the submitted programme**⁸:

3.1 This Annex to the UK Plan covers England only. Details of the position in Wales and Northern Ireland are available in separate Annexes. See section 4.2 and figures 5 and 6 for an outline of devolution and the current governance structure.

3.2 The Government is committed to eradicating bovine TB as our long-term goal. However, due to the scale and complexity of the challenges we currently face in England, requiring all the reservoirs and routes of transmission to be tackled, we anticipate that this will take many years.

Nevertheless, as a result of the existing and new measures, by protecting the low incidence areas of England and focusing on reduction of the infection prevalence in the endemic areas (both by cattle measures and by controlling the badger reservoir of infection), by the end of the next five years we are hoping to achieve:

- OTF designation for some counties of England,
- sustained low incidence of sporadic TB breakdowns in the remaining non-endemic counties; and
- a gradual reduction in herd and animal TB incidence in the endemic area (see Section 7).

3.3 This Annex of the UK bTB Eradication Plan reflects the Bovine TB Eradication Programme for England, which was published on 19th July 2011. This was driven by the Coalition Government's commitment, as part of a package of measures, to develop affordable options for a carefully-managed and science-led policy of badger control in areas with high and persistent levels of TB in cattle. The Eradication Programme sets out a comprehensive and balanced package of measures to tackle TB in cattle, badgers and other animals, including the Government's intention to introduce

⁸ A concise description of the programme is given with the main objective(s) (monitoring, control, eradication, qualification of herds and/or regions, reducing prevalence and incidence), the main measures (sampling and testing regimes, eradication measures to be applied, qualification of herds and animals, vaccination schemes), the target animal population and the area(s) of implementation and the definition of a positive case.

an evidence-based and carefully monitored cull of badgers in the highest bTB incidence areas of England. The Programme describes the approach in detail and reflects the determination to tackle TB in cattle, badgers and non-bovine farmed animals. The approach is:

- Comprehensive: tackling TB in cattle, non-bovine farmed animals, and wildlife; addressing all transmission routes to tackle TB in cattle (cattle to cattle and between badgers and cattle). Making best use of all available tools.
- Risk-based: targeting controls on disease risk, based on veterinary advice and discretion, and making the best possible use of resources.
- Staged: seeking to stop the disease spreading in the short-term, bringing it under control, and ultimately eradicating it.

3.4 Cattle-based TB control measures will continue to be the foundation of the control programme across England and these measures have been further strengthened in 2012. Further details on measures planned for 2013 are provided below. We are also enhancing other measures to promote biosecurity, provide advice and support for farmers and tackle TB in other species. This is in addition to reaffirming our commitment to cutting-edge research, particularly to develop effective cattle and oral badger vaccines against TB as quickly as possible. For further information on the Bovine TB Eradication Programme for England please see <http://www.defra.gov.uk/publications/2011/07/19/pb13601-bovine-tb-eradication-programme> .

3.5 Defra is continuing to develop its eradication programme, with control measures tailored to different levels of herd risk. These include considerations of: local epidemiology; proximity to high incidence areas; current disease restrictions in place; repeated breakdowns; evidence of a wildlife reservoir; and historic incidence of bovine TB. Measures are then developed after considering appropriate scientific and epidemiological data and applied nationally and, where appropriate, regionally, supported by local veterinary knowledge.

3.6 Defra recognises that additional measures that go beyond the minimum requirements laid down in EU law will be required as we make progress towards eradication and the control framework in England already goes beyond EU requirements in a number of respects. These are:

- Compulsory pre-movement testing for cattle moving out of OTF herds that are tested annually or every other year (higher risk herds);

- 3km radial testing around new OTFW breakdowns in the low incidence area (from January 2013);
- Use of interferon-gamma blood testing in all herds in the low incidence area with OTF status withdrawn (OTFW) and certain OTFW breakdowns in the high incidence area;
- Enhanced measures for breakdowns in the edge of the high risk area (see paragraph 3.13);
- Additional testing in high-risk OTFS breakdowns to re-gain OTF herd status accreditation;
- Use of the single intradermal tuberculin test in certain circumstances;
- Use of severe interpretation of the comparative intradermal tuberculin test in all herds with OTF status withdrawn;
- Development of a risk-based trading scheme in 2013 (see also paragraph 3.16).

3.7 Following the completion of the FVO mission to the UK (England and Wales only) in September 2011 to evaluate the operation of the bovine TB eradication programme, the Government in England is fully committed to implement the action plan developed in response to the auditors' recommendations. Action has already been taken or is under way to address the issues identified by the FVO inspectors during the course of the audit, including the removal of exemptions from the requirements to pre-movement test, taking action to prevent untested cattle movements taking place between high and low TB risk areas and tightening of restocking rules for TB-restricted herds. The **section below** provides further detail and timescales.

3.8 The Bovine Tuberculosis Sub-Group Task Force visited the UK in March 2012 to provide further advice on developing the eradication programme. We received the Task Force's report at the end of May 2012 and are considering their recommendations carefully. We have already taken action on the recommendation on the tightening of movement controls around Cattle Tracing System (CTS) links and Sole Occupancy Authorities

(SOAs) as part of the package of measures that came into effect in July 2012. We are taking forward analysis on a number of the other recommendations, including on the extended use of gamma interferon testing, improving OV performance and carrying out an analysis of risks of movements from TB-restricted herds.

3.9 We will continue to work closely with the Commission throughout 2013 as we develop and implement the changes, and to monitor the effectiveness of these and other recently implemented measures.

Measures for further consideration and implementation in 2013 in England

Bovine TB surveillance

3.10 The surveillance strategy for cattle herds England will be substantially revised for 2013 and beyond. The overall aim of the strategy is to introduce a more stable, cost effective and targeted bTB surveillance regime that takes into consideration the heterogeneous geographic distribution of the disease in England, allows us to target our scarce resources better and allows us to eventually move towards regional OTF status for eligible counties (or groups of counties) according to the Council Directive 64/432. This will also satisfy the Commission's request to protect the low incidence areas and to use counties as the administrative areas for setting TB testing frequencies. We have also taken on board the Task Force's recommendation to set the surveillance testing regime on a more stable footing and to increase testing frequency beyond the current buffer between high and low incidence areas.

3.11 From January 2013, England will be divided into two testing frequency areas: an annual testing area in the south-west and west of the country, where the disease is endemic, and a four-yearly testing area in the south-east, east and north of the country, where the disease is sporadic and primarily non-indigenous. Whilst the testing frequencies, by and large, reflect the disease situation in each area, the annual testing area will be extended well beyond the endemic areas, with many counties allocated a higher testing frequency than required by Council Directive 64/432/EEC (as amended). The four-yearly testing area covers the counties that qualify for low testing frequency, with incidence of bTB below 0.1% (see Table 3). TB surveillance around OTF Withdrawn (OTF-W) breakdowns in the four-yearly testing area will be enhanced and extend beyond the immediately contiguous herds,

to better determine whether there has been any localised spread of disease. Herds within a 3km radius of the case which is initially identified will require an immediate skin test and then follow up tests 6 months later and, if results are negative, 12 months thereafter. During this time, these herds will require pre-movement testing.

3.12 The new strategy is a significant step change to the approach we have taken in the past and is part of a bigger strategic overview necessary to protect the low incidence areas. The strategy reflects the differing epidemiological status of bTB in different parts of England. There is a clear distinction between the endemic area of the West of England and the low incidence counties of the North and East of England. In addition, we are developing an enhanced strategy (the „edge area’ strategy) for those counties in the newly expanded annual testing area that adjoin the four-yearly testing area to stop the geographical spread of the disease into these areas. Furthermore, the measures that we are taking to enhance surveillance in the four-yearly testing area (for example radial testing around OTFW breakdowns and annual testing of individual, higher risk herds) will also allow us to protect the low incidence counties in England better than in the past. The new approach also results in a considerable increase in the area and number of herds under annual testing through the change to a county-based approach and provides a more stable basis for assessing disease incidence in coming years.

3.13 The rationale behind the strategy is supported by the substantial body of epidemiological evidence that demonstrates that bovine TB is not endemic in the proposed four-yearly testing area. Thorough epidemiological investigation has determined that the vast majority of the few OTFW breakdowns identified in this area are caused by the movement of infected cattle from the TB endemic areas of England and Wales that have evaded detection through our domestic pre-movement testing regime.

3.14 We are treating all the counties in the 4-yearly testing zone as one homogeneous epidemiological unit, although for some counties the incidence of OTFW herds may have slightly exceeded the 0.1% threshold in certain years between 2006 and 2011. This methodology is consistent with that used in Scotland for surveillance purposes prior to OTF status and in 2009 to support their designation as an OTF region of the UK.

3.15 In addition, all the low incidence counties in England were already on four-yearly TB testing in 2012, having originally moved from annual to 2-, 3-yearly testing many years ago and eventually 4-yearly herd testing in the early to mid-1990s. They have remained on 4-yearly routine herd testing ever since, given the sporadic, mostly non-native nature of bTB in those counties. Cattle herds in those counties have already gone through the process of gradual reduction of testing frequency envisaged in the Directive.

3.16 Annex A of 64/432/EEC contemplates exemptions from routine herd testing for discrete, isolated beef finishing units and cattle of age under 24 months outside annual testing areas. Such animals are generally currently exempted from routine TB surveillance in the 4-yearly tested counties, but we do test all young cattle that are intended for breeding/replacement, irrespective of their age. This is of course supplemented by post-mortem meat inspection during commercial slaughter of cattle entering the human food chain.

Table 3 - Results of TB herd surveillance carried out in 2006-2011 in the counties in the low incidence (four-yearly testing) region of England (only indigenous OTFW breakdowns included)

Year	number of bovine herds per year (2006-11) (a)	number of herds tested during that year	Number of new confirmed breakdowns (OTF status withdrawn) (b)	Prevalence (%) of infected herds		Confirmed breakdowns (OTF status withdrawn) on 31 December (c)	number of officially free herds at 31 December (a) - (c)	% of officially free herds (a) - (c) / (a)
				Crude prevalence of infected herds (b)/(a) (%)	Herd prevalence adjusted for the duration of each OTFW breakdown (i.e. the percentages of our current test interval calculation for England)			
2006	23338	6659	27	0.11569115		12	23326	99.9485817
2007	22698	6298	23	0.10133051		11	22687	99.9515376
2008	22362	5354	19	0.08496557		11	22351	99.9508094
2009	22411	4891	26	0.11601446		18	22393	99.9196823
2010	22374	6371	35	0.15643157		21	22353	99.9061411
2011	22175	to follow	29	0.1307779	0.097608713	20	22155	99.9098083

Composite percentage over the 6-year supervisory period

Table 3a – Number of OTFW breakdowns and annual percentage of OTF herds in 2006-2011 in the counties in the four-yearly testing region of England (only indigenous OTFW breakdowns included)

Counties	Number of indigenous OTFW breakdowns and Annual total percentages of OTF herds					
	2006	2007	2008	2009	2010	2011
BEDFORDSHIRE	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)
CAMBRIDGESHIRE	0 (100)	0 (100)	0 (100)	1 (99.74227)	0 (100)	1 (99.77117)
CLEVELAND	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)
CUMBRIA	5 (99.86617)	0 (100)	3 (99.91916)	1 (99.97263)	2 (99.94534)	4 (99.8877)
DURHAM	0 (100)	1 (99.91166)	0 (100)	0 (100)	1 (99.91063)	0 (100)
ESSEX	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)
GREATER LONDON	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)
GREATER LONDON - EAST	0 (100)	0 (100)	0 (100)	0 (100)	1 (96.77419)	1 (97.22222)
GREATER MANCHESTER	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	1 (99.80545)
HERTFORD	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)
HUMBERSIDE	0 (100)	1 (99.88914)	0 (100)	1 (99.8895)	1 (99.88901)	0 (100)
ISLE OF WIGHT	0 (100)	0 (100)	1 (99.48454)	0 (100)	0 (100)	0 (100)
ISLES OF SCILLY	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)
KENT	0 (100)	0 (100)	0 (100)	1 (99.88208)	0 (100)	0 (100)
LANCASHIRE	2 (99.91504)	1 (99.95662)	1 (99.95508)	4 (99.82063)	5 (99.77619)	1 (99.95404)
LINCOLNSHIRE	1 (99.90637)	0 (100)	2 (99.80989)	3 (99.71292)	0 (100)	2 (99.80334)
MERSEYSIDE	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)
NORFOLK	0 (100)	2 (99.81785)	0 (100)	0 (100)	1 (99.90999)	0 (100)
NORTH YORKSHIRE	1 (99.97613)	0 (100)	0 (100)	1 (99.9755)	3 (99.92636)	5 (99.87712)
NORTHUMBERLAND	0 (100)	0 (100)	0 (100)	0 (100)	1 (99.91625)	1 (99.91742)
SOUTH YORKSHIRE	0 (100)	0 (100)	0 (100)	1 (99.82238)	1 (99.82206)	0 (100)
SUFFOLK	1 (99.85816)	1 (99.84779)	1 (99.84448)	0 (100)	0 (100)	0 (100)
SURREY	0 (100)	0 (100)	0 (100)	2 (99.5338)	0 (100)	0 (100)
TYNE & WEAR	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)	0 (100)
WEST SUSSEX	1 (99.83389)	2 (99.65398)	0 (100)	0 (100)	2 (99.63768)	1 (99.82143)

WEST YORKSHIRE	1 (99.92717)	3 (99.76852)	3 (99.76744)	3 (99.77082)	3 (99.77029)	3 (99.76888)
	12	11	11	18	21	20
Total for the LIA	(99.94858)	(99.95154)	(99.95081)	(99.91968)	(99.90614)	(99.90981)

3.17 The counties in each surveillance testing area are depicted in Figure 5, and the development of the proportion of cattle herds in each testing frequency is shown in Figure 6. As a result of the planned increase in herd testing coverage, we estimate that in 2013 61% of all cattle herds in England will be tested annually, up from 49% in 2012, with the remaining herds on background four-yearly testing.

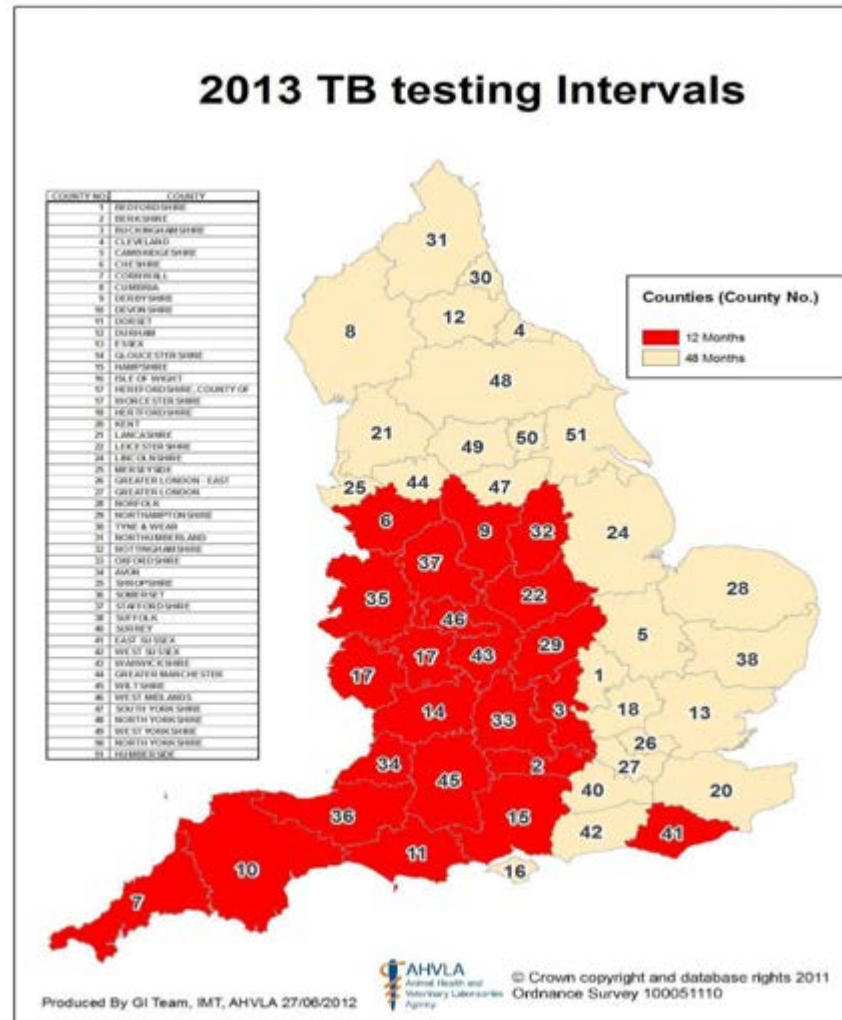


Figure 5 - New TB routine herd testing intervals for England from 2013 onwards

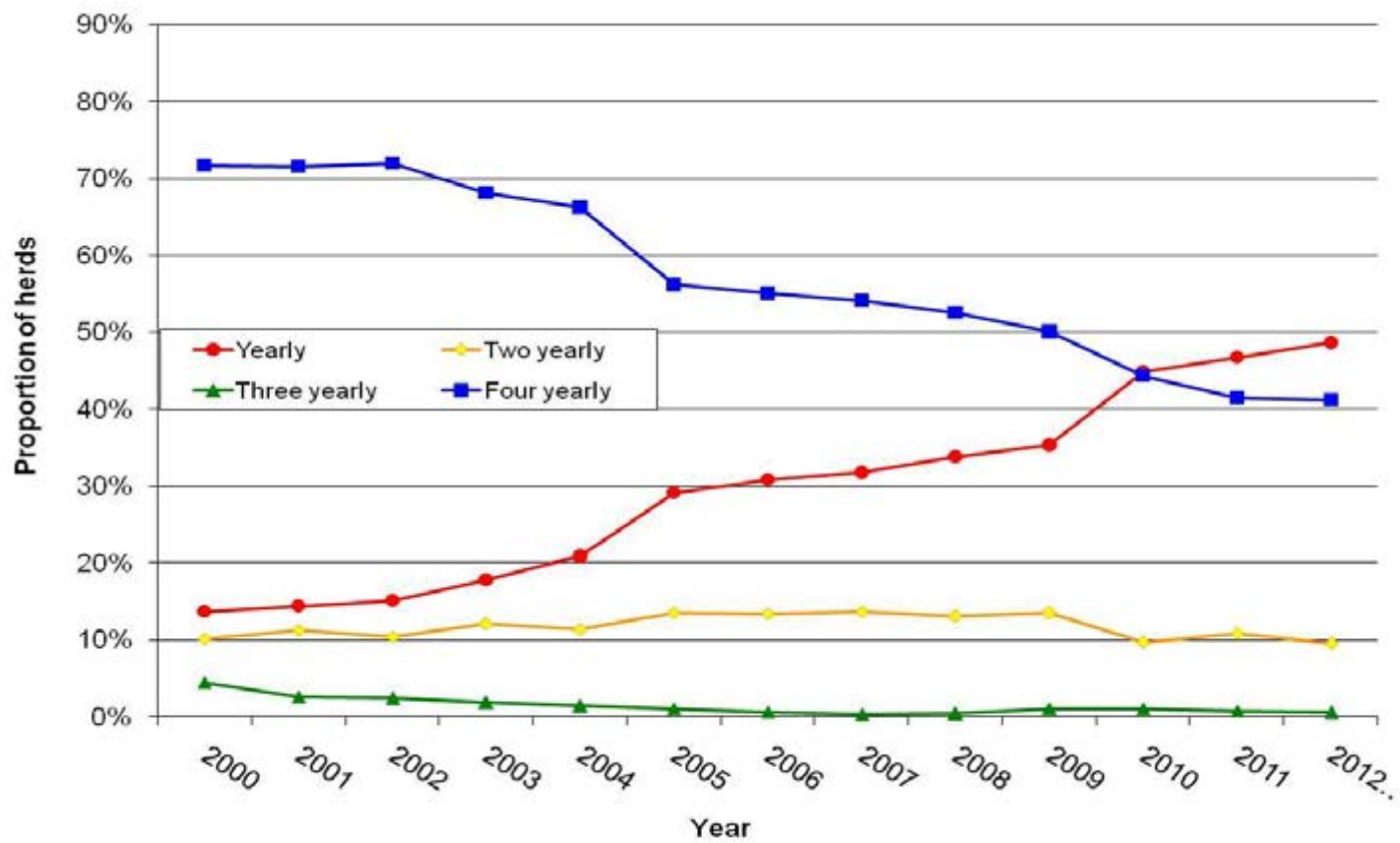


Figure 6 – Annual distribution of English herds according to their routine testing interval (2000-2012)

3.18 As well as introducing a new strategy for the low incidence areas, we are also considering introducing a tailored strategy to tackle the geographical spread of disease. This could be achieved by introducing a new policy targeted at the edge of the high risk area. The following measures could form part of this policy:

- Improved collaboration and information sharing at a local level between stakeholders.
- Increase our understanding of the factors which are driving the spread of disease at the edge of high risk areas through enhanced epidemiological investigations.
- Increased use of additional diagnostic tools such as the IFN-gamma test to improve our understanding of where disease is currently emerging and to facilitate rapid clearing of infection when it is identified in new areas.

3.19 In addition we also plan to start a number of other projects to enhance the bTB surveillance regime. These include:

- Comparison of 6-week versus 8-week culture incubation periods at AHVLA laboratories. The results from this project as well as the recommendations of the review being carried out by the EU Reference Laboratory on culturing processes will inform the need to amend our TB culture protocols. See Section 6.2 for details of the current microbiological procedures.
- Rolling out changes to the interferon-gamma testing deployment policy, following the outcome of scientific and policy reviews.
- Extending the training of field veterinary officers on the use of SPIDA (bTB mapping and epidemiology tool) that began in 2012.
- Rolling out of the *M. bovis* spoligotype out of home range-alerts.
- Training Veterinary Officers in epidemiological investigation of TB breakdowns. Summary of breakdown epidemiological reporting is now possible as the data are included in the AHVLA new IT system as electronic forms. epidemiological investigations.
- Extending the AHVLA internal quality assurance of skin testing by Official Veterinarians (private vets) and strengthening the sanctions for poor testing standards.

- Analysing the circumstances in which use of the single intradermal test would be beneficial to improving disease control. Currently to increase the sensitivity of skin-testing carried out during OTFW breakdowns a more severe interpretation of the SICCT is used. Using the single intradermal test offers an alternative way in which the sensitivity of the skin-test might be increased. When testing animals for export from England to other EU member states only the bovine-only interpretation of the skin-test is considered (see paragraph 4.47). In addition, veterinary officers dealing with OTFW breakdowns have the discretion to remove all animals which react to the bovine tuberculin as direct contacts. Previous research suggests that wider use of the single intradermal test within the high incidence area would lead to the identification of additional infected animals in which infection would have been confirmed by culture of the presence of visible lesions. However, this would also significantly increase the number of false positive reactors which would need to be removed and compensated for. To further improve our understanding of the consequences of using the single intradermal test further research has been commissioned on the consequences of using this test specifically in the high incidence areas; and
- Plan to commission research in 2013 to understand the factors (including social factors) which could be responsible for the rise in the number of TB slaughterhouse cases and to identify ways of improving our slaughterhouse surveillance for bovine TB.

Movement controls

3.20 After implementing new cattle movement controls in 2012 Defra consulted industry with further proposals. As a result, the following additional measures will be introduced in early 2013:

- We will be abolishing the use of Approved Quarantine Units (AQUs). From the 1st January 2013, owners of TB restricted herds will no longer be able to move calves to AQUs. Once de-stocked after this date, all AQUs will have their licences permanently revoked. The final deadline for depopulating AQUs will be the end of 2013, though we fully expect most AQUs to be depopulated before that date.

- Licensed movements on to all new breakdown herds (both OTFW **and** OTFS) will only be considered after the herd's first official post-breakdown test and will be dependent on a satisfactory veterinary risk assessment. This will extend our current arrangements on re-stocking OTFW herds to all breakdown herds.
- The movement window for any licensed movements (to live) of cattle between TB-restricted herds will be reduced from 60 days to 30 days after a test with negative results.
- More robust protocols for identifying and dealing with cases of non-compliance with the operating conditions for Approved Finishing Units e.g. where significant or repeated breaches are identified the license to operate will be withdrawn.

3.21 A review of options for a bTB **risk-based trading** system is being carried out during 2012. The first meeting of an industry-led advisory group focusing on risk-based trading took place in early July 2012. It intends to put recommendations to Ministers by the end of 2012 on both short and longer term measures to be introduced.

Targets

3.22 We are looking at developing improved disease prevalence and incidence targets (see paragraph 3.2 and section 7.4 for further details).

Badger control

3.23 In December 2011, the Government announced its intention to proceed with a carefully-managed and science-led policy of badger control in England, as part of a package of measures to tackle TB in cattle. The Government's policy is to enable farmers and landowners to cull and/or vaccinate badgers under licences granted under the Protection of Badgers Act 1992 and Wildlife and Countryside Act 1981. Defra's "Guidance to Natural England on the implementation and enforcement of a badger control policy" (issued under section 15(2) of the Natural Environment and Rural Communities Act 2006 ("the NERC Act")) sets out what is required, on the basis of current scientific evidence, in order for any cull of badgers to be effective, safe and humane. In order to be granted a licence, a group of farmers/landowners will need to meet strict licence conditions. The

Government's role will be to operate the licensing regime and monitor the effectiveness, humaneness and impact of the badger control measures. Defra has defended a Judicial Review of the badger culling decision. As a first step, there would be a pilot of the policy in two areas to confirm our assumptions about the effectiveness (in terms of badger removal), humaneness and safety of culling. We are continuing to proceed with preparations for the two badger culling pilots. Natural England issued the first culling licence (17 September 2012) for West Gloucestershire and the second culling licence (4 October 2012) for West Somerset. However concerns were raised that as new survey results revealed higher than anticipated badger numbers in the two pilot area, therefore the organisers of the pilots could not be confident of removing the required 70 per cent of the badgers in the two pilot areas this autumn. Defra has therefore agreed to postpone the pilot culls until summer 2013 to allow farmers to continue their preparations and have the best possible chance of carrying out the cull effectively. See also Section 4.58 – 4.60.

Compensation

3.24 We have started a discussion with stakeholders on a future TB strategy and striking a fair balance of shared responsibilities and costs between industry and government. This includes possible options for the transfer of some TB testing costs and reducing the levels of compensation payments as part of cost-sharing with the cattle industry. Further informal consultation will be carried out over the autumn of 2012 with a formal consultation planned later in the year.

Compliance and enforcement

3.25 We are strengthening cross-compliance penalties in herds with overdue testing and where reactors have not been properly isolated. We are also in the process of agreeing a new framework for Local Authorities to carry out enforcement activity.

3.26 Some of these new measures will form a package of new measures to be announced in October 2012, with a view to implementation at the start of 2013. This will include further detail on revised movement controls and the new surveillance strategy for the low incidence area.

Table 4 - Timetable for further measures introduced in 2012 and 2013

Year	Measure	Timescale
Surveillance		
	Roll out out-of-home-range alert system for <i>M.bovis</i> spoligotypes, following training of AHVLA field staff	Sept 2012
	Issue of new instructions for OV field audit of skin testing and introduction of sanctions for poor performance.	Nov 2012
	Announce a call for a research project to scrutinise slaughterhouse surveillance to identify weaknesses and ways to improve sensitivity.	Oct 2012
	Announcement new surveillance strategy (October package)	Oct 2012
	Implementation of new surveillance regime	Jan 2013
Movement controls		
	Completion of consultation exercise on proposals on: (i) re-stocking of new breakdown herds; (ii) change to the period of validity of pre-movement testing of restricted herds (from 60 to 30 days); and (iii) future of Approved Finishing and Quarantine Units.	Aug 2012

	Announcement by Ministers on way forward following consultation	Oct 2012
	Implementation of changes flowing from consultation	Jan 2013
	All AQUs abolished and depopulated	Dec 2013
Badger control		
	Two pilot culls go ahead in Gloucestershire and Somerset	Summer 2013
Other measures		
	Introduction of revised protocols for dealing with long term persistent breakdowns, following a pilot.	Late 2012/early 2013

3.27 We will be further strengthening cattle controls during 2013, including further reviewing our pre-movement testing policy in the context of applying a risk based approach to the derogation for movements between OTF herds.

Summary of controls in the submitted programme

3.28 The attached list provides an overview of controls

General

- Terminology used to describe the TB status of herds (e.g. Officially Tuberculosis Free (OTF) or status Withdrawn (OTFW) or Suspended (OTFS) consistent with EU legislation.
- Tailored policies to reflect area disease incidence and risks.

- The management of the TB surveillance and control functions carried out on the Animal Health and Veterinary Laboratory (AHVLA's) integrated IT system („Sam’), which includes immediate updates on customer records will be visible by all in AHVLA, direct transmission of TB test data through interfaces with OV practices, Food Standards Agency (FSA) meat hygiene inspectors and the TB culture laboratory, all of which will improve the quality and assurance of disease test data..
- Animal husbandry best practice guidance.
- Provision of advice and support for farmers. AHVLA has also been delivering enhanced veterinary advice for farmers in England experiencing their first bovine TB breakdown, through extended disease investigation visits. We are continuing to work with the veterinary profession to deliver focused veterinary advice (through private vets) to owners of herds affected by long-term breakdowns.
- Projects are also taking place (for example the Cheshire Edge Area Board and the South West TB Advisory Service) to raise awareness and provide advice on TB and prevention. Defra is also working closely with the Farm Crisis Network to provide business advice for farmers affected by impacts of TB breakdowns.
- Involvement of stakeholders in agreeing approach to TB management and developing the eradication plan and programme. In England, the Animal Health and Welfare Board of England (AHWBE) makes recommendations to Defra Ministers on strategic animal health and welfare policy and the TB Eradication and Advisory Group advises the AHWBE on bTB matters. Both these bodies include members from Defra, AHVLA, the farming industry and the veterinary profession.
- Registration, identification and movement reporting of all cattle (and other livestock species).
- Monthly publication of bTB statistics, including number of herds registered, TB tests carried out, new herd breakdowns (total and OTFW), reactors and other animals slaughtered, tests overdue and herds under movement restrictions.
- A wide-ranging bTB research programme.

Surveillance

- New active surveillance regime of compulsory comparative skin testing of all herds at appropriate intervals. See above and section 4 for more details. The new approach is based on counties and is epidemiologically more sound than the previous, parish-based, retrospective approach. It allows targeting of more intensive surveillance resource in areas where it can have a real disease control impact (e.g. the edge area) and prevents wasting resource where disease control impact is minimal (non-endemic areas).

- Annual testing in high incidence and high risk areas that are likely to have endemic bTB in order:
 - to allow early removal of infected cattle,
 - to prevent disease spread, and
 - to comply with legislative requirements for surveillance.

- Annual testing in a substantial buffer area around the high incidence area in order:
 - to account for the already identified, slow geographic spread,
 - to ensure early detection of spread if it happens and to prevent further spread,
 - to ensure adequate testing of these areas for future OTF status, and
 - to comply with legislative requirements for surveillance.

- Four-yearly testing in the areas where bTB is not endemic, supplemented by slaughterhouse surveillance and risk based surveillance in order:
 - to ensure that introduced disease does not go undetected,
 - to allow surveillance evidence to be maintained for future application of regional OTF status, and
 - to allow a faster return of affected herds in low incidence areas to the default 4-yearly testing regime and derogation from pre-movement testing, reflecting their true risk status.

- Slaughterhouse surveillance of all animals slaughtered for food production across the country.
- Pre-movement testing of all cattle leaving herds in the annual testing area and herds designated higher testing frequency for risk reasons in the four-yearly testing area (herds dealing with stock frequently, bull hirers, heifer reares, post-breakdown herds, herds within a 3-km zone of an OTFW breakdown for 18 months post breakdown etc.).

Control of infection in herds

- Use of epidemiological and other data to inform and assess effectiveness of policies (annual surveillance report and other *ad hoc* reports).
- Use of veterinary discretion to inform actions at a local level to reflect local disease risks.
- Regular TB epidemiology/risk assessment workshops for AHVLA regional veterinary leads (RVLs) and TB lead veterinary officers .
- Annual TB epidemiological summaries for each Region that are collated into an annual national TB field epidemiology report.
- Immediate movement restrictions and suspension of OTF status on herds with overdue TB tests (zero tolerance) and active management of all overdue tests by AHVLA.
- Where skin test reactors (or culture-positive slaughterhouse cases) are detected, the following additional measures are adopted to eliminate the infection from the herd and contain its spread to other herds:
 - Cattle movement restrictions.
 - DNA tagging of reactors at the point of disclosure (from April 2011)
 - Isolation, removal and slaughter, of test reactors and contacts within 10 working days, followed by post-mortem examination of all of these animals and culture of tissue samples from a representative number of reactors (if more than one).
 - Only one retest is permitted for inconclusive reactors.

- Compensation paid for animals compulsory slaughtered based on table valuations in England. Reduced compensation payments for overdue testing were introduced in July 2012.
- Short interval testing (at > 60 day intervals (max. 90 days)) – one clear short interval test required for OTFS herds and two required for OTFW herds where there is demonstrable evidence of TB is found at post-mortem examination or through laboratory culture certain, or in certain higher risk OTFS breakdowns which will therefore have an extended period under restriction.
- Severe (re-)interpretation of the skin test where demonstrable evidence of *M. bovis* infection is found at PM examination/culture (OTFW herds).
- Epidemiological enquiry by a veterinary officer, using a standardised report form into the causes of the breakdown and advice to herd owners on prevention measures.
- Forward and back-tracings from OTFW breakdown herds and check testing of herds that are contiguous to those breakdowns. 3-km radial testing of herds around OTFW breakdowns in the four-yearly testing area.
- Ancillary interferon (IFN)-gamma testing of all OTFW herds identified in low incidence areas, and certain OTFW herds in the higher risk areas suffering chronic or severe breakdowns.
- Occasional stamping out of severely infected groups or entire herds (partial or total depopulation).
- Check testing of breakdown herds 6 and 18 months following the restoration of their OTF status. Pre-movement testing required of any cattle moved to other herds during that period.
- Appropriate cleansing and disinfection of buildings, transport and equipment in OTFW herds.
- Enhanced surveillance and controls are being introduced in the area at the edge of the TB endemic area in England where there has been ongoing spread of the geographical area impacted by TB to rapidly identify areas of concern, understand the extent of the spread, and to prevent TB becoming endemic in new areas.
- Additional measures for certain breakdowns in a previously clean area.

- TB control measures in wildlife, including limited injectable badger vaccination (Badger Vaccination Deployment Project) in England and the planned badger culling pilots.
- Rolling out of a voluntary risk-based cattle trading scheme in 2013.
- Development of further measures for dealing with the disease in species other than cattle (e.g. camelids and goats).
- Where the OTF status of a dairy herd is suspended or withdrawn, AHVLA will notify the Chief Environmental Health Officer of the local food authority to ensure compliance with food hygiene regulations, including the pasteurisation of milk and withholding from the human food chain any milk produced by individual reactor cows.
- Provision of biosecurity advice to herd owners.

Movement controls

- No restocking of herds where official bTB freedom has been withdrawn until after the first official test (from January 2012) and subject to a satisfactory risk assessment.
- We are reducing bTB risks from linked holdings by introducing more consistent and tighter movement controls:
 - new Cattle Tracing System (CTS) links are not allowed between premises in different bTB risk areas and we will remove annual and open-ended CTS links in a staged approach (i.e. as/when the link operators apply for their approved status to be renewed) which will be completed by 30 June 2013.
 - New applications for the establishment of Sole Occupancy Authorities (SOAs) or for the addition of new premises to existing SOAs have not been permitted since 1st July 2012.
 - For existing SOAs (of which only around 10% include premises that are more than 10 miles apart) TB controls are applied in the same way to all parts of the SOA. For example, for SOAs with premises in different TB risk areas the routine testing frequency for all premises is set at the level of testing in the highest TB risk area and any TB related movement restrictions are applied in all parts of the

SOA. The one exception is on pre-movement testing. On 1 July 2012 we removed the exemption to pre-movement test cattle moved within higher risk SOAs i.e. those that include premises in different TB risk areas. The new legal requirement to pre-movement test applies to all cattle movements within these SOAs, it is not limited only to movements of more than 10 miles. However, where the premises of the SOA all lie within the same TB risk area we do not require pre-movement testing, we will be reviewing this requirement during 2013.

- The Farming Regulation Task Force has recommended the abolition of SOAs in England. In its response to the Task Force report, the UK Government has agreed in principle to abolish SOAs subject to the costs, benefits, implementation and regulatory impacts of doing so. Work to establish the costs and benefits is due to be completed by the end of 2013. However, measures to effect the abolition of all SOAs in England, if agreed, could not be completed before 2014/15.
- Compulsory pre-movement testing of over 42-day old cattle moving out of OTF 1- or 2-yearly tested herds, paid by herd owners.
- In addition there is the requirement to pre-movement test animals from low incidence areas in England before movement to Scotland (unless they have spent all their lives in a low incidence area or are moving directly to slaughter in Scotland).
- Use of post movement testing is encouraged as best practice, in particular for herds in low TB incidence and risk areas that source cattle from higher risk areas.

4. Measures of the submitted programme

4.1. *Summary of measures under the programme*

4.1 *Duration of the programme:* The programme submitted is for the year 2013. This Plan includes the latest measures which will be in place for 1st January 2013 and outlines the current thinking on how controls might be amended in the future. This plan builds on the 2010, 2011 and 2012 Plans as part of the ongoing, long-term programme to control and eradicate TB from cattle in England.

4.2 Measures utilised during the 2013 programme will focus on regular testing and slaughter of reactor cattle, pre-movement testing, slaughterhouse TB surveillance and supplementary use of the IFN-gamma blood testing. Tighter controls on movements have been introduced from 1st July 2012 in addition to measures to reduce the risk of transmission of TB between wildlife, particularly badgers, and cattle in endemic areas will be introduced. Measures in the programme will be kept under review.

Duration of the programme: 5 years

First year: 2010

Last year: 2015

X Control

X Eradication

X Testing

X Testing

X Slaughter of animals tested positive

X Slaughter of animals tested positive

X Killing of animals tested positive

X Killing of animals tested positive

X Vaccination

X Extended slaughter or killing

Treatment

X Disposal of products

X Disposal of products

X Eradication, control or monitoring.

Other measures (*specify*):

4.2. *Organisation, supervision and role of all stakeholders⁹ involved in the programme:*

4.3 The control, monitoring and eradication of bovine TB, as with all animal health matters, will be the responsibility of national, devolved administrations of the UK. Defra will remain the central competent authority for TB in the UK, as well as being the competent authority in England:

Bovine TB Programme

Department for Environment, Food and Rural Affairs (Defra) – responsible for policy in England

9 Millbank

c/o 17 Smith Square

London SW1P 3JR

4.4 This structure also emphasises the need to engage and work closely with stakeholders in developing eradication programmes. A new **Animal Health and Welfare Board for England** (AHWBE) was established in 2011. The AHWBE brings together independent people with the relevant knowledge and skills, and senior government officials. The AHWBE makes direct recommendations to Ministers on strategic policy affecting the health and welfare of kept animals in England including farm animals, horses and pets (excluding the welfare of zoo and circus animals). The new Board was established based on the findings from the Independent Responsibility and Cost Sharing Advisory Group, which published the findings of their work on how animal keepers can play a greater role on tackling animal disease. A new sub-group of the Board (the **Bovine TB Eradication Advisory Group for England** (TBEAG)) has been established. TBEAG will continue the valuable work carried out by the **TB Eradication Group for England** (established in November 2008) but with membership broadened to include additional areas of scientific expertise and conservation

⁹ Describe the authorities in charge of supervising and coordinating the departments responsible for implementing the programme and the different operators involved. Describe the responsibilities of all involved

knowledge, as well as a broader range of farming experience. For further information see <http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/controls/tbeag/>.

Delivery of TB Controls in England

4.5 The competent authorities for field delivery of bTB control policy in England on behalf of Defra are set out in the table and figure 7 below.

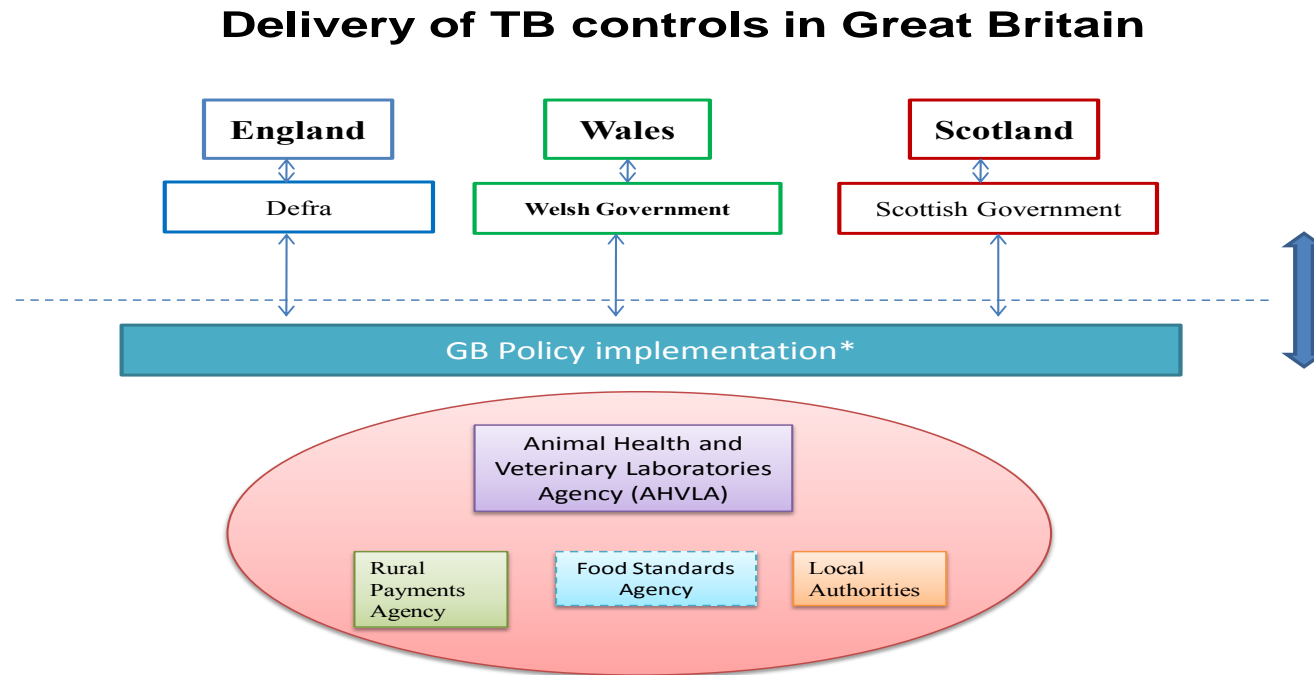
4.6 Animal Health and Veterinary Laboratories Agency (AHVLA) is the lead agency in Great Britain for delivering the overarching strategy laid down by central Government. AHVLA has the authority to deal with local issues in line with this strategy and leads on individual case management. All field based operations are overseen by the Director of Animal Health for England. If there is any doubt about what type of action is permitted, AHVLA will ask TB Programme in Defra for a view. In England, AHVLA consists of four regions (see Figure 8), each led by a Regional Operations Director supported by a Regional Veterinary Lead (RVL) and a Regional Management Team.

