



## Annex I.b : Programme for the eradication of bovine Tuberculosis, bovine Brucellosis or sheep and goat Brucellosis (*B. melitensis*) submitted for obtaining EU cofinancing

Member States seeking a financial contribution from the European Union for national programmes of eradication, control and surveillance shall submit online this application completely filled out.

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- 7) For simplification purposes you are invited to submit **multi-annual programmes**.
- 8) As mentioned during the Plenary Task Force of 28/2/2014, you are invited to submit your programmes in **English**.

**Submission Date**

Thursday, May 28, 2015 18:54:00

**Submission Number**

1432835645866-4748



# Standard requirements for the submission of programme for eradication, control and monitoring

## 1. Identification of the programme

Member state: IRELAND

Disease: Bovine tuberculosis

Species: Bovines and buffalo

This program is multi annual: yes

Type of submission: New multiannual programme

Request of Union co-financing  
from beginning of:

2016

To end of

2018

# Standard requirements for the submission of programme for eradication, control and monitoring

## 1.1 Contact

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## 2. Historical data on the epidemiological evolution of the disease

Provide a concise description of the following indicators :

- Number of serologically positive domestic pigs compared to previous year
- Number of virologically positive domestic pigs compared to previous year
- Number of serologically positive wild boar/feral pigs compared to previous year
- Number of virologically positive wild boar/feral pigs compared to previous year
- An assessment of the evolution of the indicators along the years is requested as well as obstacles and constraints identified that hamper the progress of eradication.

(max. 32000 chars) :

In 1954 individual herd registration, based on the herd as the epidemiological unit i.e. all the animals in the herd regardless of ownership, commenced in tandem with the introduction of a bovine tuberculosis (bTB) eradication programme, (BTBEP) operated by the then Department of Agriculture. Irish legislation was introduced covering all Mycobacterial spp. that may cause TB in bovines, with a broad definition of what constituted a reactor under the BTBEP namely "an animal which by reason of a test or otherwise a veterinary inspector believes or suspects is affected with bovine tuberculosis or is capable of infecting other animals with bovine tuberculosis" to ensure that all possible TB infected animals could be compulsorily removed. At that time an estimated 80% of cattle herds were TB infected. Disease (bTB) and incidence fell rapidly from 17% animal incidence overall (22% cows) to less than 0.5% in 1965 at which stage all herds had individually at some stage achieved Officially Tuberculosis Free (OTF) status in accordance with Directive 64/432/EEC and no herds of unknown status remained in Ireland.

The Single Intradermal Comparative Tuberculin Test (SICTT) has been the routine test used in Ireland since the commencement of the BTBEP. The use of the SICTT, in Ireland, was justified to the EEC prior to Ireland becoming a member of the EEC and the SICTT was subsequently incorporated into Directive 64/432/EEC by Directive 80/219/EEC. For details and for the recommendations for the text used to edit Annex B of Directive 64/432/EEC please see Schneider, W., Augier, J., Cavrini, C., Dam, A., Dobbelaer, R., Gayot, G., Haagsma, J., Herbert, N., Jorgensen, J., Leslie, I., O'Reilly, L., Rees, H. (1979) Final report of the sub-group of the Scientific Veterinary Commission on tuberculins 2577/VI/79-EN Rev.4 on behalf of

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Commission of the European Communities, Directorate-General for Agriculture VI/B/II2 and also Directive 79/111/EEC. The same 1979 report (page 20) also references that when joining the EEC Denmark, Ireland, and the United Kingdom were allowed derogation to “retain the methods applied in their territory for declaring a herd of cattle officially free of tuberculosis”, as defined in Directive 64/432/EEC, rather than, presumably, those specified in Directives 77/391 and 78/52/EEC. Having brought all herds to OTF status by 1965, Ireland has, since 1980, complied with the requirements of Directive 64/432/EEC in order for herds to retain OTF status or to restore OTF status, where status has been suspended or withdrawn according to this Directive.

The TB eradication programme has, since its inception, been constantly subject to review e.g. reviews conducted by Irish Veterinary Association 1979; EU Commission 1981; Irish Farmers Association 1982; Irish Veterinary Union 1982; Irish Veterinary Association 1982, Interdepartmental review Group 1983; Conjoint report of the veterinary groups 1984; Economic and Social Research Institute (Report) 1986 and, more recently, reviews instigated by Ireland, by International TB experts, further EU Commission reviews, reviews and recommendations by the EU TB Task Force and the FVO.

In 1988, in response to recommendations from the many reviews that predated its establishment ERAD, a specialised agency, was established to implement the programme which included veterinary post-mortem surveillance of all animals intended for human consumption and, a comprehensive testing programme, using a more potent bovine tuberculin (30,000 I.U./ml) and a more severe interpretation than that required by Directive 64/432/EEC. The ERAD programme involved additional and more frequent testing of administrative/local ‘black spot’ geographic areas with perceived higher disease prevalence, known high-risk herds, contiguous herds, herds that were linked epidemiologically, extended herd-restriction and also pre-movement testing. However, these measures failed to have any appreciable impact on the incidence of the disease and, in 1992, authority for determining policy and strategy and for managing the programme reverted to the Department of Agriculture, Food and the Marine (DAFM) where it has since been managed by the ERAD Division. One of the significant conclusions from the 1988-1992 period was that TB (*M. bovis*) is endemic in badgers (*Meles meles*) and, by acting as a maintenance host wildlife reservoir for disease, they are one of the main factors affecting the disease levels and the primary constraint to the eradication of bTB in Ireland.

The Table attached at Annex 2 entitled ‘Cattle Population Trends and TB incidence 1960-2014.doc’ outlines the cattle population trend over the past four decades and the disease incidence during that period. In light of experience in implementing recommendations from the above many and varied reviews together with specific scientific research, instigated since 1988 in particular, substantial modifications have been introduced to the programme (e.g. more frequent testing of and more strict test interpretation in high risk herds and those contiguous to herds undergoing a TB breakdown, outward movement restrictions on cattle in contiguous herds prior to testing, the restriction of inconclusive reactors, which pass the re-test, to the holding of disclosure).

### Note on Epidemiological unit classification

Each single unique epidemiologically distinct herd is allocated a herdnumber for the purpose of general disease control. 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 agents 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 which may comprise parcels of land that are separated by some distance but, because of general proximity and/or management practices, constitute one epidemiological unit. Where the parcels of land used by the farmer are located in more than one administrative division and/or are sufficiently far distant to warrant being treated as two (or more) epidemiological units or where disease

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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).

### Main measures 1992 – 2015

Each herd is tuberculin tested at a minimum once annually, in accordance with Directive 64/432/EEC Annex A I.2 and full disease and movement control measures apply to each herd. Herds that are considered to be epidemiologically related have mandatory tracing and checking in the event of suspicion of disease in any of the herds. All parts of a herd which belong to the same 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. The measures implemented thus included: an annual round screening test of all herds, routine veterinary post-mortem slaughter surveillance, controls on movement of animals, restriction of holdings, removal and slaughter of reactors, appropriate follow-up testing, including the use of blood tests as an adjunct to the skin test, specific targeted additional risk-based testing, curtailment of outward movement from herds on a high risk testing programme, compensation for farmers whose herds are affected by disease, a focused badger population control measures where they have been implicated as a probable cause of TB, badger vaccination where population control measures have been implemented for a minimum of 3-years and TB levels in cattle have declined satisfactorily plus a research programme (including continued badger vaccination research to prevent the spread of TB within and from that species). A more detailed description of the programme measures is set out in Section 4.

### Main results

The 2015 BTBEP is the fifth year of a 5-year eradication programme covering the period 2011-2015. The Table referred to above (Cattle Population Trends and TB incidence 1960 -2014.doc) outlines the cattle population trend and compares the disease incidence during that period. It portrays (i) the considerable progress made in the early years of the programme, (ii) the stagnation in efforts to reduce the incidence of the disease in the period 1965 to 1999 and (iii) the progressive reduction, with some annual variations, in the level of the disease since 1999 particularly regarding herd incidence which fell from 7.7% in 1999 to 3.64% in 2014 the lowest level since the programme started in the 1950's. More particularly, as noted by the EU TB Task Force, there has been a very significant reduction in the incidence of bovine TB in Ireland since 2008, when the EU re-commenced co-funding the programme. In effect, the Task Force noted that herd incidence has fallen by 34% (from 5.88% to 3.88%) between 2008 and 2013. Herd incidence fell further in 2014 to 3.61% and the decline has continued into 2015 (16% reduction on the same period in 2014). In Ireland's view, the measures provided for in the programme to address a major source of the disease (badgers) has been a key factor in bringing about this substantial improvement. Having regard to the progress achieved since 2008 and taking account of the reduction in the incidence of TB in badgers in recent years and the likely future developments in relation to the vaccination of badgers (see below), we believes that the programme currently in place is an effective programme and, if amended from time to time in light of on-going scientific developments and research, is capable of eradicating the disease by 2030. This target has been incorporated as a strategic objective in DAFMs vision for agriculture to 2025.

