



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Unit 04 - Veterinary Control Programmes

SANCO/12867/2010

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

## **Eradication programme of Bovine Tuberculosis**

**Approved\* for 2011 by Commission Decision 2010/712/EU**

**Ireland**

\* in accordance with Council Decision 2009/470/EC

## 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)<sup>1</sup>

#### 1. Identification of the programme

Member State: Ireland

Disease(s)<sup>2</sup>: Bovine Tuberculosis

Request of Community co-financing for<sup>3</sup>: 2011

Reference of this document: TB Programme 2011:

Contact (name, phone, fax, e-mail): Mr. Richard Healy, Principal Officer, E-mail: [Richard.healy@agriculture.gov.ie](mailto:Richard.healy@agriculture.gov.ie)

Tel (01) 5058738, Fax (01) 01 6012783

Date sent to the Commission: xx April 2010

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- 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

## 2. Historical data on the epidemiological evolution of the disease(s)<sup>4</sup>:

### 2.1 General Background

A scheme for the eradication of bovine tuberculosis in cattle commenced in Ireland in 1954. The scheme rapidly reduced the animal disease incidence from 17% overall to less than 0.5% in 1965. By 1965 all herds had individually at some stage over the previous 11 years achieved Officially Tuberculosis Free (OTF) status in accordance with Directive 609/432/EEC and no herds of unknown status remained in Ireland. This remains the position. The animal disease incidence has fluctuated between 0.3% and 0.6% since 1965. During the period 2001 to date, the level of animal disease incidence has remained consistently below 0.5% and was 0.4% in 2009. The main factors affecting the disease levels in the early stages of the programme were the continuing expansion of the national herd and latterly it has been realised that the primary constraint to eradication is the reservoir of the disease endemic in a wildlife host sharing the pasturage area. Consistent efforts to achieve a sustained reduction are on going and the measures included in the 2011 programme have the objective of reducing and eradicating the disease.

#### 1954-1965

Prior to 1954, an estimated 80% of cattle herds and 17% of animals in Ireland were infected with TB. Individual herd registration and a herd numbering system commenced in the mid-1950s to facilitate the administration and management of disease eradication programmes. It was decided that an individual herd represented a single epidemiological unit, i.e. the animals, regardless of ownership, which are for the time being on a particular farm unit shall be regarded as a herd, and, in case only one animal is for the time being on a particular unit, the animal shall be regarded as being a herd. Intermixing of one herd with other herds was not permitted. This position has been maintained to the present time.

A voluntary scheme for the eradication of bovine tuberculosis in cattle commenced in September 1954, initially in counties Sligo and Clare. The scheme was gradually extended to other areas and intensified from 1958 onwards, and was given a statutory basis Diseases of Animals (Bovine Tuberculosis) Act, 1957. The scheme was prompted by the desire to preserve trade but also by concerns about reduced animal productivity and worries about human infection from the heavily infected animal population. The measures included provision for the identification and declaration of areas in which bovine tuberculosis is to be eradicated, testing in those areas, removal and slaughter of reactors and the provision of compensation to farmers. In the early years of the programme very rapid and significant progress was made with large numbers of reactors being removed. Between 1959 and 1962, 120,000 to 160,000 reactor animals per annum were removed as part of the eradication programme. By 1965 the scheme succeeded in

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<sup>4</sup> A concise description is given with data on the target population (species, number of herds and animals present and under the programme), the main measures (testing, testing and slaughter, testing and killing, qualification of herds and animals, vaccination) 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, graphs or maps.

reducing the tuberculin reactor rate to about 0.5%. (see Table page 11).

#### 1965-1988

While substantial progress had been made 1954-1965, approximately 20 - 40,000 reactors per annum continued to be identified from 1965 onwards (see Table page 11). The measures were substantially the same as those used in 1954-1965 period though now extended to the whole country. The legislation was consolidated and enhanced under The Diseases of Animals Act 1966.

#### 1988-1992

In April 1988, a new initiative, ERAD, the Eradication of Animal Disease Board, was established by the Irish Government as a specialised agency to implement a vigorous four-year TB eradication programme. ERAD was an executive agency of the Department of Agriculture, Fisheries and Food with a Board representative of the various interests, such as farmers and veterinarians, involved in TB eradication. ERAD was further mandated to implement the recommendations made by a number of bodies which had reviewed the bovine TB eradication programme in the previous number of years and had formed views as to why the test and cull programme as operated had not succeeded in eradicating tuberculosis. In summary the view expressed by these bodies was that Ireland would succeed in eradicating TB as had been achieved in other countries in Europe if testing were done sufficiently stringently, for a sufficiently long enough time, including pre-movement testing, and if increased frequency of testing in high incidence areas, severe interpretation, rapid removal of reactors and herd depopulation were implemented. The measures implemented by the ERAD Board therefore included all of these measures: pre-movement testing, a comprehensive testing programme using a more potent tuberculin (30,000 I.U./ml) and a more severe interpretation than that required by Directive 64/432/EEC, both at individual herd, including full herd depopulation, and at area based level. The ERAD programme also incorporated a very considerable strategic component that involved additional and more frequent testing of administrative/focal 'black spot' geographic areas with perceived higher disease prevalence (twice/annum), known high-risk herds, contiguous herds, herds that were linked epidemiologically and also extended herd-restriction (a 3<sup>rd</sup> clear herd level test before status restoration). Herds were also risk-categorised according to disease incidence, with a specific strategy applied to each category. The ERAD programme resulted in just over 44 million tests being completed and 151,000 reactors being removed over the four-year period from a population of some 6.9 million animals. This was a 50% higher reactor extraction rate than under previous programmes. During this period the badger came to be suspected as a reservoir species responsible for the maintenance of bovine TB in Ireland. Investigations into their contribution commenced in the mid 1980s with a number of small-scale field investigations, including those in Counties Galway and Cork that led to the establishment of the East Offaly project in 1989 investigating the extent of the role of badgers.

The main conclusion drawn from the IIRAD Board programme was that the additional measures introduced in the period concerned were extremely costly but had not contributed significantly to progression towards disease eradication. It was evident that eradication would be much more protracted than had been originally envisaged, that special emphasis needed to be placed on the development of technological tools, that infection in badgers, in particular, was a significant constraint to progress and that a programme to firstly contain, then systematically and progressively reduce the disease should be pursued while the technological tools required for eradication, including a vaccine for badgers which is not currently available, were in development. In 1992, authority for determining policy and strategy and for managing the disease programme was again assumed by the Minister for Agriculture, Fisheries and Food.

#### 1992-2009

The TB eradication programme has been operated by the Department of Agriculture, Fisheries and Food since 1992 when the responsibility for managing the disease programme was transferred back to the Minister for Agriculture, Fisheries and Food. Since this time the results of the East Offaly and Four Area Badger Projects have become available and have been peer reviewed and published in the scientific literature. These projects have demonstrated that a marked reduction in the levels of tuberculosis and a significant reduction in the risk of a herd experiencing a TB breakdown was observed when the local badger population was maintained at a low level. The number of reactors has fallen steadily since 1998, but with some annual fluctuations evident.

An interim wildlife control strategy is in place where badger capturing and removal takes place in areas associated with bovine herd TB breakdowns. The selected areas are subject to continuing surveillance and capture whilst we await the outcome of concurrent vaccine development programme. The area subject to capture is added to each year, in accordance with terms of an agreement with the appropriate licensing authority (the badger is a protected species subject to conservation under the terms of the Berne Convention). The scale of government intervention in relation to the wildlife reservoir increased significantly following the Social Partnership Agreement of 2000 (Programme for Prosperity and Fairness). Under the terms of this agreement, a number of specific measures were put in place. Since 2004, badger capture is concentrated on those areas that yielded some 70% of all standard reactors (cattle) to the tuberculin test. Badger capture is limited and under current agreements will not exceed an area greater than 30% of agricultural land in Ireland. This agreement may be re-negotiated during 2010 as it is likely that the 30% threshold will be exceeded before the end of 2011 and the results of the badger vaccination trial will not yet be available.

The development and implementation of a vaccine strategy for use in badgers in Ireland is a key component of the strategy to eradicate bovine tuberculosis. There is no such vaccine with (or without) proven efficacy available anywhere in the world suitable for mass delivery to a wildlife population. However, the expectation is that, if an efficacious vaccine is developed and badger vaccination is successful in preventing disease transmission between badgers and subsequently between badgers and cattle, the

existing comprehensive control and surveillance programme for cattle will then be capable of bringing about eradication considering that intradermal tuberculin tests and programmes of far less sophistication than that used in Ireland have proven themselves to be adequate to permit the eradication of bovine tuberculosis in a number of Continental European countries, without the need for ancillary blood-based tests or sophisticated computer, laboratory and GIS tools. Work to date is showing promising results: a suitable candidate vaccine has been identified and efficacy following oral delivery has been demonstrated in a laboratory environment. Results of this work are peer-reviewed and published on a regular basis. As part of the next stage of the process, a field trial on oral delivered vaccine commenced in autumn 2008. Under the first stage of this trial, the badger population in the targeted area was captured, counted, identified and sampled to determine the badger population density and TB prevalence to optimise the trial area. Under a capture and release strategy, the first vaccine delivery (oral) to badgers in a natural environment commenced in Autumn 2009 and the trial involving badger vaccination will continue for three to four years. The objective of the field vaccination trial is to provide information as to the efficacy of this oral vaccine in reducing the level of TB infection in the badger population under study. The field trial represents the first use of a wildlife vaccine, albeit in a limited way, in the Irish eradication programme. If the field trial is successful, the introduction of a national badger vaccination strategy will reduce the need to remove TB infected badgers as tuberculosis levels fall in both cattle and badgers. However, it will be some time before the benefits of the vaccine will become evident, and the current badger removal policy is unlikely to be changed in the medium term. Work done to date will also be used in order to ensure that the vaccine developed will be in compliance with the European standards as regards safety, non-transmissibility, irreversibility of attenuation and immunogenic properties with a marketing authorisation in accordance with Directive 2001/82/EC and thus available for use in other problem areas.

## **2.2 Main measures 1992 – 2011**

The measures implemented during this period include those submitted in the programme for 2010; these and changes introduced for the 5-year programme commencing 2011 are included in detail later in this document. In summary, the measures include an annual round screening test of all herds, controls on movement of animals, restriction of holdings, removal and slaughter of reactors and specific targeted testing, including the use of blood tests, with appropriate follow-up testing, compensation for farmers whose herds are affected by disease, a focused badger population control where they have been implicated as a probable cause of TB and continued work towards the development and introduction of a vaccine to prevent TB in badgers.