Organisation name	Responsibilities	IT systems used
Animal Health and Veterinary Laboratories Agency (AHVLA)	Executive Agency of Defra primarily responsible for ensuring that farmed animals in Great Britain are healthy, disease free and well looked after. The lead delivery body on TB issues, carrying out or managing: <ul style="list-style-type: none"> • Routine on-farm surveillance (skin testing) • Enhanced surveillance • Annual testing interval review • Skin test training and audit • Control measures <ul style="list-style-type: none"> ○ Service of movement restrictions and movement licences ○ Testing regime including gIFN ○ Isolation of reactors and public health controls 	“Sam”– customer registration, contact history and management of testing schedules for routine surveillance including electronic collation and submission of TB test results and breakdown management including Post Mortem Examination, epidemiological and financial data. <u>Links to other IT systems – VLA</u>

	<ul style="list-style-type: none"> ○ Reactor removal and compensation ○ Post-mortem examination and sampling ○ Case management ● Approval of special types of units (e.g. approved finishing units and dedicated slaughter gatherings) ● Monitoring compliance ● Enforcement in conjunction with Local Authorities ● Field epidemiology (including use of Disease Report form – a revised version of which will be available shortly) to inform management and control decisions. ● Laboratory support to Defra’s Animal Disease Surveillance and Control Programme, including diagnostic services. ● Provides epidemiological and data analysis. ● Wide-ranging involvement in TB research and development ● Regional network of veterinary laboratories in England <p>Links to the other agencies through agreements. Delivers policy in partnership with private veterinarians appointed to carry out certain activities on the behalf of Ministers. These Official Veterinarians comprise a testing network of approx 4400 OV’s in 1100 practices within an overall surveillance network of approx 10,200 OV’s in 2,200 practices.</p>	<p>database; CTS; RITA etc</p> <p>Sam is the new AHVLA IT system and a TB specific module was rolled out in 2011 and the use of the existing systems (<u>Vetnet and the TB Information System - TBIS</u>) has been phased out</p> <p>VLA database – this is a two-way information flow with AHVLA Field Services offices. The database receives data from AHVLA Field Services (e.g. reactor sample submission details) and data sent back to Field Services (e.g. culture results).</p> <p>CTS (see below)</p>
<p>Rural Payments Agency (RPA) (incorporating the British Cattle Movement Service)</p>	<p>The RPA is an Executive Agency of Defra. The competent authority for livestock movements, identification, imports, deaths and tracing for all cattle to be used for animal health (surveillance, planning and control) and subsidy control purposes.</p>	<p>The Cattle Tracing System is administered by BCMS and is the central database to register all cattle movements, births and deaths.</p> <p>The RPA also administer the RITA system, which provides Sam with core data on holdings to maintain up-to-date customer information.</p> <p>Link of IT systems to Sam.</p>

Food Standards Agency (FSA)	The FSA is a Non-Ministerial Government Department set up to protect public health and customer interests in relation to food. It is directly accountable to Parliament and publishes the advice it issues. It is led by a Board appointed to act in the public interest (not representing industry sectors). It has policy responsibility in the UK for the implementation of the EU Food Hygiene Regulations, which are enforced by the Local (food) Authorities. The functions of what was formerly the Meat Hygiene Service have been assumed into the FSA. This covers post mortem examination on carcasses of cattle slaughtered for food consumption; and reactors or dangerous contacts identified by AHVLA, slaughtered in licensed red meat abattoirs.	
Department of Health (incorporating the Health Protection Agency)	The Health Protection Agency (HPA) – a non-departmental public body incorporates local Health Protection Units, each of which has teams of health professionals including a Consultant in Communicable Diseases (CCDC). CCDCs are specialist doctors who risk-assess and, where necessary, instigate TB screening of human in-contacts upon receipt of a notification from AHVLA of <i>M. bovis</i> infection in a cattle herd. There are equivalent public health protection bodies in Wales.	
Local Authorities	Monitoring and enforcement of animal health aspects of TB legislation will be borne by the Trading Standards Departments of Local Authorities throughout GB. Environmental Health departments of Local Authorities enforce EU feed and food (e.g. dairy) legislation. Local Authorities liaise at a local level with AHVLA in relation to enforcement of bTB legislation and with BCMS on cattle identification issues.	Local Authorities maintain the Animal Movement Licensing System, which is the key data source for Local Authorities when monitoring compliance. AHVLA uses the system to approve animal gatherings and monitor movement standstills. The system has links to Sam and CTS
Environment Agency	Disposal of by-products including disposal of reactors unfit to enter an abattoir and milk from reactor cows	
Food & Environment Research Agency	Wildlife and husbandry issues (including involvement in the Badger Vaccine Deployment Project)	

4.7 There is a centralised tracings centre in Cardiff covering the whole of Great Britain (Figure 8).



* TB policy implemented by multi- agency delivery partners

Figure 7 – Delivery of animal health controls in Great Britain

4.3. *Description and demarcation of the geographical and administrative areas in which the programme is to be implemented*¹⁰:

4.8 United Kingdom (England)

4.9 As Scotland has achieved OTF status the UK Eradication Plan covers England, Wales and Northern Ireland. **This annex focuses on England; separate annexes have been submitted in respect of Wales, Northern Ireland and Scotland.** There continues to be close liaison between the four national administrations to ensure that policies are co-ordinated between the different countries and that opportunities to work in collaboration are realised. This ensures that the fundamental measures for controlling TB remain consistent throughout the UK with tailored policies where appropriate to reflect different epidemiological risks. Scientific, epidemiological and socio-economic evidence continues to be collected and analysed to enhance the current control regime; to support decision-making on the future direction of the TB Programme; and to ensure that veterinary discretion is applied appropriately for specific risk areas. These data, information, structures and processes are integral to the programme and therefore form a key component of the Bovine TB Eradication Plan. Close engagement with stakeholders is also fundamental in developing an effective eradication programme.

4.4. *Description of the measures of the programme*¹¹:

4.4.1. Notification of the disease:

4.10 In compliance with Council Directives 64/432/EEC as amended and 78/52/EEC, bovine TB (defined as infection of cattle with *M. bovis*) will remain a notifiable disease of cattle. Under domestic legislation (the Tuberculosis (England) Order 2007 (as amended)), any person who suspects the

¹⁰ Describe the name and denomination, the administrative boundaries, and the surface of the administrative and geographical areas in which the programme is to be applied. Illustrate with maps.

¹¹ A comprehensive description needs to be provided of all measures unless reference can be made to Union legislation. The national legislation in which the measures are laid down is also mentioned.

presence of TB in a bovine animal within their charge is legally required to notify their local AHVLA office immediately (whether it is clinical signs in the live animal or tuberculous lesions in a carcass). AHVLA will carry out an official investigation of the herd of origin of such animals (by clinical examination and skin testing) to establish whether infection is present. The isolation of *M. bovis* from tissues of any mammal other than man is also notifiable to the AHVLA in Weybridge. Under the Tuberculosis (Deer) Order 1989, TB is also a notifiable disease in deer.

4.11 All cattle destined for human consumption are subject to post-mortem inspection at slaughterhouses. Additionally, FSA meat inspectors will continue to carry out post mortem examinations on all carcasses of non-reactor cattle from Officially TB Free (OTF) status suspended (OTFS) and Officially TB Free (OTF) status withdrawn (OTFW) herds slaughtered in abattoirs, as well as all skin and gamma-interferon test reactors and direct contacts slaughtered by AHVLA. Extended enhanced TB sampling and awareness training to staff in all red meat abattoirs, including those abattoirs that do not slaughter cattle has been in place since 2011 and this has led to increased detection rates. They also plan to improve monitoring of sample submission and confirmation rates to inform the need for future intervention. Reactors displaying characteristic lesions of TB in typical sites will confirm infection in that animal and, if the first such case the herd, the herd's OTF status will be withdrawn (OTFW). Where TB is suspected from typical lesions, identified at routine commercial slaughter of cattle from OTF herds, AHVLA will trace and issue movement restrictions on the herd of origin within two working days of receipt of notification from the FSA, and the herd's OTF status will be automatically suspended pending further investigation and the receipt of culture results.

4.12 All cases with suspect tuberculous lesions detected during commercial slaughter will undergo tissue sampling for histological and bacteriological examination at AHVLA. Between 60-70% of those slaughterhouse cases will be expected to yield *M. bovis* on culture based on historical data. Following suspension of OTF status and a veterinary risk assessment, the local AHVLA office may decide to arrange for an immediate tuberculin skin test of the herd of origin or wait for the laboratory results. In situations where it is difficult to decide on visual inspection whether or not the lesions in a slaughterhouse case are tuberculous, a preliminary diagnosis based on histopathological examination at the AHVLA is available within two weeks. The skin check test if carried out will initially be interpreted at standard interpretation pending the culture results, when

reinterpretation may be necessary. If this test gives negative results and the tissue cultures prove negative for *M. bovis*, the herd's OTF status will be automatically restored and the herd will be marked forward for the normal testing interval for the herd in that area. By contrast, should the laboratory culture and/or skin test results prove positive for bovine TB, the normal procedures following the disclosure of a positive test reactor will be followed and the OTF status will be withdrawn pending further herd testing at 60 day intervals.

4.4.2. Target animals and animal population:

4.13 The programme will target all bovine herds and animals (including Asiatic water buffalo and bison) kept on agricultural premises in England over 42 days old for surveillance purposes and breakdown control purposes, although in some circumstances AHVLA may require testing of all bovines in the herd, including calves under 42 days of age. In addition the legislation and programme will contain certain measures to address other reservoirs and sources of TB (including some non-bovine species and wildlife).

4.4.3. Identification of animals and registration of holdings:

4.14 All herds and holdings will be registered in accordance with Directive 64/432/EEC as amended. All cattle holdings must be registered onto the Cattle Tracing System (CTS), operated by the British Cattle Movement Service. All registered premises will be recorded onto this system. The CTS Online allows cattle owners to:

- Register new cattle births;
- Report cattle movements and deaths;
- See the life history of their cattle;
- See a list of the cattle on their holding;
- Check the movement history of an individual animal; and
- Download information on their cattle for use in their farm management software.

4.15 In addition, the Cattle Identification Regulations 2007 for England require farms to retain registers for 10 years, and in any other case (e.g. markets) for 3 years, from the end of the calendar year in which the last entry was made.

4.16 The livestock identification system provides traceability of cattle from birth to death. It underpins all disease control programmes for cattle, including bovine TB and provides general assurance for consumers of the place of origin of beef and dairy products. Cattle are identified by a unique Official Animal Identification number (OAI), which is provided by the competent authority, the BCMS. All cattle born after 1 January 1998 must have an approved ear tag in each ear, bearing its unique OAI, which will remain with the animal throughout its life. Animals born in, or imported into England, before 1 January 1998 may continue to be identified by a single tag. Cattle born after 1 July 2000 must be identified by a UK 12 digit numeric ear tag. All cattle must be tagged within 20 days of birth, although in the case of dairy animals, at least one of the tags must be fitted within 36 hours of birth. In addition, all cattle born in, or imported, since 1 July 1996, must have a valid cattle passport. This details the unique eartag number given to the animal, movement history between holdings (farms/markets/slaughterhouses), the breed, sex and date of birth of the animal. Passports must be applied for within 27 days of birth (within 7 days of the 20-day tagging deadline). Details of all births, movements between holdings (farms, markets and slaughterhouses) and deaths of individual cattle, must be notified to the BCMS for entry on the central database, the Cattle Tracing System (births within 27 days of the event, movements within 3 days of the event, death within 7 days of the event).

4.17 Unannounced spot checks, based on a risk analysis of holdings, will be carried out by payment agency inspectors on 3% of holdings, to check that keepers are complying with all cattle identification and registration requirements, and an annual report on the results will be sent to the Commission by 31 August 2013 as required by Commission Regulation (EC) No 1034/2010. If errors are found cattle movement restrictions will be imposed (such as whole herd movement restrictions). In addition, any keeper found to be deliberately breaking the cattle identification rules may be

prosecuted. If the courts find that a keeper is guilty of an offence they may impose penalties, including fines of up to £5,000 and possible custodial sentences, or £10,000 and custodial sentences under fraud legislation.

4.4.4. Qualifications of animals and herds¹²:

4.18 The TB control programme in England will be conducted under the Tuberculosis (England) Order 2007 (as amended). There are no recorded herds of unknown TB status in GB. Maintenance, suspension, withdrawal and re-qualification of OTF herd status will be in accordance with paragraphs 2 and 3 of Annex A of Directive 64/432/EEC. Briefly, all herds will be designated OTF. If herds are placed under TB movement restrictions due to skin test reactors, suspect slaughterhouse cases, inconclusive reactors detected within 3 years of an OTFW TB breakdown, delayed (overdue) TB testing, presence of suspect clinical cases (very unusually), or any combination of those situations, the OTF status will initially be **suspended** (OTFS). Cattle herds will have their OTF status **withdrawn** (OTFW) whenever characteristic lesions of TB are detected at post-mortem examination of test reactors, or *M. bovis* is isolated in tissue samples from any animal in the herd. OTFS herds with a history of OTFW breakdowns or adjoining an OTFW herd will incur one extra herd test at 60 days with negative results to regain OTF status.

4.4.5. Rules on the movement of animals:

4.19 In accordance with Council Directive 78/52/EC (Article 14), whilst an investigation is being carried out, the herd will be placed under official surveillance and movements of cattle into or out of the herd will not be permitted except to a limited number of destinations (including direct to slaughter), always under licence from AHVLA. Following a TB breakdown the entire holding is restricted. Only in exceptional circumstances do we lift restrictions on epidemiologically separate groups of cattle provided they are not within, or contiguous to, the same land parcel on which the infected group of cattle are kept. In all such cases there must first be a satisfactory veterinary risk assessment to verify separation by location, management and time. Cattle on all land parcels that comprise the entire holding remain ineligible for export from the UK whilst any part of the

¹² To mention only if applicable.

holding is under restriction. Additionally we carry out pre-export checks to ensure that within the 180 days preceding the pre-export test the cattle have not been resident in a herd subject to TB restrictions (i.e. OTF suspended or withdrawn) or with unresolved TB inconclusive reactors (see paragraph 4.46). There are detailed guidelines in place for the derestriction of parts of a holding. We will review and tighten these instructions and work to phase out the practice by the end of 2014. Suspected animals within the herd will also be isolated pending slaughter (reactors and contacts) or re-testing (inconclusive reactors). Appropriate follow-up re-testing of OTFS and OTFW herds, at minimum intervals of 60 days, will take place to eliminate residual infection and restore OTF status in accordance with paragraph 3 of Annex A of Directive 64/432/EEC. Local Authorities monitor and enforce movements from non-OTF herds.

4.20 Licensed cattle movements on to all new breakdown herds (both OTFW **and** OTFS) will only be considered after the herd's first official post-breakdown test and will be dependent on a satisfactory veterinary risk assessment. Controlled cattle movements off TB restricted premises are permitted only in limited cases where this is considered necessary in terms of business viability and acceptable on the basis of veterinary risk assessment. Such movements may also be permitted for animal welfare reasons (e.g. address overstocking problems, where there is shortage of feed or housing, or to treat cattle). These options have been developed by veterinary experts to ensure they did not materially increase disease spread risks. In all cases a documented and satisfactory Veterinary Risk Assessment – to be completed by an AHVLA Veterinary Officer – is required before movement license requests can be approved. Field instructions are provided to AHVLA staff to ensure VRAs are objective, consistent and robust. The movement window for any licensed movements (to live) of cattle between TB-restricted herds will be reduced from 60 days to 30 days after a test with negative results.

Pre-movement testing (PrMT) of cattle moving from OTF herds in GB

4.21 The derogation at Annex A, section I-1 of 64/432/EEC is being applied in England. However pre-movement TB testing is nevertheless mandatory for **domestic movements of cattle between OTF holdings** in England as an additional control measure to protect the low incidence areas

of the country, to reduce the risk of moving infected cattle between herds in the high incidence areas and as a surveillance tool to supplement the routine TB herd testing regime.

4.22 The Tuberculosis (England) Order 2007 requires that all cattle 42 days old and over moving out of 1- or 2-yearly tested OTF herds in England must be tuberculin skin tested with negative results in the 60 days prior to the movement, subject to certain limited exemptions. In addition, animals from low incidence (3- and 4-yearly testing) areas in England must also be skin tested before movement to Scotland, unless they have spent all their lives in a low incidence area or are moving direct to slaughter. A number of exemptions were removed and movement controls in general were tightened from 1 July 2012 (see section 2.13). The remaining exemptions continue to apply. However, we will review our pre-movement testing policy again in 2013 in the context of applying a risk based approach to the derogation for movements between OTF herds, in particular the current testing exemption for movements of cattle to/from common land. Movements currently exempted are:

- Directly to slaughter;
- To slaughter via a market from which all animals go to slaughter;
- To exempt markets approved by AHVLA;
- To exempt finishing units approved by AHVLA;
- To slaughter via approved finishing units;
- To approved collection centres;
- To (and from) common land;
- Between premises under the same SOA located in lower TB risk (3 or 4-yearly testing) areas;
- From holdings that are subject to routine annual testing solely for public health reasons (farms open to the public and producers-retailers of unpasteurised milk);
- From approved semen collection centre;

- For veterinary treatment; and
- To agricultural shows where cattle are not housed and not kept on the showground for more than 24 hours and provided that the animals either go directly from the show to slaughter or are returned directly to their premises of origin.

4.23. In general, pre-movement tests are privately arranged and paid for by herd owners, though AHVLA supplies the tuberculin used in the tests free of charge. Cattle tested with negative results as part of a routine surveillance or any other official TB test paid for by the Government in an OTF herd may also qualify as being pre-movement tested for domestic purposes, provided that their movement takes place in the ensuing 60 days.

4.24 Between 1 March 2006 and 31 December 2011, 1987 reactors were identified in 1151 herds from dedicated pre-movement tests in England; and a further 2698 inconclusive reactors (IRs) were also identified during the same period. In 2010, 7.5% of all new TB breakdowns in England were identified through PrMT. Additionally a further 6,514 reactors were disclosed as a result of follow-up testing in herds with pre-movement test positive animals.

4.25 Herd owners wishing to move cattle to another farm or to a market must retain copies of their TB test charts as proof of testing and are advised to retain evidence of the relevant PrMT exemption for non-tested stock. Those farmers marketing cattle will be asked for copies of this evidence as assurance of the test status of their animals. Non-compliance with the pre-movement testing policy is an offence under the TB Order. The AHVLA Pre-Movement Testing Monitoring Unit check every month a proportion of all cattle movements on the Cattle Tracing System (CTS) against AHVLA cattle TB testing records, for possible PrMT breaches. Suspected breaches are reported to the Local Authorities for investigation and, if appropriate, prosecution. In addition, compliance with TB testing requirements, including PrMT, is one of the criteria used for Common Agricultural Policy (CAP) cross-compliance checks, so that illegal movements of animals can result in a reduction to the owner's Single Payment.

4.26 Where a PrMT-eligible animal is identified as not being tested, the animal will be placed under movement restrictions and subject to a post-movement test paid for by the owner of the holding. If this post-movement test is not completed within 60 days, the whole herd is placed under movement restrictions (OTF status suspended) until such time as the cattle test clear.

4.4.6. Tests used and sampling schemes:

4.27 As contemplated in Directive 64/432/EEC, the Single Intradermal Comparative Cervical Tuberculin (SICCT) test will continue to be the primary screening test for bTB in England. There is also local veterinary discretion to interpret only the bovine reaction. Additionally, and in line with the recommendations of the EU Task Force TB sub-group (SANCO/10200/2006 Final), the IFN-gamma blood test will be used in specific OTFW herds as an ancillary parallel test to enhance sensitivity. Further analysis is being undertaken during 2013 to assess other ways of enhancing the sensitivity of the routine TB testing regime in England, including expanding the use of severe interpretation of use of the single intradermal test.

TB surveillance - routine tuberculin skin herd testing programme

4.28 All herds and animals are included in the monitoring programme.

4.29 A new routine surveillance regime will be in place from 1st January 2013. This will see an expanded area under annual testing (the high incidence area) and the creation of a low incidence area on background four-yearly testing, where the sporadic breakdowns can, in the vast majority of cases, be attributed to bought-in infection from the high incidence area that has evaded detection through pre-movement testing. Enhanced surveillance (3km radial testing) will take place around TB breakdowns in the low incidence area to confirm that localised spread has not occurred. In addition, all raw cows' drinking milk must originate from OTF herds. All dairy herds and on-farm bed and breakfast facilities that produce and retail unpasteurised

milk to the final consumer are subject to annual testing regardless of the default testing frequency in their area. Other herds considered to be a higher risk (e.g. dealers, bull hirers etc) will also be placed on annual testing. Further detail and justification for the strategy can be found in section 3.11.

4.30 To optimise the effectiveness of TB surveillance in the low incidence, four-yearly tested area, the testing of herds will be organised so as to ensure that an equal proportion of routine herd tests will be carried out each year. This approach, known as 'temporal smoothing', ensures that herd tests are distributed equally across the area over the testing cycle.

4.31 AHVLA will also carry out investigations of any clinical suspects notified to them. However, this is likely to only occur in a small number of cases as animals with clinical signs of TB are rarely seen on farms. Details of passive TB surveillance carried out in slaughterhouses can be found in paragraphs 4.11-4.12.

4.32 The herd owner will be responsible for arranging scheduled tests under the routine surveillance programme, which will be paid for by Government. AHVLA will give herd owners advance notice of the 2 or 3 month window in which the test must be completed by their nominated Official Veterinary practice. Test notification letters will be sent centrally from AHVLA to ensure consistency of notification across England and Wales. Official Veterinarians (OVs) will also be notified by AHVLA of the due dates for their clients' herd tests. To ensure compliance with the tuberculin testing programme, a **zero tolerance regime for overdue tests** was introduced in February 2005, whereby a herd's OTF status is automatically suspended as soon as a TB test becomes overdue. AHVLA actively manage these overdue tests by a combination of formal warnings and staged sanctions, potentially leading to a reduction in Single Farm Payments and referral of the herd owner to the Local Authority for prosecution. Defra introduced from 1st July 2012 new rules when there is a failure to comply with testing requirements which may also affect the amount compensation received for any TB reactor animals with a reduction in compensation of up to 95%. Once tested, a herd is marked forward in the

AHVLA database for its next TB test according to the normal TB testing frequency for the area and taking also into account the herd's TB history and TB risk factors.

4.33 Routine and other skin tests are carried out by OVs, AHVLA veterinarians and AHVLA veterinary paraprofessionals¹³ (fully trained lay testers working under the direction of AHVLA veterinary officers¹⁴). Training is provided by AHVLA with new OVs supervised by AHVLA (including one supervised test for OVs after 6 months). A formal process for auditing of TB testers at 24-month intervals has been rolled out through AHVLA's Operations Manual. The process provides for comprehensive and auditable quality assurance of our TB testing programme, by setting out clear audit criteria and procedures and standards against which testers are to be measured (for example such as use of equipment and correct completion of paperwork), and corrective actions to be taken (e.g. re-training and possible suspension from TB testing until re-training and successful audit completed). Since January 2010, AHVLA has also been delivering enhanced veterinary advice for farmers going through their first bovine TB breakdown, through extended disease investigation visits. We are working with the veterinary profession to deliver focused veterinary advice (through private vets) to owners of long-term breakdown herds. Additionally an enhanced OV auditing programme is being piloted in Wales, with a view to roll out across England and Wales following evaluation of the pilot.

4.34 This enhanced programme will provide more robust quality assurance of veterinary training and skills on TB has been developed by AHVLA to supplement existing training of its own TB testers and Official Veterinarians. A comprehensively revised and expanded OV training programme has also been completed and details of the roll-out process are currently being finalised. AHVLA has developed an improved TB training package that will

¹³ Pre-export tests have to be carried out by a veterinary surgeon.

¹⁴ The UK has a comprehensive, tried- and-tested programme for training and assessment of paraprofessional TB testers. They are required to undergo a rigorous training programme under the direct supervision of a Veterinary Inspector. To complete this they are required to have undertaken a number of TB tests, and seen and identified a number of reaction types and demonstrated a minimum level of competence before appointment. They are thereafter audited, on an „unannounced’ basis, within three to six months of initial appointment followed by regular field audits by full-time Defra veterinary staff at the same interval and to the same clearly-defined standards as veterinary TB testers.

be rolled out to new OV's. This will give consistency across Great Britain as OV's will receive the same training – the same package delivered in the same way. There is an element of pre-course work to provide background understanding prior to training, comprehensive and interactive training in groups, maximum 12 in size, with a self-assessment paper, and followed by post course work. This will increase consistency and quality of TB testing, in not only providing the same training to all but also in establishing a better understanding of TB control and management amongst OV's.

Control measures in infected herds for the restoration of OTF status

Management of TB incidents

4.35 For a summary of controls see section 3.21. and 4.36. In accordance with paragraph 3A in Annex A of 64/432/EEC, some procedures may be relaxed and will not apply where the OTF status of the herd remains only *suspended*. *Withdrawal* of OTF status is triggered by positive identification of *M. bovis* infection in the herd (i.e. detection of classical TB lesions at post-mortem and/or isolation of the organism by tissue culture). In addition, herds with a history of TB in the herd (as defined by confirmed incidence of TB in the herd within the last three years) and / or the presence of TB in the local area (as defined by confirmed incidence of TB in a contiguous herd) will be placed under restriction for longer periods and be required to pass further skin tests to reduce the risk from undisclosed and recurrent infection within the herd or spread of disease to other herds.

4.36 In the 4 year testing areas in England enhanced TB surveillance processes are in place for new, confirmed TB breakdowns where the cause cannot be attributed to recently purchased cattle. This comprises additional testing of cattle herds and a survey of dead badgers and wild deer identified in an area within a 3 km radius of the OTFW holding.

Tuberculin test

4.37 Tuberculin testing of cattle will continue to be the main TB surveillance and control tool in England in 2013. Testing is by the single intradermal comparative cervical test (SICCT), using 0.1 ml of bovine (30,000 IU/ml) and avian (25,000 IU/ml) PPD tuberculins manufactured by

Prionics AG in Lelystad, The Netherlands under a 3-year supply contract awarded in Dec 2009. This paired presentation of tuberculins received a Marketing Authorisation for use in UK and a number of other MSs from the Veterinary Medicines Directorate in December 2010.

4.38 The interpretation of the comparative reactions to the injection of tuberculin will vary depending on the TB history and status of the herd. **Standard interpretation** in line with section 2.2.5.2 of Annex B of Directive 64/432/EEC will be used for herds with no recent history of bovine TB, or no visible evidence of infection at post mortem or following laboratory culture of recently disclosed reactors. In line with SANCO/10200/2006 Final recommendations and section 2.2.5.3.5 of Annex B of the Directive, a more **severe interpretation** will be applied to 60-day Short Interval Tests (VE-SI) carried out in OTFW (see above), to maximise the probability of detecting infected animals.

Interferon gamma diagnostic blood test

4.39 In line with Directive 64/432/EEC, in GB, the **interferon-gamma** (IFN-gamma or BovigamTM) test will be used as an ancillary parallel test, alongside the tuberculin skin test in specified circumstances. Using both tests in parallel in this way enhances the sensitivity of testing so enabling as many infected cattle in a herd as possible to be identified and removed from the herd at the earliest opportunity.

4.40 Under this policy the primary focus of the IFN-gamma test will be in OTFW breakdown herds in lower risk (4 yearly testing) areas and at the edge of the high risk area; the objective being to reduce the risk of new, intractable TB hotspot areas becoming established in hitherto low prevalence areas and to prevent the expansion of the high risk area. The test will also be used in certain herds (e.g. with particularly severe TB problems) in other areas of high TB incidence. The use of the IFN-gamma test will be mandatory on tuberculin test-negative animals in all OTFW new TB incidents in the 4 year testing zones in England. Discretionary use is for all skin test negative animals in herds in high risk areas with persistent, confirmed infection that fail to resolve through repeated short-interval tuberculin skin tests and that have in place certain biosecurity controls. IFN-gamma can also be used on skin test negative animals in severe TB incidents, to inform decisions around whole or partial herd slaughter.

4.41 In England, between 23 October 2006 and end July 2012, 107,809 IFN-gamma blood tests were performed on cattle from 3,936 herds, identifying 8,371 positive animals. All IFN-gamma test positive animals are treated as TB test reactors and quickly removed to slaughter.

4.42 Occasionally, in exceptional circumstances, AHVLA may use a modified IFN-gamma test with more specific *M. bovis* antigens as a serial test of skin test reactors and inconclusive reactors in chronic OTFS herd breakdowns arising in 4-yearly testing areas, where non-specific cross reactions to tuberculin are suspected. The serial IFN-gamma test may also be deployed for re-testing of suspected fraudulent tuberculin test reactors presenting with abnormal skin responses.

4.43 The use of the IFN-gamma test is currently being reviewed by Defra.

Inconclusive reactors (IRs)

4.44 Any animals identified as IRs by the SICCT test read under standard interpretation will only be re-tested once after an interval of 60 days and will be removed as reactors if their status remains unresolved at that stage, in line with Annex B to Directive 64/432/EEC. At the discretion of the case veterinary officer, IRs in OTFW breakdown herds which do not automatically become reactors under severe interpretation may, on occasions, be designated direct contacts and slaughtered straight away before they undergo re-testing.

Imported cattle

4.45 All cattle imported into GB from non-OTF EU Member States and other parts of the UK (Northern Ireland, Isle of Man) must comply with the TB certification conditions set out in Council Directive 64/432/EEC (as amended). Cattle from Northern Ireland and the Isle of Man are subject to pre-movement testing within 30 days of departure using the comparative skin test. Additionally, post import skin testing of cattle from Northern Ireland,

the Republic of Ireland, Isle of Man, and any non-OTF EU Member States is conducted 60 to 120 days after arrival in GB, unless the animals are destined for direct slaughter. Movement restrictions are not applied to either the animal or the herd during this period before the test is conducted. Based on a risk assessment, it may also be necessary to carry out TB checks and testing of certain consignments from third countries.

Exports of cattle to other EU Member States

4.46 Cattle of at least 42 days of age that are intended for intra-Community trade are TB tested in the 30 days prior to the date of export (as per Article 6 of Directive 64/432/EEC) using the single intradermal comparative cervical test. However, **only the bovine reaction will be considered** when interpreting the test results in such animals. In line with Council Directive 64/432/EEC (point 2.2.5.3.4 in Annex B), any animals showing a positive bovine reaction (i.e. an increase in the skin fold thickness greater than 2 mm or the presence of oedema 72 ±4 hours after tuberculin injection) will not be certified for intra-Community trade. Cattle on all land parcels that comprise the entire holding remain ineligible for export from the UK whilst any part of the holding is under restriction. Additionally we carry out pre-export checks to ensure, inter alia, that eligible cattle for export have not been resident in the 180 days on any holding with some form of on-going TB restriction (i.e. OTF suspended or withdrawn) or with unresolved TB inconclusive reactors. We will be reducing the numbers of occasions where we de-restrict holdings in this way and will phase out the practice by the end of 2014.

Control in non-bovine animals

4.47 Suspicion of disease in the carcase of non-bovine species is notifiable. Passive surveillance is and will continue to be carried out on domestic livestock other than cattle (farmed deer, sheep, pigs, camelids and goats) mainly by meat inspection in animals going through licensed abattoirs, necropsy of suspect clinical cases by AHVLA, or via the surveillance network provided by OV's and private veterinary surgeons. A programme of additional training of Meat Hygiene Inspectors in abattoirs and awareness raising among private vets about the symptoms of TB in non-bovine animal carcasses took place in 2011. If bacteriological tests confirm infection with *M. bovis* in non-bovine animals, where appropriate, movement restrictions

will be imposed by AHVLA and usually only lifted following two clear tuberculin tests, and also the local Health Protection Unit's CCDC is informed. *M. bovis* infection in all non-bovines is monitored by AHVLA. The application of movement restrictions to non-bovine farmed animals is currently being reviewed in England to consider whether the present arrangements are proportionate and fit for purpose.

4.4.7. Vaccines used and vaccination schemes:

Badger vaccination

4.48 Recognising that action to address the wildlife reservoir of bovine TB is needed, a **Badger Vaccine Deployment Project** using a licensed injectable vaccine (Badger BCG) has been in progress in England since Summer 2010. The deployment project is developing practical know-how for vaccinating badgers.

4.49 This was the first practical use of a vaccine for TB in badgers outside research trials. Vaccination is taking place in the Stroud area of Gloucestershire and was selected from those with the highest historical incidence of bovine TB in cattle. This area of some 100km² of cattle farms has been targeted, with vaccination planned to continue for five years. More than 625 badgers were vaccinated in this area in 2011. The deployment project is designed to build farmer confidence in vaccines as a key tool in an eradication programme; build a core of trained lay vaccinators with practical experience in identifying, trapping and vaccinating badgers which could be used for a broader roll out of injectable or oral vaccines. BadgerBCG is also now available for use across the country if farmers wish to use vaccination as a way of reducing transmission risks to their herds. In December 2011, a decision was taken to cull badgers to control TB in England and from 2012 to 2014 £250,000 grant funding is being made available each year through the Badger Vaccination Fund to support and encourage badger vaccination to help mitigate against the negative effects of culling brought about by perturbation, when no other physical buffers are available. In 2012 Vaccination Fund grants are also available to community and voluntary organisation members to support lay vaccinator training or re-certification.

4.50 Research is under way to develop an oral BCG vaccine and suitable bait formulation as this may offer the most practicable application of a vaccine to a wildlife population in the longer term, if technical barriers can be overcome. The efficacy of candidate oral vaccine formulations is currently being tested in captive badger challenge studies at the Animal Health and Veterinary Laboratories Agency (AHVLA). Research into a suitable bait for the oral vaccine, and field studies evaluating strategies for deploying the bait, are being carried out by AHVLA and the Food and Environment Research Agency (FERA). However, developing an oral vaccine against TB in badgers is proving more difficult than originally hoped. This means that a usable oral badger vaccine could be many years away. We cannot say with any certainty if and when an oral badger vaccine might be available for use in the field.

Cattle vaccination developments

4.51 Research continues to be funded into **cattle TB vaccination** experiments with BCG and other vaccine candidates, which include a range of live attenuated and sub-unit vaccines. EU legislation currently prohibits the use of TB vaccines in cattle, and Directive 64/432/EEC would prevent trade in vaccinated cattle because vaccination with BCG sensitises cattle to the skin test causing them to react as if they were infected. However, vaccination offers an additional, valuable tool for controlling and eradicating bovine TB, in particular in endemic areas, so research is being carried out in GB to develop and validate tests to differentiate infected from vaccinated animals (so-called **„DIVA’ tests**) to address the legal concerns. An application for a UK Marketing Authorisation for BCG in cattle was submitted to the UK Veterinary Medicines Directorate in January 2012. VMD completed its initial assessment of the licensing application in June 2012 and has requested additional information before further consideration can be given to the application. A DIVA test which can differentiate infected from vaccinated cattle, based on the gamma interferon test, has been developed and validated in laboratory studies.

Research projects

4.52 The Bovine TB Science Advisory Body (SAB) was set up in January 2008 to provide independent advice to Defra's Chief Scientific Advisor and Chief Veterinary Officer on TB-related research. The SAB consists of three sub-groups focusing on specific areas of Defra's TB research portfolio: epidemiology and wildlife risks; diagnostics; and vaccines. We are continuing to invest in a substantial (~£7.5m/annum) research programme which aims to help improve the epidemiological understanding of the TB situation in GB and support the further development of tools and measures for tackling the disease, including cattle and badger vaccines, improved diagnostics and enhanced surveillance and control measures.

4.53 Defra funds a wide-ranging TB research and development programme aimed at improving our understanding of the disease and at developing novel tools and refining existing tools and how we apply them to tackle the disease. It covers many branches of science (including immunology, vaccination, diagnostics, epidemiology, ecology and genetics), as well as social science and economics. Between 1991/92 and 2011/12 Defra funded over 100 individual research projects, and invested approximately £93 million in TB research and development. In recent years, an increasing proportion of this research budget has been directed towards developing vaccines and associated diagnostic tests. Further details of ongoing research and reports of completed projects can be found at <http://randd.defra.gov.uk>.

4.54 Following consideration of the Government's priorities, and a range of advice – including that of TB SAB - we have identified the following as priorities for our evidence programme:

- Development of a licensable oral badger TB vaccine;
- Development of licensable injectable cattle TB vaccines, including non-sensitising vaccines;
- Development of cattle diagnostics including a DIVA test;
- Epidemiology of the disease and modelling of the effect of different interventions;

- Understanding the spread of the disease from endemic areas;
- Ecology and behaviour of badgers as relevant to TB transmission;
- Understanding changes in badger numbers in recent years and badger ecology, particularly the effect of low level perturbation on disease transmission, to measure the effect of low level culling;
- Improved methods for detecting infected badgers or infected setts e.g. PCR-based tests;
- Non-lethal forms of badger control e.g. fertility control;
- Whole-sett culling methods e.g. gassing; and.
- Understanding the social and economic aspects of our TB policies on farmers and other stakeholders.

4.55 The budget for the TB research programme in 2012/13 is £7.5m and for 2013/14 is anticipated to be £7.8m.

- The wide-ranging TB research programme, centres on four areas:
 - Development of vaccines for use in cattle and badgers;
 - Development of improved diagnostic tests for use in cattle and badgers;
 - Economic and social research related to the impacts of TB and its control; and
 - Understanding the epidemiology of TB in cattle and wildlife, and the impact of control measures on disease spread.
- Our priorities for future research include:
 - Development of a licensable oral badger vaccine;
 - Development of a licensable cattle vaccine with an accompanying DIVA test;
 - Work towards a non-sensitising cattle vaccine;
 - Development of improved methods to detect infected badgers or setts;
 - Understanding the social and economic impacts of TB control policies;
 - Better understanding of how TB spreads from endemic areas;

- Understanding the impact of badger ecology and behaviour on TB transmission; and.
- Alternative methods of badger culling, and non-lethal methods of badger control.

Wildlife issues

4.56 There is clear evidence that transmission from badgers to cattle is a key factor in the epidemiology of bovine TB in many parts of England, especially the West Midlands, West and South-West of England. In high incidence areas, a significant proportion of herd breakdowns result from infection from badgers. Interventions to reduce transmission from badgers to cattle will therefore be an essential part of the programme designed to eradicate TB in cattle over the longer term.

Badger culling

4.57 In December 2011, Defra announced its intention to proceed with a carefully-managed and science-led policy of badger control in England, as part of a package of measures to tackle TB in cattle.

4.58 Defra's policy is to enable farmers and landowners to cull and/or vaccinate badgers under licences granted under the Protection of Badgers Act 1992 and Wildlife and Countryside Act 1981. Defra's "Guidance to Natural England on the implementation and enforcement of a badger control policy" (issued under section 15(2) of the Natural Environment and Rural Communities Act 2006 ("the NERC Act")) sets out what is required, on the basis of current scientific evidence, in order for any cull of badgers to be effective, safe and humane. In order to be granted a licence, a group of farmers/landowners will need to meet strict licence conditions. The Government's role will be to operate the licensing regime and monitor the effectiveness, humaneness and impact of the badger control measures.

4.59 Defra defended a Judicial Review of the badger culling decision. As a first step, there would be a pilot of the policy in two areas to confirm our assumptions about the effectiveness (in terms of badger removal), humaneness and safety of culling. We are continuing to proceed with preparations for the two badger culling pilots. Natural England issued the first culling licence (17 September 2012) for West Gloucestershire and the second culling licence (4 October 2012) for West Somerset. However concerns were raised that as new survey results revealed higher than anticipated badger numbers in the two pilot area, therefore the organisers of the pilots could not be confident of removing the required 70 per cent of the badgers in the two pilot areas this autumn. Defra has therefore agreed to postpone the pilot culls until summer 2013 to allow farmers to continue their preparations and have the best possible chance of carrying out the cull effectively.

4.4.8. Information and assessment on bio-security measures management and infrastructure) in place in the holdings involved:

4.60 Defra has collaborated with industry to promote wildlife bio-security advice, through production of a training DVD which has been made widely available to farmers via government and industry websites. An explanation of what TB is and what it means to have it on farm, as well as encouragement to put husbandry and biosecurity measures in place, is included in a series of leaflets given to all farmers who have a TB breakdown. The advice (AHVLA's series of 'TB in your herd' advice and guidance leaflets) has recently been updated and republished (Summer 2012).

- Since January 2010, AHVLA has also been delivering enhanced veterinary advice for farmers in England experiencing their first bovine TB breakdown, through extended disease investigation visits. We are continuing to work with the veterinary profession to deliver focused veterinary advice (through private vets) to owners of herds affected by long-term breakdowns.

4.4.9. Measures in case of a positive result¹⁵:

Officially TB Free Status and Slaughter of Animals

4.61 In line with Annex A of Council Directive 64/432/EEC as amended, OTF status will be *suspended* by service of a legal notice (known as „TB2’) on the herd owner:

- Where an animal discloses with a positive result to the tuberculin skin test (a **reactor**);
- Where a test reveals IRs only, in a herd that had OTF status withdrawn within the previous three years.
- Following the discovery of lesions suggestive of bovine TB in carcasses at a slaughterhouse;
- Where a tuberculin test becomes overdue; and
- In suspected clinical cases (although this is very rare and the first action would be to carry out a tuberculin skin test).

4.62 Following the identification of reactors they are removed for slaughter as a matter of urgency (with the majority being removed within 10 working days of disclosure). Whilst on the farm Reactors and IRs, must be immediately detained on the holding and isolated as far as practicable from other cattle in the affected and any adjoining holdings, until they are removed for slaughter or subject to further testing, respectively. The case veterinary inspector will issue the herd owner with a legal **Notice of intended slaughter** (form TB03) under Article 15 of the Tuberculosis (England) Order 2007, detailing the place and conditions of isolation for the animal(s) tailored to each affected farm. The isolation conditions are aimed to ensure spatial and temporal separation of the reactor(s)/IR(s) within a building or field so as to prevent nose-to-nose contact between the reactor(s)/IR(s) and the rest of the herd (e.g. reactor milking cows to be kept in a separate shed or field and milked last in the day).

¹⁵ A description is provided of the measures as regards positive animals (description of the slaughter policy, destination of carcasses, use or treatment of animal products, the destruction of all products which could transmit the disease or the treatment of such products to avoid any possible contamination, a procedure for the disinfection of infected holdings, the therapeutic or preventive treatment chosen, a procedure for the restocking with healthy animals of holdings which have been depopulated by slaughter and the creation of a surveillance zone around the infected holding.).

4.63 Movement restrictions will be imposed and no movement will take place unless a licence is issued by an AHVLA veterinary officer. TB testing will be carried out again at 60 day intervals (up to a maximum of 90 days). For all non-OTF herds, no on-movements are permitted until the completion of the first official test and a satisfactory veterinary risk assessment.

4.64 For reactors, a DNA eartag will be applied at the time of disclosure and a random or targeted number will be followed up by DNA matching samples taken following the slaughter of the reactor. This is to ensure that no TB reactors are retained on farms.

4.65 If postmortem evidence of *M. bovis* infection cannot be demonstrated (by post-mortem examination and culture) in any of the slaughtered reactors, OTF herd status will remain suspended and may be restored after a single skin test of all the animals over 42 days old in the herd with negative results. That herd test will be carried out at least 60 days after the effective isolation/removal of the reactor animal(s). Additionally, in England, any OTFS breakdown herds that happen to be contiguous to an ongoing OTFW breakdown, or have had their OTF status withdrawn in the preceding three years, will require two (not one) consecutive skin herd tests with negative results before regaining OTF status.

4.66 In accordance with Directive 64/432/EEC, the OTF status of a herd will be *withdrawn* (OTFW) if typical lesions of TB are seen at post-mortem examination of skin test positive reactors or following the isolation of *M. bovis* from tissue cultures. Where OTF status has been withdrawn; two consecutive herd tests with negative results must be attained before movement restrictions can be lifted and OTF status restored. Additionally, and in accordance with section 2.2.5.3.5 in Annex B of Directive 64/432/EEC, a more severe interpretation of the skin test will be adopted in all OTFW TB breakdowns. Furthermore, for OTFW breakdowns in the low incidence area, 3km radial testing will take place to establish that there has not been localised spread of infection. Herds will be subject to an immediate check test of all animals over 42 days of age. If this initial check test is negative, the herd will be marked forward for an additional 6-months later and a 12-month check test thereafter, before reverting to the default 4-yearly testing frequency for the low incidence area.

4.67 A pilot project took place in the first half of 2012 to look at long-term breakdowns and how these can be better managed to reduce disease risks (e.g. length of the breakdown). This involved the use of additional tools to gain a better understanding of the disease in the herd, and a more co-ordinated approach to case management involving VOs and OVs. A final report has been circulated and further work will be undertaken, based on the report findings, to introduce a more structured process to enhanced management of breakdown cases including triage protocols.

4.68 After regaining OTF status, OTFS and OTFW herds must undergo further skin check tests before going back to the normal area herd testing frequency. In former OTFW herds and the majority of OTFS herds, the first such test will take place 6 months after restoration of OTF status. If that test is negative, a second check test takes place 12 months thereafter. In England former OTFS herds located in 4 yearly testing zones will only require one follow up test with negative results between 6 and 12 months after OTF status restoration. During this period, any cattle moved out of the herd will be eligible for PrMT.

4.69 When OTF status is suspended or withdrawn for whatever reason, a **legal notice** (known as „TB2’) putting the herd under movement restrictions will be served on the keeper and copied to the Local Authority for enforcement procedure by their Trading Standards Department in the event of a farmer’s non compliance. For public health reasons, whenever OTF status is suspended in a dairy herd the relevant local food authority CEHO will also be notified by AHVLA, to ensure that all the milk sold from those herds is pasteurised and milk from individual reactors does not enter the food chain, as per Council Regulation 853/2004/EC. In addition, where OTF status is withdrawn after disclosure of visible lesions or positive culture results, AHVLA will inform the relevant local medical authorities, i.e. the CCDC in England (see table in paragraph 4.6).

4.70 In accordance with Annex A of 64/432/EEC, the Tuberculosis (England) Order 2007, in herds where OTF status has been withdrawn a **legal Notice (BT05)** is served on the owner **requiring cleansing and disinfection (C&D)** by a specified date following the removal of any test reactors or „affected’ animals. The AHVLA veterinary inspector will specify the conditions of C&D on the form, but this includes thorough disinfection (with a Defra-approved disinfectant) of all parts of the premises where reactors were housed or yarded (since isolation) and ensuring that any grazing

previously used by cattle will be left vacant for a minimum period of 60 days before being re-stocked. Attached to the BT05 notice there are guidelines for the completion of C&D, including the disposal of manure on TB infected farms, and a declaration to be completed and signed by the owner and returned to the local AHVLA office at the end of the breakdown. The OTF status of the herd cannot be restored until the AHVLA office has received a copy of the BT05 notice with the herd owner's signed declaration setting out the date of completion of C&D and the type (and dilution rate) of the disinfectant used by the farmer. In 2012 we introduced a target of 10% visits/physical checks undertaken by AHVLA inspectors of herd owners' compliance with the C&D requirements. Additionally, a physical check will be carried out in all instances where partial or complete depopulation of an infected farm has taken place.