Considerable effort has been expended to investigate the factors that have presented difficulties to disease eradication, to better understand and manage the bTB risk in Ireland by the introduction of relevant policy and programme modification responses and to document this (More, S.J., Good, M. (2015) Understanding and managing bTB risk: perspectives from Ireland, *Veterinary Microbiology* 176: 209–218, <http://dx.doi.org/10.1016/j.vetmic.2015.01.026>). It is noteworthy that a study by Gallagher et al. (2013) (M.J. Gallagher, I.M. Higgins, T.A. Clegg, D.H. Williams, S.J. More (2013) Comparison of bovine

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tuberculosis recurrence in Irish herds between 1998 and 2008. *Preventive Veterinary Medicine* 1;111 (3-4):237-44. doi: 10.1016/) has shown that there has been a significant reduction in bTB recurrence in Ireland between 1998 and 2008, with 2008-derestricted herds being 0.74 times (95% confidence interval: 0.68-0.81) as likely to be restricted during the subsequent study period compared with 1998-derestricted herds. The results from the study also provides further reassurance of an improved national situation, both in terms of limiting the establishment of new infection (bTB incidence) and in effectively clearing infection once detected (recurrence following derestriction).

Ireland complies fully with Commission Decision 2008/341 in that the BTBEP is based on the available relevant scientific knowledge and complies with Community legislation. The measures of the BTBEP, as selected, are the most efficient and effective measures to achieve the objective within the duration of the programme. The programme is regularly monitored and evaluated on its efficiency and effectiveness. The tools and measures adopted are cost-effective.

In summary, Ireland believes that a reduction of bTB recurrence requires effective implementation of multiple control strategies, focusing on identifying and removing residually infected cattle, and limiting environmental sources of infection, which in Ireland primarily relates to badgers. These strategies are included in the programme.

### Background to Wildlife Policy

The Irish programme seeks to address TB in all species that act as a disease maintenance host and share the environment, namely pasture, with cattle in accordance with the recommendation made by Francis (1958) (Francis, J. 1958. *Tuberculosis in animals and man: a study in comparative pathology*. Cassell & Co. Ltd.). Results from a number of small scale local reactor-removal trials in the 1980s identified a link between tuberculosis in badgers and tuberculosis in cattle in the same local areas. Formal studies i.e. the East Offaly Study (EOS), and the follow-up the Four Area Project (FAP), have shown that reducing the density of badgers over a wide area 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. Thus Ireland had the necessary scientific evidence to conclude that the main constraint to the eradication of bovine TB in the country is the presence of the disease in the Irish badger population, and a range of measures to address this constraint are now included in the BTBEP. It is now widely recognised in the scientific community, that TB is maintained independently in this species that share the same environment as cattle and that there is interspecies transmission. Recent work (Biek R, O'Hare A, Wright D, Mallon T, McCormick C, Orton RJ, et al. (2012) *Whole Genome Sequencing Reveals Local Transmission Patterns of Mycobacterium bovis in Sympatric Cattle and Badger Populations*. *PLoS Pathog* 8(11): e1003008. doi:10.1371/journal.ppat.1003008) utilising whole Genome sequencing on strains isolated from sympatric cattle and badger populations in Northern Ireland has provided the first direct genetic evidence of *M. bovis* persistence on farms over multiple outbreaks with a continued, ongoing interaction with local badgers. This study showed good correlations between genetic divergence and spatial distance, but poor correspondence to the network of cattle movements or within-herd contacts. Badger isolates showed between zero and four SNP differences from the nearest cattle isolate, providing evidence for recent transmissions between the two hosts. This supports the opinion that TB from infected badgers continually spills back into cattle where it and any subsequent bovine-to-bovine caused cases will continue to be 'cropped' by the annual testing regime in cattle, until a more permanent solution can be developed.

### Wildlife Policy

Following on from earlier findings, the Department developed (i) an interim wildlife strategy, in 2000

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(WILDLIFE POLICY (BADGERS) [HTTP://WWW.AGRICULTURE.GOV.IE/ANIMALHEALTHWELFARE/DISEASECONTROL/BOVINETBBRUCELLOSISERADICATIONSCHEMES/WILDLIFEPOLICYBADGERS/](http://www.agriculture.gov.ie/animalhealthwelfare/diseasecontrol/bovinetbbrucellosiseradicationsschemes/wildlifepolicybadgers/)), which involves the capture and removal of badgers associated with bTB breakdowns and (ii) a Government funded, Wildlife Research Programme to establish the methodology for, efficacy of and to quantify the effects of vaccinating badgers, to support and further the eradication of TB from the bovine population. It is the view of the Department of Agriculture, Food and the Marine that the implementation of the wildlife programme has contributed significantly to the reduction in the incidence of TB in Ireland in recent years. However, badgers are a protected species and in compliance with the Berne Convention local populations, even when diseased, cannot be exterminated but must be preserved to maintain genetic integrity and diversity of the species. Thus the Department is limited in the extent to which it can cull even infected populations which limits the effectiveness of the culling programme. In view of this, Ireland has been conducting research into the development of a vaccine for badgers and, in light of this research, Ireland commenced in 2014 to vaccinate badgers, with BCG by injection, in areas where they had been culled for a minimum of 3-years and where disease levels in cattle had fallen (See below for more detail).

A trial, the objective of which was primarily to provide information as to the efficacy of an individually delivered oral vaccine in reducing the level of TB infection in the wild badger population was completed in 2014. It is anticipated that the outcome of this research project will be reported on by the autumn of 2015. Other studies underway or in prospect are designed to assess the impact of badger vaccination on the incidence of TB in cattle when compared to continued badger culling. A number of badger immunological and ecology studies have also been conducted to gain further knowledge of the species with a view to developing methodologies to achieve the objective of vaccination at a population level without having to individually capture each badger being vaccinated and to reduce interspecies disease transmission.

### Impact of Badger Removal Programme

As stated above, Ireland believes that the badger culling strategy, which is aimed at addressing a major source of the disease, has been a key factor in bringing about the substantial reduction in the incidence of the disease since 2008. In 2014, TB prevalence in badgers removed as a consequence of focal culling under the programme was 13% compared with the 36.6% as reported by Murphy et al., 2010 in the initial stages of the focal culling operations and similar to the level 14.9% found in the Greenfield site badgers (i.e. badgers from areas where there had been no evidence of TB in bovines). This represents a very significant reduction in the incidence of the disease in badgers and is a direct result of the badger culling programme. It presents very strong evidence that a major source of the spread of the disease is being effectively addressed. While it is difficult to quantify the precise impact of this measure, Ireland believes that, in the absence of a badger culling programme, it is likely that the annual number of reactors disclosed would be at least 10,000 higher than that recorded in recent years. The lower number of reactors disclosed in recent years has resulted in considerable savings to the national exchequer and, by extension, has significantly reduced the level of co-funding Ireland sought by Ireland from the EU.

### 3. *Description of the submitted programme*

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

*(max. 32000 chars) :*

The specific objective of the programme is the final eradication (biological extinction) of *M. bovis* from Ireland by 2030 by addressing infection with this mycobacterium in all species in which it occurs and which share the same environment, to contribute to the high level of health for humans and animals and thereby eliminate the cost of the disease and associated controls.

The programme is a 3 year programme covering the years 2016-18.