With regard to restriction, in Ireland, a herd may be under movement restriction either for administrative or disease reasons. The administrative reasons of relevance in the context of the Bovine TB eradication programme are where a herd is restricted due to failure to conduct a TB test that has been required by the District Veterinary Office or where a TB risk has been identified and the herd is restricted awaiting test to determine the herd status such as the restriction of contiguous herds or herds where more than 20% of animals have not been tested in the previous 12-months (detailed below).

The following classification that has been used since the mid 1950s should be noted at this point

Non-officially TB free herds include:

1. Newly established herds, which have been established from animals originating in officially TB free herds, that are awaiting test(s) to attain officially free status,
2. Official TB free status withdrawn as per Directive 64/432/EEC, and
3. Official TB free status suspended as per Directive 64/432/EEC.

Each of the classes of herds 1-3 would be the subject of a legal restriction notice. The attribution, maintenance, suspension and withdrawal of qualifications are fully in accordance with Directive 64/432/EEC as amended.

### **2.3 Main results**

The Table below outlines the cattle population trend over the past four decades and a comparison of the disease incidence during that period. It portrays the considerable progress made in the early years of the Tuberculosis eradication programmes and the progressive reduction, with some annual variations, in the level of the disease since 1998 particularly regarding reactor numbers which fell from c.45,000 to 23,805 in 2009. The average number of reactor removed in the 5-year period 2005-09 was, at c.26,295, 14% lower than in the preceding 5-year period (2000-2004), despite additional use of blood tests removing increasing numbers of animals disclosed as reactor.

Year	Cattle Population Tested	Number of Animal Tests	NO. OF REACTORS	Percentage animal Disease Incidence	APT **	RPT ***
1960	4,683,700	*	139,881	2.99	-	29.9
1965	5,359,300	*	23,378	0.44	-	4.4
1970	5,956,500	*	35,982	0.60	-	6.0
1975	7,168,100	*	21,339	0.30	-	3.0
1980	6,908,900	8,878,924	29,827	0.43	3.6	4.3
1985	6,907,200	11,180,602	32,608	0.47	2.9	4.7
1990	6,899,929	12,427,144	41,419	0.60	3.3	6.0
1992	7,084,441	10,887,513	35,997	0.51	3.3	5.2
1994	7,137,696	10,435,076	30,439	0.43	2.9	4.3
1995	7,174,016	10,112,939	33,180	0.46	3.3	4.6
1996	7,412,933	10,073,859	30,400	0.41	3.0	4.1
1997	7,725,634	9,910,074	28,647	0.37	2.9	3.7
1998	7,946,989	10,677,291	44,498	0.56	4.2	5.6
1999	7,569,735	10,749,580	44,903	0.59	4.2	5.9
2000	7,032,407	10,304,162	39,847	0.57	3.9	5.7
2001	7,097,430	9,402,196	33,702	0.48	3.5	4.8
2002	7,025,096	9,400,065	28,930	0.41	3.1	4.1
2003	6,936,820	9,168,722	27,978	0.40	3.1	4.0
2004	6,992,264	8,825,720	22,967	0.33	2.6	3.3
2005	6,407,456	9,060,044	25,884	0.40%	2.9	4.0
2006	6,260,133	9,000,519	24,173	0.39%	2.7	3.9
2007	6,084,037	9,143,719	27,711	0.45%	3.03	4.5
2008	6,150,163	9,211,058	29,901	0.49%	3.25	4.9
2009	6,025,656	8,963,097	23,805	0.40%	2.66	4.0

\* Accurate figures for the total number of animal tests per year were not available until 1978.

\*\* The APT is used as a measure of the incidence of disease compared to the level of testing being carried out. The APT figures represent the number of reactor animals disclosed per 1,000 animal level tests

\*\*\* The RPT is used as a measure of the incidence of disease compared to the total population of animals. The RPT figures represent the number of reactor animals disclosed per 1,000 animals in population.



It is important to note the following classification at this point:

#### Epidemiological unit classification

Since 1957 and the inception of the Bovine TB eradication programme in Ireland each single epidemiologically distinct herd is allocated a herdnumber for the purpose of disease control. The herdnumber is issued to a registered person, who is now termed the keeper but who is not necessarily the owner of the animals that form the herd. An 'epidemiological unit' or herd is considered to be any number of animals that are held, kept or handled in such a manner that they share the same likelihood of exposure to infectious disease and that the control of the spread of infectious disease from the unit can be facilitated. The animals comprising the herd may be owned solely or jointly with others and the herd occupies parcels of land used solely or jointly with others which may comprise parcels of land that are separated by some distance but, because of general proximity and/or management practices, are considered to be one epidemiological unit. Where the parcels of land used by the farmer are located in more than one administrative division or are sufficiently far distant to warrant being treated as two (or more) epidemiological units or where disease management controls dictate that it is prudent to regard them as two (or more) epidemiological units, a herdnumber will be issued to each such unit (herd). Each herd is tuberculin tested at a minimum once annually and full disease and movement control measures will apply to each such herd and such herds are considered to be epidemiologically related with mandatory tracing and checking in the event of suspicion of disease. ALL parts of a herd being the epidemiological unit are subject to control if and when disease is identified i.e. the movement restriction applies to all the fragments used by the herd and the legislation empowers the Veterinary Inspector to confine animals to particular fragments if disease control so warrants. In any event epidemiological considerations and disease control are paramount and the determination of the appropriate epidemiological unit is made by veterinary staff of the Department of Agriculture, Fisheries and Food operating in the area and responsible for the administration of the disease eradication programme. Each new herd registration is subject to scrutiny: a veterinary approval process, an on-site investigation, including inspection and assessment of the handling and holding facilities for animals as appropriate for the number and type of animals to be kept in the herd. Holdings, as defined by Council Regulation (EC) No 73 of 2009 of 19<sup>th</sup> January 2009 namely 'holding' means all the production units managed by a farmer situated within the territory of the same Member State are also registered by a separate section of the Department of Agriculture. A holding is linked to its relevant herdnumber or herdnumbers in the Department of Agriculture, Fisheries and Food Corporate Client System database.

#### Components of the Irish bovine tuberculosis eradication programme

The current Irish eradication programme is built on a twin-track approach to tackling the disease – systematically addressing both bovine-to-bovine spread as well as a wildlife to bovine cycle. The programme is built upon conventional disease control strategies appropriate to disease control within a domesticated animal species and novel approaches to dealing with a disease that moves between domestic and wild animal populations.

The conventional 'within domesticated animal species' measures are explained further in section 3, whilst the following paragraphs provide greater clarification on the specific challenges posed by the presence of a wildlife reservoir of disease and information on the planned, purposeful, systematic, sustained and incremental approach of the Irish authorities in addressing this source of infection with a view to eradication.

#### Wildlife Reservoir as a constraint to progress towards eradication

Over the years, it has become increasingly apparent from research conducted by the Department of Agriculture, Fisheries and Food and University College Dublin that not all of the factors identified either by ERAD in the 1980's or other reviews of the Irish bovine TB eradication programme are of equal significance in constraining eradication. It follows that the solutions developed to address perceived constraints will not be equally beneficial for the Irish eradication programme. It is now recognized that the pre-eminent constraint to eradication of TB in Ireland is the existence of a significant reservoir of infection in wildlife, notably the badger. The 2010 programme currently underway is the final year of the current 5 year programme, which embodies a comprehensive tuberculin test screening of all herds, concentrating additional resources on those higher risk areas of the country producing the majority of reactors and continuing the enhanced wildlife programme established in 2005. An important conclusion drawn from intensive testing and from ongoing analysis of the outcome of annual programmes was that special emphasis needs to be placed on the control of the spread of bovine TB by wildlife and on the development of new technological tools to assist the systematic reduction of the disease. Thus, the existing arrangements will continue into 2011 to provide for a comprehensive programme aimed at preventing TB spread by wildlife (mainly badgers), including the continuation of a comprehensive diagnostic programme with the development of a vaccine to address the wildlife problem the most pressing objective of the research programme.

#### Wildlife Policy

##### Background

The first infected Eurasian badger, *Meles meles*, was detected in Ireland in 1974. It has become increasingly evident over the years that Tuberculosis in this species is endemic in Ireland. The realisation that the reason bovine TB eradication was not following the same pattern as in other European countries that had eradicated this disease was a consequence of infection in badgers was a gradual process. Results from a number of small scale local reactive-removal trials in the 1980s notably in Galway and Cork led to a number of formal studies that attempted to identify a link between tuberculosis in badgers and tuberculosis in cattle in the same local areas. The first of these formal studies, called the East Offaly Study (EOP), was carried out between 1989 and 1994 and demonstrated that a marked reduction in levels of tuberculosis in cattle was observed when the local badger population was maintained at low levels. This study was confined to one geographic area, which was not very representative of the land types found in Ireland generally. The results from the study, while compelling, were not conclusive findings. A follow-up study, the Four Area Project (FAP), was carried out at 4 sites between 1998 and 2002 and reductions in tuberculosis in cattle were again measured following the removal of badgers locally. These studies have shown that reducing the density of badgers over a wide area (the removal sites in each of

the four areas averaged circa 250 km<sup>2</sup>) to perhaps 20% of their original density and maintaining these lower densities over a number of years resulted in significantly lower levels of tuberculosis in cattle locally than had been observed prior to the commencement of the trials and a reduction in risk of a herd restriction as a consequence of bovine TB. The impact of the proactive badger removal on herd restrictions due to bovine TB in east Offaly during the period 1989-2004 has been recently re-assessed and the reduction in herd restrictions has been sustained in the project area. Where badgers have been captured in areas where seriously infected cattle herds also exist, upwards of 40% of the badgers are culture positive for tuberculosis.

While Bovine TB has been eradicated in Australia and to a very significant degree in New Zealand, both countries experienced a problem with wildlife infection that was dealt with by the widespread and systematic destruction of the wildlife reservoir. While it is acknowledged that eliminating badgers in Ireland would probably result in a more successful cattle tuberculosis eradication scheme, such a policy would be unacceptable at a number of levels. At the societal level, the destruction of one of our important native large species of mammal would be completely unthinkable. In addition, the EU is a signatory of the 1989 Convention on the Conservation of European Wildlife and Natural Habitats (Bern Convention), and the Irish government ratified this treaty in 1982. Under Irish Law (The Wildlife Act, 1976), the Eurasian badger (*M. meles*) is a protected species including protection of the underground burrows (setts) where badgers live and breed their young.