4.71 As part of the general TB control requirements, the herd keeper and the haulier contracted by AHVLA to transport the reactors to slaughter will be required to comply with the legislation with regard to the transport of any cattle as set out in Transport of Animals (Cleansing and Disinfection) (England) and (Wales) (No 3) (Amendment) Order 2003 (as amended). After unloading the animals, vehicles must be fully cleansed and disinfected as soon as is reasonably practicable, before they are used again and in any case within 24 hours after they are unloaded. Wheels, wheel arches and mud flaps must always be cleansed and disinfected whenever the vehicle is cleansed and disinfected. Livestock vehicles, whether empty or loaded, must also leave market premises "visibly clean" as part of the market licence conditions. Conditions of transport for reactors and contacts slaughtered by AHVLA and other (test-negative) animals in the affected holding are set out on the reverse of the **movement licences (TB24)** issued by AHVLA. We will consider the possibility of carrying out further checks on cleansing and disinfection of transporters to verify that vehicles have been disinfected.

4.72 Drivers leaving a market or slaughterhouse with an empty vehicle that has not been cleansed and disinfected must complete a declaration to say where they will take their vehicle for cleansing and disinfection and give the declaration to the market or slaughterhouse operator. In England we have begun the process of reviewing of cleansing and disinfection rules, including at markets and slaughterhouses. This is in addition to updated instructions and advisory material already published, as well as checks at slaughterhouses that approved disinfectants are used.

4.73 In accordance with domestic legislation, AHVLA will arrange removal of all tuberculin and IFN-gamma test reactors and direct contacts to slaughter or disposal at one of the dedicated abattoirs, with compensation paid to the owner. All test reactors and direct contacts will be valued before being removed. One of AHVLA's service delivery targets is to remove at least 90% of all such animals to slaughter within 10 working days of their identification, well within the 30-day period allowed under Article 15 of Directive 78/52/EEC. All animals compulsorily slaughtered for TB control purposes will undergo post-mortem examination by the FSA or AHVLA, and the pathological findings will inform subsequent action in the affected herd. Bovine TB infection will be officially confirmed (and OTF herd status withdrawn) by the disclosure of typical visible lesions of TB during post-mortem examination of test reactors and/or culture of *M. bovis* in primary isolation medium (see Section 6.2).

4.74 In every newly disclosed TB breakdown, at least one reactor will be sampled for bacteriological culture and molecular typing. In herd breakdowns with more than one reactor, the maximum number of animals sampled for culture will depend on the identification (or not) of visible lesions. In a newly detected breakdown, tissue specimens will be submitted from up to three representative reactors with visible lesions. If no reactors show any tuberculous lesions at post-mortem, then samples will be submitted from up to ten non-visible lesion reactors with the largest bovine-avian reaction difference. Where infection with *M. bovis* has already been confirmed in an ongoing TB incident, then any new reactors or contacts disclosed at follow-up herd test will be treated as "infection confirmed" and not sampled. The local AHVLA office may sample additional reactors at their discretion if this is considered essential to support the epidemiological investigations. Please refer to Section 6.2.1 for more details.

Stamping out the disease in heavily infected herds (depopulation)

4.75 Depopulation – whether whole-herd or partial-herd – is one of a number of interventions that may be employed in order to eradicate *Mycobacterium bovis* infection from a cattle herd. It is, by definition, crude relative to the culling of individual animals based on the results of

diagnostic testing performed on animals within the herd. It follows that the utility of depopulation comes primarily when other options have proved unable to rid a herd of infection. This remains a relatively rare scenario.

4.76 Inherent in the depopulation of a herd or a sub-set of a herd is acceptance of the fact that a proportion of the animals destroyed will be healthy and not infected with *Mycobacterium bovis*. For such action to be justifiable it is important that other less extreme options have either been exhausted or considered and deemed unsuitable and that the benefits arising from the depopulation are likely to be effective. The criteria that are in place to support decisions regarding whole- or partial-herd depopulation in England are designed to ensure that this is the case.

4.77 Applications for depopulation of infected holdings must be submitted in writing to the TB Programme Team in England by the AHVLA case veterinary officer on a case by case basis and, where supported by the Regional Veterinary Lead, take into account all of the following factors:

- Prevalence of skin test reactors in the herd or infected cohort (normally exceeding 25% of the total herd size as an indicative rule of thumb);
- Prevalence and severity of post-mortem pathological findings in the slaughtered cattle;
- The presumed source of infection for the herd;
- Risks of herd re-infection from local wildlife and other cattle herds, including the historical incidence of TB herd breakdowns in the locality. In general, whole-herd or significant partial depopulation of infected herds will seldom be considered a viable option in areas of GB with an endemic high TB incidence and an established wildlife reservoir of *M. bovis* infection;
- Risks posed to the local cattle and wildlife population;
- Herd type and husbandry and compliance with biosecurity good practice guidance; and
- Evidence of ongoing intra-herd spread of infection despite the use of repeat skin testing and ancillary parallel IFN-gamma (and sometimes TB serological) testing. In general, parallel IFN-gamma testing must take place in order to assess the prevalence of residual infection before

depopulation may be considered, but this step can be waived for individual breakdowns where only a handful of cattle remain in the affected group (~10% of the initial group size or less) or the severity and extent of infection are so overwhelming that, in the opinion of the case VO, it is not worth applying the blood test.

4.78 Depopulation will involve either the compulsory slaughter of the whole herd, or all the cattle in the herd except for one or more groups of cattle where no reactors have been found and that are not epidemiologically linked to the rest of the herd. Cleansing and disinfection of depopulated holdings will be carried out to prevent reinfection before restocking is licensed. Restocking will only be allowed once the owner has taken positive measures to mitigate the risk of reinfection or a period of time elapsed to reduce risks from residual infection on the holding. Reformed herds following depopulation for TB purposes receive 3 annual check tests and are required to pre-movement test.

4.4.10. Compensation scheme for owners of slaughtered and killed animals:

4.79 The Animal Health Act 1981 provides Defra with the discretion to slaughter any animal, which is affected or suspected of being affected with a specified disease in the interests of protecting human and animal health. This discretion is coupled with a duty to pay compensation for animals so slaughtered, with the level of compensation to be determined by Defra and paid out by AHVLA. Responsibility for meeting the costs of cattle compensation schemes and the removal and slaughter costs will rest with Defra.

4.80 Compensation for cattle compulsorily removed and slaughtered as part of the TB control programme in England is primarily paid at the average market value of similar (i.e. same category) animals. The Cattle Compensation (England) Order 2012 sets out the detailed rules for the table valuation based compensation system for bovine animals affected with bovine TB, Brucellosis and Enzootic Bovine Leukosis. The Individual Ascertainment of Value (England) Order 2012 provides for individual valuation of affected bovine animals where there is inadequate supporting sales data in a particular

month and/or category and when a previously determined table value cannot be used. Individual valuations are used only in a small minority of cases (less than 1%).

4.81 Compensation will not be provided for infected cattle identified in the course of commercial slaughter, or for any TB test positive cattle that die (or have to undergo emergency slaughter) on farm before they can be removed by AHVLA to an approved abattoir or consigned to a rendering plant if unfit to enter licensed abattoirs. From July 2012 in England, compensation will be reduced for TB reactor cattle from herds with significantly overdue TB tests.

4.4.11. Control on the implementation of the programme and reporting¹⁶:

4.82 There will be regular reporting and liaison on the delivery of different aspects of the TB programme between AHVLA and the competent authorities in England including to the UK TB Liaison Group.

4.83 Defra will produce monthly updates of TB statistics for GB which will be published online at <http://www.defra.gov.uk/statistics/foodfarm/landuselivestock/cattle/tb/national/>

4.84 Regular reports will be provided to the European Commission on progress of the disease and on the Plan (including in accordance with Article 8 of Council Directive 64/432/EEC).

¹⁶ Describe the process and control that will be carried out in order to ensure the proper monitoring of the implementation of the programme.

5. **Benefits of the programme**¹⁷:

5.1 The programme to control and eradicate bovine TB in England will have a number of benefits, including:

- The disease will be identified at an earlier stage, thus reducing the numbers of infected cattle and the number of breakdowns.
- The spread of the disease will be controlled and ultimately reduced and eradicated.
- The potential for considerable financial benefits for both the cattle sector and the Government in terms of:
 - Reduction of the production losses incurred by the cattle sector as a result of removal of diseased animals or disruption following the imposition of movement restrictions.
 - Reduced cost burden on the taxpayer by minimising the levels of compensation paid for animals compulsorily slaughtered and reducing future testing costs and AHVLA resources expended on TB issues.
 - In total Government has estimated that each confirmed new breakdown costs on average around £25,000 to the Government in compensation for animals compulsorily slaughtered as reactors or dangerous contacts and in costs of testing, and about £6,500 in costs to farmers from losses of animals, farm costs of testing, and disruption to business through movement restrictions - totalled net of compensation.
- Deriving from these financial benefits will be the maintenance of viable and sustainable beef and dairy sectors through improved consumer confidence in the quality and safety of produce.
- As part of the continued sustainability of the sector, the UK is developing a stronger export market following the lifting of the BSE related export ban. There is also a strong dairy export market. An improved TB disease situation would enable greater opportunities to strengthen the export trade.

¹⁷ A description is provided of the benefits for farmers and society in general from the public and animal health and economical point of view.

- There will be a further reduction in the, already low, risk to human health posed by *M. bovis*.
- There will be improved animal welfare through the prevention of infection and the wider societal benefits gained from the cessation of interventions relating to wildlife.
- Enhanced biosecurity on premises will have benefits in other areas of disease prevention and control.
- A regional approach according to disease risks will ensure that the measures are tailored to the circumstances and disease epidemiology in particular areas.
- The adoption of such measures will also have benefits in terms of the wider responsibility and cost sharing agenda in particular with farmers taking on a greater level of responsibility for managing the TB risk to their herd.
- An improved disease situation would link into the achievement of the AHWBE's objectives in its draft Guiding Principles for policy and delivery in England, which is to eradicate TB in England.

6. Data on the epidemiological evolution during the last five years¹⁸

Note: Due to the replacement in September 2011 of AHVLA's legacy IT support system ("Vetnet") with a completely new system ("Sam") and some changes made in the methodology for the collation of bovine TB statistics in GB, the headline figures for 2011 in England shown in sections 6.1, 6.3 and 6.4 are not directly comparable to those of previous years.

6.1. Evolution of the disease¹⁹

6.1.1. Data on herds^(a) (one table per year)

ENGLAND

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds checked ^(d)	Number of positive herds ^{(e) [1]}	Number of new positive herds ^{(f) [1][2]}	Number of herds depopulated [3]	% positive herds depopulated	INDICATORS		
									% herd coverage	% positive herds Period herd prevalence	% new positive herds Herd incidence
1	2	3	4	5	6	7	8	9 = (8/6)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
2007	Bovine	58,870	58,870	36,843	4,970	3,201	0	0	62.58	13.49	8.69
2008	Bovine	58,465	58,465	37,940	5,963	3,765	1	0.017	64.89	15.72	9.92
2009	Bovine	57,495	57,495	38,649	6,189	3,350	1	0.016	67.22	16.01	8.67
2010	Bovine	56,867	56,867	52,957	6,119	3,634	1	0.02	93.12	11.55	6.86
2011	Bovine	54,312	54,312	54,072	6,356	3,754	1	0.02	99.55	11.75	6.94
Total											

¹⁸ The data on the evolution of the disease are provided according to the tables below where appropriate.

¹⁹ No data to provide in case of rabies.

- [1] The number of positive herds includes both all herds that had their Officially TB Free (OTF) status withdrawn (“OTFW”) or suspended (“OTFS”) at some time during each year due to a TB breakdown (i.e. new and ongoing TB breakdowns).
 - [2] Total new TB breakdowns (both “OTFW” and “OTFS”) that were identified (i.e. began) in each year.
 - [3] Includes total depopulations of entire cattle holdings and any partial slaughters of discrete epidemiological groups within an infected holding that were carried out for the purposes of controlling an OTFW breakdown.
-
- (a) Herds or flocks or holdings as appropriate.
 - (b) Region as defined in the programme of the Member State.
 - (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
 - (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining or upgrading, the health status of the herd. In this column a herd must not be counted twice even if has been checked more than once.
 - (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
 - (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one animal tested positive in this period.

6.1.2. Data on animals (one table per year and per disease/species)

ENGLAND

Region ^(a)	Animal species	Total number of animals ^(b)	Number of animals ^(d) to be tested under the programme	Number of animals ^(c) tested	Number of animals tested individually ^(d)	Number of positive animals	Slaughtering		INDICATORS	
							Number of animals with positive result slaughtered or culled	Total number of animals slaughtered ^(e)	% coverage at animal level	% positive animals Animal prevalence
1	2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
2007	Bovine	5,630,015	5,630,015	4,327,222	4,327,222	18,571	18,571	19,822	76.86	0.43
2008	Bovine	5,429,987	5,429,987	4,645,263	4,645,263	26,070	26,070	27,487	85.55	0.56
2009	Bovine	5,465,000	5,465,000	4,899,144	4,899,144	24,500	24,500	25,557	89.65	0.53
2010	Bovine	5,649,802	5,649,802	5,367,444	5,367,444	23,897	23,897	24,603	95.00	0.45
2011	Bovine	5,267,474	5,267,474	5,490,248	5,490,248	25,809	25,809	26,407	104.2	0.47
Total										

- (a) Region as defined in the programme of the Member State.
(b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
(c) Includes animals tested individually or under bulk level scheme.
(d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance: milk bulk tank tests).
(e) Include all positive animals slaughtered and also the negative animals slaughtered under the programme.

[1] Under current reporting methods it is not possible to distinguish the numbers of individual animals tested for TB during the year, so this figure includes animals which may have been tested and counted more than once and explains why the animal coverage exceeded 100% (column 9).

[2] Data in columns 6 and 7 includes the numbers of skin test reactors, unresolved (twice) inconclusive reactors and gamma interferon blood test reactors, regardless of their post-mortem and culture findings.

[3] Data in column 8 includes, in addition to those in tables 6 and 7, non-reactor cattle taken as direct contacts to known infected animals in OTFW herd breakdowns and Inconclusive reactors.

6.2. Stratified data on surveillance and laboratory tests

6.2.1. *Stratified data on surveillance and laboratory tests*

Description of the used in-vitro tests:

1) The gamma-interferon blood test (Bovigam[®]) of cell-mediated immunity against *M. bovis* has been used since 2002 as an ancillary parallel test of British herds with confirmed TB breakdowns. This test was initially applied on a voluntary basis, both in the course of a field trial which ran from October 2002 to October 2005, and on an ad hoc basis in herds with confirmed *M. bovis* infection but not eligible for the trial. The figures given in the table below comprise gamma-interferon tests performed under both scenarios (in the three years 2003-2005 approximately 10,000 tests were carried out under the field trial and 14,000 were ad hoc tests). Since October 2006, Bovigam[®] is primarily being used as a mandatory parallel test alongside the comparative intradermal test to enhance the detection of infected cattle in certain prescribed situations, namely:

- New OTFW TB breakdowns in herds located in 3 or 4 yearly testing zones, after each skin test at which confirmed or standard reactors are identified;
- On skin-test negative cattle in severe OTFW TB breakdowns, to inform decisions on partial or complete depopulation;

It is also an optional parallel test for chronically infected herds that have failed to resolve by repeated short-interval skin testing and fulfil a minimum standard of biosecurity to reduce the risk of re-infection from cattle or wildlife.

2) The VetTB STAT-PAK/Chembio Rapid Test (a non-ELISA serological test that detects antibodies to a set of recombinant *M. bovis* antigens) is deployed very occasionally as an ancillary test to remove additional infected animals in herds with OTFW chronic TB breakdowns where the presence of skin and IFN-gamma blood test anergic cattle is suspected. Only a very small number of animals are subjected to serological TB testing each year (figures not shown below).

Description of the microbiological tests used:

All cattle compulsorily slaughtered for TB control purposes in GB (i.e. skin and IFN-gamma test reactors, direct contacts and any voluntarily slaughtered inconclusive reactors) undergo post-mortem examination in one of a group of 22 designated abattoirs across the country. To identify the strain of *Mycobacterium bovis* responsible for a TB outbreak, mycobacterial culture of selected lymph nodes and lesioned tissue from reactor animals is then carried out at one of the AHVLA's three „Category 3' TB laboratories (Starcross, Sutton Bonington and Weybridge), depending on the location of the abattoir in which the animals were slaughtered and sampled.

Tissue specimens from at least one animal per TB breakdown are submitted for laboratory culture, up to a maximum of three visibly lesioned (VL) reactors and, in the absence of VL reactors, a maximum of 10 non-visibly lesioned (NVL) animals. In the case of VL animals the submission consists of a small piece of a lesion from the affected organ/node. In the case of NVL reactors, the submission is made up of a pool of the lymph nodes that are more likely to harbour the bacterium. All suspect tuberculous lesions detected in the course of routine meat inspection of cattle carcasses (the so-called “slaughterhouse cases”) are also submitted for culture. Each tissue submission is allocated a reference number and all histology and culture results recorded in the AHVLA laboratory information management system (LIMS), which has an interface with the IT system used by the field offices (iSAM).

Bovine TB infection is confirmed in test reactors by the disclosure of typical visible lesions during post-mortem examination and/or culture of *M. bovis* in primary isolation medium. In other words, a TB breakdown is regarded as OTFW when at least one of the reactor animals in that breakdown is VL and/or yields *M. bovis* on culture. If the breakdown was triggered by a slaughterhouse case, TB is only confirmed (and OTF status withdrawn) upon isolation of *M. bovis* by bacteriological culture from the pathological material.

For cultural examination, approximately 20g of tissue are homogenised in a stomacher with a solution of 10% oxalic acid to decontaminate the sample. The mixture is then centrifuged and the resulting deposit washed and re-suspended in sterile phosphate buffer saline. The suspension is sown (in most cases in duplicate or triplicate) onto a different range of solid media slopes and into liquid media (MGIT, Becton & Dickinson) tubes, depending on the

type of specimen (i.e. cattle/non bovine, VL/NVL/atypical lesion, reactor/slaughterhouse case, etc.). The slopes are incubated at 37°C for up to 12 weeks: although colony growth can be observed in many VL submissions only after 3 weeks, results from samples with low bacterial counts (“paucibacillary” specimens) can often take up to 12 weeks.

Additionally, all submissions from slaughterhouse cases, plus any ‘atypical’ lesions (i.e. those found in unusual organs and/or with irregular appearance) and culture-negative VL reactors are processed separately from NVL samples and undergo full histopathological examination. Approximately 1cm³ of lesioned tissue in fixative solution is needed for that purpose. Where there is insufficient tissue for histology (or there is sufficient tissue with histopathology suggestive of TB, but a negative culture), the original inocula are sown again and the original cultures re-incubated for a further six weeks. A direct impression smear of lesioned material may also be made if required. When dried and fixed it can be stained using staining techniques for the presence of alcohol acid-fast bacilli (AAFB). A positive laboratory diagnosis of bovine TB is primarily made on morphological grounds by the characteristic appearance of the mycobacterial colonies on various solid media or, in the case of MGIT, through the detection of AAFB and spoligotyping. Histopathology results and AAFB staining are ancillary methods used to support a diagnosis based on culture observations.

AAFB that do not show growth features typical of *M. bovis* or are not recognised as *M. bovis* by spoligotyping (see below) are tested by multiplex and/or HAIN PCR. The HAIN PCR is used in addition to the multiplex PCR to identify ‘atypical’ mycobacteria that do not belong to the *Mycobacterium tuberculosis* or *M. avium-intracellulare* complexes, where necessary (e.g. *M. kansasii* in suspect TB lesions from non-bovine host species).

DNA extracted from one *M. bovis* isolate recovered per infected herd is subjected to genetic fingerprinting. Spoligotyping was the *M. bovis* genotyping technique originally used in GB. However, because two spoligotypes have been found to comprise approximately 70% of all *M. bovis* isolates from cattle in GB, an additional typing method (VNTR – “variable number of tandem repeats”) has been routinely adopted by AHVLA more recently to enhance molecular discrimination of isolates of the most common spoligotypes. Each *M. bovis* isolate is thus classified according to its spoligotype and

VNTR pattern into a given “genotype” . This information is fed back to the AHVLA case Veterinary Officers in the field to support the epidemiological investigations into the probable origin of each TB breakdown.

Description of the other used tests:

Not applicable

Region ^(c)	In-vitro tests (IFN-gamma or Bovigam [®])		Microbiological tests (bacteriological culture)		Other tests	
	Number of samples tested ^(d)	Number of positive samples ^(e)	Number of samples tested ^(d)	Number of positive samples ^(e)	Number of samples tested ^(d)	Number of positive samples ^(e)
England						
2007	23,538	2,017	11,089	3,855		
2008	14,913	2,714	13,951	4,850		
2009	18,384	1,856	9,503	4,118		
2010	16,269	509	8,632	4,398		
2011	16,197	567	9,606	4,955		
Total	89,301	7,663	52,781	22,176		

- (a) Disease and animal species if necessary.
- (b) Breeders, laying hens, etc, when appropriate
- (c) Region as defined in the approved eradication programme of the Member State.
- (d) Number of samples tested, all confounded.
- (e) Number of positive samples, all confounded

6.3. Data on infection (one table per year)

ENGLAND

Region ^(a)	Animal species	Number of herds infected ^(b) [1]	Number of animals infected [2]
2007	Bovine	3,201	18,571
2008	Bovine	3,765	26,070
2009	Bovine	3,350	24,500
2010	Bovine	3,634	23,897
2011	Bovine	3,754	25,809
Total	Bovine	17,704	119,027

[1] This includes the numbers of OTFW and OTFS breakdowns.

[2] Data includes skin test and interferon gamma test reactors, regardless of post-mortem and tissue culture results.

(a) Region as defined in the programme of the Member State.

(b) Herds or flocks or holdings as appropriate.

6.4. Data on the status of herds at the end of each year²⁰

ENGLAND

Region ^(a)	Animal species	Status of herds and animals under the programme ^(b)													
		Total number of herds and animals under the programme		Unknown ^(c)		Not free or not officially free from disease				Free or officially free from disease status suspended ^(f)		Free from disease ^(g)		Officially free from disease ^(h)	
						Last check positive ^(d)		Last check negative ^(e)							
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds [1]	Animals ⁽ⁱ⁾ [2]	Herds	Animals ⁽ⁱ⁾	Herds [1]	Animals ⁽ⁱ⁾ [2]
2007	Bovine	58,870	5,630,015	n/a	n/a	n/a	n/a	n/a	n/a	5,425	n/a	n/a	n/a	53,445	n/a
2008	Bovine	58,465	5,429,987	n/a	n/a	n/a	n/a	n/a	n/a	5,602	n/a	n/a	n/a	52,863	n/a
2009	Bovine	57,495	5,465,000	n/a	n/a	n/a	n/a	n/a	n/a	3,694	n/a	n/a	n/a	53,801	n/a
2010	Bovine	56,867	5,649,802	n/a	n/a	n/a	n/a	n/a	n/a	4,781	n/a	n/a	n/a	52,086	n/a
2011	Bovine	54,312	TBC	n/a	n/a	n/a	n/a	n/a	n/a	6,572	n/a	n/a	n/a	47,740	n/a
Total															

1] Total number of herds under TB2 restrictions (herds where OTF status has been withdrawn or suspended either because of reactors disclosed or other reasons (for example overdue tests)) at the end of the reported period.

[2] Data reports are currently not able to distinguish the numbers of animals (since tests are not linked to Official Animal Identifiers), or herds by the classifications provided in 2010. However, future reporting will make these distinctions.

(a) Region as defined in the programme of the Member State

(b) At the end of the year

²⁰ Only data to provide for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (*B. melitensis*).

- (c) Unknown: No previous checking results available
- (d) Not free and last check positive: Herd checked with at least one positive result in the latest check
- (e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*
- (f) Suspended as defined in Union or national legislation for the respective disease at the end of the reporting period.
- (g) Free herd as defined in Union or national legislation for the respective disease.
- (h) Officially free herd as defined in Union or national legislation for the respective disease .
- (i) Include animals under the programme in the herds with the referred status (left column).

6.5. Data on vaccination or treatment programmes²¹ [NOT APPLICABLE]

Year:

Region ^(a)	Animal species	Total number of herds ^(b)	Total number of animals	Information on vaccination or treatment programme					
				Number of herds ^(c) in vaccination or treatment programme	Number of herds ^(c) vaccinated or treated	Number of animals vaccinated or treated	Number of doses of vaccine or treatment administered	Number of adults vaccinated	Number of young animals vaccinated
Total									

- (a) Region as defined in the programme of the Member State
- (b) Herds or flocks or holdings as appropriate

²¹ Data to provide only if vaccination has been carried out.

6.6. Data on wildlife²²

6.6.1. Estimation of wildlife population

Year: 1994-2002

Regions ^(a)	Animal species	Method of estimation	Estimated population
England	Badger 1994-1997	Hunting bag	234,000
	Deer (Red)	Hunting bag	400,000
	Deer (Fallow)	Hunting bag	110,000
	Deer (Sika)	Hunting bag	29,300
	Deer (Roe)	Hunting bag	620,000
	Deer (Muntjac)	Hunting bag	100,000
	: Deer (Chinese water deer)	Hunting bag	650
Total			

(a) Region as defined in the programme of the Member State

²² Data only to provide in case the programme comprises measures as regards wildlife or if the data are epidemiologically relevant for the disease.

6.6.2. *Disease surveillance and other tests in wildlife (one table per year)*

Year:

Region ^(a)	Animal Species	Test type ^(b)	Test description	Number of samples tested	Number of positive samples
Total					

(a) Region as defined in the programme of the Member State

(b) Indicate whether the test is serological, virological, biomarker detection etc.

6.6.3. *Data on vaccination or treatment of wildlife*

Badger BCG licensed in March 2010 has been used as part of the Badger Vaccine Deployment Project to build farmer confidence in vaccines as a key tool in an eradication programme; build a core of trained lay vaccinators with practical experience in identifying, trapping and vaccinating badgers which could be used for a broader roll out of injectable or oral vaccines.

Region ^(a)	Square km	Vaccination or treatment programme		
		Number of doses of vaccine or treatment to be administered	Number of campaigns	Total number of doses of vaccine or treatment administered
Gloucestershire (North West of Stroud, towards the Severn Valley)	100	625	1	1 for each of the 625 badgers vaccinated
Total	100	625	1	625

(a) Region as defined in the programme of the Member State

7. Targets

7.1. Targets related to testing (one table for each year of implementation²³)

7.1.1. *Targets on diagnostic tests*

Region ^(a)	Type of the test ^(b)	Target population ^(c)	Type of sample ^(d)	Objective ^(e)	Number of planned tests
England	Tuberculin skin test	Bovines		Programme implementation (Primary screening test – surveillance, qualification and elimination of infection from herds)	6,000,000
	Gamma Interferon Assay (Bovigam)	Bovines over 6 months of age in certain infected (OTFW) herds	Heparinised Blood	Programme implementation (ancillary parallel test – elimination of infection from herds with OTF status withdrawn)	25,000
Total					

- (a) Region as defined in the programme of the Member State
- (b) Description of the test (for instance SN-test, AB-Elisa, RBT,)
- (c) Specification of the targeted species and the categories of targeted animals (for instance sex, age, breeding animal, slaughter animal, ...).
- (d) Description of the sample (for instance blood, serum, milk,)
- (e) Description of the objective (for instance qualification, surveillance, confirmation of suspected cases, monitoring of campaigns, seroconversion, control on deleted vaccines, testing of vaccine, control of vaccination,)

²³

For subsequent years of approved multiannual programmes only one table for the relevant year should be filled in.

7.1.2. *Targets on testing herds and animals*²⁴

7.1.2.1 Targets on the testing of herds^(a)

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds expected to be checked ^{(d)[1]}	Number of expected positive herds ^(e)	Number of expected new positive herds ^(f)	Number of herds expected to be depopulated	% positive herds expected to be depopulated	TARGET INDICATORS		
									Expected % herd coverage	% positive herds Expected period herd prevalence	% new positive herds Expected herd incidence
1	2	3	4	5	6	7	8	9 = (8/6)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
England	Bovine	54,000	54,000	57,900	6,400	3,800	10	0.26	107.22	11.05	6.56
Total											

- (a) Herds or flocks, or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining, upgrading, etc., the health status of the herd. In this column a herd must not be counted twice even if it has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one positive animal in this period.

[1] This is the total number of herd tests, rather than the number of individual herds tested.

²⁴ Data not to provide in case of rabies.

7.1.2.2. Targets on the testing of animals

Region ^(a)	Animal species	Total number of animals ^(b)	Number of animals ^(c) under the programme	Number of animals ^(c) expected to be tested	Number of animals to be tested individually ^(d)	Number of expected positive animals	Slaughtering		TARGET INDICATORS	
							Number of animals with positive result expected to be slaughtered or culled	Total number of animals expected to be slaughtered ^(e)	Expected % coverage at animal level	% positive animals (Expected animal prevalence)
1	2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
England	Bovine	5,400,000	5,400,000	6,000,000	6,000,000	27,000	27,000	27,500	111.1	0.45

- (a) Region as defined in the programme of the Member State.
- (b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
- (c) Includes animals tested individually or under bulk level scheme.
- (d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance milk bulk tank tests).
- (e) Include all positive animals slaughtered and also the negative animals slaughtered under the programme.

7.2. Targets on qualification of herds and animals (one table for each year of implementation)

Region ^(a)	Animal species	Total number of herds and animals under the programme		Targets on the status of herds and animals under the programme ^(b)											
				Expected unknown ^(c)		Expected not free or not officially free from disease				Expected free or officially free from disease status suspended ^(f)		Expected free from disease ^(g)		Expected officially free from disease ^(h)	
						Last check positive ^(d)		Last check negative ^(e)							
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾
England	Bovine	54,000	5,400,000	n/a	n/a	n/a	n/a	n/a	n/a	4,800	n/a	n/a	n/a	49,200	n/a
										[1]					
Total															

(a) Region as defined in the programme of the Member State

(b) At the end of the year

(c) Unknown: No previous checking results available

(d) Not free and last check positive: Herd checked with at least one positive result in the latest check

(e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*

(f) Suspended as defined for the respective disease in Union or national legislation where appropriate or according national legislation.

(g) Free herd as defined for the respective disease where appropriate in Union or national legislation where appropriate or according national legislation

(h) Officially free herd as defined for the respective disease where appropriate in Union or national legislation where appropriate or according national legislation

(i) Include animals under the programme in the herds with the referred status (left column)

[1] Of which approximately 60% will be OTFW and 40% OTFS

7.3. Targets on vaccination or treatment (one table for each year of implementation)

7.3.1. Targets on vaccination or treatment²⁵

Region ^(a)	Animal species	Total number of herds ^(b) in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Targets on vaccination or treatment programme					
				Number of herds ^(b) in vaccination or treatment programme	Number of herds ^(b) expected to be vaccinated or treated	Number of animals expected to be vaccinated or treated	Number of doses of vaccine or treatment expected to be administered	Number of adults ^(c) expected to be vaccinated	Number of young ^(c) animals expected to be vaccinated
Total									

- (a) Region as defined in the programme of the Member State
- (b) Herds or flocks or holdings as appropriate
- (c) Only for Bovine brucellosis and Ovine, Caprine brucellosis (*B. melitensis*) as defined in the programme

²⁵ Data to provide only if appropriate .

7.3.2. *Targets on vaccination or treatment²⁶ of wildlife*

Region ^(a)	Animal species	Square km	Targets on the vaccination or treatment programme		
			Number of doses of vaccine or treatments expected to be administered in the campaign	Expected number of campaigns	Total number of doses of vaccine or treatment expected to be administered
Total					

(a) Region as defined in the programme of the Member State

7.4 TB situation in England beyond 2012

7.4.1 Eradication of bTB is the long-term goal of the UK Government. In England eradication is a specific, government policy objective and halting the spatial spread of the disease is a Ministerial priority. This is reflected in the planned TB control measures in the near future.

7.4.2 The future eradication plans in England will take into consideration the heterogenous geographic distribution of bovine TB in the country. The disease is endemic in the South West and West Midlands of the country. The rest of the country, apart from a small, endemic enclave on the South coast (East Sussex), has a low incidence level of disease and virtually all confirmed cases of bovine TB in these low incidence areas can be traced back to livestock movements from the high incidence area. For the past 20 years, the edge of the endemic area has steadily, albeit slowly, advanced into the low incidence, non-endemic area.

7.4.3 We recognise that it will take time for strengthened measures to take full effect and reverse the epidemic. Our specific objectives over the next five years are therefore to:

- Further reduce the very low incidence of sporadic OTFW TB breakdowns in the counties of the North and East of England (low incidence or non-endemic regions) and deal effectively with any incursions of disease in these low-incidence areas, through the application of proactive, risk-based surveillance;
- Expand the current OTF region of the UK by moving towards similar OTF status recognition for those counties (or groups of counties) in the North and East of England that have maintained over a six-year period a very low incidence of „indigenous’ (not clearly introduced) OTFW TB breakdowns, which is below the thresholds set out in Council Directive 64/432/EEC;
- Continue to protect the non-endemic areas of England, by introducing additional measures to halt the spatial spread of the disease (see below) and by introducing risk based cattle trading strategies.

- Halt the spatial spread of the endemic area, by introducing „edge area policies’, aimed at enhancing epidemiological assessment, engaging stakeholders and early detection and effective control of infection.

- Reduce the herd and animal incidence of bTB in the endemic area of the country, by starting to address the wildlife reservoir in collaboration with the industry and moving towards greater stakeholder engagement on all control fronts.

7.4.4 As a result of existing and new measures and by focusing on the above objectives, we would expect to achieve regional OTF in some counties of England, sustained low levels of non-endemic disease in the current low incidence areas, a halt to the spatial spread of the endemic area and a reduction in disease incidence in the endemic area by the end of this five-year period.

8. Detailed analysis of the cost of the programme (one table per year of implementation²⁷)

Costs related to	Specification/Unit	Unit ²⁸	Number of units	Unitary cost in £	Total amount in £	Union funding requested (yes/no)
1. Testing						
1.1. Cost of sampling						
	Domestic animals					
1.2 Cost of the analysis						
Brucellosis and tuberculosis programmes	Tuberculin test	OV Tests	5,500,000	£3.21	£17,655,000	Yes
	Gamma-interferon test	Tests	25,000	£11.83	£295,750	Yes
	Bacteriological test	Culture tests	10,500	£111.12	£1,166,760	Yes
- ASF, CSF, SVD & Bluetongue programmes	ELISA test	N/A				
	PCR test	N/A				
	Virological test	N/A				

²⁷

For subsequent years of approved multiannual programmes only one table for the relevant year should be filled in.

²⁸

Specify the unit to which the data in the following two columns is referring to (e.g. sample, test, animal sampled etc).

	Seroneutralisation test (only for SVD)	N/A				
	Entomological surveillance test (only for Bluetongue)	N/A				
	Other (please specify)	N/A				
1.3. Other costs						
	Purchase of traps (for Bluetongue)	N/A				
	Other (please specify)	N/A				
2. Vaccination or treatment						
2.1. Purchase of vaccine/treatment						
						No
2.2. Administering/Distribution costs						
Administering in domestic animals	N/A	N/A	N/A	N/A	N/A	No
- Distribution for wild animals (please specify the type of distribution)	N/A	N/A	N/A	N/A	N/A	No

2.3. Control costs						<i>No</i>
2.4. Others (please specify)						
3. Slaughter and destruction						
3.1. Compensation of animals		Number of bovines	27,500	£1,289.14	£35,451,350	<i>Yes</i>
3.2. Transport costs						
3.3. Destruction costs						
3.4. Loss in case of slaughtering	Salvage receipts	Number of bovines	27,500	£321.89	(£8,851,975)	<i>Yes</i>
3.5 Costs from treatment of products (milk, or others –please specify)	N/A					
4. Cleaning and disinfection	N/A					

5. Salaries (staff contracted for the programme only)		TB policy staff	39	£33,333.33	£ 1,300,000	No
6. Consumables and specific equipment	N/A					
7. Other costs						
Tuberculin		Per dose	5,500,000	£0.19	£1,045,000	Yes
	TOTAL				£48,061,885	

ANNEX II – WALES ERADICATION PLAN

ANNEX I

Standard requirements for the submission of national programmes for the eradication, control and monitoring of the animal diseases or zoonoses referred to in Article 1(a)²⁹

1. Identification of the programme

Member State: United Kingdom

Disease(s)³⁰: Bovine Tuberculosis

Request of Union co-financing for³¹: 2013

Reference of this document: Wales (UK) 2013 TB Eradication Plan

Contact (name, phone, fax, e-mail):

Stephen Jackson

Bovine TB Eradication Programme

Welsh Government

Tel 0300 062 2165

Email:stephen.jackson@wales.gsi.gov.uk

Date of submission to the Commission: 14th September 2012

²⁹ In the case of the second and subsequent years of a multi-annual programme that has already been approved by a Commission Decision, only section 1, section 7 and section 8 need to be completed.

³⁰ One document per disease is used unless all measures of the programme on the target population are used for the monitoring, control and eradication of different diseases.

³¹ Indicate the year(s) for which co-financing is requested.

2. Historical data on the epidemiological evolution of the disease(s)³²:

Great Britain

1. The efforts to eradicate bovine tuberculosis (bovine TB) from Great Britain (GB) pre-date the first legal initiatives in this area at European Community (EC) level and were initially driven by public health concerns and the desire to increase the productivity and welfare of the national cattle herd. Following the accession of the UK to the European Community (EC; later the European Union, EU) in 1973, British cattle producers were required to comply with the rules laid down in Directive 64/432/EEC (as amended), including certification of TB testing of exported animals and official TB freedom of herds.

2. The single intradermal comparative cervical tuberculin (SICCT) test was introduced in 1947 (with the “mammalian” (*Mycobacterium tuberculosis*) tuberculin replaced by the more potent and specific Weybridge *M. bovis* PPD tuberculin in 1975) and the voluntary herd schemes up to the 1950s were replaced by compulsory schemes. The whole of GB became 'attested' on 1st October 1960 (i.e. each cattle herd was certified as being subject to regular tuberculin intradermal testing with immediate slaughter of any reactors). For the next two decades there was a steady decline in the incidence of reactor cattle, clinical cases and infected herds detected and every year new counties would be designated bovine TB-free areas in which the herd testing frequency could be gradually relaxed to reflect the improved situation.

3. The Eurasian badger (*Meles meles*) was first identified as a possible wildlife reservoir of infection for cattle in the early 1970s in parts of the Southwest of England where a high incidence of bovine TB persisted despite enhanced herd control measures (bovine TB “hotspots”). A series of different strategies were developed throughout the 1970s, 80s and 90s to tackle this wildlife source of *M. bovis* in England and Wales, along with further cattle-based measures. In 1979 the lowest bovine TB incidence was recorded in GB, with 0.49% of all herds tested having a reactor, which equated to 0.018% of all cattle tested.

4. However, the progressive reduction in bovine TB incidence stalled in the mid-1980s. Gassing (1975-1982) and „clean ring’ (1982-1986) strategies were used prior to an “interim” badger culling strategy in place between 1986 and 1997, whereby badgers were removed only from farms where a bovine TB incident had been confirmed by culture of *M. bovis* and where, following investigation, it was thought that badgers were the most likely source.

³² A concise description is given including target population (species, number of herds and animals present and under the programme), the main measures (sampling and testing regimes, eradication measures used, qualification of herds and animals, vaccination schemes) and the main results (incidence, prevalence, qualification of herds and animals). The information is given for distinct periods if the measures were substantially modified. The information is documented by relevant summary epidemiological tables (in point 6) complemented by graphs or maps (to be attached).

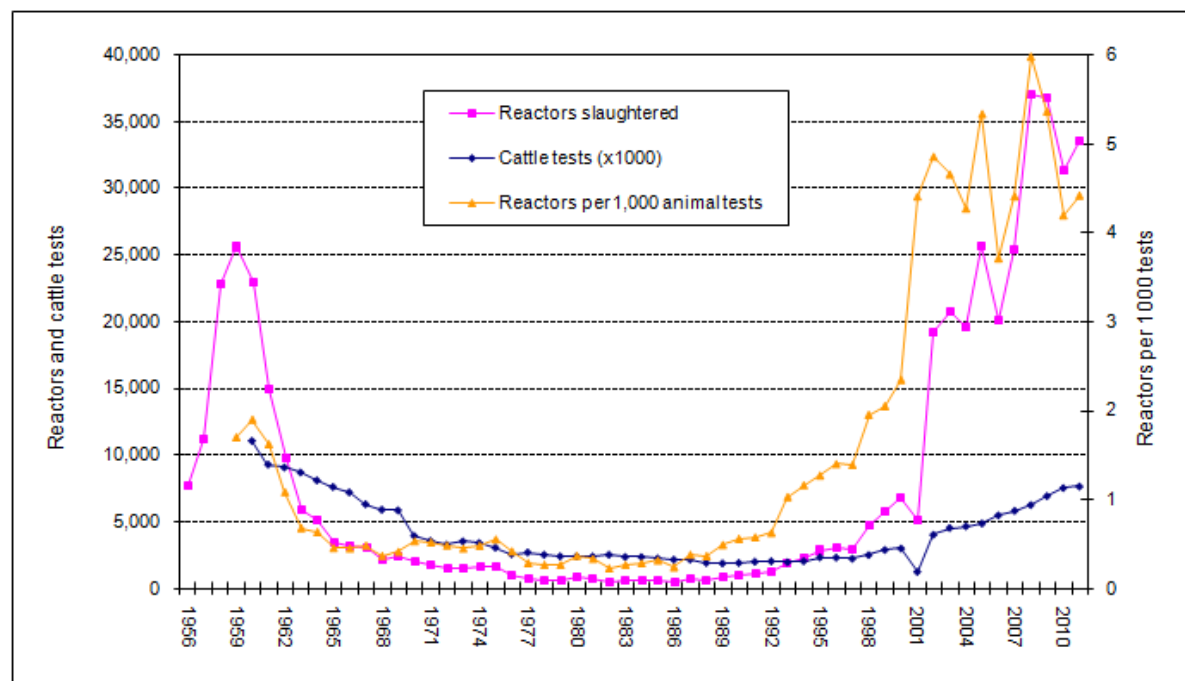


Figure 1: Annual number and rate of TB test reactors disclosed in GB between 1956 and 2011.

5. In 2001, the national bovine TB testing programme, as well as most field-based bovine TB research projects, was severely disrupted due to a major outbreak of Foot and Mouth Disease, which led to anomalous bovine TB statistics from 2001 to early 2003. This 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 herd testing resumed.
6. The Krebs’ report published in 1997 concluded that “the sum of evidence strongly supports the view that, in Britain, badgers are a significant source of infection in cattle”. The main recommendation stemming from this review was to set up a controlled field experiment (the Randomised Badger Culling Trial – „RBCT”) overseen by the Independent Scientific Group on cattle TB (ISG) to quantify in a scientific way the impact of culling badgers on TB incidence in cattle. Immediately after the publication of the report in December 1997 the Government suspended all badger removal operations, pending the implementation of this trial.

7. The Final Report of the ISG published on 18 June 2007 included the findings of the RBCT. Evidence from the RBCT showed that at least 40% of cattle herd breakdowns in high incidence areas were caused by badgers. However the ISG concluded that badger culling (carried out in the way that was done in the RBCT) was unlikely to contribute positively, or cost effectively, to the control of cattle TB in Britain. It also concluded that there was substantial scope for improvement of control of the disease through the application of heightened control measures directly targeting cattle.

Wales

8. Legal responsibility for animal health and welfare matters in Wales is vested in the Welsh Ministers. The power is derived from the Animal Health Act 1981. The functions were devolved, in all but a small number of areas, in relation to Wales by 2005.

9. Since 2006, a further range of control measures were introduced in Wales (along with England), including a compulsory pre-movement tuberculin test of all cattle over 42 days old moving out of annually and biennially tested herds and the use of the interferon-gamma (IFN-g) test to supplement the skin test in certain circumstances.

10. In April 2008 the Welsh Government announced a comprehensive TB Eradication Programme designed to tackle all known sources of the disease (mainly cattle, badgers, goats, camelids and deer) and restrict the spread of the disease by those animals. The programme included tailored policies that recognised regional variations in the pattern of the disease. A TB Eradication Programme Board was established and an additional £27.7m budget (i.e. in addition to existing budgets for surveillance, compensation etc held by Defra and the Welsh Government) was put in for 2008/9 – 2010/11. The Board first met in April 2008 and the work was split into nine component parts. The component parts included cattle surveillance and controls, biosecurity, compensation, vaccination, non-bovine species, Intensive Action Area (IAA), enforcement, statistics and governance.

11. The first priority was to test all cattle herds across Wales within a concentrated timeframe in order to gain a more accurate picture of the spread of bovine TB and provide data for subsequent decisions on Wales' testing regime. TB Health Check Wales (1 October 2008 to 31 December 2009) was established to test all registered cattle herds in Wales.