Section 4 details the measures of the programme which can be summarised as follows:

- The national herd is tested at a minimum once annually (round test screening), in addition to any consequential testing arising,
- Restriction, under legislation, of test positive herds,
- Early removal of reactors and the provision of compensation to farmers,
- Post mortem surveillance by veterinarians of all animals slaughtered for human consumption and traceback to herd(s) of origin. Target set 1.5 submissions/1000 slaughtered for non-TB granulomas (i.e. demonstrating comprehensive slaughterhouse surveillance for bTB).
- Epidemiological investigation of bTB outbreaks including trace-back and trace-onward of infected/potentially infected animals and of movement of animals into and out of herds that are detected as bTB infected,
- Mandatory 30-day pre-movement test on animals exported and on exceptional movements permitted between restricted herds,
- Targeted blood testing (Interferon- $\gamma$  assay) as an adjunct to the skin test in certain bTB infected herds, (details in section 4.4.6.1)
- Specific testing programme for OTF higher risk herds i.e. herds contiguous to index herds where OTF status is withdrawn and infection acquisition and spread is evident in the index herd (2 or more infected animals); herds that have had OTF status restored following an outbreak where within herd infection acquisition and spread was evident.
- Movement controls, as detailed in section 4.4.5.4, out of OTF herds higher risk herds (as defined in previous indent)
- Use of Herdfinder, comprising GIS and mapping data as submitted by farmers to support claims for payment under EU funded support schemes, to focus the testing programme and controls,
- Maintenance of the local badger population at reduced levels (within the constraints of the Berne Convention) where associated with TB breakdowns and following epidemiological linkage to TB outbreak in cattle, for a minimum of 3 years before moving to a vaccination regime.
- Computerised system for organising, recording and follow-up of tests; control of animal movements; traceback and trace forward of epidemiologically linked animals
- Badger vaccination and ecological studies to address questions of efficacy of badger vaccination for TB and optimise vaccine delivery methodology.
- On-going research into optimum vaccination methods.
- Implementation of quality control measures on all aspects of the programme (tuberculin potency checks, AIM/AHCS linkages, PVP training/results monitoring/field supervisions, testing facilities, reactor checks, ring trials etc.).
- Capture, vaccinate (BCG injection) and release (badger) where population control measures have been operated and disease levels in sympatric badgers and cattle have reduced (removal had been conducted for a minimum of 3-years).



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- Use of strain typing in local epidemiological investigations and studies.
- Wildlife (badger) oral vaccination – conditional on a Marketing Authorisation in compliance with EU legislation has been obtained for such a vaccine - in areas that have never been subjected to cull and where removal had been conducted for a minimum of 3-years (Else vaccination with BCG injection will continue).

In essence, the programme, which is risk based and guided heavily by science as provided for at Point 5 (d) of the Annex to Commission Decision 2008/341/EC, provides for a comprehensive testing regime, contains significant relevant controls on the movement of cattle from high risk herds and seeks to address the main ongoing source of the disease (badgers). It includes a suite of measures including conventional test, slaughter and movement controls for bovines and measures designed to deal with TB in the sympatric wildlife population e.g. reducing the population density of M.bovis infected badgers in areas where they are seen to be contributing to bovine TB prevalence in tandem with BCG TB vaccine deployment in badgers (by capture and injection) where populations have already been reduced while research for the development and licensing of an effective oral TB vaccine is ongoing.

As stated earlier in section 2, wildlife policy, substantial research has and is being undertaken by DAFM into the development and deployment of a badger vaccine for TB. Projects, involving vaccine development, have highest priority as the outcome will enable ongoing development of the strategy to 2020. Vaccine efficacy and the success of oral-deployment measures will determine how long it will take to have effective coverage and protection at a population level for badgers and also if continued culling will or will not be required and/or for how long. It is hoped (and expected) that the vaccine trials will show that vaccination is sufficiently effective to have a beneficial impact on the transmission of TB from badgers to cattle and also that vaccine-bait deployment studies will result in a satisfactory vaccine delivery model. If so, Ireland will be in a position to routinely deploy oral vaccine to badgers sometime before 2020 (pending determination of the optimal delivery and vaccine deployment methodology and licensing of the final vaccine formulation as required under EU Medicines Directive).

In view of the significant contribution of the badger culling programme to the reduction in the incidence of TB in Ireland and the likely contribution of vaccination of badgers in the future, we believe that the costs associated with badger culling and vaccination should be eligible for co-funding and we are applying for funding for these costs under this programme in accordance with Article 11 of Regulation 652/2014 which provides that costs other than those listed in Art 11(a) to (h) may be eligible for funding in exceptional and duly justified cases.

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## 4. Measures of the submitted programme

### 4.1 Summary of measures under the programme

Duration of the programme: 2016 - 2018

#### **First year :**

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

#### **Last year :**

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

*Other, please specify*

#### 4.1.1 Timeline for the eradication

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*Provide the timeline foreseen for the eradication with detailed justification (max. 32000 chars) :*

The specific objective of the programme is the final eradication (biological extinction) of *M. bovis* from Ireland by addressing infection with this mycobacterium in all species in which it occurs and which share the same environment, to contribute to the high level of health for humans and animals and thereby eliminate the cost of the disease and associated controls. As indicated above, having regard to the progress achieved since 2008 and taking account of the reduction in the incidence of TB in badgers in recent years and the likely future developments in relation to the vaccination of badgers, Ireland believes that the programme currently in place is an effective programme and is capable of eradicating the disease by 2030.

The operational objective of this 3-year programme, 2016-2018 inclusive, with respect to sympatric animal species in which *M. bovis* causes infection is to continue to progressively reduce the measured and measureable disease parameters such as prevalence in wildlife and domestic species that act as maintenance hosts for *M. bovis*.

With respect to humans the Health Protection Surveillance Centre <http://www.hpsc.ie/> collates and publishes figures on the incidence of TB in humans attributed to *M. bovis* and the annual number of such cases each year is 6 (2011), 4 (2012), 5 (2013) and 3 (2014) [not all cases relate to Irish born people]. For TB cases born in Ireland the peak age group is >64yrs and without a current identified exposure risk it is probable that the exposure is historical in nature.

## 4.1.2 Interim targets in relation to the timeline for eradication

*based on herd prevalence and herd incidence at different periods in link with the timeline for eradication (max. 32000 chars) :*

The interim objective is to reduce the herd incidence of TB by 60% by 2020 compared with 2013 levels.

## 4.2 Organisation, supervision and role of all stakeholders involved in the programme

*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.*

*(max. 32000 chars) :*

### 4.2.1. Programme and Policy

The initiation and drafting of the programme and policy is the responsibility of the ERAD (Eradication of Animal Disease) Administrative and Veterinary HQ Divisions of the DAFM under the responsibility of a Director of Animal Health and Welfare and Deputy Chief Veterinary Officer (DCVO). In consultation with ERAD HQ, the programme delivery is implemented through the Department's regional Veterinary offices (RVOs) which are operated and managed by Area Management teams (AMTs) whose main function is to ensure delivery of the programme and verification of the effectiveness of controls.

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### 4.2.2. Veterinary Laboratory Services

The Veterinary Laboratory Services (VLS) comprises the Central Veterinary Research Laboratory (CVRL) and the Regional Veterinary Laboratory (RVL) at Backweston in Co. Kildare, the Brucellosis Laboratory, Cork, and five RVLs located in Athlone, Cork, Kilkenny, Limerick and Sligo. The Bacteriology/Parasitology Division of the VLS provides a number of services to the BTEP, including:

- Culture and histopathological examination of diagnostic samples, including those submitted from the slaughterhouse surveillance programme;
- Potency assays on the bovine tuberculin protein purified derivative used in the TB test in conjunction with staff from ERAD division;
- DNA 'fingerprinting'/strain typing of *M. bovis* isolates;
- Evaluation of new methods for the identification and typing of *M. bovis*;
- Serological tests to aid diagnosis in problem herds.

Other laboratory services are additionally contracted to provide specific support services to the programme including primary tissue collection from badgers for submission to the CVRL for culture, routine and developmental work on IFN- $\gamma$  Assay, evaluation of new serological tests to aid TB diagnosis, support for badger vaccine development and deployment.

### 4.2.3. Veterinary Public Health Inspection Service

The Veterinary Public Health Inspection Service (VPHIS) of the Department in conjunction with the Food Safety Authority of Ireland (FSAI) is responsible for ensuring food safety in slaughtering premises, cutting premises, cold stores, meat and meat products premises, and poultry slaughtering establishments.

VPHIS, under the aegis of a DCVO, has a permanent staff complement of c. 183 veterinary inspectors and technical staff and engages some 610 private veterinarians on a part-time basis. All cattle presented for slaughter in the State undergo a veterinary post-mortem inspection under the control and supervision of VPHIS staff in one of some 30 plants in which cattle are slaughtered, or, in the case of abattoirs, under the control and supervision of the veterinary staff of the various Local Authorities. For the purpose of Regulation (EC) No 854/2004, supervision of the Local Authority (i.e. smaller, locally based) slaughter plants is conducted under contract to the FSAI (Food Safety Authority of Ireland) which ensures Veterinary Post-mortem Procedures are conducted under a standardised SOP developed in conjunction with the FSAI so as to facilitate the recording of the incidence of zoonotic agents at the level of primary production as required by EU Directive 99 of 2003. All granulomas detected at slaughter are submitted for laboratory examination to the CVRL and pending determination of the outcome the supplying herds are restricted (status suspended).