Following on from the findings of the EOP and FAP, the Department's strategy in relation to badgers is two-fold viz (i) an interim strategy which is currently applied systematically in the field involving the humane capture and the removal of badgers where they are implicated in an outbreak of TB and (ii) a parallel government funded research programme to establish the efficacy and quantify the effects of vaccinating badgers, all in support of the eradication of TB from the bovine population. The strategy is set out in more detail below:

(i) **Interim Wildlife Strategy**

**Capturing and removal of badgers associated with bovine tuberculosis breakdowns**

- Breakdowns of tuberculosis are investigated by DAFF veterinarians using a standard epidemiological investigative methodology and a probable cause sought for the outbreak. The primary objective of this investigation is to establish firstly that more than one bovine animal is or has been infected within the herd and if the infection is bovine in origin e.g. an introduced animal is the likely source of the breakdown or there has been recrudescence in a latently infected bovine and if no source of infection is otherwise apparent to establish if badgers were present in the local environment of the herd.
- If an introduced or latently infected bovine animal(s) has been ruled out as causing the breakdown and spread within the herd, and if signs of badger activity are found on lands of, or on lands adjacent to the index herd, a survey of the local area is organised by DAFF staff to a radius of 1 km out from the affected farm. Where setts (badger burrows) are located, the locations are recorded on a GIS database along with the sett characteristics. Before capturing at any setts can take place, candidate setts must first be approved for

capture by a staff person from the DAFF Wildlife Unit who independently verifies that the sett is within 2 km of a tuberculosis-affected farm. Badgers are captured using a specifically designed stopped-body restraint, and humanely dispatched using a 0.22 calibre bullet. Trained contractors, who are monitored and supervised by DAFF staff, carry out capturing. Approval to capture a sett is currently contingent on the total area under capture nationally being maintained below 50% of the agricultural land as described in the previous section.

- A further element of the medium term strategy is to limit any capturing during the months of February and March each year specifically to areas that were captured previously. This measure is prompted by animal welfare concerns due to the risk of capturing lactating females that in turn would lead to the possibility of orphaned offspring. Returning to areas previously captured ensures a lower risk of capturing any badger, and an even lower risk of capturing a female badger and an even lower risk again of capturing a lactating female

In conclusion, the wildlife strategy outlined is a pragmatic response, based on sound science, to a complex problem. The national badger population is a valued resource and the limitations applied to the proportion of lands where capturing will be permitted guarantee the survival of the species. The hope of developing an oral delivery system of BCG that will reduce the impact of tuberculosis in badgers is a realistic one. Confining capturing of badgers to areas where herds must first be identified with proven tuberculosis that was not caused by infected cattle is a further safeguard against unnecessary removal of badgers. Removing heavily infected badgers from localities where cattle breakdowns have been identified can only but benefit the surviving test negative cattle as well as the badgers in the wider area surrounding the removal zones. Doing nothing when confronted by a known problem is not an option in the Irish situation. Evolving a strategy among a diverse range of stakeholders which is a sub-optimal solution for some, but which is accepted by all, as a fair compromise is a triumph for common sense and a tribute to the generosity of all involved.

The Wildlife Unit established by DAFF as part of the ERAID Division is responsible for the implementation of policy in respect of the badger and bovine tuberculosis issues. The majority of tuberculosis breakdowns are clustered in Ireland and the locations of these clusters remains relatively constant. Conservation of a healthy badger population nationally is a key objective of the medium term strategy, so at the heart of the strategy is a commitment on the part of DAFF to guarantee that population control by capturing of badgers will be confined, cumulatively, to not more than 50% of the agricultural land of the country. This unit has implemented an enhanced population control policy since 2005 and at the end of 2009 25.6% of agricultural land was included for population control (note again commencement of initial population control measures is predicated by an outbreak in cattle involving more than one bovine animal but which is non-bovine).

The national capturing effort is applied more intensively in those areas where tuberculosis in cattle herds is both persistent and chronic (see map on this page). Using kernelling/smoothing techniques, it is possible to delineate areas comprising roughly 30% of the agricultural land, which yield roughly 70% of all standard interpretation skin test positives via the SICIT (72 hour bovine increase greater than 72 hour avian increase by more than 4mm).

In the areas marked green on the map, capture will not take place over more than 60% of the agricultural land, whereas elsewhere, capturing will be capped at 20% of agricultural land. Overall, this guarantee will ensure that capturing will never exceed an area greater than 30% of the agricultural land in Ireland or, conversely, badger habitats in 70% of the agricultural land will be safeguarded.



From analysis of data accumulated from the various projects it is evident that badger main sets are distributed as far apart from one another as is possible. By averaging the nearest neighbourhood distances of main sets from all Four Area Project and the East Offaly Project sets, we achieve a crude estimate of the expected nearest neighbourhood distance nationally (917 metres) and also an approximation of the territorial area of a social group. This provides a robust estimate for calculating land treated for each sett assigned to a WAC capture block. All sets assigned to an approved capture block are assumed to be treated. all sets are buffered to 500 metres and overlapping circles are merged to avoid over-estimating captured land.



Figure 1. 500-metre buffer generated around setts in a capture block in County Laois. The callout numbers are the number of badgers caught to-end 2007 at each sett within the block.

The treated area figures are cumulative from commencement of WAI activities in 2004. Figure 1 gives an example of the area associated with treatment for a capture block in County Laois (3,973,967 square metres). At the end of December 2005, some 8% of agricultural land nationally was under capture and this rose to 14.1% end 2006, 18.5% end 2007, 22.07% end 2008 and at end of 2009 25.6% of agricultural land was under capture, ranging from 46.22% in the county with the highest % to 11.61% in the lowest and being added to nationally at the rate of 3.5% per year. Over time, the specific areas subject to control (individually determined by bovine TB breakdowns) coalesce to provide large areas of the country subject to treatment.

### (ii) Wildlife Research Programme

A sustained comprehensive research programme continues to focus on the development of new technological tools. Special emphasis has been placed on keeping fully up to date with relevant scientific developments internationally and in this regard we have research relationships with colleagues in UK, US, Canada and NZ. Of particular significance is the work being undertaken in regard to wildlife involvement in disease spread and the studies into non-specific infection. The focus of a large element of our research programme has been directed at devising means to address this problem in order to reduce the levels of TB in both the cattle and badger populations primarily through the development of a badger vaccine.

The current badger vaccine development programme commenced in 2001 and is focussed on establishing and quantifying the protective effects of vaccinating badgers with *Bacillus Calmette-Guérin* (BCG) vaccine. Under the umbrella of this badger vaccine development programme a series of sequential experiments have been undertaken and reported on. The first captive badger study established that it was possible to produce tuberculosis in badgers by inoculation via the endobronchial route using a wide range of doses of *M. bovis* (from <10 to >1000 organisms). By that means, we were able to reliably establish an experimental infection that mimics the natural disease. In a follow up study we then determined that the optimum dose for *M. bovis* infection in vaccine/challenge studies was 10,000 organisms and by serial necropsy that the optimum time to examine badgers in vaccine studies was 12 weeks after challenge. As part of these studies, we developed and assessed a range of *in vitro* diagnostic assays based on the immunological responses to challenge. The first vaccine/challenge study demonstrated that badgers could be successfully vaccinated with BCG by either the subcutaneous route or the mucosal route. The protective effect of BCG vaccination was measured as a decrease in the severity of the experimental disease when compared to non-vaccinated controls. This study established as 'proof of the principle' that BCG vaccine induced a protective host response that limited the distribution and severity of disease in the experimentally challenged badgers. The second vaccine/challenge study demonstrated that badgers could be successfully vaccinated orally with BCG encapsulated in a lipid formulation to protect it against gastric secretions. Again the protective effect of BCG vaccination was measured as a decrease in the severity of the experimental disease when compared to non-vaccinated controls. A third vaccine/challenge study to examine the duration of protection induced by a single oral dose of BCG has also been completed. The study demonstrated that the protective effect of vaccination was still present 12 months after vaccination.

We are now satisfied, on the basis of this novel Irish research, that BCG administered orally to badgers results in protective effects following experimental infection with *M. bovis*. The next stage within this overall research programme is to carry out a large-scale field trial, which commenced with preliminary field survey work, badger identification and sampling to determine population density and TB prevalence in 2008. The field trial is using an oral delivery system which is the method of choice for any broad scale application of vaccine. The trial will also provide a practical base for understanding the logistics of oral delivery to wild badger populations. The aim of the vaccine field trial will be to demonstrate protection and estimate efficacy of BCG in a wild badger population by comparing prevalence of tuberculosis in a group vaccinated badgers with a similar group of non-

vaccinated badgers. The population under study will require a minimum prevalence of infected badgers of ~ 30% to ensure a high level of natural challenge to vaccinated and non-vaccinated badgers. For statistical purposes, it is estimated that a minimum of 300 badgers is needed for the study. The first vaccine delivery to badgers in Autumn 2009 captured the required target number of badgers. The project will vaccinate 50% of the susceptible animals by the oral route using BCG encapsulated in an oral formulation. Each area of the study site will be trapped on at least three times per year. Blood samples will be taken from each badger each time it is captured and the badger will be subjected to a clinical examination. The study design is robust such that culling can be tolerated within the study area where a herd breakdown due to badgers occurs. The data obtained from the post mortem examination of cull badgers will be used in the final analysis. At the end of the study the area will be depopulated, as far as practicable, and all captured badgers will be subjected to detailed PM, histology and culture. The vaccine protection and vaccine efficacy will be estimated by comparing the number of infected badgers in the vaccine group with the number in the non-vaccinated control group and the relative extent of the disease encountered in both groups. Tuberculosis cases will be defined by the bacteriological isolation of *M. bovis*.

In parallel with the field trial, other key components of a vaccine program that need to be addressed include: How to incorporate badger vaccination into the national tuberculosis program; Registration of BCG for use in badgers; and understanding the pros and cons of alternative vaccination strategies.

#### Future studies

##### *Vaccine Bait*

When vaccine becomes part of the national TB programme, it is currently proposed that baits will be distributed by hand into badger setts. Hand distribution will be used to avoid inadvertent exposure of livestock and humans to the vaccine. To reach the threshold of herd immunity we will need to know, for example, the effects of season and population density on uptake as well as the effect of diet, competing food sources, rate of bait application and the frequency of vaccination on the population coverage. This is an active area of research at present.

The field vaccination trial, which is a critical component of the vaccination development programme, is a very substantial undertaking that will involve the introduction of a vaccine into a population of badgers over a large area in the south-east of the country for a period of at least 3 years. The objective of the field vaccination trial is primarily to provide information as to the efficacy of an oral vaccine in reducing the level of TB infection in the wild badger population under field study. The field trial project is scheduled to last three years and it is planned that the outcome of this research project will be reported on by 2013. Obviously final decisions regarding the application of this strategy nationally must await the completion of this trial but this area in the south-east of the country is the first step in the active application of vaccine to badgers within the national eradication programme. In



the event that the vaccination trial is successful, incorporation of field vaccination of badgers into the national Bovine TB Eradication Programme – the culmination of the various research elements described above will then commence. A number of separate, smaller badger vaccination trials in other areas will be undertaken before the conclusion of the initial project detailed above. Vaccination, by intramuscular injection of captured badgers is planned for the first of these additional trial areas during 2011, with the objective of providing information on the other aspects of badger vaccination, including its empirical contribution to reducing or maintenance of reduced levels of bovine tuberculosis in cattle in the chosen project areas where a badger reduction protocol has been followed for at least the 3-prior years. In parallel with these badger vaccination trials, ancillary work will continue in a number of related areas, including strain typing in associated badger and cattle populations; badger movement studies; and studies into the genetic diversity of badgers.