12. All herds were tested. This was a 31% increase in testing over the period and resulted in the slaughter of an additional 200 test positive cattle from 103 herds, 48 herds with reactors at first test and a further 55 herds on re-test of inconclusive reactors. This work required the Animal Health and Veterinary Laboratories Agency (AHVLA) to take handling equipment onto a small number of holdings with inadequate handling facilities and then reclaim the costs from the cattle keepers. Health Check Wales also resulted in an agreed procedure between Local Authorities and AHVLA to improve enforcement and resolve all long running overdue TB test cases.

13. It was decided in July 2009, on the basis of the interim results from Health Check Wales, that all cattle holdings in Wales would be subject to annual testing (whole herd tests) from 2010, with no return to testing frequencies being set at a parish level.

14. Whilst on an annual testing regime (since January 2010), IFN-gamma testing has been deployed in the lower risk areas (predominately north Wales), where epidemiological evidence suggests it is warranted, to prevent the establishment of new bovine TB hotspots. Since this time the IFN-gamma test has also been used in OTFW breakdowns outside this area, where disease attributed to a wildlife origin is not considered already to be endemic.
15. The single re-testing of inconclusive reactors (IRs) was introduced on 1 March 2009 in Wales (following its voluntary introduction in December 2008) in accordance with Directive 64/432/EEC.
16. To encourage better practice by cattle keepers, the Tuberculosis (Wales) Order 2010 introduced a new method for calculating the compensation value of animals slaughtered due to bovine TB. Compensation is based on cattle keepers complying with the required timings for bovine TB testing, adhering to the relevant legislation and best practice guidance.
17. The 2010 Order also amended the rules relating to Pre-Movement Testing so that exemptions to testing are not fully prescribed in the legislation but via an administrative process, thus enabling the Welsh Ministers, following consultation, to react swiftly to changing circumstances. A number of the Pre-Movement Testing exemptions were removed at the same time in order to tighten up movement controls and reduce the risk of disease spread. The Order also introduced powers to slaughter wild/un-testable cattle.
18. In 2010 an Intensive Action Area (IAA) was established in West Wales where the risks associated with the principle wildlife reservoir of TB infection (badgers) would be tackled alongside additional cattle disease control measures. The IAA is approximately 288km² and is primarily located in north Pembrokeshire, but includes small parts of Ceredigion and Carmarthenshire. This is one of the areas with the highest incidence of bovine TB in Europe. A map of the IAA can be found at the following link: <http://wales.gov.uk/topics/environmentcountryside/ahw/disease/bovinetuberculosis/intensiveactionpilotarea/mapofiaa/iaamappub/;jsessionid=SRCFQ3fB86ZPLFG5C1qxJlp43FkGVhGglGL7h1GpmF7pwJ58nT1c!1219044931?lang=en>
19. Following previous unsuccessful attempts to introduce badger culling within the area, the Minister for Rural Affairs made the Badger (Control Area) (Wales) Order 2011 on 31 March 2011 which would have enabled a Government led cull of badgers in the IAA.
20. The terminology used to describe the TB status of cattle herds has changed in January 2011 from “unrestricted”, “unconfirmed” and “confirmed breakdown” to OTF herds, herds with OTF status “suspended” (OTFS) and herds with OTF status “withdrawn” (OTFW). The new terminology more accurately conveys the TB status of the herd and has the added advantage of aligning us with the language used in EU legislation (as outlined in Annex A of Council Directive 64/432/EEC).

21. Policy change at the same time introduced a revised, veterinary risk-based approach to the treatment of higher-risk breakdown herds with a recent history of TB infection or adjoining an OTFW herd. Such herds are now reclassified as OTFW and are subject to the same requirements as other OTFW breakdowns including tracing and contiguous testing. These enhanced controls better reflect the true infection status of the herd and provide greater assurance that these higher risk herds are free of disease before restrictions are lifted. It is recognised that an unknown, but substantial proportion of the total number of herds with reactors are likely to represent true *M. bovis* infections, particularly in the endemic areas.
22. The Tuberculosis (Wales) Order 2011 was introduced on 31 March 2011 to provide a legislative framework for dealing with bovine TB in non-bovine species, specifically camelids, goats and deer.
23. Since 2007, the Welsh Government has been providing additional advice for farmers on biosecurity and husbandry measures in relation to TB in their herd. Over the same period, the Welsh Government has introduced a number of projects to provide advice through private veterinary surgeons based on the specific circumstances of individual premises. This work includes a five year biosecurity project in the IAA, Regional Eradication Delivery Board initiatives in North Wales and the Gower and a □Royal Veterinary College (RVC) project to evaluate current animal husbandry practice in prolonged bovine TB breakdown herds in south west Wales.
24. Since April 2011, the Welsh Government has been implementing a programme of DNA tagging to identify reactors at the point of disclosure, to provide better identification, traceability and control of reactors.
25. There is also a substantial on-going national (GB) research programme which is managed by Defra on behalf of all administrations. Further information of ongoing research and reports of completed projects can be found at <http://randd.defra.gov.uk> and section 4.52 of the TB Eradication Plan for England (Annex I).
26. The 2010 UK (GB) Eradication Plan provides a more detailed history of the evolution of GB TB epidemiology and policy.

2.1 Current position (Wales)*

27. The provisional total number of new TB herd incidents in Wales during the period 1 January to 31 December 2011 (1,038) was slightly higher than for the same period in 2010 (1,030). This occurs against the background of a fall in the total number of registered cattle herds from 13,034 in 2010 to 12,819 in 2011. However, this was consistent with the additional testing effort made during 2011, which led to 7 per cent more TB herd tests and 0.7 per cent more animal tests being completed than in the previous year. The provisional number of new TB herd incidents where their OTF status was withdrawn in 2011 was 488 (with the status of 67 breakdowns unclassified pending the results of laboratory investigations) compared with a final

figure of 503 for 2010. 13.7 per cent of herds were under restriction due to a TB incident at some point during 2011; a similar proportion to 2010. See Figures 2 and 3 below for data on OTFW incidents in Wales per 100 „live’ herds between 1990 and 2010 and cattle slaughtered in Wales between 1990 and 2010.

28. The picture of TB varies across Wales; during January-August 2011 46 per cent of new TB incidents were in South-West Wales, 27 per cent in South-East Wales and 26 per cent in North Wales. This was similar to 2010, as shown in figure 4.

29. Wales moved to annual testing on a national basis on 1 January 2010 (6 monthly testing regime for herds located within the IAA) and this increase in surveillance will have had an impact on the figures from 2010 relative to previous years.

*Note: the figures provided for Wales exclude incidents, tests etc which have not been allocated to a region as identified in the published Defra statistics. This is consistent with the other statistics outlined within the tables of the plan. The 2010 figures used in paragraph 27 are sourced from Sam based data and differ slightly from those sourced from VetNet used for 2010 and earlier in the tables in section 6.

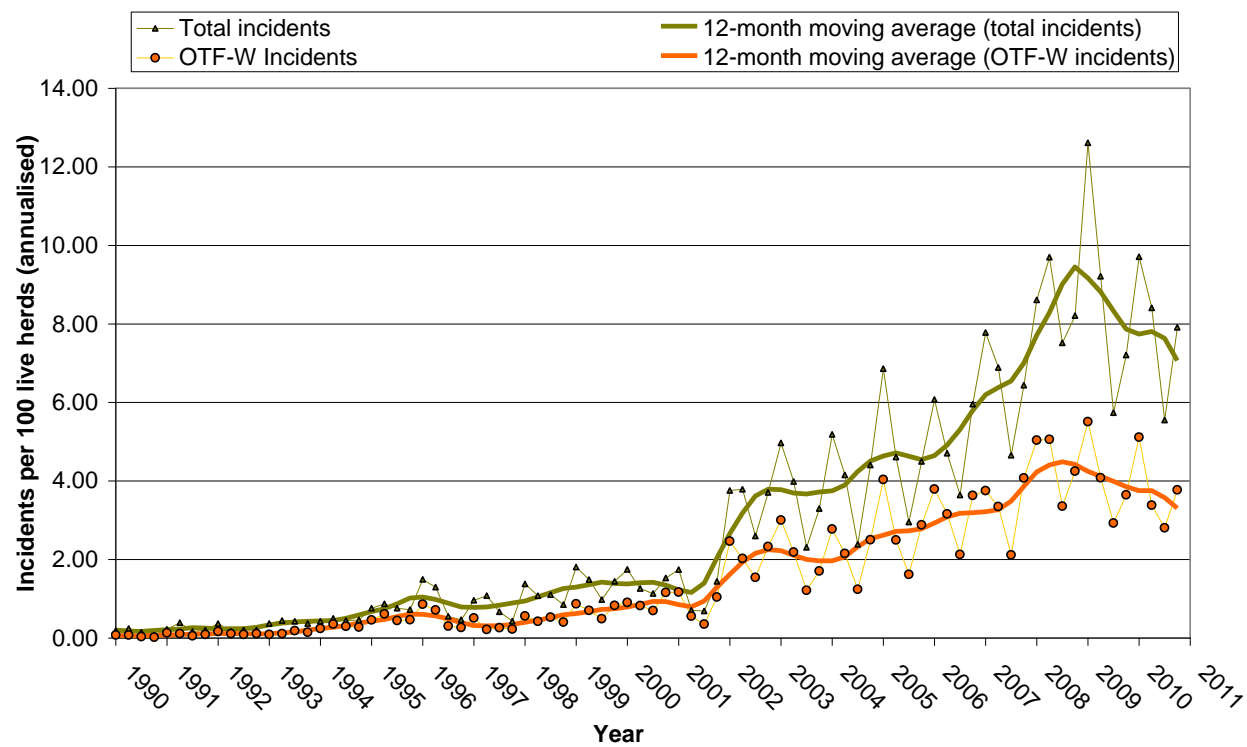


Figure 2: Annualised, quarterly number of total and OTF-W incidents in Wales per 100 'live' herds, between January 1990 and December 2010

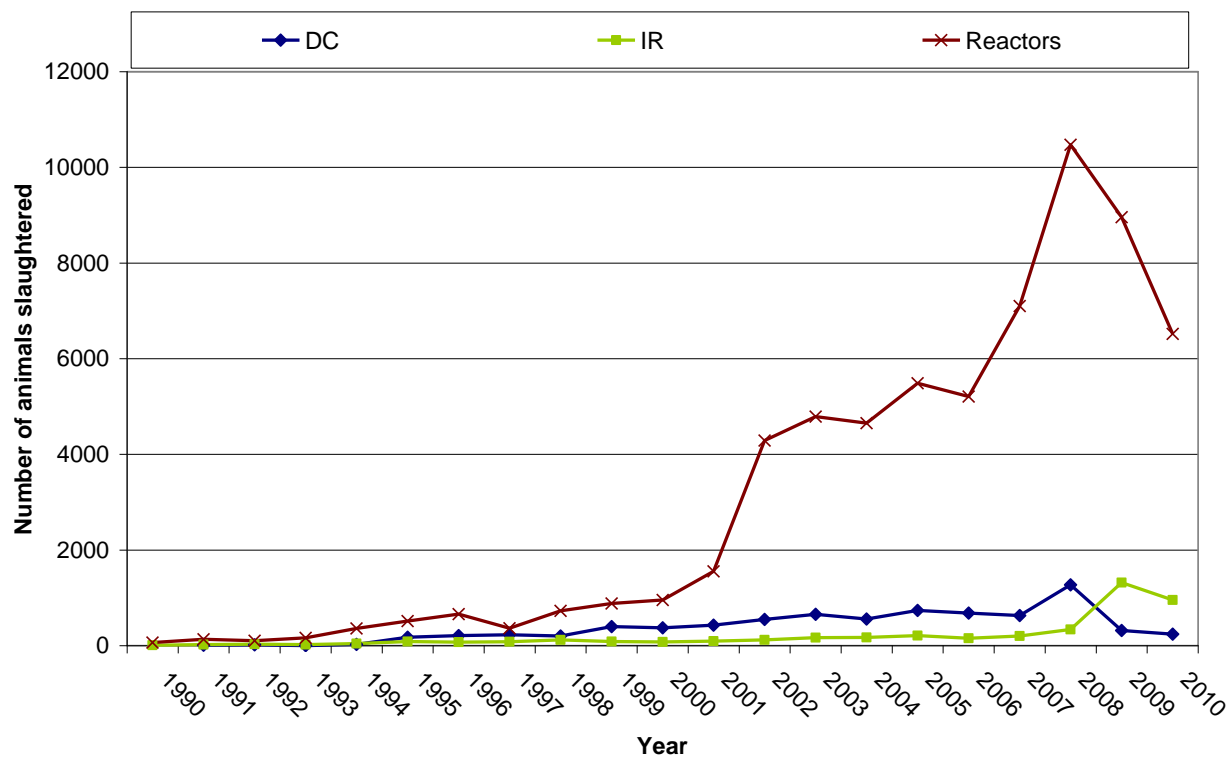


Figure 3: The number of suspected bovine TB cases originating from Welsh herds that were slaughtered for different reasons between 1990 and 2010, by year of slaughter. For this figure IR includes IRx1, IRx2 and IRx3.

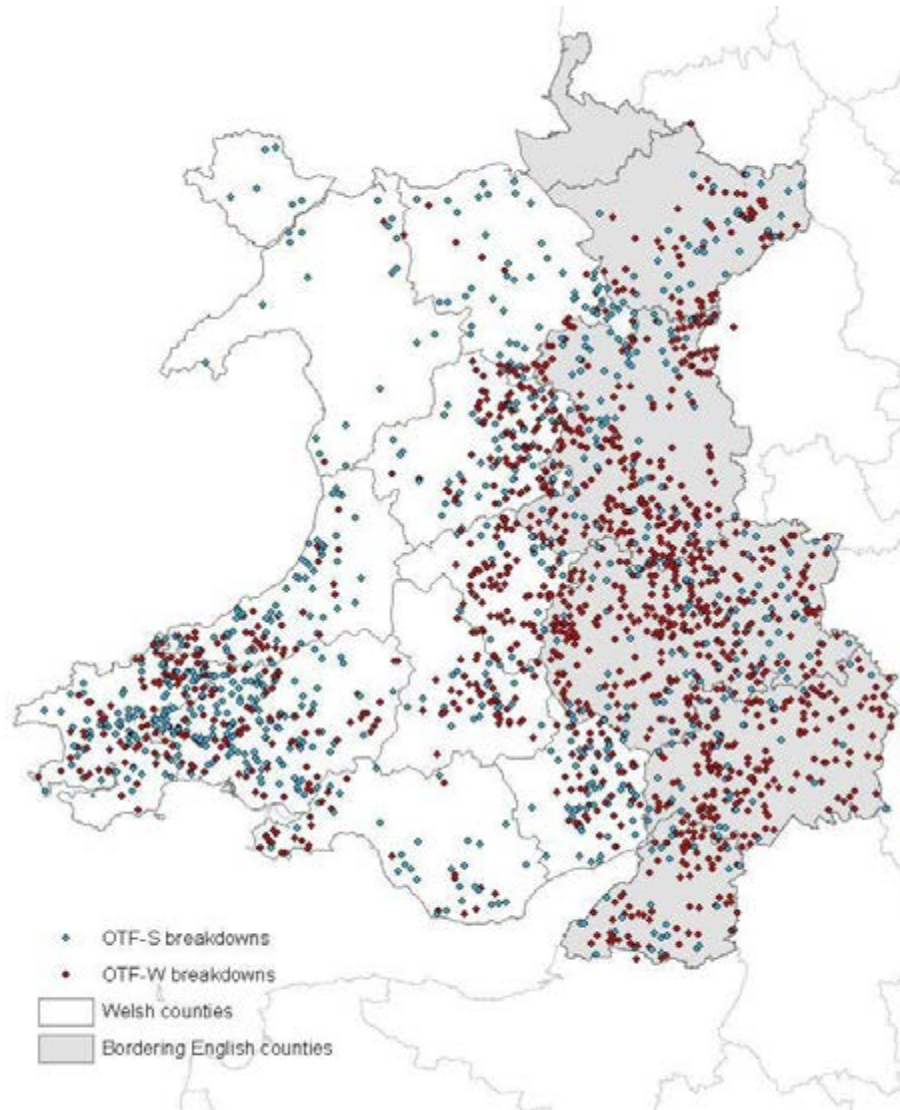


Figure 4 - Geographical distribution of new OTF-W and OTF-S incidents occurring in Wales and bordering English counties in 2010)

30. Following Welsh elections in May 2011, the new government introduced a formal commitment to take a science led approach to tackling bovine TB. In line with this commitment, the Minister for the Environment and Sustainable Development commissioned a review of the evidence base regarding the eradication of bovine TB in Wales. This was overseen by the Chief Scientific Adviser, Professor John Harries. The report from the review, which was provided to the Minister in December 2011, together with other evidence, was used to design a “Strategic Framework for bovine TB Eradication” for Wales covering the next 4 years. The report of the review can be found at the following link: <http://wales.gov.uk/topics/businessandconomy/csaw/publications/120702bovinetbrpt/?lang=en>

31. The Strategy acknowledges that in building on existing cattle and biosecurity measures, „Welsh Government will deal with all sources of bovine TB, including in wildlife, in its efforts to achieve the goal of eradicating bovine TB within the IAA and from Wales’. The strategic framework in full is available on the Welsh Government’s website: <http://wales.gov.uk/topics/environmentcountryside/ahw/disease/bovinetuberculosis/bovinetberadication/tbstrategicframework/?lang=en>

32. The announcement by the Minister included reference to his decision to pursue a badger vaccination project in the IAA (rather than culling) and plans for the extended use of the badger vaccine in Wales. Other policy changes included improvement in the management of long running and persistent TB herd breakdowns; the piloting of an audit of TB testing carried out by Official Veterinarians in Wales; a voluntary scheme to see how bovine TB breakdown data may be made available to neighbouring farms; and the establishment of a pilot advisory service which will provide a full range of business and personal support to farmers affected by TB. There has also been a Badger Found Dead Survey underway in the IAA from March 2012.

33. As well as the actions outlined in the strategic framework, this plan also introduces policy changes that have been brought in as a result of the recommendations of the Food and Veterinary Office (FVO)'s audit that took place in the United Kingdom (UK) from 5 to 16 September 2011, which assessed the application of the national programme for eradication, and compliance with EU regulations. These will, from January 2013, include:

- In line with European Union Directive 78/52 movements of cattle in Wales from TB restricted herds (other than to slaughter) must be made within 30 days of a clear TB test.
- In TB breakdowns where the OTF status has been withdrawn no cattle movements onto restricted premises should be authorised pending completion of the first short interval test. However, in exceptional circumstances, authorised movements under a specific licence may be considered, for example :
 - replacement of suckler calves on welfare grounds
 - purchased bulls in exceptional circumstances only and where AI cannot be used as an interim measure
- In TB breakdowns where the OTF status has been suspended no cattle movements onto restricted premises should be authorised pending

completion of the first short interval test. However, in exceptional circumstances, authorising movements under a specific licence may be considered, for example:

- replacement of suckler calves on welfare grounds
 - purchased bulls in exceptional circumstances only and where AI cannot be used as an interim measure and
 - movements where the conclusions of a veterinary risk assessment are satisfactory.
- This is to limit the number of cattle which may potentially become infected when undisclosed infection remains on breakdown premises following the disclosing test.

34. The plan also takes account of engagement with the Commission as a consequence of the advice given during TB Eradication Task Force visit of March 2012 and the 2011 audit of expenditure incurred by the UK for the bovine TB monitoring and eradication programme for 2010.

35. Further measures will be developed after considering appropriate scientific and epidemiological data and applied nationally and, where appropriate, regionally, supported by local veterinary knowledge. They will be designed to ensure that the Welsh Government continues to take a robust and consistent approach to eradicate bovine TB.

3. Description of the submitted programme³³:

36. This Annex to the UK Plan covers Wales only. Details of the position in England and Northern Ireland are available in separate Annexes.

37. The Environment Minister John Griffiths announced on 20 March 2012 a “Strategic Framework for the Eradication of bovine TB in Wales”. This builds on the previous TB Eradication Programme in Wales which was in place from April 2008. The Welsh strategic framework includes a range of control measures which will be incorporated into policy in a progressive manner. Existing measures are summarised below and described in more detail in section 4.

38. The Welsh Government’s overall approach to TB is guided by Government policy on sustainable development and specifically a sustainable agriculture sector and the guiding principles of the ‘Animal Health and Welfare Strategy for Great Britain’ published in 2004, namely:

³³ A concise description of the programme is given with the main objective(s) (monitoring, control, eradication, qualification of herds and/or regions, reducing prevalence and incidence), the main measures (sampling and testing regimes, eradication measures to be applied, qualification of herds and animals, vaccination schemes), the target animal population and the area(s) of implementation and the definition of a positive case.

- Working in Partnership
- Prevention is better than cure
- Clearer understanding of costs and benefits
- Understanding and accepting roles and responsibilities
- Delivering and enforcing standards effectively

The Strategy can be found at the following link:

<http://wales.gov.uk/topics/environmentcountryside/ahw/animalhealthandwelfarestrategy/ahwspubindex/ahws/?lang=en>

39. Animal health policy is a devolved matter, so Governments in Wales and England implement policies that reflect their regional circumstances whilst working together to ensure a consistency and similarity of approach where appropriate. See section 4.2 for information on governance structures in Wales.

Surveillance

40. In accordance with Directive 64/432/EEC all herds and holdings will be registered. The Welsh Government and Defra are currently examining the mechanisms and rules for the registration of herds and holdings. Decisions concerning future policies in this area will be made following receipt of a report considering policy changes which is expected in January of 2013.

41. The TB status of herds will be either Officially Tuberculosis Free (OTF), Officially Tuberculosis Free Suspended (OTFS), or Officially Tuberculosis Free Withdrawn (OTW). The registration, identification and movement reporting of all cattle (and other livestock species) will be in accordance with Directive 64/432/EEC.

42. An effective surveillance regime that includes:

- Active surveillance by compulsory comparative skin testing of all registered cattle herds on an annual basis (including the requirement for Pre Movement Testing).
- Abattoir surveillance and back-tracing of the herds of origin of any carcasses with suspect tuberculous lesions.
- Additional targeted skin testing of OTF herds (and animals) at risk: e.g. herds contiguous to OTFW breakdowns, re-formed herds (following depopulation for bovine TB control purposes), animals traced from OTFW breakdowns, follow up testing in herds recently

- re-gained OTF status, imported cattle etc.
- Surveillance of non bovines, primarily passive.

Control

43. Immediate restriction of premises where there is a suspicion or confirmation of disease (skin test reactors or culture-positive slaughterhouse cases) to eliminate the infection from the herd and contain its spread to other herds:

- Cattle movement restrictions.
- DNA tagging, isolation, removal and slaughter, with compensation, of test reactors and contacts within 10 working days, followed by post-mortem examination of all of these animals and culture of tissue samples from a representative number of reactors (if more than one).
- Short interval testing (at > 60 day intervals (max 90 days)) with different approaches taken (e.g. depending on whether demonstrable evidence of TB is found at post-mortem examination or through laboratory culture (OTF suspended vs OTF withdrawn)).
- Epidemiological enquiry by a veterinary officer, using a standardised electronic report form (Disease Report Form (DRF)) into the causes of the breakdown and advice to herd owners on prevention measures).
- Forward and back-tracings from OTFW breakdown herds and check testing of herds that are contiguous to those breakdowns.
- Ancillary IFN-gamma testing of all OTFW herds identified in low incidence areas (primarily in North Wales), certain OTFW herds in the higher risk areas suffering chronic or severe breakdowns and where epidemiological advice suggests that it is warranted.
- Occasional slaughter of severely infected groups or entire herds (partial or total depopulation).
- Appropriate cleansing and disinfection of buildings, transport and equipment in OTFW herds.

44. Immediate movement restrictions and suspension of OTF status on herds with overdue TB tests (zero tolerance) and active management and resolution of all overdue tests by AHVLA with enforcement action where necessary.

45. Compensation paid for animals compulsorily slaughtered based on individual valuations including reduced compensation if keepers do not comply with the regulations, Veterinary Improvement Notices (VINs) or allow their TB tests to become overdue.

46. Check testing of breakdown herds 6 and 18 months following the restoration of their OTF status.

47. Use of veterinary discretion to inform future actions according to disease risk locally.

48. For Sole Occupancy Authorities (SOAs) in Wales, TB controls are applied in the same way to all parts of the SOA. As part of the ongoing review of Pre-Movement Testing exemptions, from the earliest opportunity in 2013, movements within a SOA will be limited to a maximum of 10 miles from the main holding (see paragraph 86).

49. Other measures in place include:

- Compulsory pre-movement tuberculin testing of over 42-days old cattle from Welsh herds, paid by herd owners.
- Tailored policies to reflect area disease incidence and risks (for example the IAA in south west Wales and Regional Eradication Delivery Board projects on the Gower peninsula and in north Wales).
- Pre-movement testing stickers as proof of testing available on a voluntary basis to inform risk based trading.
- Additional measures for certain breakdowns in a previously clean area.
- The Tuberculosis (Wales) Order 2011 introduced legislative arrangements for preventing and managing incidents of bovine TB in non-bovine animals, specifically camelids, goats and deer.
- Quality assurance procedures for TB testing
- Enhanced biosecurity - to encourage farmers to follow best practice advice from private vets in order to deal with existing disease quickly and to keep clean areas free of disease.

In order to accelerate TB eradication in Wales, the Welsh Government recognises that measures are required that go beyond the minimum requirements laid out in EU law. The following enhanced measures are underway:

- Annual testing across Wales which the Welsh Government believes is an over implementation of testing as there are clearly still low incidence areas in Wales
- 6 monthly testing of cattle herds in IAA
- Compulsory Pre-Movement Testing across Wales.
- Use of gamma interferon testing where appropriate.
- Inform risk based trading by introduction of a voluntary pre-movement testing sticker scheme attached to cattle passports which indicate when cattle were last clear tested
- Enhanced regional biosecurity measures
- Badger vaccination within the IAA and identification of other areas and circumstances where badger vaccination could contribute to TB eradication in Wales.

50. In autumn 2011, the TB in Cattle function of VetNet (AHVLA's old legacy IT system) was shut down and the management of the TB

surveillance and control functions was transferred to AHVLA's new IT system („Sam’). The Sam system replaces a number of older systems used to manage bovine TB testing and is held by AHVLA on behalf of Wales, England and Scotland to ensure standardised recording of testing and disease incidence.

51. Due to the change over of IT systems and as a result of some changes made in the methodology for the collation of bovine TB statistics in GB, the figures for 2011 for Wales as shown in section 6 are not directly comparable to those of previous years.

4. Measures of the submitted programme

4.1. *Summary of measures under the programme*

Duration of the programme: The programme submitted is for 5 years

This Plan includes the latest measures which are expected to be in place for 1st January 2013 and builds on the previous plans of 2010-2012 as part of the ongoing, long-term programme to eradicate TB from cattle in Wales.

First year: 2010

- ✓ Control
- ✓ Testing
- ✓ Slaughter of animals tested positive
- ✓ Killing of animals tested positive
- Vaccination
- Treatment
- ✓ Disposal of products
- ✓ Eradication

Last year:2015

- ✓ Eradication
- ✓ Testing
- ✓ Slaughter of animals tested positive
- ✓ Killing of animals tested positive
- ✓ Extended slaughter or killing
- ✓ Disposal of products
- ✓ Vaccination

4.2. *Organisation, supervision and role of all stakeholders³⁴ involved in the programme:*

52. The control, monitoring and eradication of bovine TB, as with all animal health matters, will be the responsibility of national, devolved administrations of the UK. The competent authorities for determining the policy based on EC Decisions for Wales is :

Chief Veterinary Officer for Wales
Welsh Government
Cathays Park
Cardiff CF10 3NQ

53. The TB Eradication Programme for Wales is overseen by a **Programme Board** with membership including the farming industry, veterinary profession, AHVLA and the Welsh Government. In addition, three **TB Regional Eradication Delivery Boards** ensure that delivery of policy is specific to regional and local conditions and that it is implemented effectively. These regional boards integrate existing responsibilities and include representatives from AHVLA, the farming industry, veterinary profession, auctioneers, Local Authority Trading Standards and the Welsh Government.

54. The TB Eradication Programme **Technical Advisory Group** (TAG), brings together scientific, veterinary, social science, disease modelling, agricultural economics and public health expertise to provide expert technical advice on the design and delivery of the component projects of the Programme.

55. The **Animal Health and Welfare Strategy (AHWS) Steering Group** is responsible for the implementation of the GB Animal Health and Welfare Strategy in Wales and involves a wide range of industry, welfare, veterinary, and Government stakeholders and is also the TB Eradication Programme's key stakeholder group.

56. There is close liaison between the devolved structures, including at a GB level through the UK TB Liaison Group so that a consistency of approach is maintained across GB and Northern Ireland.

³⁴ Describe the authorities in charge of supervising and coordinating the departments responsible for implementing the programme and the different operators involved.
Describe the responsibilities of all involved

Delivery of TB Controls in Great Britain

57. The competent authorities for field delivery of TB control policy in Wales on behalf of the Welsh Government and the GB position are set out in the table and figure 5 below.

Organisation name (Address)	Responsibilities	IT systems used
<p>Animal Health and Veterinary Laboratories Agency (AHVLA) Block C, Government Buildings, Whittington Road, Worcester. WR5 2LQ and New Haw, Addlestone, Surrey. KT15 3NB</p>	<p>Executive agency of Defra primarily responsible for ensuring that farmed animals in Great Britain are healthy, disease free and well looked after. The lead delivery body on TB issues, carrying out or managing:</p> <ul style="list-style-type: none"> ○ Routine on-farm surveillance (skin testing) ○ Enhanced surveillance Skin test training and audit ○ Control measures ○ Service of movement restrictions and movement licences ○ Testing regime including g-IFN ○ Isolation of reactors and public health controls ○ Reactor removal and compensation ○ Post-mortem examination, sampling, bacteriological culture and molecular typing. ○ Case management and veterinary risk assessment ○ Approval of special types of units (e.g. approved finishing units and dedicated slaughter gatherings) ○ Monitoring compliance 	<p>“Sam”– customer registration, contact history and management of testing schedules for routine surveillance including electronic collation and submission of TB test results and breakdown management including post mortem examination, epidemiological and financial data.</p> <p>Links to other IT systems – VLA database; CTS; RITA etc</p> <p>Sam is the new Animal Health IT system and a TB specific module was rolled out in 2011.</p>

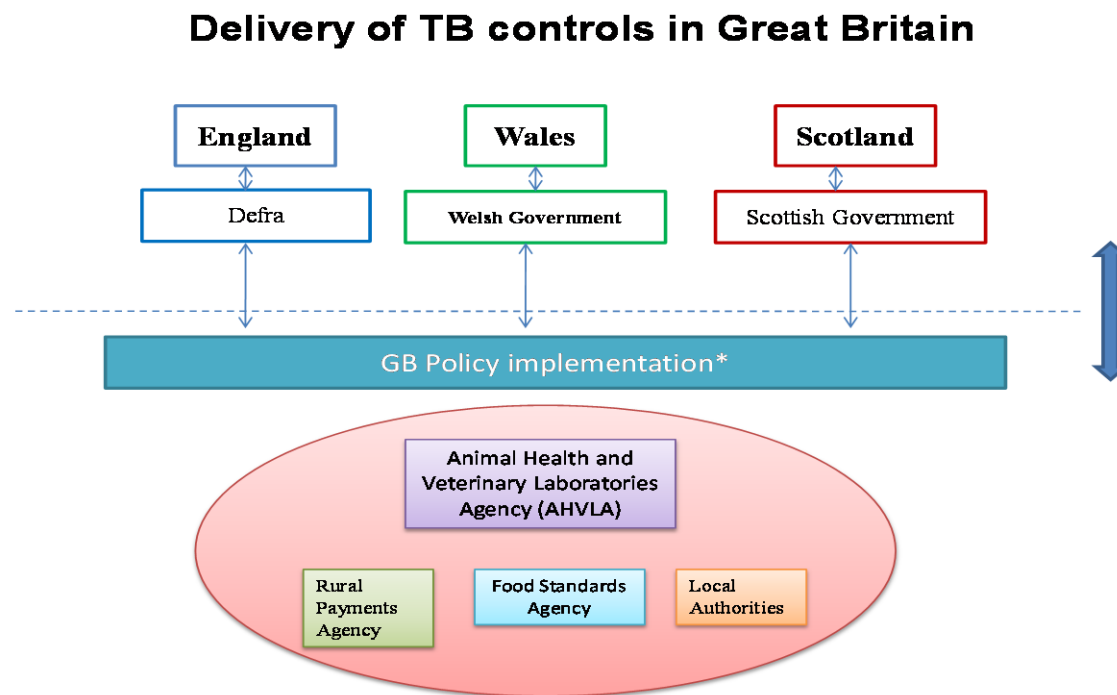
	<ul style="list-style-type: none"> ○ Enforcement in conjunction with Local Authorities ○ Field epidemiology to inform management and control decisions. ○ Laboratory support to the Programme, including diagnostic services. ○ Provides epidemiological and data analysis. ○ Wide-ranging involvement in TB research and development ○ Regional network of veterinary laboratories <p>Links to the other agencies through agreements. Delivers policy in partnership with private veterinarians appointed to carry out certain activities on the behalf of Ministers. These Official Veterinarians comprise a testing network of approx 4400 OVs in 1100 practices within an overall surveillance network of approx 10,200 OVs in 2,200 practices.</p> <p>There is a centralised tracings centre in Cardiff, south east Wales covering the whole of Great Britain</p>	<p>VLA database – this is a two-way information flow with AHVLA Field Services offices. The database receives data from AHVLA Field Services offices (e.g. reactor sample submission details) and data sent back to Field Services (e.g. culture results).</p> <p>CTS (see below)</p>
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<p>Rural Payments Agency (RPA) (incorporating the British Cattle Movement Service)</p> <p>British Cattle Movement Service (BCMS), Curwen Road, Derwent Howe, Workington, Cumbria. CA14 2DD</p>	<p>The RPA is an Executive Agency of Defra. The competent authority for livestock movements, identification, imports, deaths and tracing for all cattle to be used for animal health (surveillance, planning and control) and subsidy control purposes.</p>	<p>The Cattle Tracing System is administered by BCMS and is the central database to register all cattle movements, births and deaths.</p> <p>The RPA also administer the RITA system, which provides Sam with core data on holdings (for example the county parish holding number) to maintain up to date customer information.</p> <p>Link of IT systems to Sam.</p>
<p>Food Standards Agency (FSA)</p> <p>Food Standards Agency, Aviation House, 125 Kingsway, London. WC2B 6NH</p>	<p>The FSA is an independent UK organisation (Non-Ministerial Government Department) set up to protect public health and customer interests in relation to food. It is directly accountable to Parliament and publishes the advice it issues. It is led by a Board appointed to act in the public interest (not representing industry sectors). The functions of what was formerly the Meat Hygiene Service have been assumed into the FSA. This covers post mortem examination on carcasses of cattle slaughtered for food consumption; and reactors or dangerous contacts identified by AHVLA, slaughtered in licensed red meat abattoirs.</p>	

<p>Public Health Wales 14 Cathedral Road Cardiff CF11 9LJ</p>	<p>Public Health Wales has teams of health professionals including a Consultant in Communicable Diseases (CCDC). CCDCs are specialist doctors who risk-assess and, where necessary, instigate TB screening of human in-contacts upon receipt of a notification from AHVLA of <i>M. bovis</i> infection in a cattle herd.</p>	
<p>Local Authorities</p>	<p>Monitoring and enforcement of animal health aspects of TB legislation will be borne by the Trading Standards Departments of Local Authorities throughout GB. Environmental Health departments of Local Authorities enforce EU feed and food (e.g. dairy) legislation. Local Authorities liaise at a local level with AHVLA in relation to enforcement of bovine TB legislation and with BCMS on cattle identification issues.</p>	<p>Local Authorities maintain the Animal Movement Licensing System, which is the key data source for Local Authorities when monitoring compliance. AHVLA uses the system to approve animal gatherings and monitor movement standstills. The system has links to Sam and CTS</p>
<p>Environment Agency Environment Agency National Customer Contact Centre PO Box 544 Rotherham S60 1BY</p>	<p>Disposal of by-products including disposal of reactors unfit to enter an abattoir and milk from reactor cows.</p> <p>From 1 April 2013, a Single Environment Body will be established and will bring together the functions of the Countryside Council for Wales, the Environment Agency Wales, and the Forestry Commission Wales</p>	

Food and Environment Research Agency The Food and Environment Research Agency Sand Hutton York YO41 1LZ	Wildlife and husbandry issues (including involvement in the Welsh Badger Vaccination Programme)	
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58. There is a centralised tracings centre in Cardiff, south east Wales covering the whole of Great Britain.



* TB policy implemented by multi-agency delivery partners

Figure 5 – Delivery of animal health controls in Great Britain

59. The Welsh Government is responsible for the organisation and supervision of TB compensation valuations which are made at market value based on individual valuation by professional “warranted” valuers. In October 2007, the Welsh Government appointed three Monitor Valuers to address concerns that farmers were being overcompensated for TB reactor cattle. This supplemented other measures which include a revised list of “warranted” valuers and the automatic justification of valuations that exceed a set threshold, currently of pedigree animals valued at £4,000 or over and commercial animals valued at £1,800 or over.

60. TB valuations are closely monitored by the Welsh Government and detailed reports on key trends are produced on a regular basis by its TB Statistics Project Manager. The Monitor Valuers meet with the Welsh Government on a monthly basis to scrutinise all valuations, seeking justification and requesting comparable market data in all relevant cases. Valuers that fail to provide appropriate justification are removed from the list of “warranted valuers”. The process is continually reviewed with changes introduced where appropriate.

61. AHVLA is the lead agency in delivering the surveillance and controls for bovine TB eradication. AHVLA has the authority to deal with local issues in line with this strategy and leads on individual case management.

62. AHVLA activity in Wales is overseen by the Director Wales. Operations are delivered from offices based in Carmarthen and Caernarfon and managed by a Wales Operations Director.

63. The Welsh Government has a Service Level Agreement (SLA) in place with AHVLA to manage the delivery of its policies. The SLA includes a description of the main activities, costs and performance indicators to track delivery. Performance against the SLA is reviewed regularly and as a minimum through formal monthly meetings. If there is any doubt about what type of action is permitted, AHVLA will seek advice from the Welsh Government.

64. The Operational Delivery Partners Forum (Wales) provides a mechanism to facilitate effective communication, cooperation and coordination of activities between those with responsibility for enforcement of animal health and welfare, occupational health and safety, public health, and food and feed legislation in Wales. This forum which meets quarterly consists of representation from AHVLA, Rural Inspectorate (Wales) (RIW), BCMS/RPA, Health & Safety Executive (HSE), Welsh Government policy teams, FSA, Local Authorities (LAs), Food Fraud Co-ordination Unit (Wales) (FFU), Egg Marketing Inspectorate (EMI) and Welsh Local Government Association (WLGA).

4.3. Description and demarcation of the geographical and administrative areas in which the programme is to be implemented³⁵:

65. United Kingdom (Wales).

4.4. Description of the measures of the programme³⁶:

4.4.1. Notification of the disease:

In compliance with Council Directives 64/432/EEC as amended and 78/52/EEC, bovine TB is a notifiable disease. Under domestic legislation, the Tuberculosis (Wales) Order 2010 and Tuberculosis (Wales) Order 2011, any person who suspects the presence of TB in a bovine animal or non-bovine animal (camelid, goat or deer), within their charge is legally required to notify the Welsh Ministers immediately. Work is underway on an Order to consolidate the current Tuberculosis (Wales) Order 2010, the Tuberculosis (Wales) Order 2011 and the Tuberculosis (Testing and Powers of Entry) (Wales) Order 2008 in one new TB order. The intention is to consult with stakeholders on a new TB order in early 2013 with a view to it coming into force later that year.

66. Suspect TB lesions detected at post-mortem examination of cattle (and other farm and companion mammals) are also notifiable. AHVLA will carry out an official investigation of the herd of origin of such animals (by clinical examination and skin testing) to establish whether infection is present. Bovine TB will be defined as infection with *M. bovis* (*M. caprae* has not been isolated in GB).

67. Slaughterhouse inspection of all cattle destined for human consumption is a key tool in our surveillance strategy for TB, supplementing the tuberculin skin testing regime to identify additional infected herds that evade detection by (or are infected between) skin tests. This is consistent with one of the recommendations in the EU Taskforce TB sub-group report (SANCO/10200/2006 final).

68. Since 2011, the FSA has extended TB sampling and awareness training to staff in all red meat abattoirs, including those abattoirs that do not slaughter cattle. They also plan to improve monitoring of sample submission and confirmation rates to inform the need for future intervention. Reactors displaying characteristic lesions of TB in typical sites will confirm infection in that animal and, if the first such case in the herd, the herd's Official TB

³⁵ Describe the name and denomination, the administrative boundaries, and the surface of the administrative and geographical areas in which the programme is to be applied. Illustrate with maps.

³⁶ A comprehensive description needs to be provided of all measures unless reference can be made to Union legislation. The national legislation in which the measures are laid down is also mentioned.

Free (OTF) status will be withdrawn (OTFW). Where TB is suspected from typical lesions, identified at routine commercial slaughter of cattle from OTF herds, AHVLA will trace and issue movement restrictions on the herd of origin within two working days of receipt of notification from the FSA, and the herd's OTF status will be automatically suspended (OTFS) pending further investigation and the receipt of culture results.

69. All cases with suspect tuberculous lesions detected during commercial slaughter will undergo tissue sampling for histological and bacteriological examination at VLA. Between 60-70% of those slaughterhouse cases will be expected to yield *M. bovis* on culture based on historical data. Following suspension of OTF status and a veterinary risk assessment, the local AHVLA office may initiate an immediate tuberculin skin test of the herd of origin or wait for the laboratory results. In situations where it is difficult to decide on visual inspection whether or not the lesions in a slaughterhouse case are tuberculous, a preliminary diagnosis based on histopathological examination is available within two weeks. The skin check test if carried out will initially be interpreted at standard interpretation pending the culture results, when reinterpretation may be necessary. If this test gives negative results and the tissue cultures prove negative for *M. bovis*, the herd's OTF status will be automatically restored and the herd will be marked forward to its routine testing date. By contrast, should the laboratory culture and/or skin test results prove positive for bovine TB, the normal procedures following the disclosure of a positive test reactor will be followed and the OTF status will be withdrawn pending further herd testing at 60 day intervals. A clear check test will be required in high risk herds where culture results from cases suspected at commercial slaughter prove negative for *M. bovis* before OTF status can be regained.

4.4.2. Target animals and animal population:

70. The programme will target all bovine herds and animals (including Asiatic water buffalo and bison) kept on agricultural premises in Wales over 42 days old for surveillance purposes and all bovines of any age for control purposes. In addition the legislation and programme will contain measures to address other reservoirs and sources of TB (including some non-bovine species and wildlife).

4.4.3. Identification of animals and registration of holdings:

71. All herds and holdings will be registered in accordance with Directive 64/432/EEC as amended. All cattle holdings must be registered onto the Cattle Tracing System (CTS), operated by the British Cattle Movement Service (BCMS), which has been in operation since 1998 and was introduced primarily to support BSE control measures. All registered premises will be recorded onto this system. The CTS Online allows cattle owners to:

- Register new cattle births;
- Report cattle movements;
- See the life history of their cattle;
- See a list of the cattle on their holding;

- Check the movement history of an individual animal; and
- Download information on their cattle for use in their farm management software.

72. In addition, the Cattle Identification Regulations 2007 require farms to retain registers for 10 years, and in any other case (e.g. markets) for 3 years, from the end of the calendar year in which the last entry was made.

73. In GB the livestock identification system provides traceability of cattle from birth to death. It underpins all disease control programmes for cattle, including bovine TB and provides general assurance for consumers of the place of origin of beef and dairy products. The domestic rules are governed by Regulation (EC) 911/2004 which set out detailed requirements for the implementation of Council Regulation 1760/2000/EC. Cattle are identified by a unique Official Animal Identification number (OAI), which is provided by the competent authority, the BCMS. All cattle born after 1 January 1998 must have an approved ear tag in each ear, bearing its unique OAI, which will remain with the animal throughout its life. Animals born in, or imported into Great Britain, before 1 January 1998 may continue to be identified by a single tag. Cattle born after 1 July 2000 must be identified by a UK 12 digit numeric ear tag. All cattle must be tagged within 20 days of birth, although in the case of dairy animals, at least one of the tags must be fitted within 36 hours of birth. In addition, all cattle born in, or imported into GB, since 1 July 1996, must have a valid cattle passport. This details the unique eartag number given to the animal, movement history between holdings (farms/markets/slaughterhouses), the breed, sex and date of birth of the animal. Passports must be applied for within 27 days of birth (within 7 days of the 20-day tagging deadline). Details of all births, movements between holdings (farms, markets and slaughterhouses) and deaths of individual cattle, must be notified to the BCMS (births within 27 days of the event, movements within 3 days of the event, death within 7 days of the event). BCMS will then input this data into the Cattle Tracing System (CTS).

74. Unannounced spot checks, based on a risk analysis of holdings, will be carried out by Rural Inspectorate Wales on 5% of holdings, to check that keepers are complying with all cattle identification and registration requirements, and an annual report on the results will be sent to the Commission as required by Commission Regulation 499/2004/EC. If errors are found, cattle movement restrictions will be imposed (such as whole herd movement restrictions). In addition, any keeper found to be deliberately breaking the cattle identification rules may be prosecuted. If the courts find that a keeper is guilty of an offence they may impose penalties, including fines of up to £5,000 and possible custodial sentences, or £10,000 and custodial sentences under fraud legislation.