### 4.2.4. Keepers

Individual keepers are responsible for the testing of their herds so as to maximise herd health protection and certification status of herds. In particular, they are responsible for arranging annual herd tests, with their private veterinary practitioners (PVPs), within timescales prescribed for them by the Department in order to comply with the Directive, and for payment of test performance fees directly to PVPs in respect of, in general, one test/annum (estimated to cost farmers €25m per annum). Farmers, in addition, contribute towards the general cost of the eradication programme including research, reactor transport and additional compensation measures via a levy system, amounting to approximately €5m per annum. During field visits by Department personnel, additional quality control checks are carried out on farm for testing facilities and animal welfare.

Consultations on the operation of the TB programme are held at local and national level between the Department and the Farmer Organisations (representing the keepers) on a regular basis. The fact that farmers contribute to the overall cost of the programme ensures that they are significant stakeholders in

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the programme and, by their contribution, reduce the cost burden on both the Irish exchequer and the claims made by Ireland to the EU when the programme is co-funded.

### 4.2.5. Private Veterinary Practitioners

TB testing is, in general, performed by authorised PVPs, who are contracted to comply with the terms and conditions set out by the Department for tuberculin testing. PVPs are also reminded each year of the professional advices that they should provide to their clients in respect of bovine TB and procedures when a bTB outbreak has been detected or is underway. The Department ordinarily pays for the performance of any tests under the programme additional to the legal yearly test requirement or pre-movement tests. Before attending a herd to test PVPs must obtain a download of the herd profile from the Animal Identification and Movement system (AIM) database via AHCS in order to ensure that all animals in the herd are presented and tested; this will be further subject to computer checks when the test report is submitted to the AHCS. PVPs are subject to ongoing monitoring and supervision by the Department. Furthermore herds experiencing an outbreak of TB are subjected to epidemiological investigation by Department personnel. During field visits by Department personnel, additional quality control checks are carried out on-farm, with respect to testing facilities, the reactor animals with regard to the appearance, location and regression of reactions, fitness to transport and aspects of animal welfare. Random selections of samples are taken for correlation with IFN- $\gamma$  assay for quality control purposes. Consultations on the operation of the BTBEP are held at local and national level between the Department, PVPs and the PVP representative organisations.

### 4.2.6. Milk Processors

Trade in milk is governed by Regulation 2004/853/EC of the European Parliament which establishes that milk originating from herds that do not have OTF status must be heat-treated and that milk from animals showing a positive or inconclusive reactor result to the tuberculin test must not be used for human consumption. Milk from the healthy animals in the herd can be used in the manufacture of milk products but must first undergo a heat treatment equivalent to pasteurisation provided authorisation has been granted. The Department is legally obliged to inform persons to whom milk is supplied of the restriction or de-restriction of a herd under the programme. During the visits to the reactor herds, checks are carried out to ensure that reactors are isolated, that milk from reactor/inconclusive reactor animals is not being supplied to the food business operator (FBO) as per milk supply contract between producer and FBO and that it is being properly disposed of. Notices informing the FBO that a supplier herd is experiencing a breakdown and the number of cows involved (including inconclusive reactors) are automatically generated and sent by the Department's Animal Health Computer System (AHCS).

### 4.2.7. Valuers

In general, suitably qualified valuers, who are authorised by the Department, value reactor animals on the basis of current market values and by reference to guidelines drawn up by Department staff. The work of valuers is closely supervised by the Department. Department personnel visiting reactor herds will also report any visible defects of the reactors that might downgrade valuation, for cross referencing against the relevant valuation reports.

### 4.2.8. Reactor Collection Service

Reactors are, in general, transported free of charge from the holding to designated factories for slaughter. This service is operated by the Department on the basis of contracts awarded to private hauliers following a tender procedure. Hauliers are subject to supervision by the Department.

### 4.2.9. Slaughterplants tendering to receive reactors

Reactor animals (apart from exceptional cases where no compensation is payable to the farmer) are

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slaughtered by plants selected by the Department on the basis of a weekly tendering arrangement. Prices paid by the plant for reactors are monitored by ERAD on a regular basis.

### 4.3 Description and demarcation of the geographical and administrative areas in which the programme is to be implemented

*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.*

*(max. 32000 chars) :*

Ireland has a centralised administrative structure, i.e. no separate autonomous regions, 16 Regional veterinary offices (RVOs) units serve the 26 counties and 29 DVO areas. A Superintending Veterinary Inspector (SVI) oversees the veterinary aspects of the programme within each RVO. Delivery of the programme in the RVOs is overseen by two AMTs, each consisting of a Senior Supervisory Veterinary Inspector (SSVI), an SVI, an R/AP and an Area Superintendent, covering the North and South of the country. These AMTs liaise with ERAD HQ in relation to implementation of the TB eradication programme. The table attached at Annex 3 shows the herds under the programme etc. in each county for 2014.

### 4.4 Description of the measures of the programme

*A comprehensive description needs to be provided of all measures and detailed reference must be made to Union legislation. The national legislation in which the measures are laid down is mentioned.*

#### 4.4.1 Notification of the disease

*(max. 32000 chars) :*

In full compliance with Directive 64/432/EEC, Bovine Tuberculosis is a notifiable disease under the Animal Health and Welfare Act 2013. Under legislation, veterinary practitioners, keepers and others who have reason to suspect that the disease may be present are required to notify the SVI at the RVO.

#### 4.4.2 Target animals and animal population

*(max. 32000 chars) :*

All bovine animals in Ireland are included in the programme. In OTF herds undergoing test home bred calves <6-weeks of age are routinely exempted from test, as provided for in the Directive, in all other test situations calves < 6-weeks are subjected to test. 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 moving to the open market must have been tested within the previous 12 months and the holding is not under

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restriction.

### *4.4.3 Identification of animals and registration of holdings including detailed reference to relevant Union legislation and its implementation in the Member State for this disease*

*(max. 32000 chars) :*

All herds are registered as the epidemiological units (see section 2 above) in accordance with Directive 64/432/EEC and the registration functions additionally for control of diseases not included in that Directive e.g. BVD, IBR, FMD. 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/identity card.

### *4.4.4 Qualifications of animals and herds including detailed reference to relevant Union legislation and its implementation in the Member State for this disease*

*(max. 32000 chars) :*

The eradication programme is conducted under the Animal Health and Welfare (Bovine Tuberculosis) Regulations 2015 and the Animal Health and Welfare Act 2013. The attribution, maintenance, suspension and withdrawal of qualifications are in accordance with Directive 64/432/EEC as amended. AHCS has been programmed to ensure compliance with Directive 64/432/EEC is maintained and is reprogrammed as necessary to ensure compliance with additional measures as they are included in the programme.

At the end of each year, Ireland reports to the EU as required under Decision 2008/940 on surveillance done and suspect submissions for laboratory investigation from non-bovine domestic and wild species. Apart from bovines, there are no animals routinely tested under the programme. Dairy goat herds are required to have a TB control plan in place under Regulation (EC) 853/2004 laying down specific rules for food of animal origin. Under this plan, goats that die on farm require post mortem, goats slaughtered for human consumption will have veterinary examination and a number of skin tests will be performed. If dairy goats are on a holding with cattle they must be tested at the same frequency as the cattle. The 2014 census contained details of 970 keepers who had a total of 14,928 goats – 81% of keepers have less than 10 goats and only 4% have 100 or more goats. If (non-dairy) goats are present with a TB confirmed herd these are also required to be tested and, if there are test failures, or TB is suspected in these or any other species, it is compulsory to notify DAFM. Any animals of a susceptible species slaughtered for human consumption have a veterinary ante- and post-mortem examination. Suspect TB in all species is notifiable under Irish Law.

### *4.4.5 Rules of the movement of animals including detailed reference to relevant Union legislation and its implementation in the Member State for this disease*

*(max. 32000 chars) :*

A bovine animal may only be moved out of or into a herd or accepted for routine slaughter at a registered abattoir/slaughter plant if the individual animal is identified and properly documented (passport or a movement permit). Bovine animals may not be moved into a herd or from a herd, except direct to slaughter, unless the herd from which it comes and the individual animal have been tested within the previous 12 months. 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. Movement control, from a

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disease and movement eligibility perspective, is enhanced by the linkage of the AHCS with AIM at export locations, markets and slaughter premises which ensures that movement of ineligible animals is prevented or detected, in addition, under national legislation, Animal Health and Welfare (Bovine Movement) Regulations 2014 (SI 521 of 2014), Ireland requires all animals moving from one holding to another to be checked against the AIM database before moving. In the event of a detection of an ineligible animal at a market, AIM sends an alert message to the RVO(s) with responsibility for the herds involved. With regard to farm to farm movements, without transit through a market, the AIM system requires all such movements to be subject to the prior issue of a "Compliance Certificate" by the system; the certificate will be refused for ineligible animals. The most recent TB test dates for individual animals are displayed at point of sale in markets and for animals in the herd are available to the keeper who has access to his herd profile electronically.