### **3. Description of the submitted programme<sup>5</sup>:**

#### **Main Objective**

Bovine Tuberculosis is a notifiable disease in Irish legislation and all herds in Ireland are included in the programme. The 2011 TB Programme is the first year of a new 5-year eradication programme 2011- 2015. The objective of the programme is the eradication of TB from the cattle which is based on a range of conventional test, slaughter and restrict movement methodologies and at the same time to deal with TB in the wildlife population by reducing the badger population in areas where they are seen to be contributing to bovine TB prevalence while a vaccine for TB in badgers is in development and under trial.

There has been a significant improvement in the incidence of the disease since 1999. For example, despite the increased use, of Interferon-gamma Assay in infected herds, the number of reactors detected annually has fluctuated slightly from year to year but has fallen from approx 45,000 animals in 1999 to 23,805 animals in 2009.

The herd incidence continues to fall and, during the same period, has fallen from 7.7% in 1999 to 5.09% in 2009. As referred to previously in this section, Ireland complies fully with EU Directive 64/432/EEC.

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<sup>5</sup> 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 (testing, testing and slaughter, testing and slaughter, testing and killing, qualification of herds and animals, vaccination), the target animal population and the area(s) of implementation and the definition of a positive case.

#### 4. Measures of the submitted programme

##### 4.1. Summary of measures under the programme

Duration of the programme: The programme herewith submitted is the annual programme for 2011 and is part of a 5 year eradication programme 2011-2015. Measures introduced during the lifetime of the previous programme will continue with increased focus on badger-population control in problem endemic areas and increased use of supplementary tests to augment the SICCT; these include the Interferon-γ Assay, the anamnestic ELISA and other tests currently under development in Ireland.

Duration of the programme:

First year: 2011

Last year: 2015

- ☑ Control
- ☑ Testing
- ☑ Slaughter of positive animals
- ☑ Killing of positive animals
- ☑ Vaccination
- ☑ Treatment
- ☑ Disposal of products

✓ Eradication

✓ Testing

✓ Slaughter of positive animals

☑ Killing of positive animals

✓ Extended slaughter or killing

☑ Treatment

☑ Disposal of products

Badger vaccination trials

✓ Results from badger vaccination trials and programme adaptation accordingly.

✓ Monitoring or surveillance

✓ **Other measures (Specify):** Section 3 details the measures of the programme which are summarised below:

- epidemiological investigation of disease outbreaks including trace-back and trace-onward of infected/potentially infected animals, and of movement of animals into and out of restricted herds,
- the national herd is tested annually, together with consequential testing arising as a result of identifying and controlling infection, as per the requirements of Directive 64/432/EEC, as amended, and additional risk based testing as defined and detailed in this eradication programme.
- early removal of reactors and the provision of compensation to farmers,
- mandatory 30-day pre-movement test on animals exported,
- computerised system for recording and follow-up of tests and animal movements, traceback and trace forward of epidemiologically linked animals
- in the short term, the contribution of infected badgers to the spread of disease in bovines continues to be quantified and analysed. In this regard, the Department is continuing to operate various badger based research projects,

- in the medium term, badger population control/reduction is focussed on the higher risk-areas of the country where disease is clustered and is subject to detailed epidemiological investigation determining that bovine sources are unlikely,
- in the medium term also, work is progressing on a project, the objective of which is to develop a vaccine for use in badgers that would lead to a reduction in the level of infection in that species, thereby reducing the number of organisms being shed and subsequently the level of transmission to the cattle population.

The programme measures include the following:

#### **Annual “Round” screening test**

Ireland requires all herds to be tested at least once every 12 months.. The Department of Agriculture, Fisheries and Food issues schedules of herd tests to private veterinary practitioners in phases throughout the year. Farmers, under cost-sharing agreements, pay the private veterinary practitioners directly to carry out one test per annum. Reminders are sent out as appropriate to ensure testing is carried out on the prescribed dates. Where necessary, holdings are restricted for non-compliance with the instruction to test under the Round test regime.

#### **Consequential testing**

Other tests for TB include reactor re-test, factory lesion re-test, post de-restriction (risk-based post-status-restoration) test, contiguous test, Special check tests including new herd test, forward and back-trace tests, tests on higher risk assessed herds and export certification test (further details of these test types are found in section 7.2.1 of this document). Consequential testing not mandated by the Directive is risk based, dictated by epidemiological considerations and takes into consideration studies conducted and data analysis by a specially established Centre for Veterinary Epidemiology and Risk Analysis (CVERA) which is located in University College, Dublin.

#### **Restriction**

If a tuberculin test reactor is disclosed in a herd, legally the holding is automatically restricted for 30 days. Animals are not permitted to be moved onto or off the holding except under and in accordance with the terms of a movement permit (see below). A formal restriction notice is issued in respect of the holding and this remains in force until formally withdrawn by a further notice. On receipt of the restriction notice, the farmer is required to surrender all passports in respect of the eligible animals on the holding, if these have not already been surrendered. Other circumstances where a herd will be restricted so as to control bovine tuberculosis or for the purpose of administering the eradication programme include:

- for failure to comply with testing obligations
- where a herd is in excess of 6-months tested and is placed on a contiguous programme to an active high risk breakdown.

- where *M. bovis*-suspect lesions have been detected post-mortem,
- where disease has been traced to or from the herd,
- where following the slaughter of an animal whose previous test is between 12-18 months the herd has in excess of 20% of animals not tested in the previous 12-months,
- where an animal whose previous test is in excess of 18-months is slaughtered
- where the herd is otherwise considered to be epidemiologically linked to infection.

#### **Epidemiological analysis of disease breakdowns and severe interpretation**

A herd is subject to a risk categorisation process following epidemiological assessment and categorised into either 'Higher' (H-type i.e. confirmed infection with spread) or 'Lower' (L-type i.e. infection not confirmed and/or no spread evident) risk, based on outbreak severity. Herds with two or more TB infected animals over the course of the episode (duration of restriction under TB Order), as evidenced by the detection of lesions or by animals failing the SICCT at standard interpretation, are ordinarily classed as H (infection with concurrent spread giving a higher risk of positives at next herd test i.e. a 'H' breakdown episode). On epidemiological grounds, a herd may be classified as H even though reactors/infection have not been identified/confirmed in that herd. A Veterinary Inspector may determine on epidemiological grounds that a herd is unlikely to be infected with *M. bovis* or other members of the *M. tuberculosis complex* and that therefore H classification is inappropriate (e.g. in NSL/Atypical herd situations).

All H-type breakdowns receive a more detailed epidemiological investigation by a Veterinary Inspector of the Department of Agriculture, Fisheries and Food to determine the likely source of infection, the geographic focus and the risk of spread. Many of these will additionally have an investigation conducted on the farm itself. Where resources permit, additional investigations are conducted as deemed necessary by the local Veterinary Management and, in the case of any lesser breakdowns, where the herd keeper specifically requests an investigation it is conducted. In this manner, resources are directed where they will be most effective i.e. *M. bovis* infected herds, where the herd is experiencing a high risk breakdown, the interpretation level of the tuberculin test may be increased to what in Ireland is referred to a 'severe interpretation' where animals which, under the interpretation levels set in Directive 64/432/EEC would be classified as an inconclusive reactor animal, would be removed in accordance with article 2.2.5.3.5 of Annex B. In infected groups of animals, interpretation may also reflect just the response at the site of injection of PPD bovine. (See also parag. on Herds with high level of infection and on Wildlife measures). Additional testing on epidemiologically linked herds and of herds in the environs of an outbreak is conducted as a matter of routine.

### Herds with higher level of infection

The epidemiological analysis is carried out using information available on the herdfile, data available from computer records and from the Farm Visit Report Form. (form ER 76B) where a farm visit has been conducted. Herds, which are considered to have confirmed infection, are defined as 'class H breakdown herds' (see detail previous). For the 2011 programme, the IFNy-assay and/or other blood tests will continue to be carried out in such herds following disclosure of infected animals as considered appropriate for the purpose of identifying additional infected animals. Animals which show positive reaction to the IFNy-assay will be removed under the programme and subjected to appropriate individual post-mortem and laboratory examination as necessary. Full herd depopulation is a consideration when the level of infection in a herd is high and/or severe interpretation of the tuberculin test, supplementary blood testing has failed to resolve the problem and where it is considered that herd depopulation will facilitate the establishment of a herd free from TB on a long-term basis.

After the mandatory post de-restriction test has been carried out, the epidemiological data for herd level is finalised and subjected to analysis by CVERA. These analyses have clearly shown that infection in badgers is a feature in the majority of breakdowns and that breakdowns occurring as a consequence of cattle movement (some 7% of breakdowns) are less severe, transitory in nature and rarely result in disease transmission to other animals in the new herd. (see also parag on Wildlife measures).

#### *4.2. Organisation, supervision and role of all stakeholders<sup>6</sup> involved in the programme:*

**The Department of Agriculture, Fisheries and Food.** Overall co-ordination and management of the TB Eradication Programme is conducted by the ERAD (Eradication of Animal Disease) Division of the Department of Agriculture, Fisheries and Food under the responsibility of an Assistant Secretary and Deputy Chief Veterinary Officer with a team of Administrative, Technical and Veterinary staff.

#### Keeper testing obligations

Individual keepers are responsible for the testing of their herds so as to maximise herd health protection and certification status of herds. Keepers and their practitioners are jointly developing appropriate total herd health protection strategies. Keepers themselves are responsible for arranging annual herd tests, within timescales prescribed by the Department, with their veterinary practitioners, and for payment of fees directly to practitioners in respect of one test/annum. Any second or subsequent herd level TB test within the 12-month period will, ordinarily, be arranged and paid for by the Department. In this regard also, the testing programme will be complemented in the event of detection/suspicion of TB by epidemiological investigation, prompt valuation and removal of reactor animals and feedback to farmers and veterinary practitioners.

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<sup>6</sup> 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.

#### **Description and demarcation of the geographical and administrative areas in which the programme is to be implemented<sup>7</sup>**

The programme is operational throughout Ireland and is currently managed through 20 administrative areas each with a District Veterinary Office (DVOs). The number of DVOs will be reduced strategically to 16 during the course of 2010/2011. Each DVO has a team of administrative staff, Technical Agricultural Officers and Veterinary Inspectors under the management of a Superintending Veterinary Inspector (SVI). Ireland is divided into 2 regions and the activities of DVOs are co-ordinated in a regional structure under the Regional Senior Superintending Veterinary Inspector (SSVI). A focused strategy will operate in areas with a higher disease incidence, based on herd categorisation and contiguous testing arrangements.