4.4.4. Qualifications of animals and herds³⁷:

75. The TB Eradication Programme in Wales will be conducted under domestic legislation: primarily the Tuberculosis (Wales) Order 2010 (until the time it is revoked and replaced by a new TB Order for 2013, where the intention is to consolidate the 2010 and 2011 TB Orders). Maintenance, suspension, withdrawal and re-qualification of OTF herd status will be in accordance with paragraphs 2 and 3 of Annex A of Directive 64/432/EEC. Briefly, all herds will be designated OTF unless placed under TB movement restrictions due to skin test reactors, suspect slaughterhouse cases, inconclusive reactors detected within 3 years of an OTFW TB breakdown, delayed (overdue) TB testing, if presenting (very unusually) as suspect clinical cases, or any combination of those situations, in which case the OTF status will be suspended (OTFS). Cattle herds with reactors will also have their OTF status withdrawn in the absence of positive bacteriological culture if an epidemiological risk is identified. Cattle herds will have their OTF status withdrawn (OTFW) whenever lesions typical of TB are detected at post-mortem examination of test reactors, or *M. bovis* is isolated in tissue samples from any animal in the herd.

76. Herds in Wales that have had their OTF status suspended due to a TB breakdown and have a history of OTF status withdrawn in the previous three years, or are contiguous to an OTFW herd (or for epidemiological reasons), unless a Veterinary Risk Assessment determines otherwise, will be designated OTFW and be subject to the same requirements as all OTFW herds including contiguous and tracing testing.

4.4.5. Rules on the movement of animals:

77. In accordance with Council Directive 78/52/EC (Article 14), whilst an investigation is being carried out, the herd will be placed under official surveillance and movements of cattle into or out of the herd other than directly to slaughter will not normally be permitted. A limited number of exceptions might be considered, always under licence from AHVLA and normally following the completion of the first short interval herd test. Following a TB breakdown the entire holding is restricted. Only in exceptional circumstances do we lift restrictions on epidemiologically separate groups of cattle provided they are not within, or contiguous to, the same land parcel on which the infected group of cattle are kept. In all such cases there must first be a satisfactory veterinary risk assessment to verify separation by location, management and time. Cattle on all land parcels that comprise the entire holding remain ineligible for export from the UK whilst any part of the holding is under restriction. Additionally we carry out pre-export checks to ensure that within the 180 days preceding the pre-export test the cattle have not been resident in a herd subject to TB restrictions (i.e. OTF suspended or withdrawn) or with unresolved TB inconclusive reactors (see paragraph 112). There are detailed guidelines in place for the

³⁷ To mention only if applicable.

derestriction of parts of a holding. We will review and tighten these instructions and work to phase out the practice by the end of 2014. Suspected animals within the herd will also be isolated pending slaughter (reactors and contacts) or re-testing (inconclusive reactors). Appropriate follow-up re-testing of OTFS and OTFW herds, at minimum intervals of 60 days, will take place to eliminate residual infection and restore OTF status in accordance with paragraph 3 of Annex A of Directive 64/432/EEC. Local Authorities monitor and enforce movements from non-OTF herds.

78. Suspected animals within the herd will also be isolated pending slaughter (reactors and contacts) or re-testing (inconclusive reactors). Appropriate follow-up re-testing of OTFS and OTFW herds, at minimum intervals of 60 days, will take place to eliminate residual infection and restore OTF status in accordance with paragraph 3 of Annex A of Directive 64/432/EEC. Local Authorities enforce movements from non-OTF herds.

79. Approved Quarantine Units (AQUs) were introduced in Wales to provide an outlet for calves from TB restricted holdings which lack the facilities for rearing. There are currently 2 AQUs in Wales.

80. As a result of concerns, arising from the FVO mission in September 2011, the licensing of new AQUs was suspended. From 1 January 2013, the Welsh Government will begin the process of closing down and destocking the 2 existing AQUs in Wales with a view to completing the process and revoking all licenses by the end of 2013.

81. Work will need to be undertaken to identify an alternative model for TB affected farmers needing to find outlets for calves.

82. One option for this might be, the concept of "rearing" AFUs on the basis that:

- calves are only able to move on to regular AFUs or to slaughter;
- they meet the strict criteria set for AFUs;
- they are not permitted within the low incidence areas of Wales.
- They must be indoors and wildlife proof.

83. Both Wales and England support the principle of Approved Finishing Units (AFUs), and encouraged the setting up of more specialist TB isolation units. AFUs can accept clear tested cattle, moved under license, from herds with a breakdown. These can be used to overcome animal health and welfare issues that can arise when premises are subject to movement restrictions due to TB breakdowns. AFUs in Wales are non-grazing units i.e. housed where restricted cattle move for fattening/ finishing. These are permitted only within areas of high incidence outside of North Wales and cattle can move from these units only to slaughter.

84. AHVLA will undertake an unannounced compliance inspection of all AFUs and AQUs (prior to their abolishment from January 2013), which will be in addition to any application or re-application inspections.

Pre-Movement Testing

85. Under the Tuberculosis (Wales) Order 2010, it is a statutory requirement that all cattle 42 days old and over moving from OTF free herds in Wales must have had a clear comparative tuberculin skin test within the 60 days prior to the movement (Pre-Movement Test) unless one of a limited number of exemptions applies. In compliance with Article 19(ii) of Council Directive 78/52/EEC animal movements from herds that are non-OTF status must now ensure that animals have had a clear comparative tuberculin skin test within the 30 days prior to the movement (Pre-Movement Test) unless one of a limited number of exemptions applies.

86. In Wales the Pre-Movement Testing exemptions continue to be reviewed in light of emerging risks and eradication priorities, the Welsh Government is currently reviewing exemptions and intends to amend the following from the earliest possible date:

- Exemption for movement between herds having shared rights to common land, animals will now **only** be able to return to their home holding.
- Animals may only return to their holding of origin from market (but will be subject to the 6 day standstill as per normal movements).
- Movements within a Sole Occupancy Authority (SOA) will be limited to a maximum of 10 miles from the main holding*.

* The „Working Smarter Report’ to the Welsh Government recommended, amongst other things, the abolishment of SOAs in Wales and in its response to the Task Force report, the UK Government has agreed in principle to abolish SOAs subject to the costs, benefits, implementation and regulatory impacts of doing so. Work to establish the costs and benefits is due to be completed by the end of 2013. However, measures to effect the abolition of all SOAs in Wales, if agreed, could not be completed before 2014/15.

87. The following exemptions are managed administratively using provisions in the Tuberculosis (Wales) Order 2010 Order and will continue to be managed and reviewed on this basis, they are:

- Cattle in herds subject to 3-4 yearly routine surveillance testing unless they are moving to agricultural shows in Wales.
- Cattle that would be subject to 3 or 4 yearly routine TB testing if not for reasons of public health e.g. cattle on open farms, producers/retailers of raw milk, AI studs.
- Cattle moving direct to slaughter or to slaughter markets.
- Cattle moving directly to approved (exempted) finishing units or markets for animals not Pre-Movement Tested.

- Cattle moving directly to approved TB finishing units for cattle under movement restrictions for TB or approved TB collection centres.
- Cattle moving from markets.
- Cattle movements within premises sharing rights of common.
- Cattle moving between holdings within the same Single Occupancy Authority.
- A bovine animal moving to a place for veterinary treatment and returning direct to its premises of origin.

88. Between 1 March 2006 and 31 December 2011, 553 reactors were identified in 333 herds from dedicated Pre-Movement Tests in Wales; and a further 1,101 inconclusive reactors (IRs) were also identified during the same period.

89. All Pre-Movement Tests are arranged and paid for by the herd owner. AHVLA supplies the tuberculin used in the test free of charge. Routine surveillance and other TB tests paid for by the Government may also qualify as Pre-Movement Tests.

90. Herd owners must retain copies of their TB test charts as proof of testing and are advised to retain evidence of the relevant exemption for non-tested stock. Those marketing cattle will be asked for copies of this evidence as assurance of the test status of their animals. In 2011, following a successful pilot in North Wales, the Welsh Regional Eradication Delivery Boards introduced a national voluntary scheme to use stickers on cattle passports as a basis to demonstrate that the cattle have been Pre-Movement Tested. Non-compliance with the Pre-Movement Testing policy is an offence under the Tuberculosis (Wales) Order 2010. The AHVLA Pre-Movement Testing Monitoring Unit check, on an ongoing basis, a proportion of all cattle movements on the Cattle Tracing System (CTS) and cattle testing records for possible Pre-Movement Testing breaches. Suspected breaches are reported to the local authorities for investigation and, if appropriate, prosecution. In addition, compliance with TB testing requirements, including Pre-Movement Testing, is included within Common Agricultural Policy (CAP) cross compliance checks i.e. illegal movements of animals can result in a reduction to the owner's Single Payment and could affect the compensation paid for TB reactors.

91. Any identified non Pre-Movement Tested cattle are placed under movement restrictions and subject to a Post-Movement Test paid for by the owner of the holding. If the Post-Movement Test is not completed within 60 days, the whole herd is placed under movement restrictions (OTF status suspended) until such time as the cattle test clear.

4.4.6. Tests used and sampling schemes:

92. As contemplated in Directive 64/432/EEC, the Single Intradermal Comparative Cervical Tuberculin (SICCT) test will continue to be the primary screening test for routine herd surveillance in Wales. Additionally, and in line with the recommendations of the EU Task Force TB sub-group

(SANCO/10200/2006 Final), the IFN-gamma blood test will be used in specific OTFW herds as an ancillary parallel test to enhance sensitivity.

TB surveillance - routine tuberculin skin herd testing programme

93. All cattle herds in Wales will continue to be subject to an annual testing regime in 2013 and will, therefore, be required to comply with Pre-Movement Testing requirements when moving cattle.

94. The herd owner will be responsible for arranging scheduled tests under the routine surveillance programme, which will be paid for by Government. AHVLA will give herd owners advance notice of the 2 or 3 month window in which the test must be completed normally by their nominated Official Veterinarian (OV) practice. Test notification letters will be sent centrally from AHVLA to ensure consistency of notification. OVs will also be notified by AHVLA of the due dates for their clients' herd tests. Routine and other skin tests can also be carried out by AHVLA Veterinary Officers (VOs) and AHVLA veterinary paraprofessionals (fully trained lay testers under the direction of AHVLA VOs).

95. To ensure compliance with the tuberculin testing programme, a zero tolerance regime for overdue tests was introduced in February 2005, whereby a herd's OTF status is automatically suspended whenever a TB test has not been completed by its due date. AHVLA actively manage these overdue tests by a combination of formal warnings and staged sanctions, potentially leading up to a reduction in Single Farm Payments and referral to the Local Authority for prosecution. In Wales, a failure to comply with testing requirements may also affect the amount compensation received for any TB reactor animals. In the event of non-cooperation by a herd owner, there are specific powers in Wales for inspectors to enter land and to obtain a warrant for purposes of testing bovine and other animals for disease. Once tested, if clear, a herd is marked forward in the AHVLA database for its next TB test according to its existing TB testing window.

96. AHVLA will also carry out an investigation of clinical suspects notified to them. However this is likely to only occur in a small number of cases. Details of passive surveillance carried out in slaughterhouses can be seen at paragraphs 4.4.1.

97. Control measures in infected herds for the restoration of OTF status:

- Management of TB incidents
- Where test reactors are identified or disease is suspected clinically or at slaughter, a range of measures will be taken to contain and eliminate the infection as quickly as possible. Veterinary discretion is applied where appropriate, which often means that enhanced measures are applied in comparison to the baseline (for example g-IFN test usage where appropriate).
- Herd restrictions will be imposed (OTF status suspended) and limited movements of cattle into and out of the herd can only take place under a

licence issued by AHVLA.

- Reactor animals will be identified with a DNA eartag at the point of disclosure.
- Rapid removal of reactors and contacts within 10 days of disclosure to a licensed abattoir (if the animal is potentially fit for human consumption) or animal by-products approved collection centre/disposal site.
- Compensation for reactors and contacts, with reduced compensation payable in Wales to farmers who do not comply with legal requirements, testing and Veterinary Improvement Notices.
- Post mortem examination of reactors and contacts with tissue culture of selected animals. Where demonstrable evidence of *M. bovis* is found in at least one reactor (typical macroscopic lesions and/or isolation of *M. bovis*), the OTF status of the herd is automatically withdrawn.
- Where a dairy herd has its OTF status suspended, AHVLA will notify the Chief Environmental Health Officer of the local food authority to monitor compliance with food hygiene regulations, including the pasteurisation of milk and withholding from the human food chain any milk produced by individual reactor cows.
- Notification of animals with visible lesions and/or positive culture to the local medical authorities (CCDC) for risk assessment of human in-contacts on the farm.
- Skin testing of the whole herd at least 60 days after removal or effective isolation of reactors and then every 60 (up to 90) days thereafter, restoring OTF status if the results are negative at one (most OTFS herds) or two (OTFW herds) consecutive tests.
- Severe (re-)interpretation of the skin test where demonstrable evidence of *M. bovis* infection is found at Post Mortem examination/culture (OTFW herds).
- Risk-based approach to the testing of herds that are related, eg history of withdrawn OTF status within 3 years, and/or contiguous to cattle holdings with OTFW breakdowns, unless a Veterinary Risk Assessment determines otherwise.
- Ancillary in vitro TB testing (gamma interferon testing) in specified circumstances in OTFW herds.
- Epidemiological enquiry including molecular typing of *M. bovis* isolates.
- Provision of biosecurity advice to herd owners, including completion of an electronic Disease Report Form to establish, amongst other things, the likely source of infection.
- Risk based approach to source and spread tracings - check testing of origin herds and testing of individual animal at herds of destination where at-risk movements have been identified.
- Cleansing and disinfection of premises occupied by reactor animals. Compulsory in OTFW herds, advisory in other herds.
- Occasional partial or complete depopulation, depending on prevalence of skin and IFN-gamma test reactors and subject to veterinary risk assessment.
- Follow-up testing of OTFW and OTFS herds 6 and 18 months after restoration of its OTF status.

98. Herds where *M. bovis* has not been confirmed by post-mortem examination or bacteriological culture, but which have a history of TB (as defined by confirmed incidence of TB in the herd within the last three years); or the presence of TB in the local area (as defined by confirmed incidence of TB in a contiguous herd) will be classified as OTF withdrawn status unless a veterinary assessment determines otherwise and associated tracings and contiguous testing will be applied.

Pilot Project – Enhanced Management of Persistent TB Breakdowns

99. The FVO audit of bovine TB control procedures in September 2011 reinforced the need to review actions where individual TB herd breakdowns require additional measures or considerations in order to eradicate infection from that holding and, as a consequence, the risk of wider disease spread.

100. The „Enhanced Management of Persistent TB Breakdowns’ was a small scale, but important pilot project which ran from 1st February – 8th June 2012. The aim of the project was to help AHVLA to better understand how it can address key concerns from the FVO regarding the management of persistent TB breakdowns in Wales as well as in England.

101. The pilot delivered its main purpose, which was to consider and trial additional measures on selected persistent TB breakdowns with a view to wider roll-out and integration of the process within business as usual. The potential longer term benefits include a reduction in the duration and severity of breakdowns and the cost and compensation bill in persistent breakdowns.

Tuberculin test

102. Tuberculin testing of cattle will continue to be the main TB surveillance and control tool in 2013. Testing is by the single intradermal comparative cervical test (SICCT), using 0.1 ml of bovine (30,000 IU/ml) and avian (25,000 IU/ml) PPD tuberculins manufactured by Prionics AG in Lelystad, the Netherlands under a 3-year supply contract awarded in December 2009. This paired presentation of tuberculins received an MA for use in UK and a number of other MSs from the Veterinary Medicines Directorate in December 2010.

103. The interpretation of the comparative reactions to the injection of tuberculin will vary depending on the TB history and status of the herd. Standard interpretation in line with section 2.2.5.2 of Annex B of Directive 64/432/EEC will be used for herds with no recent history of bovine TB, or no visible evidence of infection at post mortem or following laboratory culture of recently disclosed reactors. In line with SANCO/10200/2006 Final recommendations and section 2.2.5.3.5 of Annex B of the Directive, a more severe interpretation will be applied to 60-day Short Interval Tests (VE-SI) carried out in OTFW (see above), to maximise the probability of detecting infected animals.

104. The Welsh Government intends to consider the circumstances in which use of the single intradermal test would be beneficial to improving disease control. Currently to increase the sensitivity of skin-testing carried out during OTFW breakdowns a more severe interpretation of the SICCT is used. Using the single intradermal test offers an alternative way in which the sensitivity of the skin-test might be increased. When testing animals for export from Wales to other EU member states only the bovine-only interpretation of the skin-test is considered. In addition, veterinary officers dealing with OTFW breakdowns have the discretion to remove all animals which react to the bovine tuberculin as direct contacts. Previous research suggests that wider use of the single intradermal test within the high incidence area would lead to the identification of additional infected animals in which infection would have been confirmed by culture of the presence of visible lesions. However, this would also significantly increase the number of false positive reactors which would need to be removed and compensated for. To further improve our understanding of the consequences of using the single intradermal test further research has been commissioned on the consequences of using this test specifically in the high incidence areas.

Interferon gamma diagnostic blood test

105. In line with Directive 64/432/EEC, in GB, the interferon-gamma (IFN-gamma or Bovigam™) test will be used as an ancillary parallel test, alongside the tuberculin skin test in specified circumstances. Using both tests in parallel in this way enhances the sensitivity of testing so enabling as many infected cattle in a herd as possible to be identified and removed from the herd at the earliest opportunity.

106. Under this policy the primary focus of the IFN-gamma test will be in OTFW breakdown herds in lower risk (predominantly in north Wales) areas; the objective being to reduce the risk of new, intractable TB hotspot areas becoming established in hitherto low prevalence areas. The test will also be used in certain herds (e.g. with particularly severe TB problems) in areas of high TB incidence. The use of the IFN-gamma test will be mandatory in Wales under the following circumstances:

- On tuberculin test-negative animals in all OTFW new TB incidents, in areas where the risk is low (predominantly in north Wales);
- On tuberculin test-negative animals in severe TB incidents, to inform decisions around whole or partial herd slaughter;
- On tuberculin test-negative animals in herds in high risk areas with persistent, confirmed infection that fail to resolve through repeated short-interval tuberculin tests and have taken basic herd bio-security precautions;
- The IFN-gamma test alongside the skin test is deployed where epidemiological advice suggests that it is warranted.
- Ancillary IFN-gamma testing is also used in other areas where there is an OTFW TB breakdown and disease cannot be attributed to a wildlife origin and is not already considered to be endemic.

107. In 2011, 7,413 IFN-gamma blood tests were performed on cattle from 521 herds, identifying 627 positive animals. The number of cattle tested using IFN-gamma blood tests has increased from 4,086 in 2008.

108. Occasionally, in exceptional circumstances, AHVLA may use a modified IFN-gamma test with more specific *M. bovis* antigens as a serial test of skin test reactors and inconclusive reactors in chronic OTFS herd breakdowns arising in low incidence areas where non-specific cross reactions to tuberculin are suspected. The serial IFN-gamma test may also be deployed for re-testing of suspected fraudulent tuberculin test reactors presenting with abnormal skin responses.

109. The use of the interferon-gamma test will continue to be reviewed with the expectation of increasing use in Wales where appropriate.

Inconclusive reactors (IRs)

110. There is a one retest policy on IRs, in line with the requirements in Directive 64/432/EEC. In addition to 64/432 requirements, in Wales the severe test interpretation used in OTFW breakdown herds, identifies some cattle which are positive to both avian and bovine tuberculins, but which are considered clear testing at standard test interpretation as IR (severe only) Any cattle which give consecutive IR test results by virtue of either or both test results being IR (severe only) will be IFN –g tested and only if negative will be allowed a further skin test which must be passed or they will be slaughtered as reactors.

Imported cattle

111. All cattle imported into GB from non-OTF EU Member States and other parts of the UK (Northern Ireland, Isle of Man) must comply with the TB certification conditions set out in Council Directive 64/432/EEC (as amended). Cattle from Northern Ireland and the Isle of Man are subject to pre-movement testing within 30 days of departure using the comparative skin test. Additionally, post import skin testing of cattle from Northern Ireland, the Republic of Ireland, Isle of Man, and any non-OTF EU Member States is conducted 60 to 120 days after arrival in GB, unless the animals are destined for direct slaughter. Movement restrictions are not applied to either the animal or the herd during this period before the test is conducted. Based on a risk assessment, it may also be necessary to carry out TB checks and testing of certain consignments from third countries.

Exports

112. The normal comparative intradermal test must continue to be applied and carried out by an OV. However, only the bovine reaction should be considered when interpreting the test results in bovine animals intended for intra-Community trade. Those animals showing an increase in the skin fold thickness greater than 2mm or the presence of oedema 72 hours after tuberculin injection (i.e. a positive bovine reaction) will not be eligible for intra-Community trade, and should not be so certified. This interpretation is in line with Community legislation (Council Directive 64/432/EEC – point

2.2.5.3.4 in Annex B refers). In cases where there is partial de-restriction of a holding, no animals are eligible for intra-Community trade while they remain on the holding until the whole holding regains OTF status. Additionally we carry out pre-export checks to ensure, inter alia, that eligible cattle for export have not been resident in the 180 days on any holding with some form of on-going TB restriction (i.e. OTF suspended or withdrawn) or with unresolved TB inconclusive reactors. We will be reducing the numbers of occasions where we de-restrict holdings in this way and will phase out the practice by the end of 2014.

113. Suspicion of disease in the carcase of non-bovine species is notifiable. Passive surveillance is and will continue to be carried out on domestic livestock other than cattle (farmed deer, sheep, pigs, camelids and goats) mainly by meat inspection in animals going through licensed abattoirs, necropsy of suspect clinical cases by AHVLA, or via the surveillance network provided by OV's and private veterinary surgeons. If bacteriological tests confirm infection with *M. bovis* in non-bovine animals, where appropriate, movement restrictions will be imposed by AHVLA and usually only lifted following two clear tuberculin tests, and also the local Health Protection Unit's CCDC is informed. *M. bovis* infection in all non-bovines is monitored by AHVLA.

114. The Tuberculosis (Wales) Order 2011 which came into force on 31 March 2011 introduced legislative arrangements for preventing and managing incidents of bovine TB in non-bovine animals, specifically camelids, goats and deer.

115. It is proposed to consolidate the current Tuberculosis (Wales) Order 2010, the Tuberculosis (Wales) Order 2011 and the Tuberculosis (Testing and Powers of Entry) (Wales) Order 2008 in one new TB order. As well as consolidating these different pieces of legislation, the opportunity will be taken in the new order to introduce, where necessary, changes to the existing provisions. Any such changes would seek to address identified weaknesses or gaps in the existing legislation with the aim of ensuring that appropriate powers are in place to support the eradication programme. The intention is to consult with stakeholders on a new TB order in early 2013 with a view to it coming into force later that year.

4.4.7. Vaccines used and vaccination schemes:

Badger vaccination

116. An injectable TB vaccine for badgers ('BadgerBCG') was issued with a Limited Market Authorisation in March 2010. The vaccine is available for privately funded use in Wales by accredited, certified and licensed individuals.

117. A Welsh Government project to vaccinate badgers using "Badger BCG", administered via injection, in the IAA (approximately 288km²) in west Wales began in May 2012. In line with the recommendations of the Wales Vaccination Technical Group, vaccination will continue in the IAA for five consecutive years. The project is being developed to ensure that the potential effect can be monitored with a view to assessing its impact. Up until

23 August 2012, 747 badgers had been vaccinated in Wales.

118. The Welsh Government is working in collaboration with the National Trust to explore the practicalities of vaccinating badgers on National Trust land in Wales. The National Trust owns 45,000 hectare in Wales which includes 200 tenanted farms. A working group, consisting of Welsh Government and National Trust officials has been established to consider how best to take forward this work. The first meeting of the group took place in early September 2012.

119. Other geographical areas and situations where vaccination of badgers could contribute to TB eradication in Wales, ideally based on partnership working, are also being considered and will be subject to Ministerial decisions anticipated in 2013.

120. Research is underway to develop an oral BCG vaccine bait formulation in collaboration with Defra as this is seen as potentially the most practicable application of a vaccine to a wildlife population in the longer term, if technical barriers can be overcome.

Cattle vaccination developments

121. Research continues to be funded into cattle TB vaccination experiments with BCG and other vaccine candidates, which include a range of live attenuated and sub-unit vaccines. EU legislation currently prohibits the use of TB vaccines in cattle, and Directive 64/432/EEC would prevent trade in vaccinated cattle because vaccination with BCG sensitises cattle to the skin test causing them to react as if they were infected. However, vaccination offers an additional, potentially valuable tool for controlling and eradicating bovine TB, in particular in endemic areas, so research will also be carried out in GB to develop tests to differentiate infected from vaccinated animals (so-called „DIVA’ tests) to address these concerns.

4.4.8. Information and assessment of biosecurity measures (management and infrastructure) in place in the holdings involved:

122. The Welsh Government will continue to collaborate with industry to promote wildlife biosecurity advice (including general advice and guidance in the form of leaflets and a DVD) at critical stages of a TB breakdown including the initial visit to a new breakdown.

123. The Welsh Government will continue to provide bespoke risk assessment advice on biosecurity measures associated with TB for farmers through private veterinary surgeons. This work will be aligned to specific regional initiatives such as the IAA and the work of the south east Wales and north Wales TB Regional Eradication Delivery Boards on the Gower Peninsula and in the Wrexham area respectively.

4.4.9. Measures in case of a positive result³⁸:

Officially TB Free Status and Slaughter of Animals

124. In line with Annex A of Council Directive 64/432/EEC as amended, OTF status will be suspended by service of a legal notice (known as “TB2”) on the herd owner:

- Where an animal discloses with a positive result to the tuberculin skin test (a reactor);
- Where a test reveals IRs only, in a herd that had OTF status withdrawn within the previous three years.
- Following the discovery of lesions suggestive of bovine TB in carcasses at a slaughterhouse;
- Where a tuberculin test becomes overdue; and
- In suspected clinical cases (although this is very rare and the first action would be a TB test).

125. All reactors and IRs are required to be isolated from contact with any other cattle; reactors for immediate slaughter and inconclusive reactors for further testing. Movement restrictions will be imposed and no movement will take place unless a licence is authorised by an AHVLA vet. TB testing will be carried out again at 60 day intervals (up to max 90 days). For reactors, a DNA eartag will be applied at the time of disclosure and a random or targeted proportion will be followed up by DNA matching samples taken following the slaughter of the reactor. If post mortem evidence of *M. bovis* infection cannot be demonstrated in any of the slaughtered reactors, OTF status remains suspended and may be restored after one clear skin test for all animals within the herd at 60 days after the isolation/removal of the reactor animal(s). However, OTFS breakdown herds that happen to be contiguous to an ongoing OTFW breakdown, or have had their OTF status withdrawn in the preceding three years, will require two (not one) consecutive skin herd tests with negative results before regaining OTF status.

126. In accordance with the Directive, the OTF status of a herd will be withdrawn (OTFW) if classical lesions of TB are seen at post-mortem examination of skin test positive reactors or following the isolation of *M. bovis* from tissue cultures or there is evidence of epidemiological risk identified. Where OTF status has been withdrawn; two consecutive herd tests with negative results must be attained before movement restrictions can be withdrawn and OTF status regained. Additionally, and in accordance with section 2.2.5.3.5 in Annex B of Directive 64/432/EEC, a more severe interpretation of the skin test will be adopted in OTFW TB breakdowns. In Wales, TB breakdown herds which have had their OTF status withdrawn in the previous 3 years and/or are contiguous to a herd with an OTF withdrawn status will have an OTF withdrawn status, unless Veterinary Risk

³⁸ A description is provided of the measures as regards positive animals (description of the slaughter policy, destination of carcasses, use or treatment of animal products, the destruction of all products which could transmit the disease or the treatment of such products to avoid any possible contamination, a procedure for the disinfection of infected holdings, the therapeutic or preventive treatment chosen, a procedure for the restocking with healthy animals of holdings which have been depopulated by slaughter and the creation of a surveillance zone around the infected holding.).

Assessment determines otherwise.

127. After regaining OTF status all OTF withdrawn herds must undergo two further check tests before going back to the normal area herd testing frequency. The first test is 6 months after restoration of OTF status. If this test is negative, a second check test takes place 12 months later. During this period, any cattle moved out of the herd will be eligible for Pre-Movement Testing.

128. When OTF status is suspended or withdrawn a TB2 Notice putting the herd under movement restrictions will be served on the keeper and copied to the Local Authority for enforcement procedure by their Trading Standards Department in the event of a farmer's non compliance. For public health reasons, whenever OTF status is suspended in a dairy herd the relevant local food authority CEHO will also be notified by AHVLA, to ensure that all the milk sold from those herds is pasteurised and milk from individual reactors does not enter the food chain, as per Council Regulation 853/2004/EC. In addition, where a TB breakdown is confirmed in any cattle by visible lesions or positive culture results, AHVLA will inform the relevant local medical authorities, i.e. the CCDC in England and Wales.

129. In OTFW herds, in accordance with Annex A of 64/432/EEC, the Tuberculosis (Wales) Order 2010 Notice requiring cleansing and disinfection (BT05) by a specified date will be served on the owner immediately following the removal of any reactors or "affected" animals. This will include thorough disinfection of all parts of the premises where reactors were housed or yarded (since isolation) and ensuring that any pastures previously used by cattle will be left vacant for a minimum period of 60 days after such use if new stock are to be brought on. There are also rules for the disposal of manure on TB infected farms. AHVLA will complete a check of the BT05 declarations before releasing herds from restrictions and in all cases of partial and total depopulations will undertake a farm visit to ensure compliance.

130. As part of the general TB control requirements, the keeper will be required to comply with the legislation with regard to the transport of animals as set out in Transport of Animals (Cleansing and Disinfection) (England) and (Wales) (No3) (Amendment) Order 2003 (as amended). After unloading the animals, vehicles must be fully cleansed and disinfected as soon as is reasonably practicable, before they are used again and in any case within 24 hours after they are unloaded. Wheels, wheel arches and mud flaps must always be cleansed and disinfected whenever the vehicle is cleansed and disinfected. Livestock vehicles, whether empty or loaded, must also leave market premises "visibly clean" as part of the market licence conditions.

131. Drivers leaving a market or slaughterhouse with an empty vehicle that has not been cleansed and disinfected must complete a declaration to say where they will take their vehicle for cleansing and disinfection and give the declaration to the market or slaughterhouse operator.

132. In accordance with domestic legislation, AHVLA will arrange removal of all tuberculin test and IFN-gamma reactors and dangerous contacts to slaughter or disposal with compensation paid. All reactors and dangerous contacts will be valued before being removed. AHVLA will aim to remove such animals within 10 working days from the date on which the test results are disclosed. All animals compulsorily slaughtered for TB control

purposes will undergo post mortem examination by the FSA or AHVLA, and the pathological findings will inform subsequent action in the affected herd. Bovine TB infection will be officially confirmed (and OTF herd status withdrawn) by the disclosure of typical visible lesions of TB during post-mortem examination of test reactors and/or culture of *M. bovis* in primary isolation medium.

133. In every newly disclosed TB breakdown, at least one reactor will be sampled for bacteriological culture and molecular typing. In herd breakdowns with more than one reactor, the maximum number of animals sampled for culture will depend on the identification (or not) of visible lesions. In a newly detected breakdown, tissue specimens will be submitted from up to three representative reactors with visible lesions. If no reactors show any tuberculous lesions at post-mortem, then samples will be submitted from up to ten non-visible lesion reactors with the largest bovine-avian reaction difference. Further sampling of reactors at subsequent tests in OTFS herds will continue using the same rationale used at the disclosing test. Where infection with *M. bovis* has already been confirmed in an ongoing TB incident, then any new reactors or contacts disclosed at follow-up herd test will be treated as “infection confirmed” and not sampled. The local AHVLA office may sample additional reactors at their discretion if this is considered essential to support the epidemiological investigations.

Stamping out of heavily infected herds (depopulation)

134. If TB is widespread within the herd, in order to reduce disease incidence, total or partial depopulation will occasionally be carried out. This may be carried out in heavily infected herds in low incidence areas and will be designed to prevent the development of a potential new hotspot. In endemic areas, depopulation will only be contemplated in very severe bovine TB incidents. The decision to depopulate herds will be taken by an AHVLA vet on a case by case basis, taking into account:

- Prevalence of infection in the herd;
- Prevalence and severity of pathological findings in the slaughtered cattle;
- Risks of herd re-infection;
- Risks posed to the local cattle and wildlife population and the herd incidence in the locality; and/or
- Evidence that repeat skin testing and ancillary IFN-gamma (and sometimes TB serological) testing has failed to resolve the problem.

135. This measure will involve either the compulsory slaughter of the whole herd, or all the cattle in the herd except for one or more groups of cattle where no reactors have been found and that are not epidemiologically linked to the rest of the herd. Cleansing and disinfection procedures will have to be carried out to prevent re-infection before restocking is licensed. Restocking will only be allowed once the owner has taken positive measures to mitigate the risk of reinfection or a period of time elapsed to reduce risks from residual infection on the holding.

4.4.10. Compensation scheme for owners of slaughtered and killed animals:

136. The Animal Health Act 1981 provides government with the discretion to slaughter any animal, which is affected or suspected of being affected with a specified disease in the interests of protecting human and animal health. This discretion is coupled with a duty to pay compensation for animals so slaughtered, with the level of compensation to be determined by the Welsh Ministers. Responsibility for meeting the costs of cattle compensation schemes and the removal and slaughter costs will rest with the Welsh Government.

137. In Wales, compensation for TB affected cattle compulsorily removed and slaughtered as part of the TB control programme will be calculated on the basis of market value in accordance with the provisions of the Tuberculosis (Wales) Order 2010, which came into force in May 2010 and includes measures to link compensation to best farming practice (including appropriate biosecurity measures). Compensation payments to farmers who do not adhere to the regulations, do not follow advice provided in Veterinary Improvement Notices or allow their TB test to become overdue will see their compensation payment adjusted. Revisions to the compensation process are expected to be consulted on in early 2013 with a view to any new Order coming into force later that year. Cattle compensation for tuberculosis affected animals will be at full market value, unless otherwise specified in the legislation, as determined by individual valuations undertaken by professional valuers. Valuations are and will continue to be monitored and reviewed by professional valuers (Monitor Valuers) on a monthly basis and justification sought from valuers as necessary.

138. Compensation will not be provided for infected cattle identified in the course of commercial slaughter, or for any TB test positive cattle that die (or have to undergo emergency slaughter) on farm before they can be removed by AHVLA to an approved abattoir or consigned to a rendering plant if unfit to enter licensed abattoirs.

139. The Welsh Government will monitor TB valuations through the use of monitor valuers who will scrutinise all valuations on a monthly basis, seeking justification and requesting comparable market data in all relevant cases. Automatic justification by valuers will be required for animals that exceed a certain threshold, currently for pedigree animals valued at £4,000 or over and commercial animals valued at £1,800 or over. Detailed reports on key trends for compensation and market data will be produced on a regular basis by its TB Statistics Project Manager.

4.4.11. Control on the implementation of the programme and reporting³⁹:

140. There will be regular reporting and liaison on the delivery of the SLA between AHVLA and the Welsh Government with escalation of national issues to the UK TB Liaison Group where appropriate.

³⁹ Describe the process and control that will be carried out in order to ensure the proper monitoring of the implementation of the programme.

141. Defra will produce monthly updates of TB statistics for GB, including statistics for Wales, which will be published online at <http://www.defra.gov.uk/statistics/foodfarm/landuselivestock/cattle/tb/>

142. Regular reports will be provided to the European Commission on progress of the disease and on the Plan (including in accordance with Article 8 of Council Directive 64/432/EEC).

5. **Benefits of the programme**⁴⁰:

1. The programme to eradicate bovine TB in Wales has a number of benefits, including:
 - The disease is identified at an earlier stage, thus reducing the numbers of infected cattle and the number of breakdowns.
 - The spread of the disease is being controlled and ultimately will be reduced and eradicated.
 - The potential for considerable financial benefits for both the cattle sector and the Government in terms of:
 - Reduction of the production losses incurred by the cattle sector as a result of removal of diseased animals or disruption following the imposition of movement restrictions.
 - Reduced cost burden on the taxpayer by minimising the levels of compensation paid for animals compulsorily slaughtered and reducing future testing costs and AHVLA resources expended on TB issues.
 - In total Government has estimated that each confirmed new breakdown costs on average around £25,000 to the Government in compensation for animals compulsorily slaughtered as reactors or dangerous contacts and in costs of testing, and about £6,500 in costs to farmers from losses of animals, farm costs of testing, and disruption to business through movement restrictions - totalled net of compensation.
 - Environmental benefits
 - Deriving from these financial benefits will be the maintenance of a viable and sustainable beef and dairy sector through improved consumer confidence in the quality and safety of produce.
 - There will be a further reduction in the, already low, risk to human health posed by *M. bovis*.
 - As part of the continued sustainability of the sector, the UK is developing a stronger export market following the lifting of the BSE related export ban with 140,000 cattle exported between 1st June 2006 and 31st May 2007. There is also a strong dairy export market. An improved TB disease situation would enable greater opportunities to strengthen the export trade

⁴⁰ A description is provided of the benefits for farmers and society in general from the public and animal health and economical point of view.

- There will be improved animal welfare through the prevention of infection and the wider societal benefits gained from the cessation of interventions relating to wildlife.
 - Enhanced biosecurity on premises will have benefits in other areas of disease prevention and control.
 - A regional approach according to disease risks will ensure that the measures are tailored to the circumstances and disease epidemiology in particular areas.
2. The adoption of such measures will also have benefits in terms of the wider responsibility and cost sharing agenda.

6. Data on the epidemiological evolution during the last five years⁴¹

6.1. Evolution of the disease⁴²

6.1.1. Data on herds^(a)

Year: 2007 -2011

Region ^(b)	Year	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds checked ^(d) [1]	Number of positive herds ^(e) [2]	Number of new positive herds ^(f) [2] [3]	Number of herds depopulated [4]	% positive herds depopulated 9 = (/)x100	INDICATORS		
										% herd coverage [1] 10 = (5/4)x100	% positive herds Period herd prevalence 11 = (6/5)x100	% new positive herds Herd incidence 12 = (7/5)x100
1		2	3	4	5	6	7	8	9 = (/)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
Wales	2007	Bovine	13,946	13,946	10,548	1,515	930	0	0.0	75.6	14.4	8.8
Wales	2008	Bovine	13,667	13,667	12,201	1,895	1,193	4	0.2	89.3	15.5	9.8
Wales	2009	Bovine	13,249	13,249	16,092	2,114	1,175	4	0.2	121.5	13.1	7.3
Wales	2010	Bovine	13,034	13,034	15,745	1,781	1,036	3	0.2	120.8	11.3	6.6
Wales	2011	Bovine	12,819	12,819	11,758	1,757	1,038	4	0.2	91.7	14.9	8.8

Data extracted: 2007 – 12/2/09, 2008 – 2/3/09, 2009 – 31/3/10, 2010 – 28/4/11, 2011 – 12/9/12.

Data for 2011 has been sourced from a new IT system and is based on changed definitions and may not necessarily be comparable with previous years.

[1] For 2007-2010 it was not possible to identify the number of individual herds checked (tested) in any given period. The figures are a count of all tests so herds which were checked more than once in the same year (e.g. to regain OTF status) will be counted more than once. For 2011 the figure presented represents the number of CPHHs that have had a test and not the total number of tests they have had throughout the year, ie CPHHs are counted once only. This explains the decrease in % of herd coverage (column 10) in 2011 (with the remainder completed in advance or soon after the end of the calendar year.).

[2] For 2007-2010 the number of positive and new positive herds includes both “confirmed” and “unconfirmed” breakdowns, i.e. all herds with at least one test reactor identified, regardless of post-mortem and laboratory findings. For 2011 the number of positive herds includes herds that had their Officially TB Free (OTF) status withdrawn (“OTFW”) or suspended (“OTFS”) at some time during 2011 due to a TB breakdown (i.e. new and ongoing TB breakdowns).

⁴¹ The data on the evolution of the disease are provided according to the tables below where appropriate.

⁴² No data to provide in case of rabies.

[3] The herd TB incidence calculations is based on all new TB incidents (“confirmed” and “unconfirmed” 2007-2010, OTFW and OTFS for 2011).

[4] Includes total depopulations of entire cattle holdings *and* any partial slaughters of certain epidemiological groups within an infected holding.

- (a) Herds or flocks or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining or upgrading, the health status of the herd. In this column a herd must not be counted twice even if has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one animal tested positive in this period.

6.1.2. Data on animals (one table per year and per disease/species)

Year: 2007-2011

Region ^(a)	Year	Animal species	Total number of animals ^(b)	Number of animals ^(d) to be tested under the programme	Number of animals ^(c) tested [1]	Number of animals tested individually ^(d) [1]	Number of positive animals [2]	Slaughtering		INDICATORS	
								Number of animals with positive result slaughtered or culled [2]	Total number of animals slaughtered ^(e) [3]	% coverage at animal level	% positive animals Animal prevalence
1		2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
Wales	2007	Bovine	1,246,334	1,246,334	1,188,606	1,188,606	7,171	7,171	7,913	95.4	0.6
Wales	2008	Bovine	1,140,060	1,140,060	1,408,492	1,408,492	10,542	10,542	12,043	123.5	0.7
Wales	2009	Bovine	1,117,000	1,117,000	1,409,887	1,409,887	9,951	9,951	10,433	126.2	0.7
Wales	2010	Bovine	1,165,041	1,165,041	1,870,732	1,870,732	7,321	7,321	7,690	160.6	0.4
Wales	2011	Bovine	1,101,673	1,101,673	1,867,642	1,867,642	7,427	7,427	7,971	169.5	0.4

Data extracted: 2007 – 12/2/09, 2008 – 2/3/09, 2009 – 31/3/10, 2010 – 28/4/11, 2011 – 12/9/12.

Data for 2011 has been sourced from a new IT system and is based on changed definitions and may not necessarily be comparable with previous years.

[1] These figures are the total number of animal tests. Currently it is not possible to distinguish the number of individual animals tested and therefore animals tested more than once during the year will be counted more than once. This accounts for the animal coverage exceeding 100% (column 10).

[2] Data in columns 7 and 8 include the numbers of skin test reactors, unresolved (twice) inconclusive reactors and (from 2006) gamma interferon test reactors, regardless of their post-mortem and culture findings

[3] Data in column 9 includes, in addition to those in tables 7 and 8, non-reactor cattle taken as direct contacts to known infected animals in OTFW herd breakdowns and Inconclusive reactors

- (a) Region as defined in the programme of the Member State.
- (b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
- (c) Includes animals tested individually or under bulk level scheme.
- (d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance: milk bulk tank tests).
- (e) Include all positive animal slaughtered and also the negative animals slaughtered under the programme.

6.2. Stratified data on surveillance and laboratory tests

6.2.1. *Stratified data on surveillance and laboratory tests*

Description of the used in-vitro tests:

In principle ancillary tests may be used to increase either the sensitivity or specificity of testing. The former of these applications accounts for the vast majority of current usage. The use of ancillary tests to increase overall test sensitivity in those circumstances where it is considered necessary to prioritise sensitivity over specificity remains under constant review in order to ensure that best use is made of the options currently available.

1) The gamma-interferon blood test (Bovigam[®]) of cell-mediated immunity against *M. bovis* has been used since 2002 as an ancillary parallel test of British herds with confirmed TB breakdowns. This test was initially applied on a voluntary basis, both in the course of a field trial which ran from October 2002 to October 2005, and on an ad hoc basis in herds with confirmed *M. bovis* infection but not eligible for the trial. The figures given in the table below comprise gamma-interferon tests performed under both scenarios (in the three years 2003-2005 approximately 10,000 tests were carried out under the field trial and 14,000 were ad hoc tests). Since October 2006, Bovigam[®] is primarily being used as a mandatory parallel test alongside the comparative intradermal test to enhance the detection of infected cattle in certain prescribed situations, namely:

- In new TB breakdowns where OTF status has been withdrawn in herds located in a designated area of North Wales where incidence remains low relative to other areas of Wales;
- For rapid retesting of animals that give two consecutive inconclusive results to the skin test at severe interpretation (where these results are not also inconclusive at standard interpretation in which case the animal would be culled);
- On skin-test negative cattle in severe confirmed TB breakdowns, to inform decisions on partial or complete depopulation;

It is an optional parallel test for chronically infected herds that have failed to resolve by repeated short-interval skin testing and fulfil a minimum standard of biosecurity to reduce the risk of re-infection from cattle or wildlife.

It is also used as a discretionary test: to increase sensitivity and remove cattle with early infection in endemic areas:

- to inform case management decisions such as partial or total depopulation of a herd
- to inform suspicions of fraudulent reactors to the skin test.

2) The VetTB STAT-PAK/Chembio Rapid Test (a serological test based on the detection of antibodies to a set of recombinant *M. bovis* antigens) is occasionally deployed in herds with chronic TB breakdowns where anergy to the skin and gamma-interferon blood test is suspected. A very small number of animals are subjected to serological testing each year (figures not shown below).