Under the programme, movements of animals from 'high-risk' herds are further regulated (see section 4.4.5.4 below for details). In general, restricted herds, intending to move animals in, must have had at least one clear reactor retest (see section 4.4.5.3 below for details).

Regulation (EC) no 854/2004 of the European Parliament and of the Council lays down specific rules for examination of animals intended for human consumption. It further provides that all animals that are presented to a slaughterhouse for slaughter must as a general rule be slaughtered there. Accordingly, where an animal not tested within the previous 12 months leaves a holding and is presented for slaughter, the animal will be slaughtered. However, appropriate action must be taken at herd level in order to ensure compliance with TB testing rules and to minimise the risk of onward spread of disease to other herds. Thus where an animal is presented for slaughter and the previous test on that animal is between 12-18 months the animal will be slaughtered but the test status of the herd will be assessed. Herds where more than 20% of individual animals have not been tested within the previous 12-months will be restricted. Where an animal is presented for slaughter and the previous test on that animal is in excess of 18 months, the animal will be slaughtered and the herd of origin will be restricted. (Report Sanco 2010-8408-5).

### 4.4.5.2. Movement of animals FROM a 'restricted' holding

Controlled trading rules apply to herds with restricted status (OTF suspended/withdrawn or, under Irish legislation, trading status suspended i.e. are not allowed to trade animals on the open market). Since January 2013, the Department effectively manages and controls the movement of cattle from restricted herds through a permit system from AHCS for test reactors to slaughter or exceptionally to the DAFM research farm (Report SANCO 2010-8408-7) and for test negative animals through the AIM computer system. This AIM system is programmed to automatically prohibit all movement of animals from restricted herds, other than to slaughter and, if deemed necessary, movement even to slaughter can be prohibited. Restricted herds are identified as such by the AIM system via its linkage to AHCS and the controls by the system are such that it is not possible for a herdowner to move cattle from a restricted herd to another farm, or mart or for export. For example, if a herdowner attempts to move an animal from a restricted herd to a mart, the AIM system (which is linked to the mart) will "flag" the animal as coming from a restricted herd and will "reject" the animal at the mart, making it impossible for the animal to be sold. With regard to farm to farm movements, if the animal is located in a restricted herd, the system will not generate the "Compliance Certificate", thereby preventing the movement. The Department has made it clear to farmers that any attempt to move cattle from a restricted holding, other than to slaughter, (or in exceptional, mainly welfare, related cases, for test negative animals only with specific DAFM authorisation under permit to a feedlot – See Section 4.4.5.3 for details - (Report SANCO 2010-8408-7)) would result in a reduction in compensation payments and the application of penalties, under Cross Compliance, to payments made under the Basic Payment Scheme and Rural Development Schemes. Any animals moving between restricted herds (OTF status suspended or withdrawn for TB rather than for administrative reasons) are required to have been tested with negative results within the



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30 days prior to movement.

By their nature exceptions are not normal and outward movements from restricted herds, other than directly to slaughter, are avoided except when necessary to alleviate or prevent a welfare problem (which would then breach EU legislation). Where the movement is necessary, the movements take place under permit by DAFM and are permitted only if the moved animals have been clear on a test within the 30 days pre-movement. As stated by the TB Task Force during the meeting held in March 2014, any such movements lead to restrictions on the holding into which the animal has moved and on all epidemiologically linked units/holdings and further risk mitigation measures are put in place as determined necessary by the VI in respect of the receiving herd.

### 4.4.5.3 Movement of animals INTO a 'restricted' holding:

The Irish programme permits movements into restricted herds only under permit when such movements fully comply with Article 17 of Directive 78/52/EEC in that the herd is not re-stocked until the cattle over six weeks old remaining in it have passed one or more official tuberculosis tests after the slaughter of those animals considered to be infected. The general rule is that, animals may not be moved into a restricted holding prior to removal of the reactor(s) or TB-infected animal(s) and the completion of a clear retest and the SVI/VI-in-charge of the herd is satisfied that the risk of exposure from and to the moved-in animals is minimal. Note: available research suggests that there is no statistically significant increased risk to introducing animals to a herd after a retest has been conducted regardless of the test result (Clegg, T.A., Blake, M., Healy, R., Good, M., Higgins I.M., More, S.J. (2013). The impact of animal introductions during herd restrictions on future herd-level bovine tuberculosis risk. *Preventive Veterinary Medicine* 109, (3–4):246–257 PREVET (2012), <http://dx.doi.org/10.1016/j.prevetmed.2012.10.005>) (Report SANCO 2010-8408-6, 2010-8408-7).

The following categories of exceptions are provided for:

- Assembly of newly established herds (OTF status suspended)
- Introduction of a replacement stock bull(s) (The bull must have passed a TB test within the previous 30 days)
- Emergency replacement suckler calf (where a calf suckling a cow dies and must be replaced)
- Movement of a farmers own 'test negative' animals for welfare reasons. The movement must be necessitated by the need to alleviate or prevent a welfare problem and the animals in question must have passed a 30 day pre-movement test.
- Movement into a non-breeding beef herd that meets the feedlot criteria (note below) where the SVI is satisfied that there is no evidence of within herd acquisition of infection (i.e. no evidence of transmission of infection) and the herd poses minimal risk of infecting other cattle because of effective isolation from other herds.

Note: A 'Feedlot' herd designation exists solely in the context of a TB diagnosis in the herd and consequent loss of OTF status and restriction. A Feedlot is merely a subset within those herds that operate a beef fattening enterprise. A 'Feedlot' herd is a herd that comprises a 'non-breeding' unit which disposes of all cattle direct for slaughter and fulfils at least one of the following three criteria: (i) the cattle are permanently housed (never on pasture) or (ii) there are no contiguous holdings/lands with cattle or (iii) the boundaries are walled, double fenced or equivalent so as to prevent any direct contact with cattle on contiguous lands/premises/holdings. Thus a Feedlot herd, is a herd that poses minimal risk of infecting other cattle because of effective isolation from other herds. 'Feedlot' herds that fatten females must have the capability of rearing any unplanned calves until slaughtered or OTF status has been restored. When a herd that meets the criteria to be regarded as a 'Feedlot' herd is restricted under the TB Regulations, either by virtue of test reactors or detection of *M. bovis* in a slaughtered animal, when veterinary opinion is that there is no evidence of a within-herd TB focus or spread of infection, a special official supervisory and testing protocol is established to, as far as possible, facilitate the enterprise to

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function as a commercial entity while complying with animal health legislation and practice. Such herds are not exempted from testing or disinfection requirements. Feedlot herds that continue to acquire and finish cattle while restricted are ineligible for compensatory payments for test reactors acquired while restricted. The ER22 requires that any manure and slurry on the holding is stored for at least two months prior to being moved off or spread on the holding (time is in effect a mechanical disinfection procedure). When TB is diagnosed, the restriction notice (ER22) specifies conditions with respect to disinfection of premises and equipment and also storage and spreading of manure/slurry that must be respected. Test reactors must be removed under permit and within the timeframe specified (ER30) by the RVO. OTF status will only be restored to a restricted feedlot herd in full compliance with Directive 64/432/EEC. (Report Sanco 2010-8408-6). When the OTF status is restored to an erstwhile feedlot designated herd no additional controls apply over and above any other OTF status herd.

Herds that are designated feedlot normally source animals from OTF herds in the open market and rarely or never from other restricted herds. Some Feedlots will, however, when necessary to help to alleviate or prevent an animal welfare problem in a restricted herd, accept a proportion of cattle, under official permit, from these herds. Such cattle are subjected to a 30 day pre-movement test and therefore present minimal risk on movement. Feedlots which accept such cattle are immediately restricted (normally they will only accept such cattle when already restricted). Feedlots are incentivised to achieve OTF status because access to certain, higher value, markets which have purchasing rules that go beyond EU Regulations, will only take meat from OTF herds. Thus there is a financial incentive for feedlots to strive to attain and maintain OTF status.

4.4.5.4 Movement of animals disclosing an inconclusive reactor test result and animals from herds regarded as high-risk under the programme i.e. contiguous to a high risk breakdown (TB and within herd spread evident) and herds with OTF status restored following a high risk breakdown .

**Inconclusive Reactor Animals:** Since 2012, any animal that has been disclosed with an inconclusive reactor response, and that passes the mandatory retest at/after 42 days is prevented from moving for the duration of its lifetime, except to slaughter or exceptionally to a registered feedlot from where it shall move within a reasonable timeframe direct to slaughter.