#### **4.4. Description of the measures of the programme<sup>8</sup>:**

**4.4.1. Notification of the disease:** In full compliance with Directives 64/432/EEC and 78/52/EEC, Bovine Tuberculosis is a notifiable disease under the Diseases of Animals Act 1966. Under legislation, veterinary surgeons are required to notify the Superintending Veterinary Inspector at the District Veterinary Office of details where, on clinical grounds, tuberculosis is suspected. Keepers who have reason to suspect that the disease may be present in their herds are also obliged to notify the District Veterinary Office.

**4.4.2. Target animals and animal population:** All bovine animals in Ireland are included in the programme. There is no category of herd, or individual animal greater than 6 weeks old or animals involved in cultural or sporting events excluded or exempted from tuberculin testing. For trade within Ireland, the current legal requirement is that each animal must

<sup>7</sup> 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.

<sup>8</sup> A comprehensive description needs to be provided of all measures unless reference can be made to Community legislation. The national legislation in which the measures are laid down is mentioned.

have been tested within the previous 12 months and the holding is not under restriction. In this regard, S.I. No. 32 of 2003 provides the current legal basis, which requires cattle to have been tested within this time frame.

**4.4.3. Identification of animals and registration of holdings:** All herds, being the epidemiological unit, are registered in accordance with Directive 64/432/EEC. Holdings are registered in accordance with Council Regulation (EC) No 73 of 2009. Ireland has operated a system of herd (epidemiological unit) registration and individual bovine tagging since the 1950s. The current national system (S.I. No. 77 of 2009 refers) is in accordance with Regulation 1760/2000. Ireland currently continues to maintain an individual animal passport on which the details of the animal's tuberculin tests are recorded as part of the disease control measures in operation. This system is enhanced by the linkage of the Animal Health computer system with the Animal Identification and movement system at markets and slaughter premises. The most recent test dates for individual animals in the herd are also available to the keeper who has access to his herd profile electronically. These developments will facilitate the removal of test dates from passports as part of a simplification process and, it is anticipated, progression towards a full movement permit system over the lifetime of this programme.

**4.4.4. Qualifications of animals and herds:** The eradication programme is conducted under the Bovine Tuberculosis (Attestation of the State and General Provisions) Order, 1989 and amendments thereto under the Diseases of Animals Act 1966. The attribution, maintenance, suspension and withdrawal of qualifications are fully according to Directive 64/432/EEC as amended.

**4.4.5. Rules on the movement of animals:** The eradication programme is conducted under the Bovine Tuberculosis (Attestation of the State and General Provisions) Order, 1989 and amendments thereto under the Diseases of Animals Act 1966. Bovine animals may not be moved into a herd or from a herd unless the animal in question has been tested within the previous 12 months. Furthermore, a bovine animal may only be moved out of or into a herd or accepted for routine slaughter at a registered abattoir if the individual animal is accompanied by its passport or a movement permit issued by an authorised officer of the Department of Agriculture, Fisheries and Food. All animals moved for slaughter purposes receive an examination in accordance with Regulation 854/2004/EC. Also as referred to previously in section 3, Ireland complies fully with EU Directive 64/432/EEC in that it carries out 30-day pre-movement TB testing on all eligible bovines exported to the EU.

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<sup>9</sup> To mention only if applicable.

### Movement of animals from a 'restricted' holding

Controlled trading rules apply to herds with restricted status (OIT suspended/withdrawn). These herds are risk-categorised on the basis of infection levels and are subject to a tailored testing (interpretation & test frequency) regime. In Ireland, animals can only be moved from a restricted herd if an officer, authorised by the Minister under the animal disease legislation, issues a permit allowing such movement. In this context, an authorised officer is not obliged to allow an animal to move but may allow the movement of such animals where the officer is satisfied that the movement is necessary and should not result in the spread of IB to other animals. The officer may attach special conditions relating to the movement as considered necessary. The vast majority of such permits are for animals moving directly from the herd to a slaughter plant. Movement may be allowed by an authorised officer where it is considered that there are reasons why such movement is necessary e.g. for immediate, urgent or necessary veterinary treatment in a veterinary hospital; or where animal welfare reasons dictated that such movement is necessary to prevent unnecessary suffering. In practice, such movements are rare and, when allowed, have conditions attached to ensure that the eradication programme is not compromised as a result of the movement. Movement may be permitted to registered feedlots which specialise in the finishing of animals for slaughter, are under restriction, test at proscribed intervals (not less than annual) and are not considered to pose a risk of infection to others. Movement conditions would cover, bearing in mind the animals involved and the location to which the movement was being permitted, aspects such as isolation of the animal(s) involved, disinfection, transport, restriction of the new holding location, testing requirement and frequency as is considered relevant to the particular circumstances. The legislation is written for enabling purposes to facilitate and legalise considered action in an emergency or in unusual circumstances. (Note that a small number of animals move, under permit, each year for research purposes to the Department of Agriculture, Fisheries and Food Central Veterinary Research Laboratory Farm. These animals would include reactor animals to be used for the purpose of conducting routine potency trials on tuberculin.)

A key objective is the rapid removal of reactor animals. A national Reactor Collection Service ensures that animals are in general removed within one week of valuation agreement. The target is to have all animals identified as reactors removed within 30-days of identification. Holdings are thoroughly disinfected prior to de-restriction. This function is carried out at the direction of a veterinary inspector and under supervision of Department Technical Officers.

### Pre-movement tests

Ireland complies fully with EU Directive 64/432/EEC in that it carries out 30-day pre-movement TB testing on all eligible bovines exported to the EU and otherwise (Ireland avails of the derogation provided for under point 1.1.(c) of Annex A to the Directive, which states as follows: "*However, the competent authority may not require this test to be carried out for movements of animals on its own territory if the animal is from an officially tuberculosis-free herd...*").



For trade within Ireland, the current legal requirement is that each animal must have been tested within the previous 12 months and the holding is not under restriction. In this regard, S.I. No. 32 of 2003 provides the current legal basis, which requires cattle to have been tested within this time frame. The eradication programme, however, places special emphasis on pre-movement testing as a key husbandry practice to assist herd health protection. Keepers are encouraged to acquire pre-movement tested animals as part of their overall herd health strategy decided with their veterinary practitioners. It is a legal requirement that the date of the most recent tuberculin test is displayed on an electronic screen when an animal is presented for sale at market. Markets and slaughter premises have access to an on-line system so that the latest test-data available on the Animal Health Computer System (AHCS) is now available for electronic display. Currently the date of tuberculin test must also be entered onto the animal's passport by the testing veterinary practitioner. In this manner, the person acquiring an animal is informed of the interval since the last tuberculin test. This methodology is scheduled to change as technological changes facilitate. In 2009, 259,395 animals were specifically pre-movement tested (private test) for TB at individual animal level and many others would have been tested during a herd level test immediately prior to movement. (See also note below on pre-movement test for domestic animals). As is detailed below under "Pre-movement testing", the benefits of a nation-wide compulsory pre-movement test do not indicate that this is the most appropriate manner to expend resources.

#### Pre-movement test for domestic movements

In accordance with the terms of the previous national social partnership agreement entitled the 'Programme for Prosperity and Fairness' (PPF) (2000), it was agreed by all parties that measures would be adopted with the objective of reducing the levels of TB by 50% within the succeeding four years (delayed by 1 year due to Foot and Mouth Disease outbreak) and prolonged necessarily as discussions for the next agreement continued into 2006. These measures were implemented in consultation with farming and veterinary bodies. With the end of the original 'four-year' programme i.e. at the end of calendar year 2005, the situation was reviewed. One of the items considered, at that time, was the re-introduction of a pre-movement test or equivalent for TB. A pre-movement test for TB on all bovine animals had previously been a requirement under the Irish Bovine Disease Eradication Programme(s). However, data analysis had revealed that there was little benefit accruing to the programme as a result of such a broad based requirement and it was not cost effective. The currently available evidence is that the lack of a compulsory pre-movement test (other than the 12 month window which operates at present) is not seen as a major constraint to further progress in the Irish eradication programme. Published investigations of disease episodes in Ireland have shown that in only 37% of the disease episodes investigated, adult cattle had been introduced into the infected herds. The purchased animals were positively ruled out as being the source of the problem in 45% of those cases. In only 5% of the remaining herds - less than 2% of all outbreaks - were purchased animals positively identified as being the source of the infection. Separately other work demonstrated that an outbreak as a consequence of a purchased animal was transitory and that spread to other cattle in the herd infrequent. The benefit or otherwise of pre-movement testing is kept under review and the latest work on the subject to assess if there was a category of herd from which pre-movement test might have a benefit has shown that <1% of animals that move even from very high risk herds will show a positive test for bovine tuberculosis over the 2 year period following sale (Wolfe, et al. 2009; The risk of a positive test for bovine tuberculosis in cattle purchased from herds with and without a recent history of bovine tuberculosis in Ireland. *Preventive Veterinary Medicine* 92, 99-105.). Farmers

pay the testing veterinarian directly for the majority of the testing carried out each year at an estimated cost of circa €35m in 2009, as well as contributing to the cost of compensation by way of disease levy. Any significant departure from the agreed programme and/or new initiative requires solid data and demonstrable benefits for agreement to be reached within this process of social partnership. It is clear from the data analysis that the re-introduction of a compulsory pre-movement test would not be best use of available resources in terms of overall expenditure on TB eradication. Consequently, the Department does not intend to introduce either a general or targeted compulsory pre-movement test at this time.

**4.4.6. Tests used and sampling schemes:** The eradication programme is conducted under the Bovine Tuberculosis (Attestation of the State and General Provisions) Order, 1989 and amendments thereto under the Diseases of Animals Act 1966. While the principal test used in the programme is the Single Intradermal Comparative Test as specified in Council Directive 64/432 EEC (as amended), considerable work has been undertaken on the development of laboratory based blood tests for TB and this work will continue during the 2011-2014 programme.

#### Supplementary testing

In accordance with Article 5 of Annex B of Directive 64/432, supplementary testing is also a feature of the Irish eradication programme. The epidemiological investigation indicates the focus of risk and thus forms the basis for requiring testing (termed special check testing) outside the normal frequency of testing in Officially Free Status herds as proscribed by the Directive. The title of the test (test type) also determines the prioritisation for completion e.g. a round test is the annual test issued in conformity with the Directive for those herds with risk category D (default) – this is the lowest risk category – and, while it must be completed within the prescribed time frame (i.e. yearly), it has the lowest priority. Thus, **more frequent testing** is conducted in higher risk areas and on higher risk herds e.g.:

- following restoration of status after a high-risk breakdown, herds are placed on a 6-monthly herd-testing regime for the succeeding one and a half years (**Post-de-restriction/ special check test**).
  - check testing of herds in problem areas (**special check test**);
  - following disclosure of a reactor, a special contiguous testing programme for herds adjoining infected herds is operated (**contiguous tests**);
- tests are additionally conducted on herds with epidemiological links, including traceback and trace-onward indicating a risk of infection (**special check test**).