Description of the used microbiological tests:

Mycobacterial culture and, in some cases, histology of lymph nodes both with and without visible tuberculous lesions (VL and NVL) is routinely undertaken by the Animal Health and Veterinary Laboratories Agency to identify the causative strain of the bacterium. All cattle compulsorily slaughtered for TB control purposes (i.e. skin test reactors, direct contacts and γ -IFN test positives) undergo post-mortem examination, unless they are killed on farm and post mortem examination is not needed to increase understanding of the epidemiology of the outbreak or inform subsequent testing. Tissue specimens (VLs or, in the case of NVL reactors, a pool of lymph nodes) from at least one animal per breakdown (and usually more) are then submitted for culture. All suspect tuberculous lesions detected in the course of routine meat inspection of cattle carcasses (“slaughterhouse cases”) are also submitted for culture. Bovine TB is confirmed in test reactors by the disclosure of typical visible lesions during post-mortem examination and/or culture of *Mycobacterium bovis* in primary isolation medium. In other words, a TB breakdown is confirmed when at least one of the reactor animals in that breakdown is VL and/or yields *M. bovis* on culture. In slaughterhouse cases, TB is only confirmed upon isolation of *M. bovis* by bacteriological culture from the pathological material.

For cultural examination approximately 1cm³ of tissue is homogenised in a stomacher with a solution of 5% oxalic acid (to decontaminate the sample) and then centrifuged. The resulting deposit is washed and re-suspended in sterile saline buffer. The suspension is sown (in most cases in duplicate or triplicate) onto a different range of solid media slopes, depending on the type of submission. The slopes are incubated at 37°C for up to six weeks. Although colony growth can be observed in many cases after 3 weeks, results from samples with low bacterial counts („paucibacillary’ specimens) usually take up to six weeks. Additionally, all VL submissions (i.e. slaughterhouse cases and VL reactors) are processed separately from NVL samples and undergo full histopathological examination. Approximately 1cm³ of lesioned tissue in fixative solution is needed for that purpose. Where there is insufficient tissue for histology (or there is sufficient tissue with histopathology suggestive of TB, but a negative culture), the original inocula are sown again and the original cultures re-incubated for a further six weeks. A direct impression smear of lesioned material may also be made if required. When dried and fixed it can be stained using the Ziehl-Neelsen method for the presence of acid-fast bacilli. Laboratory diagnosis of bovine TB is primarily made on morphological grounds by the characteristic appearance of the mycobacterial colonies on various growth media. Histopathology results and Ziehl-Neelsen staining are ancillary methods used to support a diagnosis based on culture observations.

Acid-fast organisms that do not show growth features typical of *M. bovis* or are not recognised as *M. bovis* by spoligotyping (see below) are tested by „multiplex’ PCR. This PCR technique is used to distinguish bacteria of the *Mycobacterium tuberculosis* complex (MTBC) and those of the *M. avium-intracellulare* complex from other organisms belonging to the genus *Mycobacterium*. This is now used as a primary tool and has replaced biotyping at VLA. It is a particularly important tool for assisting with the diagnosis of suspect TB lesions in slaughterhouse cases and species other than cattle (e.g. deer).

DNA extracted from every mycobacterial isolate is subjected to genetic fingerprinting to support epidemiological investigations into the origin of TB breakdowns. Spoligotyping is the principal *M. bovis* genotyping technique used in GB. However, because two spoligotypes have been found to comprise approximately 70% of all *M. bovis* isolates from cattle in Britain, an additional typing method (VNTR - „variable number of tandem repeats’)

was adopted by VLA more recently, to enable a finer strain discrimination of the most widespread spoligotypes. Each *M. bovis* isolate is thus classified according to its spoligotyping and VNTR pattern into a certain 'genotype'.

Year:2007-2011

Region ^(a)		In-vitro tests (Bovigam®)		Microbiological tests (bacteriological culture)		Other tests	
		Number of samples tested	Number of positive samples	Number of samples tested	Number of positive samples	Number of samples tested	Number of positive samples
Wales	2007	3,231	551	4,014	900		
Wales	2008	4,086	1,142	5,076	1,103		
Wales	2009	7,063	1,217	4,007	1,001		
Wales	2010	7,757	548	2,515	842		
Wales	2011	7,413	627	3,004	830		

- (a) Region as defined in the programme of the Member State.
 (b) Indicate whether the test is serological, virological etc.

6.3. Data on infection (one table per year)

Year:2007-2011

Region ^(a)	Year	Animal species	Number of herds infected ^(b) [1]	Number of animals infected [2]
Wales	2007	Bovine	930	7,171
Wales	2008	Bovine	1,193	10,542
Wales	2009	Bovine	1,175	9,951
Wales	2010	Bovine	1,036	7,321
Wales	2011	Bovine	1,038	7,971

[1] This includes the numbers of confirmed and unconfirmed breakdowns (2007-2010), OTFW and OTFS for 2011.

[2] Data includes skin test and gamma interferon test reactors, regardless of post-mortem and tissue culture results.

(a) Region as defined in the programme of the Member State.

(b) Herds or flocks or holdings as appropriate.

6.4. Data on the status of herds at the end of each year⁴³

Year: 2007-2011

Region (a)	Year	Animal species	Status of herds and animals under the programme ^(b)													
			Total number of herds and animals under the programme		Unknown ^(c) [1]		Not free or not officially free from disease[1]				Free or officially free from disease status suspended ^(f)		Free from disease ^(g) [1]		Officially free from disease ^(h)	
							Last check positive ^(d)		Last check negative ^(e)							
			Herds	Animals (i)	Herds	Animals (i)	Herds [1]	Animals (i)	Herds [2]	Animals (i)	Herds [2]	Animals (i) [1]	Herds	Animals (i)	Herds	Animals (i) [1]
Wales	2007	Bovine	13,946	1,246,334	n/a	n/a	n/a	n/a	n/a	n/a	2,078	n/a	n/a	n/a	11,868	n/a
Wales	2008	Bovine	13,667	1,140,060	n/a	n/a	n/a	n/a	n/a	n/a	1,160	n/a	n/a	n/a	12,507	n/a
Wales	2009	Bovine	13,249	1,117,000	n/a	n/a	n/a	n/a	n/a	n/a	1,240	n/a	n/a	n/a	12,009	n/a
Wales	2010	Bovine	13,034	1,165,041	n/a	n/a	n/a	n/a	n/a	n/a	1,370	n/a	n/a	n/a	11,664	n/a
Wales	2011	Bovine	12,819	1,101,673	n/a	n/a	n/a	n/a	n/a	n/a	n/a[3]	n/a	n/a	n/a	n/a [3]	n/a

Data extracted: 2007 – 12/2/09, 2008 – 2/3/09, 2009 – 31/3/10, 2010 – 28/4/11, 2011 – 12/9/12.

Data for 2011 has been sourced from a new IT system and is based on changed definitions and may not necessarily be comparable with previous years.

[1] Data reports are currently not able to distinguish the numbers of animals or herds by the classifications provided.

[2] Total number of herds under TB2 restrictions, including those restricted due to an overdue test, at the end of the reported period.

[3] The status of herds at the end of 2011 is currently not available.

(a) Region as defined in the programme of the Member State

(b) At the end of the year

(c) Unknown: No previous checking results available

(d) Not free and last check positive: Herd checked with at least one positive result in the latest check

(e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*

(f) Suspended as defined in Union or national legislation for the respective disease at the end of the reporting period.

(g) Free herd as defined in Union or national legislation for the respective disease.

(h) Officially free herd as defined in Union or national legislation for the respective disease .

(i) Include animals under the programme in the herds with the referred status (left column).

⁴³

Only data to provide for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (*B. melitensis*).

6.5. Data on vaccination or treatment programmes⁴⁴ [NOT APPLICABLE]

Year:

Region ^(a)	Animal species	Total number of herds ^(b)	Total number of animals	Information on vaccination or treatment programme					
				Number of herds ^(c) in vaccination or treatment programme	Number of herds ^(c) vaccinated or treated	Number of animals vaccinated or treated	Number of doses of vaccine or treatment administered	Number of adults vaccinated	Number of young animals vaccinated
Total									

- (a) Region as defined in the programme of the Member State
- (b) Herds or flocks or holdings as appropriate

⁴⁴ Data to provide only if vaccination has been carried out.

6.6. Data on wildlife⁴⁵

6.6.1. Estimation of wildlife population

Year: 1994-2002

Regions ^(a)	Animal species	Method of estimation	Estimated population
Wales	Badger	Survey of Setts (National sample 1994-1997)	42,000
	Deer (Red)	Stakeholder opinion (February 2008) ^(b)	200
	Deer (Sika)	Stakeholder opinion (2005)(c)	<100
	Deer (Fallow)	Stakeholder opinion	10,000
	Deer (Roe)	Stakeholder opinion	5,000
	Deer (Muntjac)	Stakeholder opinion	5,000
	Chinese Water Deer	Stakeholder opinion	0

(a) Region as defined in the programme of the Member State

(b) Welsh Government (2010). *Wild Deer Management in Wales: An issues paper to inform the preparation of a management strategy and action plan for wild deer in Wales.*

(c) 2. Battersby J. (2005). *UK Mammals: Species Status and Population Trends.* JNCC.

⁴⁵ Data only to provide in case the programme comprises measures as regards wildlife or if the data are epidemiologically relevant for the disease.

6.6.2. *Disease surveillance and other tests in wildlife (one table per year)*

Year: : Wales, 2007-2011

Region ^(a)	Animal Species	Test type ^(b)	Test description	Number of samples tested	Number of positive samples
All Wales	Badger	Post mortem examination and laboratory culture	Badger Found Dead Survey (2005-06)	457	61
South Wales	Wild deer	Laboratory culture	Wild deer TB surveillance project (2007-08)	128	4
West Wales	Wild deer	Laboratory culture	Wild deer surveillance project (2009-10)	4	1
North Wales	Feral goats	Post mortem examination and laboratory culture	Feral goat surveillance project (2009-10)	20	0
IAA	Badger	Post mortem examination and laboratory culture	Badger Found Dead Survey (2012)	6	Awaiting results
Total				609	66

- (a) Region as defined in the programme of the Member State
 (b) Indicate whether the test is serological, virological, biomarker detection etc.

6.6.3. *Data on vaccination or treatment of wildlife*

Year: May-July 2012

Region ^(a)	Square km	Vaccination or treatment programme		
		Number of doses of vaccine or treatment to be administered	Number of campaigns	Total number of doses of vaccine or treatment administered
Intensive Action Area (IAA), south west Wales	288	747	1	747
Total				

(a) Region as defined in the programme of the Member State

7. Targets

7.1. Targets related to testing (one table for each year of implementation⁴⁶)

7.1.1. *Targets on diagnostic tests*

Region ^(a)	Type of the test ^(b)	Target population ^(c)	Type of sample ^(d)	Objective ^(e)	Number of planned tests
Wales	Tuberculin skin test	Bovines		Programme implementation (Primary screening test - surveillance, qualification and elimination of infection from herds)	1,870,000 [1]
Wales	Gamma Interferon Assay	Bovines	Heparinised Blood	Programme implementation (Ancillary parallel test - elimination of infection from herds)	7,400 [2]
Total					

[1] This figure is taken to be the number of all types of tests to be carried out (including testing for surveillance, qualification and elimination of infection from herds) so some herds may be counted more than once.

[2] Gamma interferon tests are deployed as a reactive measure and are only used in prescribed circumstances. In 2011 there were 7,413 gamma interferon tests.

- (a) Region as defined in the programme of the Member State
- (b) Description of the test (for instance SN-test, AB-Elisa, RBT,)
- (c) Specification of the targeted species and the categories of targeted animals (for instance sex, age, breeding animal, slaughter animal, ...).
- (d) Description of the sample (for instance blood, serum, milk,)
- (e) Description of the objective (for instance qualification, surveillance, confirmation of suspected cases, monitoring of campaigns, seroconversion, control on deleted vaccines, testing of vaccine, control of vaccination,)

⁴⁶ For subsequent years of approved multiannual programmes only one table for the relevant year should be filled in.

7.1.2. *Targets on testing herds and animals*⁴⁷

7.1.2.1 Targets on the testing of herds^(a)

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds expected to be checked ^(d)	Number of expected positive herds ^(e)	Number of expected new positive herds ^(f)	Number of herds expected to be depopulated	% positive herds expected to be depopulated	TARGET INDICATORS		
									Expected % herd coverage	% positive herds Expected period herd prevalence	% new positive herds Expected herd incidence
1	2	3	4	5	6	7	8	9 = (8/6)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
Wales	Bovine	12,800	12,800	12,800	1,760	1,040	4	0.2	100	13.8	8.1

- (a) Herds or flocks, or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining, upgrading, etc., the health status of the herd. In this column a herd must not be counted twice even if it has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one positive animal in this period.

⁴⁷ Data not to provide in case of rabies.

7.1.2.2. Targets on the testing of animals

Region ^(a)	Animal species	Total number of animals ^(b)	Number of animals ^(c) under the programme	Number of animals ^(c) expected to be tested	Number of animals to be tested individually ^(d)	Number of expected positive animals	Slaughtering		TARGET INDICATORS	
							Number of animals with positive result expected to be slaughtered or culled	Total number of animals expected to be slaughtered ^(e)	Expected % coverage at animal level	% positive animals (Expected animal prevalence) [1]
1	2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
Wales	Bovine	1,100,00	1,100,00	1,100,000	1,100,000	7,430	7,430	7,970	100.0	0.7

[1] This has been calculated based on individual animals expected to be tested in the year. Therefore the prevalence rate is higher than that shown in table 6.1.2.

- (a) Region as defined in the programme of the Member State.
- (b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
- (c) Includes animals tested individually or under bulk level scheme.
- (d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance milk bulk tank tests).
- (e) Include all positive animals slaughtered and also the negative animals slaughtered under the programme.

7.2. Targets on qualification of herds and animals (one table for each year of implementation)

Region ^(a)	Animal species	Total number of herds and animals under the programme		Targets on the status of herds and animals under the programme ^(b)											
				Expected unknown ^(c)		Expected not free or not officially free from disease				Expected free or officially free from disease status suspended ^(f)		Expected free from disease ^(g)		Expected officially free from disease ^(h)	
						Last check positive ^(d)		Last check negative ^(e)							
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾
Wales	Bovine	12,800	1,100,000	0	0	460 OTFW	-	-	-	210 OTFS 610 OD	-	11,520	-	11,520	-

- (a) Region as defined in the programme of the Member State
- (b) At the end of the year
- (c) Unknown: No previous checking results available
- (d) Not free and last check positive: Herd checked with at least one positive result in the latest check
- (e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*
- (f) Suspended as defined for the respective disease in Union or national legislation where appropriate or according national legislation.
- (g) Free herd as defined for the respective disease where appropriate in Union or national legislation where appropriate or according national legislation
- (h) Officially free herd as defined for the respective disease where appropriate in Union or national legislation where appropriate or according national legislation
- (i) Include animals under the programme in the herds with the referred status (left column)

7.3. Targets on vaccination or treatment (one table for each year of implementation) [NOT APPLICABLE]

7.3.1. Targets on vaccination or treatment⁴⁸

Region ^(a)	Animal species	Total number of herds ^(b) in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Targets on vaccination or treatment programme					
				Number of herds ^(b) in vaccination or treatment programme	Number of herds ^(b) expected to be vaccinated or treated	Number of animals expected to be vaccinated or treated	Number of doses of vaccine or treatment expected to be administered	Number of adults ^(c) expected to be vaccinated	Number of young ^(c) animals expected to be vaccinated
Total									

(a) Region as defined in the programme of the Member State

(b) Herds or flocks or holdings as appropriate

(c) Only for Bovine brucellosis and Ovine, Caprine brucellosis (*B. melitensis*) as defined in the programme

⁴⁸ Data to provide only if appropriate .

7.3.2. *Targets on vaccination or treatment⁴⁹ of wildlife*

Region ^(a)	Animal species	Square km	Targets on the vaccination or treatment programme		
			Number of doses of vaccine or treatments expected to be administered in the campaign	Expected number of campaigns	Total number of doses of vaccine or treatment expected to be administered
Wales (IAA) ¹	Badger	288	1,200	1	1,200
Total		288	1,200	1	1,200

(a) Region as defined in the programme of the Member State

1. Other geographical areas where vaccination could also be expected to contribute to TB eradication are being considered. Wider roll out of badger vaccination during 2013 will be announced in due course.

⁴⁹ Data to provide only if appropriate.

8. Detailed analysis of the cost of the programme (one table per year of implementation⁵⁰)

Costs related to	Specification/Unit	Unit ⁵¹	Number of units	Unitary cost in £	Total amount in £	Union funding requested (yes/no)
1. Testing						
1.1. Cost of sampling						
	Domestic animals					
1.2 Cost of the analysis						
Brucellosis and tuberculosis programmes	Tuberculin test	OV Tests	1,683,000	£3.21/OV test	£5,402,430	Yes
	Gamma-interferon test	Tests	7,400	£11.83	£87,542	Yes
	Bacteriological test	Culture tests	3,000	£111.12	£333,360.00	Yes
- ASF, CSF, SVD & Bluetongue programmes	ELISA test	N/A				

⁵⁰ For subsequent years of approved multiannual programmes only one table for the relevant year should be filled in.

⁵¹ Specify the unit to which the data in the following two columns is referring to (e.g. sample, test, animal sampled etc).

	PCR test	N/A				
	Virological test	N/A				
	Seroneutralisation test (only for SVD)	N/A				
	Entomological surveillance test (only for Bluetongue)	N/A				
	Other (please specify)	N/A				
1.3. Other costs						
	Purchase of traps (for Bluetongue)	N/A				
	Other (please specify)	N/A				
2. Vaccination or treatment						
2.1. Purchase of vaccine/treatment						
Tuberculosis programmes	Wild animal vaccinated, IAA	BCG & Diluent ^a	1200	£17.00	£20,400.00	<i>No</i>
2.2. Administering/Distribution costs						

Administering in domestic animals	N/A	N/A	N/A	N/A	N/A	<i>No</i>
- Distribution for wild animals (please specify the type of distribution)	N/A	N/A	N/A	N/A	N/A	<i>No</i>
2.3. Control costs	Implementation of project in IAA ^b	N/A	N/A	N/A	£1,527,500.00	<i>No</i>
2.4. Others (please specify)						
3. Slaughter and destruction						
3.1. Compensation of animals	Wales, compensation	Number of bovines	7,970	£1,636	£13,038,920	<i>Yes</i>
3.2. Transport costs	Wales, haulage plus destruction costs	Number of bovines	7,970	£30.11	£240,000	<i>No</i>
3.3. Destruction costs						
3.4. Loss in case of slaughtering	Wales, salvage	Number of bovines	7,970	£250.94	£2,000,000	<i>Yes</i>
3.5 Costs from treatment of products (milk, or	N/A					

others –please specify)						
4. Cleaning and disinfection	N/A					

5. Salaries (staff contracted for the programme only)	Wales	TB policy staff	24	£39,427.54	£ 946,261	No
6. Consumables and specific equipment	N/A					
7. Other costs						
Tuberculin	Wales	Per dose	1,683,000	£0.19	£319,770	Yes
Valuers' fees, travel and subsistence costs (includes Monitor Valuer fees)	Wales	Number of animals	7,970	£45.17	£360,000	No
	TOTAL				£24,276,183	

- a. These figures are based on the IAA Area (288sq km). An exact costing for undertaking badger vaccination projects in other parts of Wales have yet to be determined. Wider roll out of the vaccination programme will be subject to Ministerial decision.
- b. Includes Accommodation/Estate Management, Consumables, Legal, Training & Personal Development, Field Officers pay, Transportation, Health & Safety and Programme Delivery Fee costs.

ANNEX III – NORTHERN IRELAND ERADICATION PLAN

ANNEX I

Standard requirements for the submission of national programmes for the eradication, control and monitoring of the animal diseases or zoonoses referred to in Article 1(a)⁵²

1. Identification of the programme

Member State: United Kingdom (Northern Ireland)

Disease(s)⁵³: Bovine Tuberculosis

Request of Union co-financing for⁵⁴: 2013

Reference of this document: Bovine Tuberculosis 2013

Contact (name, phone, fax, e-mail): Stephen Martin, 028 90524826, 028 90524340, stephen.martin@dardni.gov.uk

Date of submission to the Commission: 14th September 2012

2. Historical data on the epidemiological evolution of the disease(s)⁵⁵:

In 1949, Northern Ireland (NI) introduced the Tuberculosis (Attested Herds) Scheme designed to encourage the establishment in NI of cattle herds officially certified as free of bovine tuberculosis. The objective then, as now, was the eradication of bovine TB from the NI herd. A voluntary register of attested herds was established. Two consecutive negative intradermal tests at two months interval were necessary to register.

By 1956, 1,209 herds were registered. Lists of attested herds were published to guide herdkeepers who wished to purchase such certified cattle.

Even with these limited measures, the incidence of bTB decreased steadily and the Voluntary Attested Herds Scheme was ended and eradication areas declared where compulsory testing would be carried out.

A transitional period between April and August 1959 saw an increase in uptake of voluntary testing. In April 1959 over 50% of NI herds were attested or supervised, by March 1960, 88% of cattle in NI were attested and on 25 November 1960, NI was declared an attested area.

Since the introduction of compulsory testing in 1959, bovine tuberculosis has been reduced to, and maintained at, a much lower level, but not eradicated. See Fig.1

⁵² In the case of the second and subsequent years of a multi-annual programme that has already been approved by a Commission Decision, only section 1, section 7 and section 8 need to be completed.

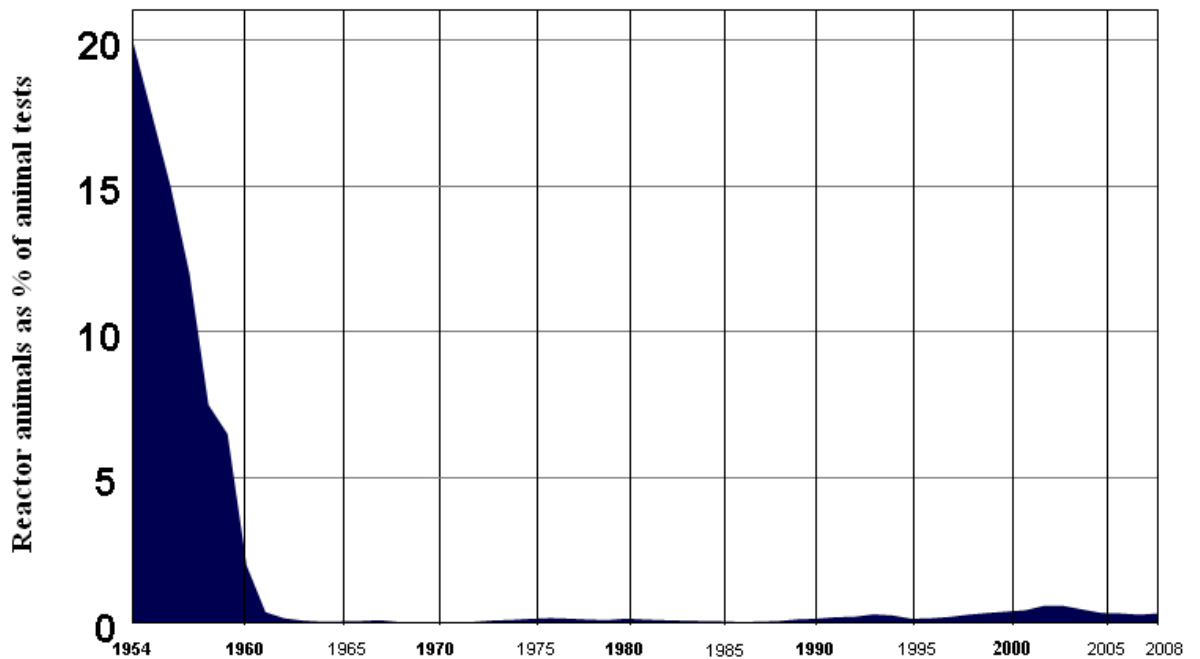
⁵³ One document per disease is used unless all measures of the programme on the target population are used for the monitoring, control and eradication of different diseases.

⁵⁴ Indicate the year(s) for which co-financing is requested.

⁵⁵ A concise description is given including target population (species, number of herds and animals present and under the programme), the main measures (sampling and testing regimes, eradication measures used, qualification of herds and animals, vaccination schemes) and the main results (incidence, prevalence, qualification of herds and animals). The information is given for distinct periods if the measures were substantially modified. The information is documented by relevant summary epidemiological tables (in point 6) complemented by graphs or maps (to be attached).

Fig. 1

Bovine TB in Northern Ireland 1954-2008



Herd testing in NI has been subject to differing test intervals. It has, however, been applied uniformly throughout the country with no areas of reduced testing at any time. During the period of 1966 to 1976, levels of disease were low enough to warrant a reduction of intensity of the live animal surveillance programme. Later disease increase was responded to by reducing the inter-test interval. See Fig. 2

Note: that the full abattoir post-mortem examination (PME) surveillance remained unchanged throughout.

Note: that NI has been on annual testing entirely since 1983.

Fig 2 Herd testing intervals in NI 1959 - present

Year	Type of herd testing
1959-1965	Annual testing
1966-1971	Biennial testing
1972-1976	Triennial testing
1977-1982	Biennial testing
1983- To date	Annual testing

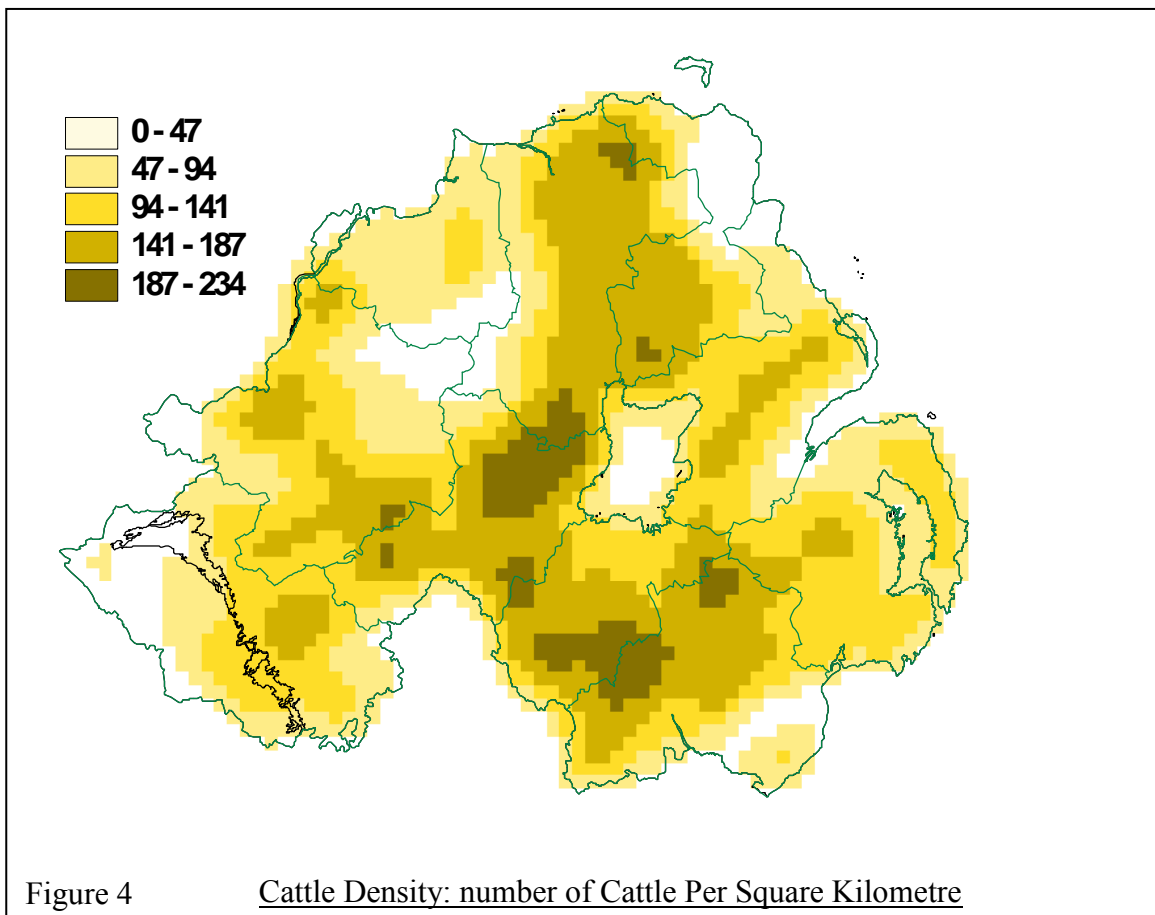
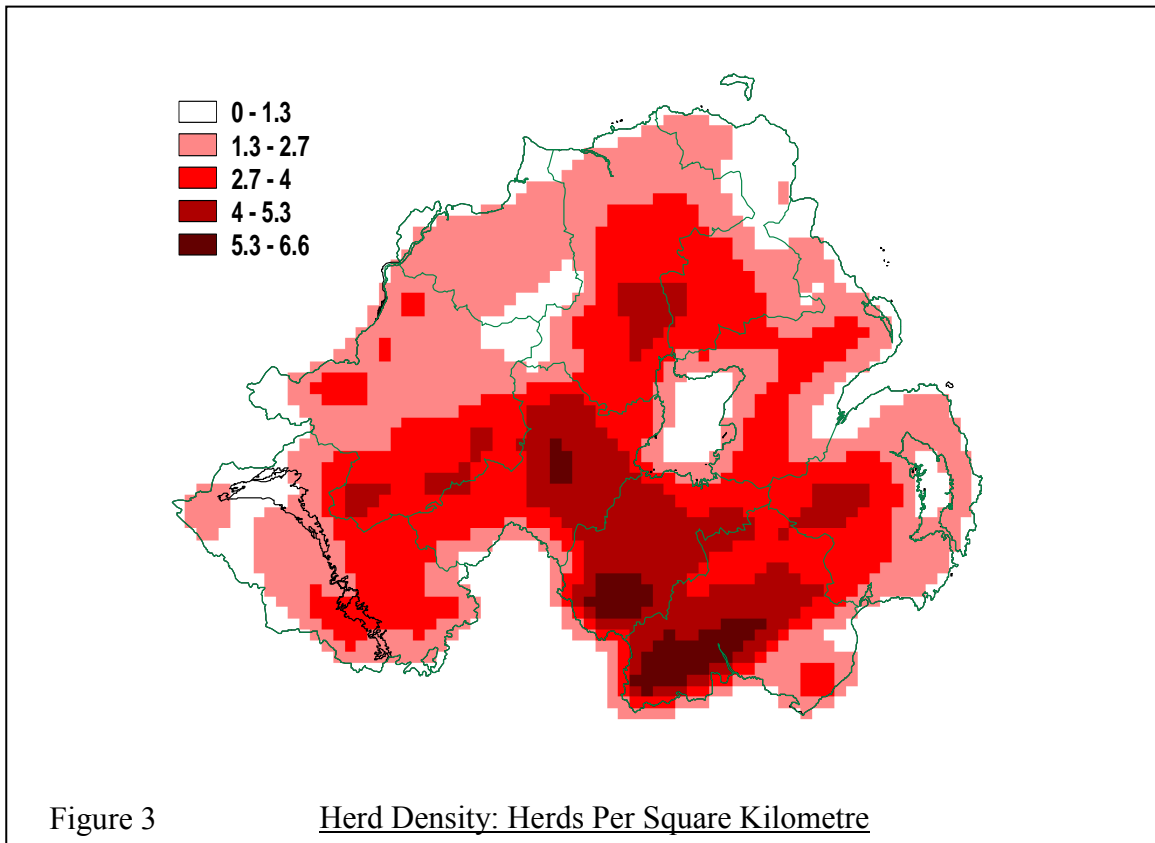
Current Demographics

There are currently 1.6 million cattle in NI, distributed among 20,500 farm businesses with cattle (June 2011). Dairy cows make up 18% of the national herd while beef cows account for 17%. Based on cattle TB tested in herds, the mean herd size has increased from 56 cattle in 1990 to 78 in 2011, an increase of 39%. However, the data are strongly skewed to the right and the median was 38 for all TB herd tests in 2011. Over half of the herds (58%) in NI have fewer than 50 cattle.

The cattle population increased by 50% in the forty years before 1989 and by approximately 6% thereafter. These increases preceded a significant rise in the incidence of bovine tuberculosis, suggesting an association with high stocking density.

The cattle agricultural industry in NI is largely grass based with feed conservation and winter housing as significant features.

Herd and cattle density is highest in the south and west, with the highest concentration, 6.6 herds per square kilometre in Counties Armagh and Down (Figures 3 and 4 (overleaf)–Method = Kernel Smoothing; bandwidth = 10km). Herds in the north and east tend to be larger than those in the south or west (median 20.4 and 15.2 eligible cattle respectively).



Epidemiological Unit

A herd is described in domestic legislation as “a group of animals kept, managed, or housed together, on a holding in such a manner and under such conditions as will, in the opinion of a veterinary inspector, minimize the possibility of infection to any other animals whether kept on the same holding or another holding.” [Tuberculosis Control Order (NI) 1999 (as amended), Part 1 S2 (1)].

Due to the small median herd size and fragmentation of land parcels, disease control measures have been developed to accommodate these features of NI agriculture and minimise disease risk accordingly.

Several cattle groups with possibly different owners, may be maintained in such a manner that contact exists that will increase the risk of disease spread. These groupings may range from routine and permanent to the transitory. Each herd will have a unique herd number and identified keeper.

When cattle have such contact, the herds will be termed “associated” and recorded on APHIS (Animal and Public Health Information System, the DARD real-time computer database) and, significantly, will be subject to the same level of status, movement control and epidemiological investigation as the group with the lowest status. Any movement restriction and status will remain until all component parts of the herd have completed any required restriction, testing etc. regime and herds may not be disassociated until all have regained Officially Tuberculosis Free (OTF) status.

Disease statistics record each herd separately, therefore an epidemiological episode at one holding with several associated diseased herds will be recorded as several episodes.

Farm fragmentation is a considerable feature of cattle agriculture in NI, including the temporary leasing of land for summer grazing. Parcels of land remote from the home farm, no matter the distance or ownership, are regarded as part of the holding and are subject to identical restriction and epidemiological investigation as the rest of the holding.

1995- Present, Recent Disease Trends

The period of the late 1990s saw, as a trend, a steady increase in herd incidence, to a peak in 2002/2003. Since 2004 there was a steady trend in reducing herd and animal incidence until 2007. Since then the trend has remained reasonably level until late 2011, when there was an unanticipated upturn in incidence.

Note that NI had an FMD episode during 2001 during which there was a suspension of both routine farming practices and routine tuberculin testing. See Figs 5& 6

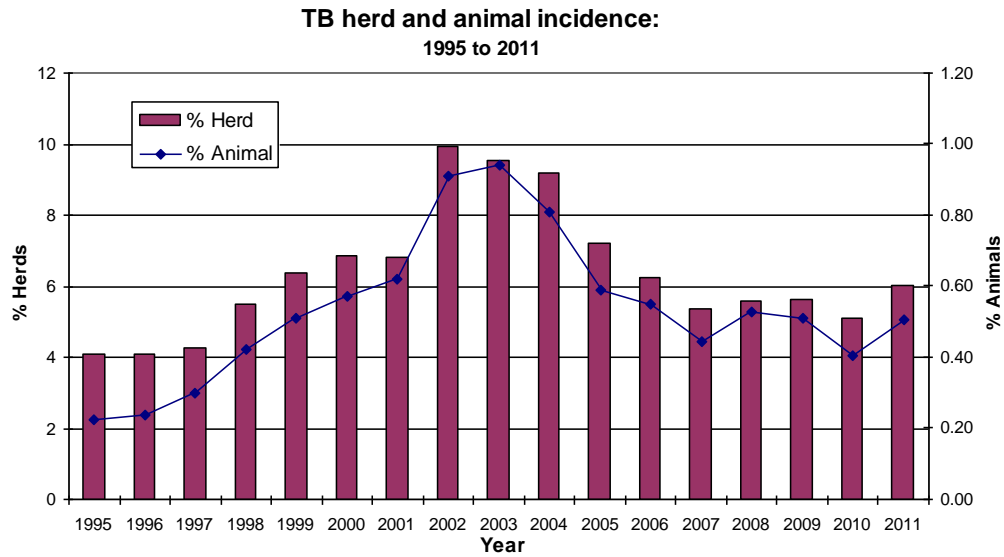


Fig. 5

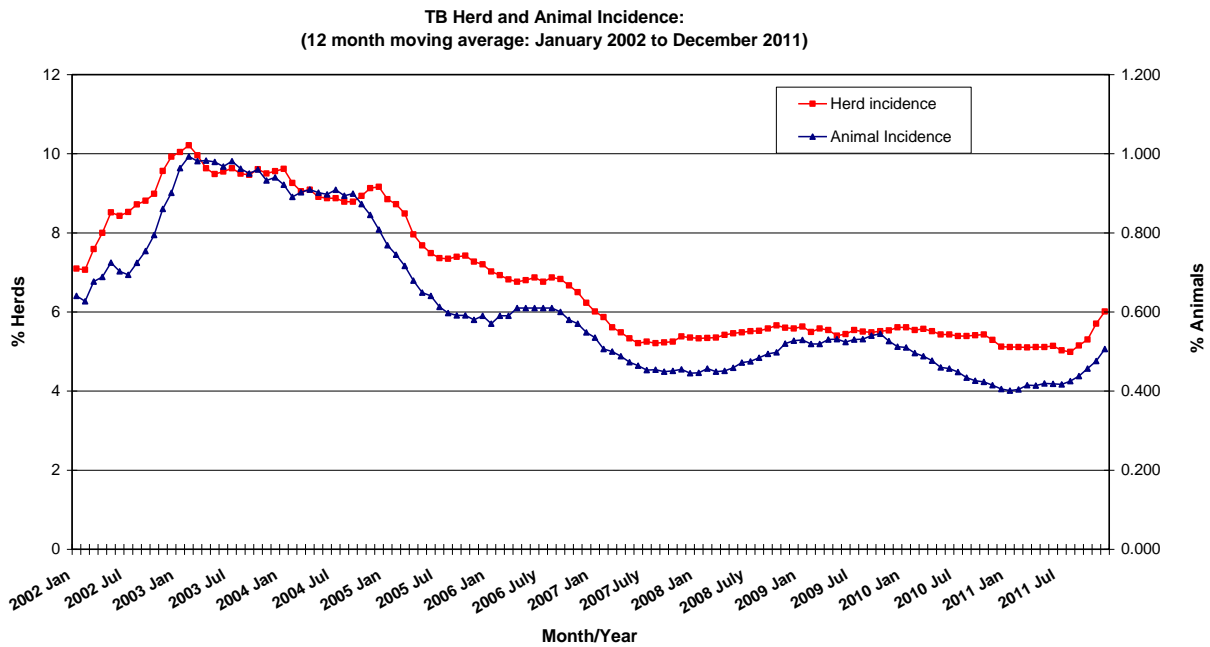
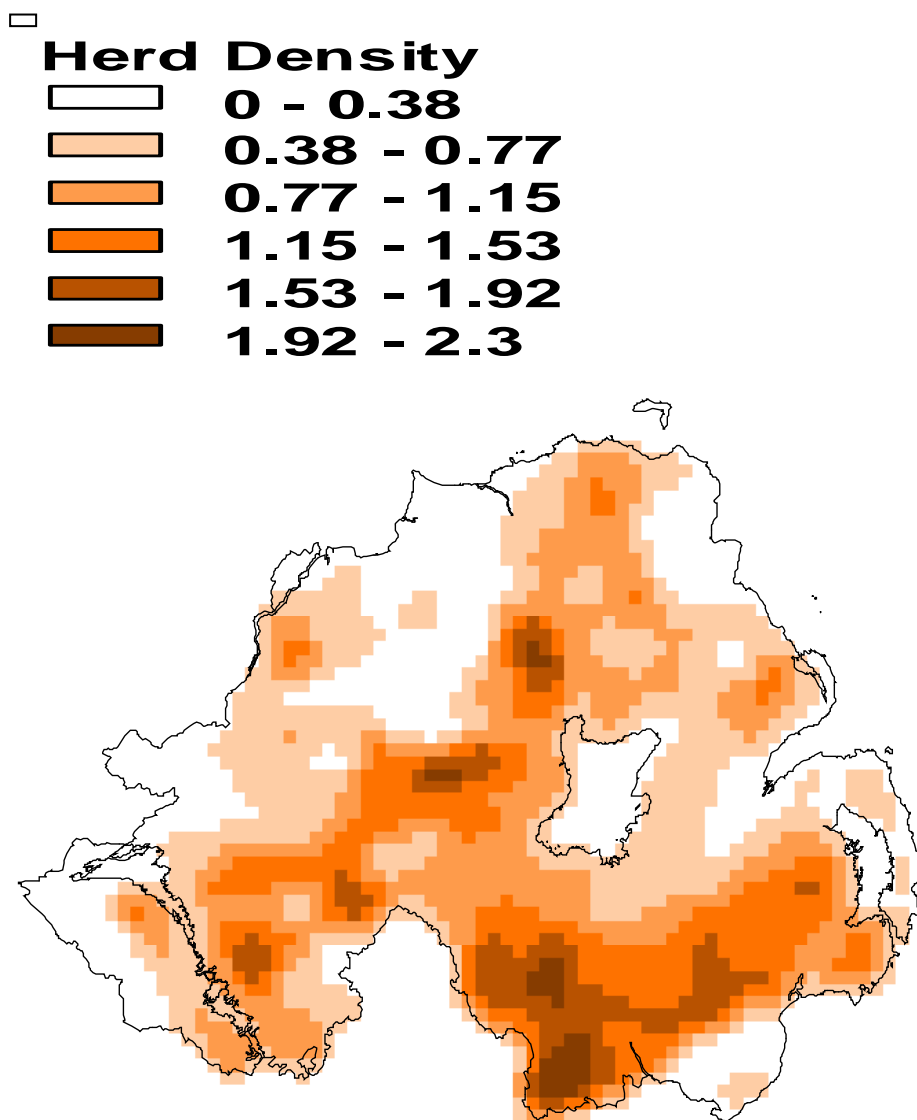


Fig 6

Although breakdowns are distributed throughout NI, traditionally the preponderance of infection has been in the southern parts of NI. Reasons for this are presently unclear: spatial analysis has demonstrated that the concentration of infection in the southern part is not entirely explained by the underlying distribution of herds and cattle. Fig. 7

Fig 7 Herd Density, based on TB-Positive Herds, Cumulative, 1995 to 2004, herds/km²

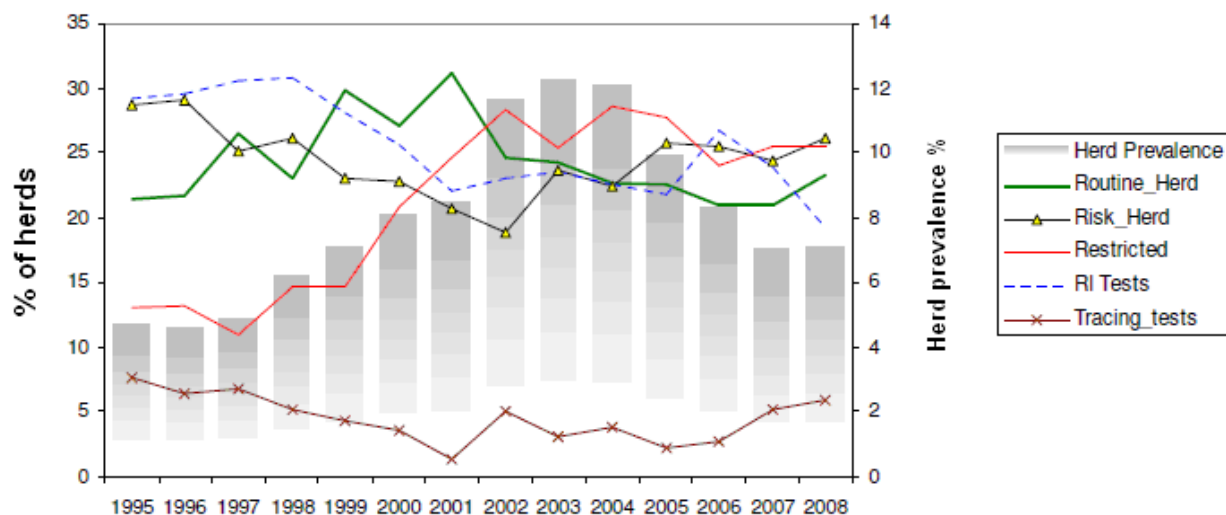


Approximately 80% of reactors are removed under standard interpretation of the Single Intradermal Comparative Cervical Test (SICCT), 14% under severe interpretation, while the remaining 6% are taken using epidemiological data and stricter interpretation criteria. All reactors are removed by government-contracted hauliers to one specific abattoir where they are examined for evidence of TB infection.

TB tests on the APHIS real-time computer database are labelled according to the reason for the test. There are specific test type categories for each type of test, allowing the data to be examined in different ways. One example is the division of tests into routine, restricted, or risk type. “Routine” tests are those conducted in Officially Tuberculosis Free herds where there is no discernible risk of infection. “Restricted” tests apply to herds with infection, while “Risk” tests are those where cattle have some potential link to infection.