**Contiguous Herds:** In accordance with changes introduced in 2012 which are intended to curtail the movement of potentially infected animals following disclosure of a high risk breakdown, Department personnel assess the herd concerned, to determine, among other issues, the relevant contiguous herds, for which a special contiguous testing programme (see section 4.4.6.3 below) is to be implemented. Those herds which are placed on the contiguous testing programme, which have not been tested within the previous 4 months, are restricted, and their trading status is temporarily suspended (other than animals moving direct to slaughter), pending test completion. As long as these herds remain OTF and on the programme, the same trade suspension pending test will apply from the 4-month anniversary of their previous test. RVOs may authorise permission for inward movement of stock under permit for a period not exceeding 30 days from the date of restriction. Free-trading status will be immediately restored once the herd reacts negatively to the test.

**Recent restoration of OTF-status following a high risk breakdown:** Following on from recommendations made by the TB-Task force in 2014, 'trade restriction' movement controls were introduced, in 2015, on the movement of stock out of herds where OTF status was restored following a high-risk breakdown. Such OTF-herds may move stock direct to slaughter and may move new-born calves (<6-weeks of age). However, with respect to the movement of other stock, the herd will be 'trade restricted' 3-months following the restoration of OTF-status test and will remain 'trade restricted' until such time as the next

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full herd level test, scheduled to be completed before the expiration of a further 5-months, has been conducted. Following this test the 'trade restriction' will be removed unless an OTF status suspension or withdrawal has been applied in which case the rules pertaining to the OTF status will supersede the trade restriction.

### 4.4.5.5 Export of Animals:

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. AIM programming via linkage with AHCS ensures that only eligible animals from OTF herds meeting all relevant criteria as specified in Directive 64/432/EEC will be issued Animal Health Certificates for export.

### 4.4.6 *Tests used and sampling and testing schemes including detailed reference to relevant Union legislation and its implementation in the Member State for this disease (including herd frequency, animal coverage in each herd, interpretation of the test,...)*

(max. 32000 chars) :

#### 4.4.6.1 Types of tests used

The principal test used in the programme remains the Single Intradermal Comparative Tuberculin Test (SICTT) as specified in Council Directive 64/432/ EEC (as amended).

In Ireland, test specificity of the SIT is, at best, between 92 and 94% as demonstrated by O'Reilly and Mac Clancy (O'Reilly and Mac Clancy. Estimation of the sensitivity, specificity and predictive value of the intradermal tuberculin test. 1978 Irish Veterinary Journal 32:127-128), who conducted a trial in TB-free herds in Ireland in 1975 in advance of the replacement of human with bovine tuberculin for the Irish programme. This work was repeated in 2008 and again in 2013 (paper in preparation) with similar results (6.3% of animals in 44.5% of bTB-Free herds false positive). To put this in context if 8.5m animal tests were performed using a test with a specificity of 94%, there would be 510,000 'false positive' animals disclosed i.e. almost 10% of the total cattle population in Ireland. Removal of 'false positive' test responders would not further the goal of eradication of bTB and thus would not have any positive cost/benefit or impact to the programme. One of the reasons that SIT specificity is so poor and the SICTT is the test of choice in Ireland is because of the almost constant opportunity for animals to be exposed to non-specific sensitizing organisms causing cross reactivity (Cooney, R., Kazda, J., Quinn, J., Cook, B., Muller, K. and Monaghan, M. Environmental mycobacteria in Ireland as a source of non-specific sensitisation to tuberculins. 1997. Irish Veterinary Journal. 50:370-373) thus necessitating the use of the SICTT. Nonetheless the specificity of the SICTT is still <100% in Ireland and it is estimated that approximately 1% of Irish herds are restricted annually under the programme as a consequence of non-tuberculous animals failing the test. The directive (Directive 64/432/EEC Annex A I 3A(b)) allows for the possibility to only suspend the status of such herds pending full laboratory examination and retest of the herd and to restore the status if bTB is not confirmed. However, as yet these herds, in which disease (TB) is not confirmed, and not epidemiologically suspected, still count in the statistical output for the eradication programme.

In order to optimise the performance of the SICTT the potency, as assayed by the manufacturer in guinea pigs, of the tuberculin, avian and bovine, used in the BTBEP are matched so as to not exceed a maximum of 500 I.U. potency difference per dose between both. In addition also so as to maximise the sensitivity (Se) Ireland routinely assays the potency of bovine tuberculin in naturally infected cattle. This conforms to the WHO (Technical Report series No. 384) recommendation that potency testing should be performed in the animal species and under the conditions in which the tuberculins will be used in

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practice. The potency of the bovine tuberculin used under the Irish programme for the last 10-plus years has been in the order of 50,000 I.U./ml as assayed in cattle and this conforms to the OIE recommendations for tuberculin used for a bTB eradication programme. The 2012 EFSA Scientific Opinion on the use of a gamma interferon test for the diagnosis of bovine tuberculosis reported the sensitivity of the SICTT in Ireland as equivalent, if not better than the published literature, they also conducted Bayesian latent class analysis and reported only marginal differences between the Se of the SICTT in Ireland as compared with the SIT elsewhere in Europe (Scientific Opinion on the use of a gamma interferon test for the diagnosis of bovine tuberculosis (2012) <http://www.efsa.europa.eu/en/efsajournal/pub/2975.htm>).

With regard to the implementation of severe interpretation, the post de-restriction, classification related check test regime and contiguous tests, provided for in the programme (see below) and regarded as tests on 'high bTB- risk' OTF-herds have, in the first instance, standard interpretation inconclusive reactors removed as reactor. In addition, if infection is confirmed by reason of the number of test reactors or otherwise, in any herd, a more severe interpretation regime, including where appropriate only having regard to the reaction at the bovine site (i.e. effectively the SIT), will apply and the interferon- $\gamma$  assay is employed with a view to removing all potentially infected animals in as short a time-frame as possible.

The Interferon Gamma assay is also used under practical field conditions as an adjunct to the tuberculin test in bTB infected herds. 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. In all herds experiencing a high risk breakdown classified as a 'H' breakdown, following disclosure of reactors to the tuberculin test, consideration is given to having the remaining animals, particularly breeding animals and animals not destined for slaughter within a short time, blood tested so that additional infected animals will be removed.

The Gamma Interferon- $\gamma$  assay has been used more widely in the programme since the beginning of 2014. During 2015 Ireland has commenced to implement the assay, without waiting for post-mortem or laboratory confirmation of infection, when and where it is clear that the herd is infected (e.g.  $\geq 4$  reactors). It is also intended in 2015 to extend the incubation phase of the assay to an additional regional laboratory and thus to further relieve the logistical issues attendant on the use of the Interferon- $\gamma$  assay and the necessity to have samples submitted for incubation within 6-hours.

Further use of the interferon-gamma assay is primarily targeted towards herds classified as high risk where the assay is of particular benefit if tuberculin testing has failed to speedily resolve the problem or where complete depopulation of a herd would be the only alternative. Experience has shown that the strategic use of gamma testing can often be equally effective as full herd depopulation in terms of clearing a herd of infection without the necessity to kill healthy non-infected animals.

Experimentally, the use of Gamma Interferon assay was also assessed in potentially exposed herds. However, while it continues to be used as an adjunct to the skin test in high risk herds, it did not prove suitable, for specificity reasons, to use as an additional screening test in contiguous herds. Gamma Interferon assay is also used for quality control and correlation purposes on a sample of SICTT reactors.

### 4.4.6.2 Annual "Round" screening test

Ireland requires each herd to be tested at least once every 12 months. The Department issues lists of herds with notification to test to PVPs throughout the year in advance of the anniversary from the previous herd test. Reminders are sent out as appropriate to ensure testing is carried out by the

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prescribed dates. Penalties for failure to test on time includes restriction of the herd, a reduction in/ forfeiture of compensation payments in the event of a breakdown, payment of testing fees (which would otherwise be paid for by the Department), possible prosecution and possible penalties on any payments due under the Basic Payment and Rural Development Programme Schemes.

### 4.4.6.3 Consequential/Supplementary testing

In accordance with Article 5 of Annex B of Directive 64/432, supplementary testing is part of the Irish TB programme.

Herds and animals in restricted herds are risk-categorised on the basis of infection levels and are subject to a customised testing (interpretation and test frequency) regime. The epidemiological investigation indicates the focus of risk and relevant epidemiological linkages and thus forms the basis for requiring testing (termed special check testing) outside the normal frequency of testing in OTF herds. 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.