The effect of the first two tests mentioned above is to ensure that higher risk herds are subject to herd tests at six-monthly intervals for a two year period.

#### Gamma interferon assay

The Gamma Interferon assay is used under practical field conditions as an adjunct to the tuberculin test in infected herds. The use of the gamma-interferon assay is targeted towards herds classified as high risk where the assay is of particular use if tuberculin testing has failed to speedily resolve the problem or where complete depopulation of the herd would be

the only alternative. A new, antigen specific, version of the gamma-interferon assay will, we understand become available shortly which may extend the use of this assay in the 2011-2015 programme. Research is continuing, therefore, to provide additional information on the use and potential of this and other possible tests.

In all herds experiencing a high risk breakdown (more than one reactor/infected animals and OTF status withdrawn) classified as a 'H' breakdown, following disclosure of reactors to the tuberculin test, consideration is given to having the remaining animals blood tested so that further infected animals will be removed. This test makes available a mechanism to remove infection from the herd earlier than on foot of the follow-up tuberculin retest set at a mandatory minimum of 60 days from the removal of the last positive reactor.

Following disclosure of a reactor, a special contiguous testing programme for herds adjoining restricted herds is implemented. Experimentally, the use of Gamma Interferon assay was also assessed in these potentially exposed herds. However, it did not prove suitable to use as an additional screening test even in such herds; this shall be re-evaluated when the new kit is available.

As regards the criteria used to decide if a herd should be depopulated, it is policy that where the level of infection in the herd is such that, despite standard and repeated tuberculin testing, the application of the Interferon- $\gamma$  assay, epidemiological assessment and strategic removal of individual animals within the herd, disease continues to spread, serious consideration is given to depopulation. In the first instance, the herd or infected group must be subjected to the Interferon- $\gamma$  assay where it has not already been used, and then the suitability for removal of the entire infected group (partial depopulation or inccontact removal) must be assessed. When the assay and/or inccontact removal has failed to resolve the problem, then depopulation of the herd must be considered. As a more general rule, cases where more than 30% of the herd has tested positive may lead to depopulation being considered, whereas if 50% of the herd are reactors then depopulation must be considered. Depopulation must also be considered where the epidemiological assessment determines that control of TB in the herd or area will be otherwise compromised such as by an inability to implement satisfactory controls in the herd. Where herd depopulation has been deemed necessary, the SVI determines an appropriate rest period for the land usually of about four months during which the keeper may not restock. Further, unless badgers have been excluded as a cause of the outbreak a badger capture programme will be conducted and a programme of resting undertaken in contiguous herds.

#### Other test development

Ireland continues to play an active role in research into the enhancement of the gamma-interferon assay and the development of other methods to diagnose bovine TB in collaboration with various research partners worldwide. A multiplex Immunoassay is currently showing particular promise for serological diagnosis of *Mycobacterium bovis* infection (Whelan et al., 2008. Clinical and vaccine immunology p1834-1838; Whelan et al. 2010 Clinical and vaccine immunology – in press; Cleg et al., 2010 Vet Micro - submitted).

**4.4.7. Vaccines used and vaccination schemes:** As previously detailed there is no TB-vaccine approved and licensed for use in either bovine animals or affected wildlife species. Over the last 10-years Ireland has been involved in a research project to develop such a vaccine for use in badgers; efficacy of a candidate vaccine has been confirmed at laboratory level and a 3-4 year duration field trial commenced in 2009 (Aznar et al. 2010 Vet Micro – submitted). to evaluate efficacy in badgers in a natural environment. If the trial demonstrates sufficient efficacy it is Ireland's intention to progress to a situation where badger vaccination will be incorporated into the programme as a matter of routine.

**4.4.8. Information and assessment on bio-security measures management and infrastructure in place in the holdings involved:** Advice on appropriate bio-security measures is provided by the Department to herdowners via leaflets, publicly etc. In addition, payment of compensation is conditional on the disinfection of the holding following a breakdown. Further, the legislation empowers the veterinary inspector to confine animals to or exclude them from particular areas of the holding if the disease epidemiological situation so warrants.

**4.4.9. Measures in case of a positive result<sup>10</sup>:** Under legislation, veterinary surgeons are required to notify the Superintending Veterinary Inspector at the District Veterinary Office of details of all positive and inconclusive test results. Some 97% of test results are communicated electronically from the office of the testing Veterinary Practitioner and the local District Veterinary Office (DVO) of the Department of Agriculture via a link to AHCS. Where bovine TB reactors are identified, legally the holding is automatically restricted for 30 days and the reactor animals are removed for slaughter via the reactor collection service which is implemented by the Department. Animals are not permitted to be moved onto or off the holding except under and in accordance with the terms of a movement permit issued by the local DVO. A formal restriction notice is issued in respect of the holding which can only be removed by issue of a formal derestriction notice. On receipt of the restriction notice, the farmer is required to surrender all passports in respect of the eligible animals on the holding, if they have not already been surrendered. Slurry and manure storage and premises disinfection requirements and procedures are notified to the farmer and appropriate follow-up re-testing takes place until final clearance test shows the herd to be clear and status is restored in accordance with Directive 64/432/EEC.

Where a suspect TB lesion is detected in a carcass from an animal originating in a clear herd, the holding is immediately restricted, the suspect lesion is subjected to laboratory examination and the herd is then subjected to the appropriate testing regime as defined in Council Directive 64/432/EEC, as amended.

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<sup>10</sup> A short description is provided of the measures as regards positive animals (slaughter, 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.).

**4.4.10. Compensation scheme for owners of slaughtered and killed animals:** It is recognised that where reactors are removed and a herd is restricted for a prolonged period because of disease, a keeper can suffer significant income loss. The programme continues to take account of this income loss and compensation in line with market values is provided for under the On-Farm Market Valuation Scheme, which provides for the independent valuation of reactor animals/herds on the basis of current market prices, together with a right of appeal for the keeper. The keeper is paid the carcase-salvage value directly by the slaughter plant and the differential between this salvage value and the valuation is paid by the Department. As was recommended by the Task Force, compensation reflects individual animal market value and is subject to a ceiling on an individual animal value.

#### **Other compensation arrangements**

In addition to compensation for the slaughter of individual animals, the Department also provides compensation to farmers for other losses, subject to conditions such as co-operation and timely compliance with tests, under the following schemes:

**Depopulation scheme:** In certain circumstances a monthly Depopulation Grant is paid for each animal removed under the depopulation measure while the holding remains under restriction preventing return to normal farming practice. The objective of this payment is to compensate the herdowner for the loss of income during the rest period.

**Income Supplement** is payable in cases where disease breakdown results in the removal of more than 10% of animals in a herd and where depopulation is not deemed appropriate. The objective is to compensate the herdowner for the loss of income arising from the removal of cattle as reactors.

**Hardship Grant** is designed to alleviate the additional feeding costs of some owner/keepers whose holdings are restricted on foot of a herd re-test during the period November to March.

Eligibility for compensation is conditional on compliance with various legislative provisions relating to the eradication programme. A penalty system, which varies with the degree of non-conformance, is in place and is kept under regular review. Farmers contribute towards the cost of compensation in the form of levies collected.

#### **4.4.11. Control on the implementation of the programme and reporting:**

Control and implementation of the programme rests with the Competent Authority who oversee the scheduling of tests, testing returns, removal of infected animals, epidemiological investigations and all aspects of the programme including evaluation of results, delivery and quality control aspects as described above. To facilitate control and implementation, considerable use is made of computerised systems developed by the competent Authority specifically for the task, such as the Animal Health Computer System (AHCS) and Herdfinder or, where appropriate, to avail of synergies between national and/or EU requirements such as the Animal Identification and Movement system (AIM).

The AHCS and the AIM are interlinked and thus more closely monitor the testing of the national herd, ensure that animals cannot evade the annual or any herd-level test and allow greater analysis of data. Refinement of the AHCS is ongoing. Further computer enhancements incorporated into AHCS during 2009 have included a module for a Reactor Herd Management system (RHMS) and a Trace-Forward and Epidemiological Investigation Tracking System. A Geographic Information System based 'Herd Finder' programme to rapidly locate and identify herds that may be, or may have been, at risk of exposure has also been developed. Additionally, resources have been allocated to continue to provide intensive laboratory analysis, including culturing and strain typing at the Department's Central Veterinary Laboratory.

#### **Other measures of submitted programme**

The comprehensive testing programme is supported by a range of support measures including

- the Reactor Collection Service,
- a secure tag identification system,
- a farmer awareness strategy
- an Animal identification and Movement system (AIM) designed to comprehensively monitor all cattle movements.
- the original computerised disease testing and management recording system was fully replaced by a modern Animal Health Computerised System (AHCS), during the 2004 programme.
- Linkage of the AIM and AHCS databases to ensure accurate herd profile production for the TB testing under the eradication programme.
- Provision of AIM (Animal Identification and Movement) live at markets, export points and slaughterhouses to provide animal status, test data and movement/export eligibility, including an animal's compliance with identification, Animal Health requirements and eligibility for sale/slaughter is confirmed before sale/slaughter in real time.
- Linkage of Veterinary Practitioners electronically to AHCS to ensure herd profile production (download) immediately preceding testing and prompt upload of test results to the Department of Agriculture local office by the end of 2007 some 97% of tests at animal level were transmitted electronically using this procedure.
- Comprehensive research programme.

5. **Benefits of the programme**<sup>11</sup>;

The agriculture, fisheries and food sector continues to make a significant contribution to the Irish economy and the most recent figures available suggests it accounts for 6.6% of GDP at factor cost, 7.5% of employment and 10% of exports. Within agriculture, over 75% of all farmers in Ireland are specifically involved in the production of beef and milk. Given the predominant position of the dairy and beef sector in Irish agriculture and as a generator of very substantial foreign earnings from the export of livestock and livestock products, the projected expenditure of c. € 70m. (which includes staff costs) will yield significant benefits, in terms of maintaining (i) the overall health of the national herd population and (ii) the ability of Irish farmers and exporters to trade in livestock and livestock products. For maximum efficiency in utilisation of limited national resources, Bovine Tuberculosis testing is predominantly carried out in conjunction with Brucellosis testing of herds.