Fig. 8

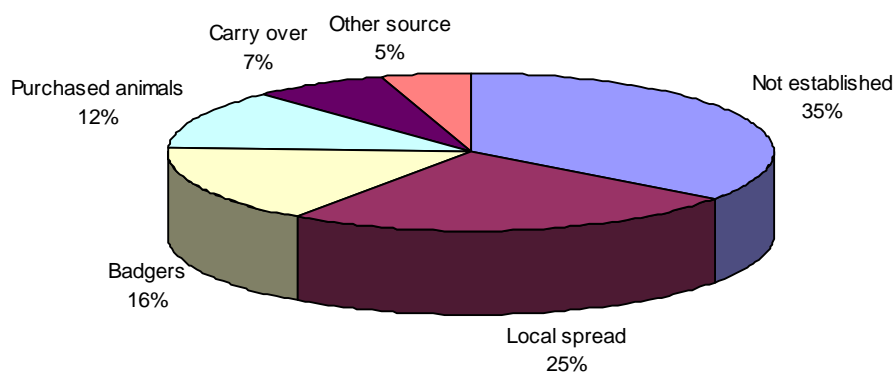
Graph showing both % test positive herds by test type and % herd prevalence



Contiguous tests are undertaken in herds that are in close proximity to infected herds, usually neighbouring them, and the higher prevalence for both reactors and lesions confirms the importance of this type of testing. This is consistent with the results from epidemiological consideration undertaken by local Veterinary Officers who attribute 25% of breakdowns to “Local Spread” (Figure 9). This is not, however, prescriptive as to the source of the outbreak in that no investigation is undertaken of infection levels or the role of badgers in the outbreak. The badger (*Meles meles*) is a protected species in NI and no culling or disturbance of them, without licence, is permitted. Thus the term “local spread” merely refers to infection being disclosed in a herd that is in proximity to another diseased herd, with little certainty in most cases as to the means of spread.

Fig. 9 Putative Infection Sources Field Recorded (with >80% confidence) cumulative 2002-2010

**Infection sources for confirmed TB herd breakdowns in 2002-10
for all DVOs (n = 8,652)**

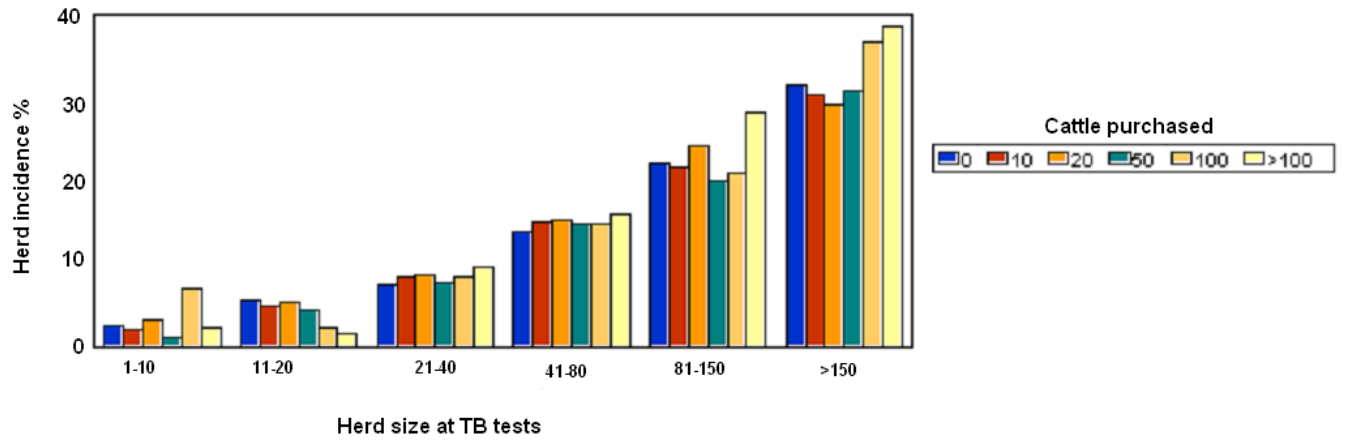


Various factors are thought to have contributed to the rise in disease incidence from 1990 to 2003. These include the following:

- The nature of farming in NI and recent changes therein;
- The role of wildlife, in particular, the Eurasian badger *Meles meles*; and
- Programme-related factors.

The farming industry in NI is traditionally characterised by high movement of cattle between and within herds; small, fragmented farms; and a high dependency on rented pasture (“conacre”). Between-herd movement is a marked feature of the cattle industry and is regulated. In 2000, 563,000 cattle, equivalent to 33% of the national herd, were recorded on the APHIS database as having moved between herds or to markets. Figure 10 shows the risk of a breakdown after adjusting for the confounding effect of herd size. There is a clear increase in risk associated with increased herd size, but the effect of purchases is equivocal in small to medium herds, which comprise the majority of herds in NI. The extent of cattle movement between premises used by a herd – so-called “within-herd” movement - has been the subject of a field study involving a year-long monitoring of all within-herd movements in a random sample of herds. The role of within-herd movement in TB epidemiology is unclear but it is likely that such movement, together with increased stocking densities and the poor economic status of farming in recent years, must play some role in disease maintenance and spread. It should be noted that all fragments of land used by a herd that becomes a breakdown are subject to the same disease control procedures, including those covering lateral risk.

Fig. 10 Risk of breakdown in the period January 2001-August 2002, stratified by the number of cattle purchased in the year 2000



Programme Development

Although the TB Programme has been in existence for many decades, it is not static. It develops strategically in response to disease levels, resource, epidemiological and novel scientific information. To ensure strategic direction is given to the programme a management structure is now in place, comprising of:-

- TB Steering Group – to oversee strategic direction.
- TB Policy Development Group – to develop proposals / manage specific projects.
- TB Programme Delivery Group – to ensure effective delivery of this programme and monitor key performance indicators

This structure brings together key persons from policy, veterinary and scientific research to give coherence to TB policy development and delivery.

Enhanced management controls with the development of a regularly applied suite of management reports of key performance indicators and routine audits have been established.

These are supplemented by central audit of specific cases including the application of discretion allowed at field level.

A number of Programme critical control points have been recognised and developed into Key Performance Indicators. These are designed to identify if there are areas that need development or resourcing. Parameters are measured monthly and delivery achievement is illustrated in a matrix and overall format.

DARD has in place a robust formal field assessment of delivery of test performance by private veterinarians under the Programme. This monitoring has been extended to those veterinarians and registered technicians directly employed by the Department of Agriculture and Rural Development (DARD in NI).

To strengthen our ability to counter fraud and to establish if a cattle identity has been altered following disclosure of a reactor, DNA sampling for comparative examination may be used.

Routine DNA sampling of reactors is conducted by the application of a DNA identity ear tag at valuation. A tissue sample from the animal's ear is harvested in a tamper-proof container and stored in a freezer. This allows comparison with an animal bearing the same identity presented for slaughter under the Programme, should there be any subsequent query about the identity of an animal. Routine surveillance to cross-check the DNA from an animal at slaughter with DNA of an animal valued has been introduced.

Further extension of this process is underway allowing the harvesting of tissue sample at time of disclosure of test result.

Wildlife

Mycobacterium bovis has been isolated from deer and badgers in Northern Ireland. It has also been isolated from the otter (*Lutra lutra*).

Deer

There are 3 main species of wild or feral deer in Northern Ireland: *Dama dama* (fallow deer), *Cervus nippon* (sika deer) and *Cervus elaphus* (red deer). A proportion of the red deer are enclosed. A survey carried out in 1995, in which deer of the three species were sampled, demonstrated a prevalence of 5.8% (397 deer sampled). A small surveillance exercise carried out in 2009, in which fallow and sika deer were sampled, revealed a prevalence of 2% (146 deer sampled). The low number of deer (less than 3,500 estimated), their restricted range, limited contact with cattle, and the enteric nature of the infection, suggests that their role in the epidemiology of bovine TB is likely to be limited if not entirely insignificant.

Badger

DARD recognises that the involvement of wildlife, mainly badgers, must be addressed if eradication is to be achieved although the extent of the badger contribution to the incidence of disease has not been quantified.

A Badger Stakeholder Group was formed in 2004 in NI, which was tasked with assessing the available information and considering the potential need for a badger management strategy within NI.

Following consideration by the Badger Stakeholder Group of the evidence available from the completion of various extensive trials elsewhere (most notably the Randomised Badger Culling Trial in GB) and the adoption of lethal intervention as a policy to control bovine TB in cattle in another Member State (the Republic of Ireland (ROI)), it was concluded in their report, published February 2008, that no recommendation could be made on the way forward for NI without first undertaking work to gather information specific to the NI situation. The Badger Stakeholder Group agreed that this should include:-

- i. a survey of the badger population in NI to determine the number and distribution of badgers,
- ii. developing a proposal for a study of the prevalence of bTB infection in badgers,
- iii. assessing the available evidence in relation to the role of badgers in bovine TB to inform an appropriate course of action in NI, including whether it is appropriate to run a badger culling pilot,
- iv. considering participation in a vaccination trial, and
- v. undertaking a cost benefit assessment of the future options for any proposed badger management strategy in NI, once the information arising from the above actions is available.

The assessment of available scientific evidence was conducted in 2008 and it was concluded that there is robust evidence that badgers are involved in the transmission of infection and contribute to the incidence of disease. However, there is little evidence upon which to base an estimate of the magnitude of the badgers' contribution to disease incidence. Evidence that intervention in badger populations is likely to achieve a cost effective overall reduction in disease incidence is weak. It was concluded that there was enough evidence to rule out a proactive cull of badgers as a cost effective means of reducing disease levels in cattle.

Following the completion of the work of the Badger Stakeholder Group, DARD established new arrangements for engaging with stakeholders on all aspects of TB policy. Since summer 2008, the Department has been working in partnership with leaders of key industry and veterinary organisations in the TB Core Stakeholder Working Group to identify more clearly what could be done to move further towards the eradication of TB in NI. Key wildlife interests have been engaged as part of this process. This has been a new partnership approach to this very complex and difficult disease problem. The work undertaken through these new stakeholder arrangements informed the Ministerial statement on the way forward on TB.

In December 2008 the then Minister of Agriculture and Rural Development made a statement outlining the way forward for TB. The long term goal is eradication and, as TB is a complex multifaceted disease, a holistic approach is to be adopted. There are 3 main strands that will be addressed in the strategy, including addressing the wildlife factor. From the wildlife perspective the priority for the first 5 year phase of the strategy will be to pursue the necessary information gathering actions and research to fill the critical knowledge gaps and build the evidence we need to make informed policy decisions about wildlife intervention in NI.

Among the information gathering actions in phase one of the Ministerial TB strategy, each of which will contribute to the evidence required are:-

- undertake a Badger Population Survey (see below, completed 2008)
- progress plans for a Badger Prevalence Survey (see below)
- progress plans for a TB Biosecurity Study to evaluate cattle and badger-related risk factors on both TB infected and clean farms in a TB high incidence area (see below)
- develop plans for a Badger Removal Trial
- support the development of vaccine for badgers (in communication with GB and ROI).

These actions will be subject to the agreement of the Minister for the Environment, where necessary, and to a business case and bids for the substantial additional funding that will be required.

Badger Population Survey

To date, two country-wide surveys have been completed to allow a fuller understanding of the number and distribution of the undisturbed badger population in NI.

The first survey was in 1994. The badger population in Northern Ireland was estimated in 1994 at 38,000 with a mean sett density of 3.51/km². It was found that a high preponderance of setts occurs in hedgerows and it was postulated that this increases the proximity of badgers to cattle, and therefore, the potential for inter-species transmission⁵⁶.

The second survey was in 2007/2008. The badger population in NI during 2007/2008 is estimated at 33,500 animals in 7,500 social groups giving a mean estimated density of such groups as 0.56 per square kilometre. It was observed that there was a positive association between areas of improved grassland and arable agriculture, and habitat cover. Density was correlated with land class, the highest densities found in drumlin farmland areas and marginal uplands. Due to the prevalence of favourable landscape features, Counties Down and Armagh had the highest density of badger social groups.

⁵⁶ Feore S.M. (1994) The distribution and abundance of the Badger *Meles meles* in Northern Ireland. PhD thesis. Queens University of Belfast.

Badger Road Traffic Accident Survey

Badgers are a protected species in NI and culling for TB control purposes is not permitted. *Ad hoc* surveys, using badgers killed by cars, have been undertaken in the past but a province-wide survey has been ongoing since the mid 1990's. An interim report has been published which noted the following:

- The prevalence of *M. bovis* in badgers was 17%.
- TB infection is geographically widespread in badgers with no evidence of clustering and no apparent association, *at regional level*, with the distribution of infection in cattle.
- Herds immediately adjacent to infected badger carcasses did not have a higher risk of infection compared to those adjacent to TB-negative animals. However, a higher proportion of herds within 3km of a positive carcass had TB compared to those within 3 km of a negative carcass and the difference was statistically significant.

The provisional conclusions arising from the survey was that there did appear to be a link between the distribution of infection in both species, although this did not indicate causality, i.e. direction of spread.

Badger Prevalence Survey

The main aims of this proposed survey were to provide baseline information on the level of *M. bovis* infection in badgers, against which the effectiveness of any possible future intervention (e.g. vaccination, removal, changes in biosecurity or a combination of these) may be measured and to establish the geographic distribution of bTB infection in the species. In addition it was also intended that the Survey would:-

- assess the extent of bias in the Road Traffic Accident survey;
- assess the association between *M. bovis* strain types in badgers and cattle through strain typing;
- estimate the within-sett prevalence in badgers;
- assess the efficacy of diagnostic blood tests for TB in badgers;
- determine *M. bovis* lesion and infection distribution in badgers; and
- gather more information on the number and spatial distribution of badger setts across NI building upon work already undertaken.

While an Economic Appraisal for the Badger Prevalence Survey was approved by the Department of Finance and Personnel (DFP) in December 2009, subsequent cost reappraisal indicates that it is too expensive, particularly as this survey is not an essential prerequisite to any subsequent badger intervention. Legal challenge is also very likely particularly as a significant proportion of any badgers removed are likely to be uninfected.

TB Biosecurity Study

A TB Biosecurity Study was conducted in a TB high incidence area in Co. Down. The Study is designed to compare farm characteristics in both herds that have recently had a TB breakdown and those that have had no recent history of a breakdown in this TB high incidence area. Consideration of selected cattle and wildlife risk factors are key elements of this research. As well as establishing relevant farm business information, a survey of on-farm buildings and a farm boundary survey were carried out. Radial badger sett survey work on and around the main farm buildings of participating farms was also undertaken. The findings

of the Study should be available later in 2012. The conclusions will inform evidence-based biosecurity advice to be provided to livestock farmers and will inform policy decisions.

Other evidence gathering projects

DARD was successful in securing an additional £4million for TB Research and Wildlife Studies and some research projects have already been commissioned with other projects to follow.

A fundamental analysis of DARD's use of the gamma-interferon (IFN-g) test in its TB Programme is already underway. The review of the gamma interferon blood test is to ensure that DARD is making the best use of it in the TB programme.

A Badger-Cattle Proximity Study using data loggers, GPS positioning technology and fixed location camera to assess badger-cattle and cattle-cattle interactions of (a) farm yards and feedstores, and (b) pasture in a TB high incidence area is also underway. The results will help to better inform our understanding of disease transmission risks; and also where biosecurity measures could best be targeted on farms here.

An International Vaccination Experts' Scientific Symposium took place in NI in May 2012. This symposium considered all relevant issues associated with vaccinating the badger to achieve a reduction in TB in cattle. We will use the information from the symposium to inform how best to proceed on badger vaccination here.

An assessment has been commissioned of farmers' understanding of and attitudes to applying biosecurity measures when dealing with diseases.

A literature review into the effect slurry spreading may have on transmission of TB is being conducted to establish 'the role of slurry in spreading TB and whether it should be treated or disinfected prior to spreading'.

In addition, a project to investigate the risk factors for herds with multiple reactors and/or chronic infection in order to further reduce disease in those herds is being developed.

A fundamental analysis of DARD's use of Variable Number Tandem Repeat (VNTR) strain typing of TB is being considered to determine how this tool can be best applied practically in the TB eradication programme and to provide a better understanding of TB transmission in NI.

DARD continues to develop collaborative links with work ongoing in England and ROI regarding the development and trialling of vaccines for bovine TB in badgers, recognising that vaccines developed for badgers may be the most feasible solution in the long term. We continue to follow closely the research and studies being conducted in Britain and ROI, including in relation to the development of an oral bait badger vaccine that can be delivered in a cost effective way. NI continues to be interested to see how the Welsh and English badger control strategies evolve and are implemented and whether they successfully withstand legal challenge.

DARD continues to work in partnership with the NI Agri-Food and Biosciences Institute (AFBI) to establish critical knowledge gaps in relation to TB and to identify and explore further research and development options that would complement and assist current research. AFBI and DARD's Veterinary Epidemiology Unit (VEU) conducted a number of literature reviews to identify and fill our critical knowledge gaps in relation to bovine TB generally and also to wildlife in particular. The TB literature reviews being carried out by AFBI were: (i)

cattle to cattle transmission; (ii) badger to cattle transmission; (iii) cattle bTB tests and effective deployment; and (iv) bTB tests in badgers. DARD's VEU conducted a literature review on badger vaccines.

Decisions will be made later in 2012 on which further additional TB Research and Wildlife Studies will be commissioned.

3 July 2012 announcement

Having considered a range of possible options for research and studies, the NI Minister for Agriculture and Rural Development announced that she sees value in undertaking work that would be unique to NI and not just an expensive duplication of what is being done elsewhere.

Therefore, following recent discussions with industry stakeholders and informed by the views of the external experts who attended the International Vaccination Symposium, the Minister has asked officials to design specific “wildlife intervention research”. This approach would involve testing live badgers; vaccinating and releasing the test negative badgers; and removing the test positive ones. It would focus on removing diseased badgers and protecting uninfected ones. This balanced approach could lead in time to a reduction in transmission of TB to cattle.

The aim of this wildlife intervention research would be to test the effectiveness of this approach on the level of TB in badgers and in cattle in NI.

The first step is to commission the necessary modelling to assist in the design of a badger TB “test, vaccinate or remove” study in NI that aims to provide a reliable evidence base in the most cost effective and least resource intensive way that is consistent with a scientific approach which is statistically robust.

When we have the results of the initial modelling, the next step will be to design the study proposal. There are a number of other preparatory actions that will be necessary. These include completing the necessary business case; securing the necessary funding; and, at the appropriate time, to seek the agreement of the Environment Minister and the issue of the necessary licences.

Wildlife Advice

Herdkeepers, both during a disease episode and as part of a broader biosecurity education programme, are given advice, both oral and written, on non-lethal biosecurity measures to adopt to reduce potential contact between infected wildlife and cattle. All herdkeepers are sent an advisory booklet on biosecurity including this advice (see web link below)

<http://www.dardni.gov.uk/biosecurity-code-booklet>

In conclusion, DARD is taking an evidence based approach to the wildlife strand of its TB strategy, the outcome of which will be informed policy decisions on wildlife intervention in NI.

Programme Related Factors

During the last 15 years, NI has experienced a Newcastle Disease epidemic (1997), Foot and Mouth Disease epidemic (2001) and BSE. All 3 diseases, but particularly BSE due to the long duration, have resulted in re-prioritisation and diversion of resources for varying periods. Although the effect of these diseases on TB prevalence is difficult to determine or define, they are likely to have had a negative impact.

3. Description of the submitted programme⁵⁷:

The targets:

Ministerial Direction

- In 2008, the then Minister of Agriculture and Rural Development made a statement that confirmed that the aspiration of the policy remains the eradication of bovine TB, and recognised the necessity of taking a phased strategic approach. Fundamental to the achievement of this aspiration is the recognition that it is necessary to take a holistic view, seen as a three-stranded approach to (1) control cattle to cattle spread, (2) address any wildlife component, and (3) create a partnership with the agricultural industry in the delivery of the strategy. The first period of five years will, through partnership working with an established core group of stakeholders, lay the foundations for future phases. Early goals are to maintain compliance with EU legislative requirements and produce more effective and efficient ways to reduce transmission from both cattle and wildlife.

DARD strategy and aim for bovine TB control in cattle in NI are contained within three published documents.

a) DARD Strategic Plan 2006-2011

Goal 3 : “to enhance animal, fish and plant health and welfare”

b) DARD Business Plan 2011-2012

2011-12 Targets

“achieve and maintain annual EU approval for the NI TB Eradication Programme”

b) DARD Veterinary Service Business Plan 2010/2011:

A key objective in this business plan, contributing to Goal three of the DARD Strategic Plan 2006-2011, is to

⁵⁷ A concise description of the programme is given with the main objective(s) (monitoring, control, eradication, qualification of herds and/or regions, reducing prevalence and incidence), the main measures (sampling and testing regimes, eradication measures to be applied, qualification of herds and animals, vaccination schemes), the target animal population and the area(s) of implementation and the definition of a positive case.

“Eradicate or considerably reduce the level of animal diseases that have public health or economic importance”.

Plans for 2012 and beyond are due shortly. There will be no reduction in the commitment to address animal diseases.

Control Procedures

NI bTB presents a distinct epidemiological picture to that in GB and it has had a separate control programme since the inception of controls. It therefore has a distinct and stand-alone NI TB Eradication Plan 2013, presented under the auspices of the UK Plan.

Current Procedures

- (a) DARD has a surveillance, compulsory removal and compensation programme. Surveillance is organised in two fully integrated approaches: PME; and live surveillance.
- (b) All animals slaughtered for human consumption undergo Post Mortem Examination (PME) as required by Council Directive 64/433 EEC. All such PMEs are completed by DARD staff. Results are available on APHIS immediately. Full integration allows immediate action to be taken by field staff, such as suspension of trading status, movement controls applied and further epidemiological measures to be instigated. Further laboratory investigations pursuant to PME findings are also fully integrated, ensuring continuity of information and security of actions. Such further investigations are carried out by the Agri-Food and Biosciences Institute (AFBI) Veterinary Sciences Division (VSD) laboratory, with full integration of results on APHIS. This surveillance approach includes the population of animals at routine slaughter and the population of reactor animals removed under the programme. AFBI is a DARD sponsored non-departmental public body.
- (c) Live animal surveillance is undertaken using three methods.
 - Export certification uses the Single Intradermal Test and interpretation as required by CD 64/432 EEC. Results are recorded on APHIS.
 - Herd and animal testing, outside export certification as above, uses the single comparative intradermal tuberculin test (SCITT) as described in CD 64/432 EEC. Results are recorded on APHIS. More severe interpretation of the SCITT results is used where considered epidemiologically necessary, and in any case where disease is confirmed.
 - Gamma interferon assay as described in CD 64/432 EEC (as amended by Regulation 1126/2002 EC) is used where considered epidemiologically necessary. It is always used as a supplementary test to the SCITT in these situations. Results are recorded on APHIS.

All skin testing is carried out by DARD veterinarians, DARD registered technicians, DARD approved private veterinarians contracted to do so either by DARD in the case of surveillance or by the herd keeper for export certification.

DARD registered technicians are personnel directly employed by DARD to undertake tuberculin testing for disease control. A small number (3) have undergone extensive training, supervision and examination before registration.

All herds in NI at all times are allocated an OT herd status, a herd status reason, and a next test type. The herd status may only be officially tuberculosis free (OTF), officially tuberculosis suspended (OTS), or officially tuberculosis withdrawn (OTW). These statuses are as defined in CD 64/432 EEC. In addition to CD 64/432 EEC requirements, where any herd in NI discloses more than five skin reactors without regard to confirmation, or where considered otherwise epidemiologically prudent, the herd is made OTW. The status reason describes the specific details of why the herd has the status allocated. The next test type describes the test that is set and best describes the test type requirement.

Movement control from all herds, at all times, is controlled by a combination of the herd status and status reason applicable to the herd. As all movements must be recorded on APHIS, including those to market and abattoir, immediate movement control is applied.

- (d) All herds in NI are tested annually as a minimum. All animals over 6 weeks of age must be presented for test in OTF herds. Failure to test results in the OTF status being suspended immediately in all cases. Therefore NI is fully compliant with CD 64/432EEC in that any herd that has not been subject to an annual test loses OTF status immediately. Further delay in testing will result in automatic increased movement sanctions and downgrading the herd status to OTW.
- (g) Herds may also undergo increased frequency of testing. This is in accordance with CD 64/432 EEC where a herd is suspected of being diseased or had disease confirmed. In addition, herds may be subject to increased testing frequency where epidemiological investigations disclose an increased disease risk, such as tracing or contiguity. For example, some 26.8% of herds in NI had more than one TB test in 2011.
- (h) Animals may not move out of a herd during performance of a test except, with the permission of the competent authority, directly to slaughter in NI.
- (i) There are no exemptions to the above testing programme at either animal level or herd level.

4. Measures of the submitted programme

4.1. Summary of measures under the programme

Duration of the programme: A voluntary Tuberculosis (attested herd) scheme was introduced in 1949 and in 1959 compulsory Tuberculin Testing was introduced. This programme has been constantly applied and developed since.

The table below details the history of testing bovines for Tuberculosis in Northern Ireland.

Duration of the programme:

First year:

- Control**
- Testing**
- Slaughter of animals tested positive**
- Killing of animals tested positive**
- Vaccination
- Treatment
- Disposal of products**
- Eradication, control or monitoring.

Last year:

- Eradication**
- Testing**
- Slaughter of animals tested positive**
- Killing of animals tested positive**
- Extended slaughter or killing**
- Disposal of products**
- Other measures (specify):**

All cattle in NI routinely slaughtered for human consumption receive a post-mortem inspection in EU approved establishments. All lesions suggestive of TB are sampled and forwarded to AFBI for appropriate laboratory analysis. All information obtained is passed to the field veterinarian responsible for the farm of origin of the slaughtered animal. This transfer of data is in realtime and fully integrated on APHIS.

4.2. Organisation, supervision and role of all stakeholders⁵⁸ involved in the programme:

The Veterinary Service of the Department of Agriculture and Rural Development (DARD in NI) is the designated Competent Authority for the control of bovine tuberculosis in NI under Council Directive 64/432/EC.

Policy responsibility in DARD lies with the Animal Health and Welfare Policy Division which is part of the Central Policy Group. Delivery responsibility belongs to Veterinary Service, with Veterinary Service Headquarters managing compensation payments and contract management.

⁵⁸ Describe the authorities in charge of supervising and coordinating the departments responsible for implementing the programme and the different operators involved. Describe the responsibilities of all involved

A TB HQ Team has a range of functions including monitoring of the programme, project management, change management and the provision of veterinary advice. Veterinary Service Field side is divided into 10 areas, called Divisions, which are further subdivided into patches. Each Patch has a nominated Veterinary Officer. Field staff involved in tuberculosis control are: administrative staff, Veterinary Officers, Animal Health and Welfare Inspectors and Valuation Officers.

A DARD Veterinary Epidemiology Unit, an Enforcement Unit, and other specialist advice is available as required in the programme.

PME surveillance and sampling is undertaken in abattoirs. All such examination and sampling is conducted by DARD staff. Reporting is direct and immediate through APHIS.

TB testing is undertaken only by DARD approved Veterinary Surgeons, using the Single Comparative Intradermal Tuberculin Test (SCITT) for internal control. Most testing is carried out by PVPs under contract to DARD but the Department also uses contract-based specialist veterinarians, VOs or registered technicians in specific instances.

Herdkeepers nominate a PVP for tests that are not directly completed by DARD. All PVPs must be DARD approved to TB test.

Approval of testing veterinarians requires the completion of field training, field practical examination and attendance at a training seminar. PVPs and directly employed TB testers are subject to routine audit of performance. This includes audit of technical application of the test under field conditions.

Laboratory testing for tuberculosis control is currently carried out at Veterinary Sciences Division, part of the Agri-Food and Biosciences Institute (AFBI).

Herdkeepers are legally obliged to notify suspicion of the disease and present all animals for testing as required. Any interference with testing or control measures is an offence.

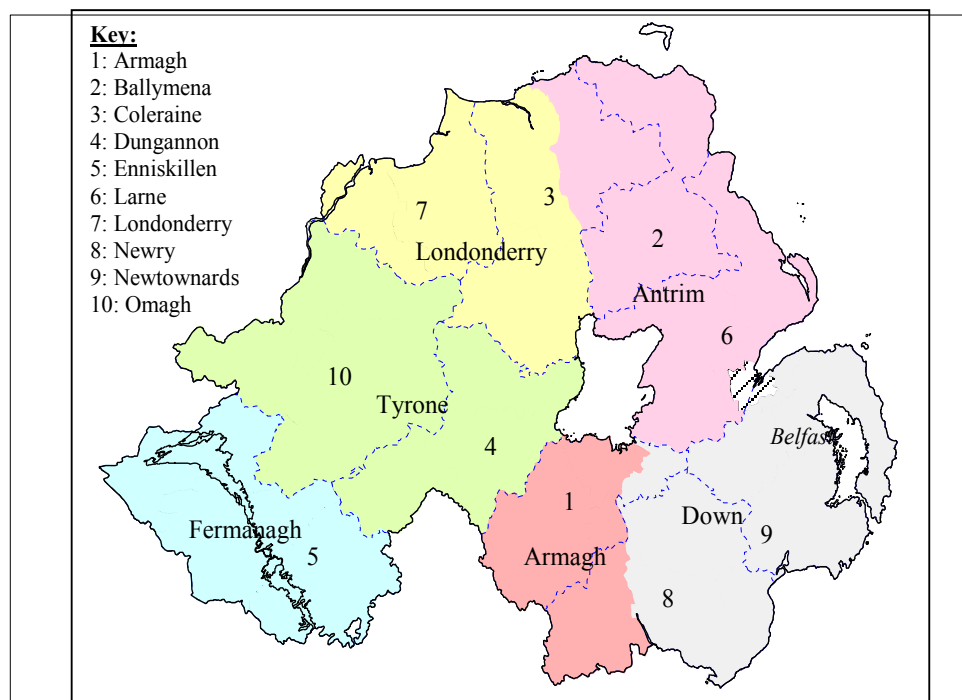
4.3. Description and demarcation of the geographical and administrative areas in which the programme is to be implemented⁵⁹:

For DARD Veterinary Service purposes, NI is divided into 10 administrative regions, each with a Divisional Veterinary Office. The regions are sub-divided into "patches", each managed by a veterinary officer (VO) supported by a team of technical officers. All are subject to common direction from DARD Headquarters through staff instructions and IT development. A centralised live animal health database ("APHIS"), incorporating an animal movement and test management system, is used for all aspects of TB disease control. APHIS capability is used to administer between-herd movement of cattle, captured using a movement notification system and permissible movement matrix, facilitated by input at markets, abattoirs and directly via the internet to herdkeepers. It facilitates management of herd-level and animal-level tests, with results recorded at animal level.

Entry of test results is virtually exclusively by direct link with the testing veterinarian via a web based system onto APHIS. Abattoir and laboratory results are similarly reported immediately on APHIS.

⁵⁹ Describe the name and denomination, the administrative boundaries, and the surface of the administrative and geographical areas in which the programme is to be applied. Illustrate with maps.

Fig 11: Illustration of Divisional Veterinary Office areas and Counties in Northern Ireland



4.4. Description of the measures of the programme⁶⁰:

4.4.1. Notification of the disease:

Notification may arise from:

- Declaration of a suspect clinical case
- Disclosure at an abattoir of a suspect TB lesion at routine slaughter
- Disclosure of a non-negative skin test result

The herd is declared OTS until the results of confirmatory tests, PME, other epidemiologically relevant information, or more than 5 skin reactors, requires the herd to be declared OTW.

4.4.2. Target animals and animal population:

The programme extends to the entire region of NI. All animals except those that are less than 6 weeks old and retained in their natal herd are required to be routinely tested for TB in NI. All animals are required to be tested in restricted herds.

⁶⁰ A comprehensive description needs to be provided of all measures unless reference can be made to Union legislation. The national legislation in which the measures are laid down is also mentioned.

Current Demographics

There are currently 1.6 million cattle in NI, distributed among 20,500 farm businesses with cattle (June 2011). Dairy cows make up 18% of the national herd while beef cows account for 17%. Based on cattle TB tested in herds, the mean herd size has increased from 56 cattle in 1990 to 78 in 2011, an increase of 39%. However, the data are strongly skewed to the right and the median was 38 for all TB herd tests in 2011. Over half of herds (58%) in Northern Ireland have fewer than 50 cattle.

There are no exceptions to control measures for sporting or cultural animals.

4.4.3. Identification of animals and registration of holdings:

All cattle herds in NI are registered with the central authority and each has been allocated a unique herd number to facilitate tracing of animal movements. All registered premises are recorded on a central computer database (APHIS). Full details of the testing programme are maintained on the database.

Under Council Regulation (EC) No 1760/2000 cattle are identified by means of a unique identification number authorised by DARD. All cattle born after 1 January 1998 are identified with an ear tag in each ear bearing the same unique identification number, which will remain with the animal throughout its life. All cattle born after 1 January 2000 must be tagged using the new all numeric tags.

Each animal's test results and movement details are held and are readily accessed on a computer database (APHIS). Epidemiological investigation and full tracing procedures in compliance with Council Regulation 1760/2000 are instigated following the detection of a diseased animal.

4.4.4. Qualifications of animals and herds⁶¹:

All herds in NI at all times are allocated an OT herd status, a herd status reason, and a next test type. The herd status may only be officially tuberculosis free (OTF), officially tuberculosis suspended (OTS), or officially tuberculosis withdrawn (OTW). These statuses are as defined in CD 64/432 EEC. In addition to CD 64/432 EEC requirements, where any herd in NI discloses more than five skin reactors without regard to disease confirmation, or where considered otherwise epidemiologically prudent, the herd is made OTW. The status reason describes the specific details of why the herd has the status. The next test type describes the test that is set and best describes the test type requirement.

OTW status is applied to a herd where:

- Disease is confirmed by PME and/or laboratory procedures.
- When disease has not been confirmed, OTW status is applied where a Veterinary Officer has considered it to be epidemiologically prudent, for example recent movement out of a herd of an animal that is disclosed as a reactor in another herd. This decision is at the discretion of the patch VO and will be based on their knowledge of the breakdown, the area, and any other relevant epidemiological evidence available to them.

⁶¹ To mention only if applicable.

- In any case, where there are more than five reactors disclosed at a skin test OTW status is routinely applied.

OTW status is removed from a herd where

- Two consecutive clear herd skin tests have been completed in accordance with CD 64/32 Annex A (3B), and
- Cleansing and disinfection procedures are completed as required. All OTW herds (due to disease) in NI are subject to DARD cleansing and disinfection inspection. No such herd will regain OTF status unless cleansing and disinfection is inspected and is approved.

OTS status is applied to a herd where:

- A suspect tuberculous lesion is disclosed at abattoir.
- Disclosure of an inconclusive reactor.
- A herd test is overdue.
- 5 or less reactors are disclosed at a test, with no PME or laboratory confirmation.
- And when, in the judgment of the patch VO, there is no over riding epidemiological reasons to apply OTW status (see OTW, above).

OTS status is removed from a herd where

- The Veterinary Officer is content that there are no epidemiological factors that indicate the herd status should be retained or made OTW (see OTW above)
- Testing is completed in accordance with CD 64/432 Annex A (3A) or, where applicable,
- The inconclusive animal is resolved by testing or slaughter with negative PME and laboratory results.
- Cleansing and disinfection procedures are completed as required. All OTS herds (due to disease) in NI are subject to DARD cleansing and disinfection inspection. No such herd will regain OTF status unless cleansing and disinfection is inspected and is approved.

4.4.5. Rules on the movement of animals:

In accordance with Council Regulation EC No 1760/2000 all calves born after 1 January 1998 must be identified with an ear tag in each ear within 20 days from the birth of the animal. All cattle identification numbers are authorised by DARD and recorded on the Animal and Public Health Information System (APHIS) computer database so that no duplication should be possible. The birth of a calf must be notified to the Department within 7 days of tagging, 27 days of birth and in any case before the animal leaves the holding of birth. All herd keepers must maintain a register of cattle born or moved into the herd. The register must show the identification number of the animal and details of replacement tags/retags. Herd keepers must also record in their register the colour, breed type, sex, date of birth and the dam's identification number (for animals born in their herd). Their register must also show the date and means of acquisition of stock, the date of movement off the holding, the address of premises to which the animal moved, or if it has died, the date and manner of disposal. These records must be retained for 10 years. From 1 January 2000 the movement permit

system was replaced by movement control documents requiring a producer to notify the Department within 7 days of an animal either leaving or arriving on his/her farm. Markets are required to notify movements on and off to the Department by the end of the next working day. However, in the case of a restricted animal the producer is required to obtain a movement licence from the Department in advance of moving the animal out of his/her herd. All movements are recorded and can be traced on APHIS. All stock on farms are checked against official records at Cattle Identification Inspections, and Tuberculosis and Brucellosis herd tests which occur at least annually, and when presented at markets or slaughterhouses. Discrepancies between the description of the animal and the details recorded on APHIS are investigated. If the discrepancy is not satisfactorily resolved a status is placed against the animal on APHIS which restricts its movement. Where the identification and traceability of an animal cannot be established at point of slaughter, the carcass will be removed from the human food chain. In the field, where the disease status of an animal cannot be clearly established from the database, the animal will be isolated and tested.

Herds with either OTS or OTW status applied are both subject to movement restrictions immediately. This is controlled through APHIS.

NI does not permit movement out of OTS or OTW herds unless direct to slaughter within NI. NI does allow live movement within the MS from herds where OTS status is applied due to an unresolved inconclusive animal where no history of BTB within three years (as per derogation under CD 64/432 Annex A 3.A (d))

NI allows movement into OTS or OTW herds except where the official veterinarian considers it epidemiologically prudent to prohibit such movements and, in any case, if there is delay in testing.

A matrix of movement restrictions is applied that is relevant to the status and status reason applied to the herd.

OTW status movement

- No live animal movements out except directly to slaughter in NI.
- Note: the movement restrictions described above may, where considered epidemiologically necessary, be increased to prevent any movement off farm even to direct slaughter or cease movement onto farm.

OTS status movement

- No live movement out except directly to slaughter in NI.
- Note: OTS herds with the status reason “RI (inconclusive) but no TB confirmed within three years” are derogated under CD 64/432EEC Annex A 3.A(d) to allow local live movement within UK. However, animals from the herd or those that have originated in the herd since the last clear herd test are not allowed to be exported to another MS.
- Note: the movement restrictions described above may, where considered epidemiologically necessary, be increased to prevent any movement off farm even to direct slaughter or cease movement onto farm.

There are no herds of unknown status in NI as all herds have a testing history. New herds may only purchase from OTF herds and as a result the status of the animals added to a new herd is known.

Overdue Tests:

Where a test becomes overdue, increasingly stringent movement controls are applied routinely as below:

- Immediately overdue, no live moves to market, export, or other holdings.
- 1 month overdue, no live moves to market, export, other holdings or slaughter. No moves in are allowed except one breeding bull on exceptional licence.

4.4.6. Tests used and sampling schemes:

- The DARD programme comprises surveillance, compulsory removal and compensation for compulsorily removed animals. The surveillance is organised in two fully integrated sections, PME and live surveillance.
- All animals slaughtered for human consumption undergo PME as required by CD 64/433 EEC. All such PMEs are completed by DARD staff. Results of PME are available on APHIS immediately. Full integration allows immediate action to be taken by field staff, such as suspension of trading status, movement controls applied and further epidemiological measures to be instigated. Further laboratory investigations pursuant to PME findings are also fully integrated, ensuring continuity of information and security of actions. Such further investigations are carried out by AFBI, (a DARD sponsored non-departmental public body) with full integration of results on APHIS. This surveillance includes both animals at routine slaughter and reactor animals removed under the programme.

Live animal surveillance is undertaken using three methods.

- Export certification uses the SIT test and interpretation as required by CD 64/432 EEC and may only be performed with the express permission of DARD. Results are recorded on APHIS.
- Herd and animal testing outside export certification uses the SCITT as described in EC 64/432 EEC. Results are recorded on APHIS. More severe interpretations of the SCITT results are used where considered epidemiologically necessary at the discretion of the patch VO, and in any case where disease is confirmed.
- Gamma interferon testing as described in CD 64/432 EEC is used where considered epidemiologically necessary. It is always used as a supplementary test to the SCITT in these situations. Results are recorded on APHIS.

Inconclusive SCITT Results:

In NI, animals are allowed one skin test with an inconclusive result without compulsory removal.

A non-negative result at a second consecutive test results in mandatory removal as a reactor animal.

Herdkeepers may be advised to slaughter the animal at any time during this period.

At a restricted herd test, where standard and/or severe interpretation may be used for disease control, any animal with an immediate previous inconclusive result is removed as a reactor if the next test result is not negative.

Pre-movement Testing

NI is fully compliant with the current requirements of pre-movement testing under CD 64/432 EEC.

All animals over 42 days are subject to the single intradermal test and interpretation within 30 days of export as required. Otherwise NI avails of the derogation available in CD 64/432EEC Annex A 1.1(c) for intra-MS movements where animals from an OTF herd are not required to be pre-movement tested.

In addition to CD 64/432 EEC requirements, in NI any animal that has not undergone a test outwith a period of 15 months must undergo a pre-movement test before live movement except directly to slaughter in NI.

Supplementary Testing

CD 64/432 EEC at Annex B Art 3 allows supplementary testing.

In NI these are

- 6 monthly test post regaining OTF status following all OTS or OTW status for disease reasons.
- Lateral check tests of contiguous herds.
- Area testing where considered epidemiologically appropriate.
- Gamma interferon testing.
- Strain typing of isolates.

Gamma Interferon Testing in NI

NI has conducted significant IFNg testing in advance of EU approval of supplementary tests. In 1990s approximately 100,000 cattle were IFNg tested in NI. Review of the results of this extensive trialling concluded that the test was best employed as a supplementary test to the skin test.

At present IFNg testing is available to herds throughout NI where it is considered by DARD that the supplementary test will remove diseased animals more rapidly in the disease process and thereby increase the speed of resolution.

Herds currently selected are those with recent confirmed disease or confirmed lesion at slaughter following a recent negative skin test. Herd keepers with IFNg positive animals that are skin negative are offered compensation. Participation with the IFNg test programme element is voluntary.

Research continues to allow further development of the assay under field conditions and the test application is kept under review.

Strain Typing of Isolates

Since 2003 VNTR (Variable Number Tandem Repeat) has been used to strain type each breakdown episode, with all cultured reactors strain typed since mid 2009. This information is available to VOs to facilitate epidemiological decisions.

Atypical, or Possibly Fraudulent, Results

- Where DARD considers the result of a test to be atypical, or possibly fraudulent, it may conduct further investigations and may, as a result, consider the result of the test null and void.
- Such results may be suggested, inter alia, by test history, veterinary observation or epidemiological information.

4.4.7. Vaccines used and vaccination schemes:

The TB Control Order (Northern Ireland) 1999 prohibits vaccination of cattle against bovine tuberculosis in NI.

4.4.8. Information and assessment on bio-security measures management and infrastructure) in place in the holdings involved:

All herd owners in Northern Ireland have been issued with the DARD production “Biosecurity Code for Northern Ireland farmers and guidance for official visitors to farm properties and recreational users of farmland.” This book describes the reasons for having a code, legal requirements, notifiable disease and reducing risks of allowing disease on to premises.

Veterinary Service officials advise herdkeepers on movements and segregation of cattle in breakdown premises, particularly in relation to preventing spread of disease to contiguous herds. Movements of personnel and equipment that have the potential to carry disease are investigated and appropriate biosecurity advice given. Herds contiguous to breakdowns also receive biosecurity advice.

4.4.9. Measures in case of a positive result⁶²:

Immediately a notification of suspect TB is made to a local DVO, the herd OTF status is removed.

This notification may arise from:

- Declaration of a suspect clinical case.
- Disclosure at an abattoir of a suspect TB lesion at routine slaughter.
- Disclosure of a non-negative skin test result.

The herd is declared OTS until the results of confirmatory tests, PME, other epidemiologically relevant information, or more than 5 skin reactors, requires the herd to be declared OTW.

OTS and OTW herds are both subject to movement restrictions immediately. This is controlled through APHIS.

A matrix of movement restrictions is applied that is relevant to the status and status reason applied to the herd.

NI does not permit movement out of OTS or OTW herds except directly to slaughter in NI. However, where a herd has OTS status due to an unresolved inconclusive with no history of bTB within three years, NI avails of the derogation in CD 64/432 Annex A 3.A (d), where intra MS movements are allowed.

Relevant laboratory tests are established and reported via APHIS.

The test regime is modified on APHIS.

The test, if applicable, is interpreted by the patch VO who may remove test negative animals considered at epidemiologically increased risk. This may include full herd depopulation if considered necessary.

Removal procedures are immediately instigated, including the legal requirement to immediately isolate the diseased animal(s). Isolation advice specific to the circumstances is given by the official veterinarian and enforced by legal notice. Compliance breaches may lead to enforcement action.

All reactors are removed by DARD subcontracted hauliers for immediate slaughter to a designated slaughter house.