All bTB infected herds are scheduled for a test six months post OTF restoration. Thus more frequent testing is conducted on higher risk herds and in herds adjacent to these herds e.g.:

- following OTF restoration after a high-risk breakdown (within herd acquisition and spread of TB), herds are placed on a 6-monthly herd-testing regime for the succeeding one and a half years (Post-de-restriction/ special check test).
- following disclosure of a high risk breakdown, a special testing programme for herds assessed as at risk by virtue of being contiguous to infection (contiguous tests; contiguous testing programme);
- tests are additionally conducted on herds with epidemiological links, including traceback and trace-onward checks 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 unless a test of higher priority dictates more frequent tests (e.g. contiguous test). Notifications to test are sent out in advance to ensure testing is carried out by the prescribed dates. Failure to test on time will lead to restriction of the herd, payment of testing fees which would otherwise be paid for by the Department, a reduction in/forfeiture of compensation payments in the event of a breakdown, possible prosecution and possible penalties on any payments due under the Basic Payment and Rural Development Programme Schemes.

Contiguous testing programme: Herds which are adjoining a herd experiencing a high risk breakdown (i.e. contiguous herds) are placed on a programme of testing whereby a herd test is scheduled for the herd each 4 months while infection is still being identified in an index herd, with the intention that the last test under the programme for a contiguous herd would be carried out no less than 60-days after the last positive reactor was removed from the index herd i.e. the programme of testing in the contiguous herds runs while the index herd is undergoing reactor retesting. The AHCS computer system has been programmed so that the programme of testing in contiguous herds runs automatically.

In effect, when Ireland refers to high risk areas, these index herds and the attendant herds on the contiguous programme are de-facto the relevant areas. If badgers are implicated in the breakdown in the "index herd" a badger removal programme will be instigated (if not already operating) in the same area, taking into account the limitations on such badger removal necessitated under the Berne Convention and agreement with the responsible Irish competent authority. As detailed in section 4.4.5.4 any contiguous herd on a 'contiguous testing programme' is immediately restricted if it has not had a TB test within the previous 4 months and is only permitted to move cattle, other than direct to slaughter,

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following a clear test. In this manner, movement of potentially infected animals from such herds is controlled.

### Pre-movement tests:

Ireland avails of the derogation provided for under point 1.1 (c) of Annex A to the Directive, which does not require pre-movement testing on all domestic movements. Ireland does not operate a network system as referred to in Article 14 of the Directive. For normal trade between herds within Ireland, S.I. No. 58 of 2015 provides the current legal basis. Each animal must have been tested within the previous 12 months and the holding not restricted.

Special emphasis is placed on pre-movement testing and keepers are encouraged to acquire pre-movement tested animals, particularly potential breeding animals, as a key husbandry practice decided with their veterinary practitioners to assist herd health protection. To facilitate this 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 to determine an animals' eligibility for movement to display the latest test-data available on AHCS (see section 4.4.11). In 2014, 558,510 male animals and 522,835 female animals moved herd within 30 days of a TB test. In addition, some 276,649 animals were specifically individually pre-movement tested (private test) for TB, and other animals would have been tested during a herd level test immediately prior to movement.

Research has indicated that the benefits of a nation-wide compulsory pre-movement test do not indicate that this is the most appropriate manner to expend resources (T.A. Clegg, S.J. More, I.M. Higgins, M. Good, M. Blake, D.H. Williams (2008). Potential infection-control benefit for Ireland from pre-movement testing of cattle for tuberculosis. Preventive Veterinary Medicine 84 94–111). In addition the EU TB Task Force, in its report in 2014, did not recommend a general pre-movement test stating "A general use of pre-movement testing is not recommended as it may provide a false sense of security without giving enough additional reduction of the risk". As detailed earlier, alternative options are used to curtail movement opportunities for potentially infected animals; these include increased herd test frequency of certain herds (ex-high risk herds, contiguous herds, trace-back and trace-forward herds) with increased herd test frequency and herd level restrictions when tests are due/overdue and animal level restrictions (e.g. ex-inconclusive reactors). From 2014 onwards, Ireland requires any animals moving between restricted herds (OTF status suspended or withdrawn for TB rather than administrative reasons) to have been tested with negative results within the 30-days prior to movement. Such movements only take place in exceptional cases to prevent or alleviate a welfare problem. The approach to risk mitigation in the Irish programme was explained in greater detail to the TB-subgroup in March 2014 and, they did not therefore recommend an area based approach to higher frequency testing.

### Post Mortem Surveillance:

Post mortem surveillance of animals slaughtered for human consumption and traceback of all granulomatous lesions detected with restriction of supplying herd pending laboratory diagnosis is a fundamental part of the TB eradication programme. Some 1.6M bovines are slaughtered annually. The annual non tuberculous granuloma detection target rate at approximately 1.5/1,000 slaughtered ensures adequate surveillance for the occurrence of TB granulomas which are then in addition to the 1.5/1,000. The rate of confirmed TB granulomas per 10,000 animals slaughtered has fallen from 20.7 in 2007 to 11.3 in 2014, which shows a continuing declining trend.

### General:

In essence, the focus of the current controls is (i) on the holding where TB has been identified (the "Index herd") where the herd occupying the holding is immediately restricted, (ii) on the herds adjoining (or

## Standard requirements for the submission of programme for eradication, control and monitoring

contiguous to) an “index herd” with a high-risk breakdown (infection acquired and/or spread on the holding) (iii) on those herds which have a recent history of having had a high-risk breakdown and which carry forward a risk of recurrence of infection and, in addition (iv) on reducing TB levels in sympatric badgers where they are implicated in TB outbreaks using a combination of population control and BCG-vaccine by injection. The position is that TB outbreaks frequently cluster around index herds and their contiguous herds: the area covered by these herds collectively is de-facto the high-risk area of relevance, the herds are subjected to additional testing and movement controls and badgers to population control for a minimum of 3-years with the aim of replacing culling with vaccination when appropriate. In this manner Ireland ensures that all herds in high risk areas have higher frequency of testing and more severe test interpretation and that measures are taken compatible with the goal of *M. bovis* eradication (biological extinction) in Ireland.

### *4.4.7 Vaccines used and vaccination schemes including detailed reference to relevant Union legislation and its implementation in the Member State for this disease*

*(max. 32000 chars) :*

As previously detailed, there is no TB-vaccine approved and licensed throughout the EU 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 to evaluate efficacy in badgers in a natural environment (Aznar, I., McGrath, G.E., Murphy, D., Corner, L.A.L., Gormley, E., Frankena, K., More, S.J., Martin, W., O'Keeffe, J.J., De Jong, M.C.M., 2011. Trial design to estimate the effect of vaccination on tuberculosis incidence in badgers. *Veterinary Microbiology* 151, 104–111). The field stage of this trial was completed in 2014, laboratory and data analysis is expected to be completed in 2015 with results available by autumn 2015. It is Ireland's intention to progress to a situation where oral badger vaccination will be incorporated into the programme as a matter of routine. Since 2012 Ireland has started replacing continued culling with vaccination of badgers with BCG to in areas where cull was maintained for a minimum of 3-years and where TB levels in cattle had fallen. TB levels and breakdowns in vaccinated areas will be specifically monitored until at least the end of 2017 so that efficacy of vaccination may be assessed. Currently all badger vaccines are delivered to the individual badger post capture i.e. capture/vaccinate/release. Work is continuing to attempt to develop an effective methodology of delivering vaccine to badgers that will not require individual capture and thus a number of ecological based studies are continuing.

There has been a significant improvement in the incidence of the disease since 1999. For example, reactor numbers have fallen from approximately 45,000 animals in 1999 to 16,145 in 2014. The herd incidence also continues to fall and has declined from 7.7% in 1999 to 3.64% in 2014. As referred to previously in this section, Ireland complies fully with EU Directive 64/432/EEC.

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

*(max. 32000 chars) :*

Advice on appropriate bio-security measures is provided by the Department to herdowners via direct advice from the local RVO in the event of a TB breakdown, leaflets, publicity etc. In addition, in herds

## Standard requirements for the submission of programme for eradication, control and monitoring

with high risk breakdowns payment of compensation is conditional on the cleansing and disinfection of the holding following a breakdown with an approved disinfectant effective against TB. Compliance checks are carried out on herds following risk assessment of the consequences of failure to complete disinfection. Furthermore, 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. (Report SANCO 2010-8408-6).