The programme is aimed at the eradication of Bovine Tuberculosis in Ireland. Bovine Tuberculosis results in significant (i) income losses to farmers in terms of reduced productivity, restrictions on trade, increased testing costs and (ii) increased public expenditure and, accordingly, increased taxation of Irish taxpayers. A successful eradication policy – or a significant reduction in the incidence of the disease – would reduce these losses/costs to farmers and taxpayers. An independent cost benefit analysis of the Bovine TB Eradication Scheme in 1992 found that the investment in disease eradication was substantially beneficial from the national economy perspective, yielding a rate of return of 16%. This investment has enabled the Irish Livestock industry to maintain and develop exports markets.

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<sup>11</sup> A description is provided of the benefits for farmers and society in general.

6. Data on the epidemiological evolution during the last five years<sup>12</sup>

6.1. Evolution of the disease<sup>13</sup>

6.1.1. Data on herds<sup>14</sup> (one table per year and per disease/species)

Year: 2009 - 2005

Situation on date: 31/12/2009

Disease<sup>(a)</sup>: Tuberculosis Animal species: Bovine

Region <sup>(c)</sup>	Total number of herds <sup>(d)</sup>	Total number of herds under the programme	Number of herds checked <sup>(e)</sup>	Number of positive herds <sup>(f)</sup>	Number of new positive herds <sup>(g)</sup>	Number of herds depopulated	% positive herds depopulated	INDICATORS		
								% herd coverage	% positive herds prevalence	% new positive herds incidence
1	2	3	4	5	6	7	8 = (7/5) x 100	9 = (4/3) x 100	10 =	11 = (6/4) x 100
2009	117,287	117,287	115,121	6,065	5,860	21	0,35%	98,2%	5,27%	5,09%
2008	118,030	118,030	116,184	7,042	6,837	25	0,36%	98,4%	6,06%	5,88%
2007	120,652	120,652	116,964	7,235	7,046	21	0,29%	96,9%	6,22%	6,02%
2006	122,392	122,392	118,925	6,736	6,386	21	0,31%	97,2%	5,66%	5,40%
2005	123,322	123,322	119,963	6,997	6,647	24	0,34%	97,3%	5,83%	5,54%

(a) Herds or flocks or holdings as appropriate.

(b) Disease and animal species if necessary.

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

(d) Total number of herds existing in the region, including eligible herds and non-eligible herds for the programme.

(e) 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 it has been checked more than once.

(f) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.

(g) 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.

<sup>12</sup>

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

<sup>13</sup> No data to provide in case of rabies.



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

Year: 2009-2005

Situation on date: 31/12/2009

Region <sup>(b)</sup>	Tuberculosis			Animal species: Bovine			Slaughtering		INDICATORS	
	Total number of animals <sup>(c)</sup>	Number of animals <sup>(d)</sup> to be tested under the programme <sup>(e)</sup>	Number of animals <sup>(d)</sup> tested	Number of animals tested individually <sup>(e)</sup>	Number of positive animals	Number of animals with positive result slaughtered or culled	Total number of animals slaughtered <sup>(f)</sup>	% coverage at animal level	% positive animals	Animal prevalence
1	2	3	4	5	6	7	8	$9 = \frac{7}{8} \times 100$	$10 = \frac{6}{6.4} \times 100$	
2009	6,025,656	6,025,656	5,914,324	5,914,324	23,805	23,805	25,114	98.2%	0.40%	
2008	6,150,163	6,150,163	6,054,387	6,054,387	29,901	29,901	32,345	98.4%	0.49%	
2007	6,084,037	6,084,037	6,009,402	6,009,402	27,711	27,711	29,277	98.8	0.46%	
2006	6,260,133	6,260,133	6,260,131	6,260,131	24,173	24,173	25,654	99.9%	0.39%	
2005	6,407,456	6,407,456	6,335,436	6,335,436	25,884	25,884	27,794	98.9%	0.40%	
Total										

(a) Disease and animal species if necessary.

(b) Region as defined in the approved eradication programme of the Member State.

(c) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.

(d) Includes animals tested individually or under bulk level scheme.

(e) Include only animals tested individually, do not include animals tested by bulk level samples (for instance: milk bulk tank tests).

(f) 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 (one table per year and per disease/species)

Year: 2009

Disease<sup>(a)</sup>: Tuberculosis

Animal species/category: Bovine

Description of the used serological tests: Interferon Gamma Assay and anamnestic ELISA in already infected herds, for inconclusive reactor animals and for research purposes.

Description of the used microbiological or virological tests: Culture is most often used for NVL (No visible Lesion) samples taken for investigative/confirmatory purposes, for many lymph node lesions a diagnosis is based on histopathological examination alone and culture is only done if there is a difficulty in making a decision based on the histopathological findings. The accuracy of histopathological decisions is quality controlled by conducting random culture confirmations. The Bacteriology/culture procedure is as follows: Samples are decontaminated with 5% oxalic acid before culture. One vial of Bactec 12 B medium, one tube of Stonebrinks medium and one tube of Lowenstein Jansen medium with pyruvate are inoculated and incubated at 37 C for 7 weeks. If Rhodococcus equi infection is suspected a blood agar plate is also inoculated. Isolates are identified based on growth characteristics including cording, AccuProbe and 'in house' PCR identification tests.

Description of the other used tests:

Region <sup>(b)</sup>	Serological tests		Microbiological or virological tests		Other tests	
	Number of samples tested <sup>(c)</sup>	Number of positive samples <sup>(d)</sup>	Number of samples tested <sup>(c)</sup>	Number of positive	Number of samples tested <sup>(c)</sup>	Number of positive samples <sup>(d)</sup>
2009	Gamma Interferon 7,063 bovine. 989 goats	1770 Bovine 20 goats	6,318 bovine ,2 Sheep, 105 Goats, 23 Deer, 1,129 Goats, 15 Deer.	3,165 Bovine, 0 Sheep, 60 Goats, 15 Deer.	2,009 Goats SICCT	15
2008	Gamma Interferon 20,389 Bovine 31 Sheep 320 Goats	5,410 Bovine 2 Sheep 80 Goats	6,656 Bovine 1,754 badgers, 138 deer, 147 goats, 14 sheep, 4 pigs	3,411 Bovine 399 Badgers 57 deer 48 Goats, 3 Sheep	5,000 Goats SICCT	
2007	17,320	~17%	7,142	3,924	242 (sheep/deer/misc)	50
2006	10,888	~18%	6,417	3,645	114 (sheep,deer,badger)	48 (culture)
Total						

(a) Disease and animal species if necessary. (b) Region as defined in the approved eradication programme of the Member State. (c) Number of samples tested. (d) Number of positive samples.

6.3 Data on infection (one table per year and per disease/species)

Year: 2009

Disease<sup>(a)</sup>: tuberculosis

Animal species: Bovine

We are unsure of what information is required under this heading- Commission Decision 2004/450/EC does not provide any definition for term 'infection'. In seeking to provide an objective measure of infection, we have been guided by Council Directive 64/432/EEC, which provides for the suspension of status of a herd where infection is not confirmed and for a different frequency of testing for the restoration of status in herds that are not confirmed as infected. The data provided below relates to animals and herds where infection has been confirmed – tuberculosis lesions having been identified in skin test reactor cattle or tuberculosis lesions having been confirmed in animals from previously OTF herds. Whilst this is a relatively crude measure of infection, it is objective and relatively comparable. We trust that this will be of value to you.

Region <sup>(b)</sup>	Number of herds infected <sup>(c)</sup>	Number of animals infected
2006	4,942	12,127
2007	5,278	12,480
2008	4,760	12,538
2009	3,999	10,537

(a) Disease and animal species if necessary.

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

(c) Herds or flocks or holdings as appropriate.

6.4. Data on the status of herds at the end of each year<sup>14</sup>

Year: 2009-2005

Disease<sup>(a)</sup>: Tuberculosis

Animal species: Bovine

Region <sup>(b)</sup>	Status of herds and animals under the programme <sup>(c)</sup>													
	Total number of herds and animals under the programme		Unknown <sup>(d)</sup>		Not free or not officially free from disease			Free or officially free from disease status suspended <sup>(e)</sup>		Free from disease <sup>(f)</sup>		Officially free from disease <sup>(g)</sup>		
	Herds	Animals <sup>(h)</sup>	Herds	Animals <sup>(h)</sup>	Last check positive <sup>(i)</sup>	Last check negative <sup>(i)</sup>	Herds	Animals <sup>(h)</sup>	Herds	Animals <sup>(h)</sup>	Herds	Animals <sup>(h)</sup>		
2009	117,287	6,025,656	0	0	1,712	186,151	1,510	153,915	292	34,207	0	0	113,773	5,651,382
2008	118,030	6,150,163	0	0	1,974	221,125	1,850	191,328	303	34,046	0	0	113,903	5,703,664
2007	120,652	6,084,037	0	0	2,303	235,513	1,733	166,470	334	33,670	0	0	116,282	5,648,384
2006	122,392	6,260,133	0	0	2,124	228,856	1,596	162,854	383	41,053	0	0	118,288	5,827,368

(a) Disease and species if necessary

(b) Region as defined in the approved eradication programme of the Member State

(c) At the end of the year

(d) Unknown: No previous checking results available

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

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

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

(h) Free herd as defined in Community or national legislation for the respective disease.

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

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

<sup>14</sup>

Only data to provide for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (*B. melitensis*), enzootic bovine leucosis (EBL) and Aujeszky's disease

6.5. Data on vaccination or treatment programmes<sup>15</sup> -- Not applicable No VACCINATION - NO TREATMENT

Year: \_\_\_\_\_ Disease<sup>(a)</sup>: \_\_\_\_\_

Animal species: \_\_\_\_\_

Description of the used vaccination, therapeutic or other scheme:

Region <sup>(b)</sup>	Total number of herds <sup>(c)</sup>	Total number of animals	Information on vaccination or treatment programme					
			Number of herds <sup>(c)</sup> in vaccination or treatment programme	Number of animals vaccinated or treated	Number of doses of vaccine or treatment administered	Number of adults <sup>(d)</sup> vaccinated	Number of young <sup>(a)</sup> animals vaccinated	
Total								

(a) Disease and species if necessary

(b) Region as defined in the approved eradication programme of the Member State

(c) Herds or flocks or holdings as appropriate

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

<sup>15</sup> Data to provide only if vaccination has been carried out.

6.6. Data on wildlife<sup>16</sup>

6.6.1. Estimation of wildlife population

Year: 2009

Method of estimation<sup>(a)</sup>: Capture returns indicate density in the range 1.5-2 animals/sq. Km

Regions <sup>(b)</sup>	Estimation of the population of the concerned wild species	
	Species:	Species:
Ireland	Badger - Meles meles – 105-140,000	
Total		

(a) The hunting bag is considered to be the standard method of estimation. If other method is used, explain

(b) Region as defined in the approved eradication programme of the Member State

<sup>16</sup> 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. *Monitoring of wildlife (one table per year and per disease/species)*

Year: 2008 Disease<sup>(a)</sup>: Tuberculosis Animal species: Badger

Description of the used serological tests:

Description of the used microbiological or virological tests: Culture of pooled samples taken from each badger for a representative number of badgers captured.