Where the welfare of the animals precludes live removal, it may be euthanized on farm. PME is available where confirmation of disease in the episode has not yet been established or where otherwise considered epidemiologically necessary by the patch VO.

Following a confirmed TB breakdown (OTW) adjoining at risk herdkeepers are alerted and their herds are allocated a contiguous herd test (Lateral Check Test, LCT), where considered appropriate following a veterinary risk assessment. If the test is not completed on time, these herds are downgraded to OTS and movement restricted. They are further tested at regular 4

⁶²

A description is provided of the measures as regards positive animals (description of the slaughter policy, destination of carcasses, use or treatment of animal products, the destruction of all products which could transmit the disease or the treatment of such products to avoid any possible contamination, a procedure for the disinfection of infected holdings, the therapeutic or preventive treatment chosen, a procedure for the restocking with healthy animals of holdings which have been depopulated by slaughter and the creation of a surveillance zone around the infected holding,).

monthly intervals until the infected herd has been cleared or until no further risk of lateral spread.

Tracing forward of animals that carry a disease risk is carried out. If it is not possible to test the traced animal then a herd level test may be set (Forward Check Test, FCT). Tracing parameters such as putative exposure windows are at VO discretion.

Note: where the traced animal has been exported live, DARD informs DEFRA (UK MS Competent Authority) of the relevant details.

Where VO discretion considers it relevant, the herds from which a TB reactor has originated or moved through are tested. These backward traced herds are downgraded to OTS or OTW until testing is completed.

A notice requiring cleansing and disinfection as the patch VO considers necessary is served and, on completion, the herdkeeper is required to notify the Divisional Veterinary Office. Advice on cleansing and disinfection is given by the VO at a farm visit and in writing, including a list of Approved Disinfectants. Completion of cleansing and inspection is inspected by DARD staff. No such herd will regain OTF status unless cleansing and disinfection is inspected and is approved.

Specific advice on the breakdown epidemiology, public health and improvement of biosecurity is given directly by the patch VO to the herdkeeper. In addition, written advice is provided.

Case conferences may be held to avail of specialist knowledge, such as advice from the Veterinary Epidemiology Unit or AFBI, where the patch VO considers it necessary.

The option exists to depopulate either fully or partially any herd when it is considered epidemiologically necessary by the DARD field veterinarians.

In the case of total herd depopulations the following action is taken:

- No animals are allowed to move into the premises for 60 days following the depopulation.
- A full Cleansing and Disinfection is required after depopulation.
- The herdkeeper is advised of the control of risk from slurry.
- Two months after re-stocking a TB test is required. If this test occurs within a year of the breakdown it is classed as reactor (RH1) test. If the RH1 is clear the restriction is removed and then a post restriction test (CHT) is set for six months later and an Annual Herd Test set twelve months after the completion of the post-restriction test. If a farm premises is depopulated for more than 12 months then the restriction is removed at 12 months and the test following the purchase of animals is classed as an Annual Herd Test.

4.4.10. Compensation scheme for owners of slaughtered and killed animals:

Reactor animals and any relevant in contact animals are valued by DARD Valuation Unit on farm prior to slaughter.

Compensation is made at 100% of market valuation directly to the herdkeeper for all classes of animals removed.

Where a herd keeper disputes a valuation, they may seek an independent valuation by an independent valuer from a DARD approved list of valuers.

This independent valuation is not final and binding, and so the herdkeeper or DARD may appeal a valuation to an independent valuation appeal panel.

In any case the animal is removed without delay.

Salvage value is paid to the competent authority.

No consequential loss compensation is made.

4.4.11. Control on the implementation of the programme and reporting⁶³:

The Bovine TB Control Scheme in Northern Ireland is run as a programme by the Veterinary Service of DARD. This is led by a Senior Principal Veterinary Officer supported by a dedicated team at HQ. This is supplemented with input from the in-house Veterinary Epidemiology Team and other sources as required. Implementation is primarily in-house at Divisional Veterinary Office level with extensive testing contracted to private veterinary practitioners (PVP).

One of the roles of the Programme team is to improve the delivery of the Programme. This includes Key Programme Performance indicators that monitors, on a monthly basis, progress against targets in the Veterinary Service Business Plan. Audit of decision making by the field staff and case audits of breakdown herds are also conducted.

A further central role is to conduct audit of work carried out by PVPs, assessing the work contracted for against required delivery targets. Some of the monitoring may be done remotely using the APHIS. For example, reactor removal times are closely monitored to ensure meeting of the in-house target that is set at less than EU requirement, and notification times for test results. Further, specialist teams of audit Veterinary Officers conduct field test audits. This includes audit of the test procedure in the field. Failure to comply fully with contractual requirements will attract sanctions as described in a formal protocol.

Detailed disease statistics are published monthly at <http://www.dardni.gov.uk/index/dard-statistics/animal-disease-statistics.htm>

5. **Benefits of the programme**⁶⁴:

The main benefits of the TB programme are indicated below.

The overall benefit to the NI farming and processing sectors is that the TB programme has been successful in reducing TB in cattle and in supporting trade in live cattle and products. The export trade in cattle, beef, milk and by-products, which was worth £1,269.4m here in 2010, is dependent on the effective implementation of the programme.

This figure is made up as follows:

live cattle exports	- £17.0m (including to GB)
animal by-products other animals	- £18.6m (including to GB) cannot separate cattle data from other animals

⁶³ Describe the process and control that will be carried out in order to ensure the proper monitoring of the implementation of the programme.

⁶⁴ A description is provided of the benefits for farmers and society in general from the public and animal health and economical point of view.

beef and sheep meat - £696.7m (including to GB) cannot separate data
milk and milk products - £537.1m (including to GB)

The vast majority of herds in NI are able to participate fully in export trade because of the programme. In the absence of an effective programme, access to export markets would not be possible. Maintenance of a programme continues to be essential to provide the guarantees necessary to enable NI cattle and their products to access EU and third country markets.

Trade in live animals is governed by Directive 64/432. Bovine animals for export to another MS must originate from an OTF herd and have been submitted to a pre-movement test for TB.

Milk Controls

The Food Standards Agency in Northern Ireland (FSA) is the Competent Authority for the relevant food related legislation (Regulation (EC) 853/2004) in Northern Ireland and the Department of Agriculture and Rural Development's Agri-food Inspection Branch enforce on their behalf.

Food business operators producing or, as appropriate, collecting raw milk must ensure compliance with the requirements laid down in the Regulation.

The herd status of all herds is always available on APHIS.

Herdkeepers and their associated milk purchasers have access to this status information through APHIS.

This status is changed as appropriate once animals have been deemed reactors, at interpretation by DARD.

In addition, herdkeepers are informed in writing of the herd status.

Dairy herdkeepers are specifically informed in writing at the start of a breakdown that milk from reactor animals must not be used for human consumption.

Where reactors are disclosed and as part of the normal programme of inspections and audits on farms and at milk purchasers, Authorised Officers will seek to identify how milk from reactor animals is managed if a breakdown occurs and will provide guidance if controls are considered insufficient.

There are **no** sales of raw milk direct for human consumption in Northern Ireland; and milk for consumption in NI is pasteurised.

Non-Milk Controls

Trade in animal products for human consumption is governed by Directive 2004/41/EC and Regulations (EC) 852/2004 and 853/2004. Meat from animals with generalized TB must not be declared fit for human consumption. In cases where lesions are confined to the lymph nodes or only one organ or only one part of the carcass, only the affected part need be declared unfit for human consumption.

Maintaining access to third country markets depends on NI continuing to comply with the relevant requirements of the OIE and such conditions as may be imposed bilaterally by our trading partners.

Human Health

In terms of human health, control of TB was one of the great public health success stories of the twentieth century. In the late 19th century TB caused 1 in 5 of deaths in the UK and even as late as the pre and post World War II period there were 50,000 TB notifications in England and Wales. Before WWII, 2,000 children died in the UK every year due to bTB. The implementation of BCG vaccines, pasteurisation of milk, and the reduction of the incidence of the disease in the cattle population contributed to the effective elimination of the disease as a major health issue in the developed countries. There were 12 cases of bTB in humans in NI from 2000-2005 and a further 7 in the period 2006-2009.

Were there to be a return to past levels of infection, the risk to the general public would be limited because of the use of BCG and pasteurisation of milk. For farm families who might consume unpasteurised milk or contract the disease through direct transmission, the risks could be significant.

However the National Institute for Health and Clinical Excellence (NICE) concluded that the overwhelming majority of the UK population was at negligible risk of *M. bovis* infection.

Animal Welfare

If the disease were to re-emerge there could be significant animal welfare problems. It is not likely that these would be acceptable to a population increasingly seeking high welfare standards.

This analysis of programme benefits suggests that although precise estimates cannot be made there are a number of significant benefits relative to a “no control situation”.

6. Data on the epidemiological evolution during the last five years⁶⁵

6.1. Evolution of the disease⁶⁶

6.1.1. Data on herds^(a) (one table per year)

Year: 2011

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds checked ^(d)	Number of positive herds ^(e)	Number of new positive herds ^(f)	Number of herds depopulated	% positive herds depopulated	INDICATORS		
									% herd coverage ^(g)	% positive herds Period herd prevalence	% new positive herds Herd incidence
1	2	3	4	5	6	7	8	9 = (/)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
N.Ireland	Bovine	25,677	25,677	23,917	1,655	1,386	7	0.4	90	6.92	6.01
Total		25,677	25,677	23,917	1,655	1,386	7	0.4	90	6.92	6.01

- (a) Herds or flocks or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining or upgrading, the health status of the herd. In this column a herd must not be counted twice even if has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one animal tested positive in this period.
- (g) The denominator is taken as the number of herds with at least 1 TB herd test in the last 4 years to ensure we capture all cattle herds. As the number of cattle herds are declining, this method gives an overestimate of the number of actual cattle herds that are in operation.

⁶⁵ The data on the evolution of the disease are provided according to the tables below where appropriate.

⁶⁶ No data to provide in case of rabies.

6.1.1. Data on herds^(a) (one table per year)

Year: 2010

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds checked ^(d)	Number of positive herds ^(e)	Number of new positive herds ^(f)	Number of herds depopulated	% positive herds depopulated	INDICATORS		
									% herd coverage ^(g)	% positive herds Period herd prevalence	% new positive herds Herd incidence
1	2	3	4	5	6	7	8	9 = (/)x100	10= (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
N.Ireland	Bovine	25,933	25,933	23,595	1,484	1,150	16	1.1	91	6.55	5.07
Total		25,933	25,933	23,595	1,484	1,150	16	1.1	91	6.55	5.07

- (a) Herds or flocks or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining or upgrading, the health status of the herd. In this column a herd must not be counted twice even if has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one animal tested positive in this period.
- (g) The denominator is taken as the number of herds with at least 1 TB herd test in the last 4 years to ensure we capture all cattle herds. As the number of cattle herds are declining, this method gives an overestimate of the number of actual cattle herds that are in operation.

6.1.1. Data on herds^(a) (one table per year)

Year: 2009

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds checked ^(d)	Number of positive herds ^(e)	Number of new positive herds ^(f)	Number of herds depopulated	% positive herds depopulated	INDICATORS		
									% herd coverage ^(g)	% positive herds Period herd prevalence	% new positive herds Herd incidence
1	2	3	4	5	6	7	8	9 = (/)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
N.Ireland	Bovine	26,287	26,287	24,023	1,608	1,293	12	0.7	91.4	7.0	5.61
Total		26,287	26,287	24,023	1,608	1,293	12	0.7	91.4	7.0	5.61

- (a) Herds or flocks or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining or upgrading, the health status of the herd. In this column a herd must not be counted twice even if has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one animal tested positive in this period.
- (g) The denominator is taken as the number of herds with at least 1 TB herd test in the last 4 years to ensure we capture all cattle herds. As the number of cattle herds are declining, this method gives an overestimate of the number of actual cattle herds that are in operation.

6.1.1. Data on herds^(a) (one table per year)

Year: 2008

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds checked ^(d)	Number of positive herds ^(e)	Number of new positive herds ^(f)	Number of herds depopulated	% positive herds depopulated	INDICATORS		
									% herd coverage ^(g)	% positive herds Period herd prevalence	% new positive herds Herd incidence
1	2	3	4	5	6	7	8	9 = (/)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
N.Ireland	Bovine	26,780	26,780	23,922	1,598	1,273	10	0.6	89.1	7.0	5.57
Total		26,780	26,780	23,922	1,598	1,273	10	0.6	89.1	7.0	5.57

- (a) Herds or flocks or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining or upgrading, the health status of the herd. In this column a herd must not be counted twice even if has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one animal tested positive in this period.
- (g) The denominator is taken as the number of herds with at least 1 TB herd test in the last 4 years to ensure we capture all cattle herds. As the number of cattle herds are declining, this method gives an overestimate of the number of actual cattle herds that are in operation.

6.1.1. Data on herds^(a) (one table per year)

Year: 2007

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds checked ^(d)	Number of positive herds ^(e)	Number of new positive herds ^(f)	Number of herds depopulated	% positive herds depopulated	INDICATORS		
									% herd coverage ^(g)	% positive herds Period herd prevalence	% new positive herds Herd incidence
1	2	3	4	5	6	7	8	9 = (/)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
N.Ireland	Bovine	26,915	26,915	24,280	1,633	1,264	5	0.3	89.3	6.9	5.35
Total		26,915	26,915	24,280	1,633	1,264	5	0.3	89.3	6.9	5.35

- (a) Herds or flocks or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining or upgrading, the health status of the herd. In this column a herd must not be counted twice even if has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one animal tested positive in this period.
- (g) The denominator is taken as the number of herds with at least 1 TB herd test in the last 4 years to ensure we capture all cattle herds. As the number of cattle herds are declining, this method gives an overestimate of the number of actual cattle herds that are in operation.

6.1.2. Data on animals (one table per year and per disease/species)

Year: 2011

Region ^(a)	Animal species	Total number of animals ^(b)	Number of animals ^(d) to be tested under the programme	Number of animals ^(c) tested	Number of animals tested individually ^(d)	Number of positive animals	Slaughtering		INDICATORS	
							Number of animals with positive result slaughtered or culled	Total number of animals slaughtered ^(e)	% coverage at animal level	% positive animals Animal prevalence
1	2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
N.Ireland	Bovine	1,590,452	1,565,646	1,607,358	1,607,358	8,136	8,136	8,620	100.0	0.506
Total		1,590,452	1,565,646	1,607,358	1,607,358	8,136	8,136	8,620	100.0	0.506

- (a) Region as defined in the programme of the Member State.
- (b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
- (c) Includes animals tested individually or under bulk level scheme.
- (d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance: milk bulk tank tests).
- (e) Include all positive animal slaughtered and also the negative animals slaughtered under the programme.

6.1.2. Data on animals (one table per year and per disease/species)

Year: 2010

Region ^(a)	Animal species	Total number of animals ^(b)	Number of animals ^(d) to be tested under the programme	Number of animals ^(c) tested	Number of animals tested individually ^(d)	Number of positive animals	Slaughtering		INDICATORS	
							Number of animals with positive result slaughtered or culled	Total number of animals slaughtered ^(e)	% coverage at animal level	% positive animals Animal prevalence
1	2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
N.Ireland	Bovine	1,604,356	1,583,229	1,582,878	1,582,878	6,404	6,404	7,144	100.0	0.405
Total		1,604,356	1,583,229	1,582,878	1,582,878	6,404	6,404	7,144	100.0	0.405

- (a) Region as defined in the programme of the Member State.
- (b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
- (c) Includes animals tested individually or under bulk level scheme.
- (d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance: milk bulk tank tests).
- (e) Include all positive animal slaughtered and also the negative animals slaughtered under the programme.

6.1.2. Data on animals (one table per year and per disease/species)

Year: 2009

Region ^(a)	Animal species	Total number of animals ^(b)	Number of animals ^(d) to be tested under the programme	Number of animals ^(c) tested	Number of animals tested individually ^(d)	Number of positive animals	Slaughtering		INDICATORS	
							Number of animals with positive result slaughtered or culled	Total number of animals slaughtered ^(e)	% coverage at animal level	% positive animals Animal prevalence
1	2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
N.Ireland	Bovine	1,612,813	1,599,025	1,601,500	1,601,500	8,198	8,198	8,905	100.2	0.512
Total		1,612,813	1,599,025	1,601,500	1,601,500	8,198	8,198	8,905	100.2	0.512

- (a) Region as defined in the programme of the Member State.
- (b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
- (c) Includes animals tested individually or under bulk level scheme.
- (d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance: milk bulk tank tests).
- (e) Include all positive animal slaughtered and also the negative animals slaughtered under the programme.

6.1.2. Data on animals (one table per year and per disease/species)

Year: 2007

Region ^(a)	Animal species	Total number of animals ^(b)	Number of animals ^(d) to be tested under the programme	Number of animals ^(c) tested	Number of animals tested individually ^(d)	Number of positive animals	Slaughtering		INDICATORS	
							Number of animals with positive result slaughtered or culled	Total number of animals slaughtered ^(e)	% coverage at animal level	% positive animals Animal prevalence
1	2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
N.Ireland	Bovine	1,643,458	1,464,025	1,640,552	1,640,552	7,299	7,299	7,888	112.1	0.45
Total		1,643,458	1,464,025	1,640,552	1,640,552	7,299	7,299	7,888	112.1	0.45

- (a) Region as defined in the programme of the Member State.
- (b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
- (c) Includes animals tested individually or under bulk level scheme.
- (d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance: milk bulk tank tests).
- (e) Include all positive animal slaughtered and also the negative animals slaughtered under the programme.

6.2. Stratified data on surveillance and laboratory tests

6.2.1. Stratified data on surveillance and laboratory tests

Year: 2011

Region ^(a)	Animal species/ category	Test type ^(b)	Description of test	Number of samples tested	Number of positive samples
N.Ireland	Bovine	Serological	Gamma interferon assay	17,123	854
	Bovine	Microbiological	Lowenstein – Jensen and Stonebrinks solid culture media and Bactec MGIT 960 liquid culture system. Molecular confirmation of culture by spoligotype	2,700	642
Total				19,823	1,496

(a) Region as defined in the programme of the Member State.

(b) Indicate whether the test is serological, virological etc.

6.2.1. *Stratified data on surveillance and laboratory tests*

Year: 2010

Region ^(a)	Animal species/ category	Test type ^(b)	Description of test	Number of samples tested	Number of positive samples
N.Ireland	Bovine	Serological	Gamma interferon assay	13,520	661
	Bovine	Microbiological	Lowenstein – Jensen and Stonebrinks solid culture media and Bactec MGIT 960 liquid culture system. Molecular confirmation of culture by spoligotype	3,887	751
	Bovine	Other	VNTR	781	742
Total				18,188	2,154

- (a) Region as defined in the programme of the Member State.
 (b) Indicate whether the test is serological, virological etc.

6.2.1. *Stratified data on surveillance and laboratory tests*

Year: 2009

Region ^(a)	Animal species/ category	Test type ^(b)	Description of test	Number of samples tested	Number of positive samples
N.Ireland	Bovine	Serological	Gamma interferon assay	14,657	1,279
	Bovine	Microbiological	Lowenstein – Jensen and Stonebrinks solid culture media and Bactec MGIT 960 liquid culture system. Molecular confirmation of culture by spoligotype	6,234	992
	Bovine	Other	VNTR	992	977
Total				21,883	3,248

- (a) Region as defined in the programme of the Member State.
 (b) Indicate whether the test is serological, virological etc.

6.2.1. *Stratified data on surveillance and laboratory tests*

Year: 2008

Region ^(a)	Animal species/ category	Test type ^(b)	Description of test	Number of samples tested	Number of positive samples
N.Ireland	Bovine	Serological	Gamma interferon assay	13,956	805
	Bovine	Microbiological	Lowenstein – Jensen and Stonebrinks solid culture media and Bactec MGIT 960 liquid culture system. Molecular confirmation of culture by spoligotype	3,286	928
	Bovine	Other	VNTR	2,780	2,752
	Bovine	Other	Histology	3,132	2,635
Total				23,154	7,120

- (a) Region as defined in the programme of the Member State.
(b) Indicate whether the test is serological, virological etc.

6.2.1. *Stratified data on surveillance and laboratory tests*

Year: 2007

Region ^(a)	Animal species/ category	Test type ^(b)	Description of test	Number of samples tested	Number of positive samples
N.Ireland	Bovine	Serological	Gamma interferon assay	8,513	653
	Bovine	Microbiological	Lowenstein – Jensen and Stonebrinks solid culture media and Bactec MGIT 960 liquid culture system. Molecular confirmation of culture by spoligotype	2,953	946
	Bovine	Other	VNTR	2,624	2,598
	Bovine	Other	Histology	2,896	2,539
Total				16,986	6,736

- (a) Region as defined in the programme of the Member State.
 (b) Indicate whether the test is serological, virological etc.

6.3. Data on infection (one table per year)

Year: 2011

Region ^(a)	Animal species	Number of herds infected ^(b)	Number of animals infected
N.Ireland	Bovine	1,390	4,425
Total		1,390	4,425

- (a) Region as defined in the programme of the Member State.
- (b) Herds or flocks or holdings as appropriate.

6.3. Data on infection (one table per year)

Year: 2010

Region ^(a)	Animal species	Number of herds infected ^(b)	Number of animals infected
N.Ireland	Bovine	1,229	3,393
Total		1,229	3,393

- (a) Region as defined in the programme of the Member State.
(b) Herds or flocks or holdings as appropriate.

6.3. Data on infection (one table per year)

Year: 2009

Region ^(a)	Animal species	Number of herds infected ^(b)	Number of animals infected
N.Ireland	Bovine	1,346	3,972
Total		1,346	3,972

- (a) Region as defined in the programme of the Member State.
- (b) Herds or flocks or holdings as appropriate.

6.3. Data on infection (one table per year)

Year: 2008

Region ^(a)	Animal species	Number of herds infected ^(b)	Number of animals infected
N.Ireland	Bovine	1,866	3,936
Total		1,866	3,936

- (a) Region as defined in the programme of the Member State.
- (b) Herds or flocks or holdings as appropriate.

6.3. Data on infection (one table per year)

Year: 2007

Region ^(a)	Animal species	Number of herds infected ^(b)	Number of animals infected
N.Ireland	Bovine	1,990	3,899
Total		1,990	3,899

- (a) Region as defined in the programme of the Member State.
- (b) Herds or flocks or holdings as appropriate.

6.4. Data on the status of herds at the end of each year⁶⁷

Year: 2011

Region ^(a)	Animal species	Status of herds and animals under the programme ^(b)													
		Total number of herds and animals under the programme		Unknown ^(c)		Not free or not officially free from disease				Free or officially free from disease status suspended ^(f)		Free from disease ^(g)		Officially free from disease ^(h)	
						Last check positive ^(d)		Last check negative ^(e)							
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾
N.Ireland	Bovine	25,677	1,565,646	0	0	509	88,022	838	89,656	1,573	133,706	n/a	n/a	22,757	1,254,262
Total		25,677	1,565,646	0	0	509	88,022	838	89,656	1,573	133,706	n/a	n/a	22,757	1,254,262

- (a) Region as defined in the programme of the Member State
(b) At the end of the year
(c) Unknown: No previous checking results available
(d) Not free and last check positive: Herd checked with at least one positive result in the latest check
(e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*
(f) Suspended as defined in Union or national legislation for the respective disease at the end of the reporting period.
(g) Free herd as defined in Union or national legislation for the respective disease.
(h) Officially free herd as defined in Union or national legislation for the respective disease .
(i) Include animals under the programme in the herds with the referred status (left column).

⁶⁷ Only data to provide for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (*B. melitensis*).

6.4. Data on the status of herds at the end of each year⁶⁸

Year: 2010

Region ^(a)	Animal species	Status of herds and animals under the programme ^(b)													
		Total number of herds and animals under the programme		Unknown ^(c)		Not free or not officially free from disease				Free or officially free from disease status suspended ^(f)		Free from disease ^(g)		Officially free from disease ^(h)	
						Last check positive ^(d)		Last check negative ^(e)							
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾
N.Ireland	Bovine	25,933	1,583,229	0	0	245	59,274	741	90,811	1,872	148,740	n/a	n/a	23,075	1,284,404
Total		25,933	1,583,229	0	0	245	59,274	741	90,811	1,872	148,740	n/a	n/a	23,075	1,284,404

- (a) Region as defined in the programme of the Member State
(b) At the end of the year
(c) Unknown: No previous checking results available
(d) Not free and last check positive: Herd checked with at least one positive result in the latest check
(e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*
(f) Suspended as defined in Union or national legislation for the respective disease at the end of the reporting period.
(g) Free herd as defined in Union or national legislation for the respective disease.
(h) Officially free herd as defined in Union or national legislation for the respective disease .
(i) Include animals under the programme in the herds with the referred status (left column).

⁶⁸ Only data to provide for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (*B. melitensis*).

6.4. Data on the status of herds at the end of each year⁶⁹

Year: 2009

Region ^(a)	Animal species	Status of herds and animals under the programme ^(b)													
		Total number of herds and animals under the programme		Unknown ^(c)		Not free or not officially free from disease				Free or officially free from disease status suspended ^(f)		Free from disease ^(g)		Officially free from disease ^(h)	
						Last check positive ^(d)		Last check negative ^(e)							
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾
N.Ireland	Bovine	26,287	1,599,025	0	0	412	78,238	673	76,759	1,985	174,685	n/a	n/a	23,201	1,269,343
Total		26,287	1,599,025	0	0	412	78,238	673	76,759	1,985	174,685	n/a	n/a	23,201	1,269,343

- (a) Region as defined in the programme of the Member State
(b) At the end of the year
(c) Unknown: No previous checking results available
(d) Not free and last check positive: Herd checked with at least one positive result in the latest check
(e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*
(f) Suspended as defined in Union or national legislation for the respective disease at the end of the reporting period.
(g) Free herd as defined in Union or national legislation for the respective disease.
(h) Officially free herd as defined in Union or national legislation for the respective disease .
(i) Include animals under the programme in the herds with the referred status (left column).

⁶⁹ Only data to provide for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (B. melitensis).

6.4. Data on the status of herds at the end of each year⁷⁰

Year: 2008

Region ^(a)	Animal species	Status of herds and animals under the programme ^(b)													
		Total number of herds and animals under the programme		Unknown ^(c)		Not free or not officially free from disease				Free or officially free from disease status suspended ^(f)		Free from disease ^(g)		Officially free from disease ^(h)	
						Last check positive ^(d)		Last check negative ^(e)							
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾
N.Ireland	Bovine	26,780	1,647,300	0	0	344	60,193	771	86,570	2,087	167,387	n/a	n/a	23,578	1,333,150
Total		26,780	1,647,300	0	0	344	60,193	771	86,570	2,087	167,387	n/a	n/a	23,578	1,333,150

- (a) Region as defined in the programme of the Member State
(b) At the end of the year
(c) Unknown: No previous checking results available
(d) Not free and last check positive: Herd checked with at least one positive result in the latest check
(e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*
(f) Suspended as defined in Union or national legislation for the respective disease at the end of the reporting period.
(g) Free herd as defined in Union or national legislation for the respective disease.
(h) Officially free herd as defined in Union or national legislation for the respective disease .
(i) Include animals under the programme in the herds with the referred status (left column).

⁷⁰ Only data to provide for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (*B. melitensis*).

6.4. Data on the status of herds at the end of each year⁷¹

Year: 2007

Region ^(a)	Animal species	Status of herds and animals under the programme ^(b)													
		Total number of herds and animals under the programme		Unknown ^(c)		Not free or not officially free from disease				Free or officially free from disease status suspended ^(f)		Free from disease ^(g)		Officially free from disease ^(h)	
						Last check positive ^(d)		Last check negative ^(e)							
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾
N.Ireland	Bovine	26,915	1,464,025	0	0	356	54,722	811	87,801	1,932	158,622	n/a	n/a	23,816	1,163,580
Total		26,915	1,464,025	0	0	356	54,722	811	87,801	1,932	158,622	n/a	n/a	23,816	1,163,580

- (a) Region as defined in the programme of the Member State
(b) At the end of the year
(c) Unknown: No previous checking results available
(d) Not free and last check positive: Herd checked with at least one positive result in the latest check
(e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*
(f) Suspended as defined in Union or national legislation for the respective disease at the end of the reporting period.
(g) Free herd as defined in Union or national legislation for the respective disease.
(h) Officially free herd as defined in Union or national legislation for the respective disease .
(i) Include animals under the programme in the herds with the referred status (left column).

⁷¹ Only data to provide for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (*B. melitensis*).

6.5. Data on vaccination or treatment programmes⁷² NOT APPLICABLE

Year:

Region ^(a)	Animal species	Total number of herds ^(b)	Total number of animals	Information on vaccination or treatment programme					
				Number of herds ^(c) in vaccination or treatment programme	Number of herds ^(c) vaccinated or treated	Number of animals vaccinated or treated	Number of doses of vaccine or treatment administered	Number of adults vaccinated	Number of young animals vaccinated
Total									

- (a) Region as defined in the programme of the Member State
- (b) Herds or flocks or holdings as appropriate

⁷² Data to provide only if vaccination has been carried out.

6.6. Data on wildlife⁷³

6.6.1. Estimation of wildlife population

Year: 2005-2009

Regions ^(a)	Animal species	Method of estimation	Estimated population
N.Ireland	Badger <i>Meles meles</i>	Scientific field survey and analysis 07/08	33,500 (95%CI 26-41.2k)
Total			

(a) Region as defined in the programme of the Member State

⁷³ Data only to provide in case the programme comprises measures as regards wildlife or if the data are epidemiologically relevant for the disease.

6.6.2. Disease surveillance and other tests in wildlife (one table per year)

Year: 2011

Region ^(a)	Animal Species	Test type ^(b)	Test description	Number of samples tested	Number of positive samples
N. Ireland	Badger <i>Meles meles</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	728	44
	Badger <i>Meles meles</i>	Other	Histology	41	11
	Badger <i>Meles meles</i>	Other	Post mortem	148	19
	Wild Deer	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	0	0
	Wild Deer	Other	Histology	0	0
	Wild Deer	Other	Spoligo typing	0	0
	Otter <i>Lutra lutra</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	0	0
	Otter <i>Lutra lutra</i>	Other	VNTR	0	0
Total				917	74

(a) Region as defined in the programme of the Member State

(b) Indicate whether the test is serological, virological, biomarker detection etc.

6.6.2. Disease surveillance and other tests in wildlife (one table per year)

Year: 2010

Region ^(a)	Animal Species	Test type ^(b)	Test description	Number of samples tested	Number of positive samples
N. Ireland	Badger <i>Meles meles</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	501	19
	Badger <i>Meles meles</i>	Other	Histology	17	0
	Badger <i>Meles meles</i>	Other	Spoligo typing	35	19
	Badger <i>Meles meles</i>	Other	Post mortem	101	10
	Wild Deer	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	2	0
	Wild Deer	Other	Histology	0	0
	Wild Deer	Other	Spoligo typing	0	0
	Otter <i>Lutra lutra</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	2	0
	Otter <i>Lutra lutra</i>	Other	VNTR	0	0
Total				658	48

- (a) Region as defined in the programme of the Member State
 (b) Indicate whether the test is serological, virological, biomarker detection etc.

6.6.2. Disease surveillance and other tests in wildlife (one table per year)

Year: 2009

Region ^(a)	Animal Species	Test type ^(b)	Test description	Number of samples tested	Number of positive samples
N. Ireland	Badger <i>Meles meles</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	530	13
	Badger <i>Meles meles</i>	Other	Histology	11	0
	Badger <i>Meles meles</i>	Other	Spoligo typing	13	11
	Badger <i>Meles meles</i>	Other	Post mortem	102	0
	Wild Deer	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	451	5
	Wild Deer	Other	Histology	5	3
	Wild Deer	Other	Spoligo typing	5	4
	Otter <i>Lutra lutra</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	0	0
	Otter <i>Lutra lutra</i>	Other	VNTR	0	0
Total				1,117	36

- (a) Region as defined in the programme of the Member State
 (b) Indicate whether the test is serological, virological, biomarker detection etc.

6.6.2. Disease surveillance and other tests in wildlife (one table per year)

Year: 2008

Region ^(a)	Animal Species	Test type ^(b)	Test description	Number of samples tested	Number of positive samples
N. Ireland	Badger <i>Meles meles</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	540	31
	Badger <i>Meles meles</i>	Other	Histology	4	2
	Badger <i>Meles meles</i>	Other	Spoligo typing	31	31
	Badger <i>Meles meles</i>	Other	Post mortem	100	14
	Wild Deer	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	0	0
	Wild Deer	Other	Histology	0	0
	Wild Deer	Other	Spoligo typing	0	0
	Otter <i>Lutra lutra</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	4	2
	Otter <i>Lutra lutra</i>	Other	VNTR	2	2
Total				681	82

- (a) Region as defined in the programme of the Member State
(b) Indicate whether the test is serological, virological, biomarker detection etc.

6.6.2. Disease surveillance and other tests in wildlife (one table per year)

Year: 2007

Region ^(a)	Animal Species	Test type ^(b)	Test description	Number of samples tested	Number of positive samples
N. Ireland	Badger <i>Meles meles</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	363	12
	Badger <i>Meles meles</i>	Other	Histology	0	0
	Badger <i>Meles meles</i>	Other	Spoligo typing	10	10
	Badger <i>Meles meles</i>	Other	Post mortem	70	10
	Wild Deer	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	0	0
	Wild Deer	Other	Histology	0	0
	Wild Deer	Other	Spoligo typing	0	0
	Otter <i>Lutra lutra</i>	Microbiological	Lowenstein – Jensen culture media and Bactec MGIT 960 system. Molecular confirmation of culture positive samples	0	0
	Otter <i>Lutra lutra</i>	Other	VNTR	0	0
Total				443	32

- (a) Region as defined in the programme of the Member State
 (b) Indicate whether the test is serological, virological, biomarker detection etc.

6.6.3. *Data on vaccination or treatment of wildlife NOT APPLICABLE*

Year:

Region ^(a)	Square km	Vaccination or treatment programme		
		Number of doses of vaccine or treatment to be administered	Number of campaigns	Total number of doses of vaccine or treatment administered
Total				

(a) Region as defined in the programme of the Member State

7. Targets

7.1. Targets related to testing (one table for each year of implementation⁷⁴)

7.1.1. *Targets on diagnostic tests*

Region ^(a)	Type of the test ^(b)	Target population ^(c)	Type of sample ^(d)	Objective ^(e)	Number of planned tests
N.Ireland	Tuberculin skin test	All bovines		Surveillance	2,365,000
	Gamma Interferon Assay	Bovines	Heparinised blood	Surveillance	18,000
	Bacteriological	Herds where disease not confirmed	Tissue	Surveillance	4,749
	Histopathology	Herds where disease not confirmed	Tissue	Surveillance	3,535
Total					2,391,284

- (a) Region as defined in the programme of the Member State
- (b) Description of the test (for instance SN-test, AB-Elisa, RBT,)
- (c) Specification of the targeted species and the categories of targeted animals (for instance sex, age, breeding animal, slaughter animal, ...).
- (d) Description of the sample (for instance blood, serum, milk,)
- (e) Description of the objective (for instance qualification, surveillance, confirmation of suspected cases, monitoring of campaigns, seroconversion, control on deleted vaccines, testing of vaccine, control of vaccination,)

⁷⁴

For subsequent years of approved multiannual programmes only one table for the relevant year should be filled in.

7.1.2. *Targets on testing herds and animals*⁷⁵

7.1.2.1 Targets on the testing of herds^(a)

Region ^(b)	Animal species	Total number of herds ^(c)	Total number of herds under the programme	Number of herds expected to be checked ^(d)	Number of expected positive herds ^(e)	Number of expected new positive herds ^(f)	Number of herds expected to be depopulated	% positive herds expected to be depopulated	TARGET INDICATORS		
									Expected % herd coverage	% positive herds Expected period herd prevalence	% new positive herds Expected herd incidence
1	2	3	4	5	6	7	8	9 = (8/6)x100	10 = (5/4)x100	11 = (6/5)x100	12 = (7/5)x100
N.Ireland	Bovine	25,500	25,500	23,595	1903	1593	15	0.8	91	8.0	6.75
Total		25,500	25,500	23,595	1903	1593	15	0.8	91	8.0	6.75

- (a) Herds or flocks, or holdings as appropriate.
- (b) Region as defined in the programme of the Member State.
- (c) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.
- (d) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining, upgrading, etc., the health status of the herd. In this column a herd must not be counted twice even if it has been checked more than once.
- (e) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.
- (f) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free* or *Suspended* and have at least one positive animal in this period.
- (g) The denominator in 'expected % herd coverage' is taken as the number of herds with at least 1 TB herd test in the last 4 years to ensure we capture all cattle herds. As the number of cattle herds are declining, this method gives an overestimate of the number of actual cattle herds that are in operation.

⁷⁵ Data not to provide in case of rabies.

7.1.2.2. Targets on the testing of animals

Region ^(a)	Animal species	Total number of animals ^(b)	Number of animals ^(c) under the programme	Number of animals ^(c) expected to be tested	Number of animals to be tested individually ^(d)	Number of expected positive animals	Slaughtering		TARGET INDICATORS	
							Number of animals with positive result expected to be slaughtered or culled	Total number of animals expected to be slaughtered ^(e)	Expected % coverage at animal level	% positive animals (Expected animal prevalence)
1	2	3	4	5	6	7	8	9	10=(5/4)x100	11=(7/5)x100
N.Ireland	Bovine	1,600,000	1,585,000	1,585,000	1,585,000	9,356	9,356	9,856	100	0.59
		1,600,000	1,585,000	1,585,000	1,585,000	9,356	9,356	9,856	100	0.59

- (a) Region as defined in the programme of the Member State.
- (b) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
- (c) Includes animals tested individually or under bulk level scheme.
- (d) Include only animals tested individually, do not include animals tested by bulk level samples (for instance milk bulk tank tests).
- (e) Include all positive animals slaughtered and also the negative animals slaughtered under the programme.

7.2. Targets on qualification of herds and animals (one table for each year of implementation)

Region ^(a)	Animal species	Total number of herds and animals under the programme		Targets on the status of herds and animals under the programme ^(b)											
				Expected unknown ^(c)		Expected not free or not officially free from disease				Expected free or officially free from disease status suspended ^(f)		Expected free from disease ^(g)		Expected officially free from disease ^(h)	
		Last check positive ^(d)				Last check negative ^(e)									
		Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾	Herds	Animals ⁽ⁱ⁾
N.Ireland	Bovine	25,500	1,600,000	0	0	364	22,204	936	57,096	1,300	79,300	23,400	1,441,400	23,400	1,441,400
Total		25,500	1,600,000	0	0	364	22,204	936	57,096	1,300	79,300	23,400	1,441,400	23,400	1,441,400

- (a) Region as defined in the programme of the Member State
(b) At the end of the year
(c) Unknown: No previous checking results available
(d) Not free and last check positive: Herd checked with at least one positive result in the latest check
(e) Not free and last check negative: Herd checked with negative results in the latest check but not being *Free* or *Officially Free*
(f) Suspended as defined for the respective disease in Union or national legislation where appropriate or according national legislation.
(g) Free herd as defined for the respective disease where appropriate in Union or national legislation where appropriate or according national legislation
(h) Officially free herd as defined for the respective disease where appropriate in Union or national legislation where appropriate or according national legislation
(i) Include animals under the programme in the herds with the referred status (left column)

7.3. Targets on vaccination or treatment (one table for each year of implementation) NOT APPLICABLE

7.3.1. Targets on vaccination or treatment⁷⁶

Region ^(a)	Animal species	Total number of herds ^(b) in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Targets on vaccination or treatment programme					
				Number of herds ^(b) in vaccination or treatment programme	Number of herds ^(b) expected to be vaccinated or treated	Number of animals expected to be vaccinated or treated	Number of doses of vaccine or treatment expected to be administered	Number of adults ^(c) expected to be vaccinated	Number of young ^(c) animals expected to be vaccinated
Total									

(a) Region as defined in the programme of the Member State

(b) Herds or flocks or holdings as appropriate

(c) Only for Bovine brucellosis and Ovine, Caprine brucellosis (*B. melitensis*) as defined in the programme

⁷⁶ Data to provide only if appropriate .

7.3.2. *Targets on vaccination or treatment⁷⁷ of wildlife NOT APPLICABLE*

Region ^(a)	Animal species	Square km	Targets on the vaccination or treatment programme		
			Number of doses of vaccine or treatments expected to be administered in the campaign	Expected number of campaigns	Total number of doses of vaccine or treatment expected to be administered
Total					

(a) Region as defined in the programme of the Member State

⁷⁷ Data to provide only if appropriate.

8. **Detailed analysis of the cost of the programme (one table per year of implementation⁷⁸)**

<u>Costs related to</u>	<u>Specification/Unit</u>	<u>Unit⁷⁹</u>	<u>Number of units</u>	<u>Unitary cost in €</u>	<u>Total amount in €</u>	<u>Union funding requested (yes/no)</u>
<u>1. Testing</u>						
<u>1.1. Cost of sampling</u>						
	Domestic animals					
	Wild animals					
<u>1.2 Cost of the analysis</u>						
- Brucellosis and Tuberculosis programmes	Rose Bengal test					
	SAT					
	Complement fixation test					
	ELISA test					
	Tuberculin test (by Private Veterinary Practitioner)	<u>Test</u>	<u>1,850,000</u>	£3.57	<u>£6,604,500</u>	<u>Yes</u>
	Tuberculin test (by Government staff –	<u>Test</u>	<u>515,000</u>	£2.86	<u>£1,472,900</u>	<u>Yes</u>

⁷⁸

For subsequent years of approved multiannual programmes only one table for the relevant year should be filled in.

⁷⁹

Specify the unit to which the data in the following two columns is referring to (e.g. sample, test, animal sampled etc).

	TVO/VOT)					
	Gamma-interferon test	<u>Test</u>	<u>18,000</u>	£19.37	<u>£348,660</u>	<u>Yes</u>
	Bacteriological test	<u>Test</u>	<u>4,749</u>	£144	<u>£683,856</u>	<u>Yes</u>
	<u>Other</u> (please specify)					
	<u>Histopathology</u>	<u>Test</u>	<u>3,535</u>	<u>£20</u>	<u>£70,700</u>	<u>No</u>
- ASF, CSF, SVD & Bluetongue programmes	ELISA test					
	PCR test					
	Virological test					
	Seroneutralisation test (only for SVD)					
	Entomological surveillance test (only for Bluetongue)					
	<u>Other</u> (please specify)					
- Rabies programmes	Serological test					
	Detection of Tetracycline in bone test					
	Fluorescent antibody test					

	Other (please specify)					
1.3. Other costs						
	Purchase of traps (for Bluetongue)					
	Other (please specify)					
<u>2. Vaccination or treatment</u>						
<u>2.1. Purchase of vaccine/treatment</u>						
- Brucellosis programmes	Domestic animal vaccinated					
- Bluetongue programmes	Domestic animal vaccinated					
- Rabies programmes	Oral vaccine dose + bait					
	Parenteral vaccine dose					
<u>- Classical swine fever programmes</u>	Oral vaccine dose + bait					

<u>2.2. Administering/Distribution costs</u>						
Administering in domestic animals						
<u>- Distribution for wild animals (please specify the type of distribution)</u>						
<u>2.3. Control costs</u>						
<u>2.4. Others (please specify)</u>						
<u>3. Slaughter and destruction</u>						
<u>3.1. Compensation of animals</u>		<u>Compensation for animals valued and slaughtered</u>	<u>9,856</u>	<u>£1,365</u>	<u>£13,453,440</u>	<u>Yes</u>
<u>3.2. Transport costs</u>		<u>Animals transported to slaughter</u>	<u>9,856</u>	<u>£8.50</u>	<u>£83,776</u>	<u>No</u>
<u>3.3. Destruction costs</u>						
<u>3.4. Loss in case of slaughtering</u>						

<u>3.5 Costs from treatment of products (milk, or others –please specify)</u>						
<u>4. Cleaning and disinfection</u>						

<u>5. Salaries (staff contracted for the programme only)</u>		<u>Staff</u>	<u>Not applicable</u>	<u>Not applicable</u>	<u>£4,700,000</u>	<u>No</u>
<u>6. Consumables and specific equipment</u>						
<u>Tuberculin</u>		<u>Litres of tuberculin (300 litres avian + 300 litres bovine)</u>	<u>600</u>	<u>£934.57</u>	<u>£560,742</u>	<u>Yes</u>
<u>7. Other costs</u>						
<u>Salvage</u>		<u>Payment for animal carcasses</u>	<u>9,856</u>	<u>-£142</u>	<u>-£1,399,552</u>	<u>Yes</u>
<u>DARD Funded Research</u>		<u>Research</u>	<u>Not applicable</u>	<u>Not applicable</u>	<u>£327,681</u>	<u>No</u>
	<u>TOTAL</u>				<u>£26,906,703</u>	

ANNEX IV - SCOTLAND ANNEX

In 2009, Scotland was designated an officially TB free (OTF) region of the UK (Commission Decision 2009/761/EC). To further protect the OTF status of Scotland, additional TB testing requirements have been in place since 28 February 2010 for cattle entering Scotland from low TB incidence areas of England. A more detailed history of the evolution of TB epidemiology and policy can be found in the 2010 UK(GB) Eradication Plan.