Description of the other used tests:

Region <sup>(b)</sup>	Microbiological or virological tests		Serological tests		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
2009	1129	159 (15%)				
2008	1754	399 (23%)				
2007	898	242 (27%)				
Total						

(a) Disease and species, if necessary

(b) Region as defined in the approved eradication programme of the Member State

6.6.3. Data on vaccination or treatment of wildlife

Year: 2009

Disease<sup>(a)</sup>: Bovine Tuberculosis – M.bovis Animal species: Badger

Description of the used vaccination, therapeutic or other scheme: NO APPROVED VACCINE CURRENTLY AVAILABLE. Project vaccine still at development and field trial stage.

Region <sup>(b)</sup>	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
2010 – experimental project to determine efficacy	70,000	Experimental projects only	3	
2009 – experimental project to determine efficacy	70,000	Experimental project only		
Total				

(a) Disease and species if necessary

(b) Region as defined in the approved eradication programme of the Member State



## 7. Targets

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

#### 7.1.1. Targets on diagnostic tests

Disease<sup>(a)</sup>

Animal species:

Region <sup>(b)</sup>	Type of the test <sup>(c)</sup>	Target population <sup>(d)</sup>	Type of sample <sup>(e)</sup>	Objective <sup>(f)</sup>	Number of planned tests
Ireland	Tuberculin Skin test	All Bovines		Programme implementation	9,000,000
	Gamma Interferon Assay	Bovines	Heparinised blood	Programme implementation and Research	15,000
	ELISA & Anamnestic ELISA	Bovines	Clotted blood	Programme and Research – focus to detect energy	1,000
	Multiplex Assay	Bovines, Goats, Badgers	Clotted samples	Programme and Research – test under development	5,000
<b>Total</b>					

(a) Disease and species if necessary

(b) Region as defined in the approved eradication programme of the Member State

(c) Description of the test (for instance SN-test, AB-Elisa, RBT, ...)

(d) Specification of the targeted species and the categories of targeted animals (for instance sex, age, breeding animal, slaughter animal, ...)

(e) Description of the sample (for instance blood, serum, milk, ...)

(f) 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, ...)

## 7.1.2.

### Targets on testing herds and animals<sup>17</sup>

#### 7.1.2.1

#### Targets on the testing of herds<sup>(a)</sup>

In our assessment and prediction of targets, we are also guided by what we have learnt from the application of badger control treatments in East Offaly and the Four Area study, where improvement in 'Herd Period Prevalence' followed on approximately three years after the initial wildlife treatment. The targets set for 2009 and 2010 reflect this belief and are challenging, yet at the same time are realistic and achievable.

#### Disease<sup>(b)</sup>: Tuberculosis

#### Animal species: bovine

Region <sup>(c)</sup>	Total number of herds <sup>(d)</sup>	Total number of herds under the programme	Number of herds expected to be checked <sup>(e)</sup>	Number of expected positive herds <sup>(f)</sup>	Number of expected positive herds <sup>(g)</sup>	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 = (7/5)x100	9 = (4/3)x100	10 =	11 = (6/4)x100
2011	116,000	116,000	114,260	5,950	5,710	15	0.25%	98.5%	5.2%	5%
2010	116,500	116,500	114,752	6,436	6,212	15	0.23%	98.5%	5.4%	5.2%
2009(actual for reference only see previous tables)	117,287	117,287	115,121	6,065	5,860	21	0.35%	98.2%	5.27%	5.09%
Total										

(a) Herds or flocks, or holdings as appropriate.

(b) Disease and animal species if necessary.

(c) Region as defined in the approved eradication programme of the Member State.

(d) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.

(e) 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.

(f) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.

(g) 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.

<sup>17</sup>

Data not to provide in case of rabies.

7.1.2.2. Targets on the testing of animals

Disease<sup>(a)</sup>: Tuberculosis Animal species: **Bovine**

Region <sup>(b)</sup>	Total number of animals <sup>(c)</sup>	Number of animals <sup>(d)</sup> under the programme	Number of animals <sup>(d)</sup> expected to be tested	Number of animals to be tested individually <sup>(e)</sup>	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 <sup>(f)</sup>	Expected % coverage at animal level	% positive animals (Expected animal prevalence)
	2	3	4	5	6	7	8	$9 = \frac{7}{8} \times 100$	$10 = \frac{6}{4} \times 100$
2011	6,000,000	6,000,000	5,910,000	5,910,000	24,000	24,000	26,000	98.5%	0.41%
2010	6,000,000	6,000,000	5,910,000	5,910,000	26,000	26,000	27,800	98.5%	0.44%
2009(actual for reference only see previous tables)	6,025,656	6,025,656	5,914,324	5,914,324	23,805	23,805	25,114	98.2%	0.40%
<b>Total</b>									

(a) Disease and animal species if necessary.

(b) Region as defined in the approved eradication programme of the Member State.

(c) Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.

(d) Includes animals tested individually or under bulk level scheme.

(e) Include only animals tested individually, do not include animals tested by bulk level samples (for instance milk bulk tank tests).

(f) Include all positive animals slaughtered and also the negative animals slaughtered under the programme.

7.2. Targets on qualification of herds and animals<sup>18</sup> (one table for each year of implementation)

Disease<sup>(a)</sup>: Tuberculosis Animal species: Bovine

Region <sup>(b)</sup>	Total number of herds and animals under the programme		Targets on the status of herds and animals under the programme <sup>(c)</sup>											
	Herds	Animals <sup>(d)</sup>	Expected unknown <sup>(d)</sup>		Expected not free or not officially free from disease		Expected free or officially free from disease status suspended <sup>(e)</sup>		Expected free from disease <sup>(f)</sup>		Expected officially free from disease <sup>(f)</sup>			
			Herds	Animals <sup>(d)</sup>	Herds	Animals <sup>(d)</sup>	Herds	Animals <sup>(d)</sup>	Herds	Animals <sup>(d)</sup>	Herds	Animals <sup>(d)</sup>		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
2011	116,000	6,000,000	0	0	1,200	135,000	1,250	120,000	300	42,000			113,250	5,703,000
2010	116,500	6,000,000	0	0	1,400	150,000	1,350	150,000	350	46,000	0	0	112,900	5,658,000
2009 (actual for reference only see previous tables)	117,287	6,025,656	0	0	1,712	186,152	1,510	153,915	493	55,826	0	0	113,773	5,651,382

(a) Disease and species if necessary

(b) Region as defined in the approved eradication programme of the Member State

(c) At the end of the year

(d) Unknown: No previous checking results available

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

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

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

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

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

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

<sup>18</sup>

Data to provide only for bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis (*B. melitensis*), enzootic bovine leucosis (EBL) and Aujeszky's disease

7.3. Targets on vaccination or treatment (one table for each year of implementation) Not applicable – NO VACCINATION and NO TREATMENT

7.3.1. Targets on vaccination or treatment<sup>19</sup>

Disease<sup>(a)</sup>:

Animal species:

Region <sup>(b)</sup>	Total number of herds <sup>(c)</sup> in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Targets on vaccination or treatment programme					
			Number of herds <sup>(c)</sup> in vaccination or treatment programme	Number of animals expected to be vaccinated or treated	Number of doses of vaccine or treatment expected to be administered	Number of adults <sup>(d)</sup> expected to be vaccinated	Number of young <sup>(d)</sup> animals expected to be vaccinated	
<b>Total</b>								

(a) Disease and species if necessary

(b) Region as defined in the approved eradication programme of the Member State

(c) Herds or flocks or holdings as appropriate

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

<sup>19</sup> Data to provide only if appropriate.

7.3.2. Targets on vaccination or treatment<sup>20</sup> of wildlife

Disease<sup>(a)</sup>: bovine tuberculosis – *M. bovis* Animal species: Badger – *Meles meles*

Region <sup>(b)</sup>	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
2012	70,000+	~ 300	1	~ 300
2011	70,000+	200-500	3	200-500
2010- Field trials (experimental)–	70,000	200-400	3	200-400
Total				

(a) Disease and species if necessary

(b) Region as defined in the approved eradication programme of the Member State

<sup>20</sup> Data to provide only if appropriate.

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

Costs related to	Specification	Number of units	Unitary cost in €	Total amount in €	Community funding requested (yes/no)
<b>1. Testing</b>					
<b>1.1. Cost of the analysis</b>	<i>Test: Tuberculin Test</i>				
	<i>Purchase of Tuberculin</i>	9,000,000	0.25	2,250,000	yes
	<i>Department paid testing fees to vets</i>	2,610,000	2.92	7,621,200	yes
	<i>Test: Gamma Interferon Assay Lab analysis</i>	15,000	17.00	255,000	yes
	<i>Test: Elisa lab analysis</i>	1,000	5.00	5,000	yes
<b>1.2. Cost of sampling</b>	<i>Gamma Interferon Assay fees</i>	15,000	2.54	38,100	yes
	<i>Test Multiplex Assay fees</i>	5,000	2.54	12,700	no
	<i>Elisa fees</i>	1000	2.54	2,540	no
<b>1.3. Other costs</b>					
<b>2. Vaccination or treatment</b>	<i>Badger Vaccination Trial-see under Pt.7</i>				
<b>2.1. Purchase of vaccine/treatment</b>					
<b>2.2. Distribution costs</b>					
<b>2.3. Administering costs</b>					
<b>2.4. Control costs</b>	<i>Capture &amp; removal badgers- See under No. 7</i>				

<b>3. Slaughter and destruction</b>						
3.1. Compensation of animals	On Farm Market valuation/Reactor Grants	23800	750	17,850,000		yes
3.2. Transport costs	Depopulation/income supplement			3,300,000		No
3.3. Destruction costs	Reactor collection Service	23800	43.33	1,031,000		No
3.4. Loss in case of slaughtering	Not applicable					
3.5. Costs from treatment of products (milk, eggs, hatching eggs, etc)	Not applicable					
4. Cleaning and disinfection	Not applicable					
5. Salaries	Not applicable			28,000,000		No
6. Consumables and specific equipment	Not applicable					
7. Other costs						
<b>Wildlife Measures</b>						
Salaries (staff contracted for the wildlife programme only)	FRS contract employees			2,500,000		yes
Wildlife Salaries				1,200,000		No
Supplies				400,000		yes
Badger Vaccination Trial				700,000		yes
Wildlife Unit Travel for DAFF Staff				400,000		no



Travel & subsistence, computerisation, Publicity/Printing, Other research Unit, Value Fees, Laboratory items not included and miscellaneous items				4,381,000	no
<b>TOTAL</b>				<b>69,946,540</b>	