In addition to TB specific advices and procedures, the Department is a 50% stakeholder in Animal Health Ireland (AHI) which has published 3 specific information leaflets for farmers, advisors and veterinary practitioners so as to provide science-based, practical advice and guidelines on bio security and disease control that are easily implemented on farm: with regard to farmers, the main areas covered include Purchasing Stock: Reducing Disease Risks, Bioexclusion and Understanding Infectious Diseases. AHI has also established a Biosecurity group, the terms of reference of which are to: (1) provide evidence-based guidelines on how to implement best-practice biosecurity measures, (2) develop new tools to biosecurity risk assess individual holdings and (3) raise awareness of biosecurity so as to support informed decision-making by Irish farmers and the broader livestock industries that will feed into national disease control programmes. In addition, AHI promotes good biosecurity practices by the judicious use of press releases, articles in the farming press, production of newsletters, attendance at farmer events etc.

Furthermore the new Rural Development Programme (RDP; 2014 – 2020) operated by the Department includes Knowledge Transfer measures across all farming sectors, including cattle farmers. It is envisaged that some 30,000 farmers will ultimately register for the programme, based on a discussion group model facilitated by an agricultural consultant. Participants are incentivised to attend and required to participate in five discussion group sessions annually for a period of three years. Each participant is required to complete an animal health plan and develop action plans on improving animal health on their farm in consultation with their veterinary practitioner. This animal health plan will focus on disease control measures and biosecurity and will be require annual revision with the veterinary practitioner.

### 4.4.9 Measures in case of a positive result including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

*A description is provided of the measures as regards positive animals and detailed referenece to the Union legislation provisions(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 infected holding). A definition of a suspicion and of a confirmation should be provided, with detailed measures implemented in both situation and how the herd is requalified as free after a positive result.*

(max. 32000 chars) :

Under legislation, veterinary practitioners are required to notify the SVI at the RVO of details of all positive and inconclusive test results within 3 days. Some 98% of test results are communicated electronically from the office of the testing PVP and the RVO via a link to AHCS.

In general, where reactors are identified and/or suspect lesions detected at slaughter, the holding of origin is restricted, the status of the herd is suspended (or withdrawn), and reactor animals are removed for slaughter. Where reactors are eligible for compensation they will be generally removed via the reactor collection service, which is organised by the Department. Legislation provides an immediate restriction when a test reactor or TB suspect animal is disclosed and DAFM then issues a formal restriction notice in respect of the holding. The restriction can only be lifted by issue of a formal derestriction notice. A quality control procedure is carried out, where possible within 5 working days of the receipt of a notification of a breakdown, with regard to testing, reactors identified, isolation of



## Standard requirements for the submission of programme for eradication, control and monitoring

reactors and disinfection as well as an assessment of contiguous herds, animal welfare and testing facilities.

Controls on the movement of animals into and out of a restricted holding are described at Pars 4.4.5.2 and 4.4.5.3 above. Slurry and manure storage and premises disinfection requirements are specified on the ER22 restriction notice (issued under the TB Regulations 2015) and may subsequently be varied during the course of an investigative farm visit. The ER22 requires that disinfection be carried out using an approved disinfectant (TB) and that any manure and slurry on the holding is stored for at least two months prior to being moved off or spread on the holding (time is in effect a mechanical disinfection procedure) (Report SANCO 2010-8408-6). Further procedures are notified directly to the farmer and appropriate follow-up re-testing takes place until the final clearance test shows the herd to be clear and the status is then restored in accordance with Directive 64/432/EEC. Compliance with the disinfection requirements are checked and penalties are applied where non-compliance is detected (Report SANCO 2010-8408-6, 2010-8408-8).

In addition, as described above, a special contiguous testing programme is conducted for relevant herds adjoining the infected herd with a high risk breakdown and some such herds will have movement restrictions imposed pending test (i.e. at 4-month anniversary of previous herd test) – see Section 4.4.5.4. Tests are additionally conducted on herds with epidemiological links indicating a risk of infection.

All TB infected herds are scheduled for test 6-months post status restoration and, 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. Ireland places herds which have experienced a high risk breakdown on a 6 month testing regime over an 18 month period after the herd tests clear of TB and OTF status is restored. This means that such herds are subjected to a more intensive testing regime (minimum 2 tests/annum) than other herds while they remain at higher risk of experiencing a further outbreak of bTB (F.J. Olea-Popelka P.W. White J.D. Collins J. O’Keeffe D.F. Kelton S.W. Martin (2004) Breakdown severity during a bovine tuberculosis episode as a predictor of future herd breakdowns in Ireland. Preventive Veterinary Medicine 63 163–172). Following the recommendation by the EU TB Task Force, in 2015, Ireland has introduced enhanced controls on the movement of animals out of High Risk herds, in particular, by shortening the 6-month movement window to 3-months post restoration of OTF status. The existing testing regime has been amended such that these high risk herds will be trade restricted after 3 months (rather than 6 months at present) from the date they test clear of TB (i.e. they will be permitted to move cattle into the herd but they will not be permitted to move cattle >6-weeks out other than direct to slaughter). The herd will be obliged to test at the latest within 8 months of the clearance test. If the herd tests clear, it will be permitted to move cattle into and out of the herd for another 6 months, after which it will be restricted and required to undergo another test. The herd will be required to undergo another test after a lapse of another 6 months period.

Notwithstanding the above, in certain circumstances, as provided for in Directive 64/432/EEC Annex A I 3A(b), where herds disclose tuberculin reactors and the herd is classified as low-risk as determined by the epidemiological criteria set down below, the disease status of herds is ‘suspended’ rather than ‘withdrawn’ and the holding is restricted. Criteria for consideration for this protocol are as follows:

- 1) the bovine minus avian increase differential must be less than 12 millimetres
- 2) no oedema present at the bovine site.
- 3) the herd must not have had its OTF status withdrawn due to bTB during the 3 years prior to this reactor and
- 4) none of the contiguous herds are concurrently undergoing a High risk breakdown.

## Standard requirements for the submission of programme for eradication, control and monitoring

The holding will be de-restricted where the criteria for eligibility continue to be met: TB is not confirmed at post mortem, laboratory examination is negative, the herd has been subjected to SICTT conducted at least 42 days after the removal of the reactor animal and the results of the herd level SICTT are negative. Where a granulomatous lesion (suspect TB) is detected at a slaughter plant in a carcase from an animal originating in a clear herd, the holding is immediately restricted, (OTF status suspended) the suspect lesion is subjected to laboratory examination and if TB is confirmed the OTF status is withdrawn and the herd is then subjected to the appropriate testing regime as defined in Council Directive 64/432/EEC, as amended.

Serious consideration is given to herd depopulation, full or partial, 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. Decisions on depopulation are made exclusively on disease and epidemiological grounds with the interest of disease control in the herd and the local area of primary concern. 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 in-contact removal) must be assessed. When the assay and/or in-contact removal has failed to resolve the problem, depopulation of the herd 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. Furthermore, unless badgers have been excluded as a cause of the outbreak a badger capture programme will be conducted and a programme of testing undertaken in contiguous herds. Where depopulation is necessary to ensure infection is removed from a herd or to remove a source of infection to a neighbourhood, it takes place in the entire epidemiological unit and it has always been part of the Irish programme. The figures provided in reports are, therefore, only where the entire epidemiological unit has been depopulated. Experience has shown that the strategic use of the gamma assay can often be equally effective in terms of clearing a herd of infection without the necessity to kill healthy non-infected animals with the result that increased and judicious use of the interferon gamma assay has reduced the imperative to depopulate herds.

### 4.4.10 Compensation scheme for owners of slaughtered and killed animals

(max. 32000 chars):

The programme takes into account the income loss experienced when a herd is restricted and reactors are removed. Compensation in line with market values is provided for under the On-Farm Market Valuation Scheme. Prior to their removal, reactor animals are valued on the basis of current market prices, with a right of appeal provided for both the keeper and DAFM. The keeper is paid the carcase-salvage value directly by the slaughter plant and the differential between this salvage value and the market valuation is paid by the Department. Compensation reflects individual animal market value but is subject to ceilings. Compensation entitlements are subject to compliance with the rules of the scheme, the Directive (64/432/EEC) and also other legislative obligations such as bovine animal identification Regulations (1760/2000). A penalty system, which varies with the degree of non-conformance, is in place.

## Standard requirements for the submission of programme for eradication, control and monitoring

### 4.4.11 Control on the implementation of the programme and reporting including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

(max. 32000 chars) :

Control and implementation of the programme rests with the Competent Authority at headquarters in conjunction with the Area Management Teams at regional level. The implementation or delivery of the programme takes place in regional RVOs. Controls on implementation include scheduling of tests, checks on testing returns, rapid removal of infected animals, epidemiological investigations and all aspects of the programme, including evaluation of results, delivery and quality control aspects. To facilitate control and implementation, considerable use is made of computerised systems developed by the Competent Authority specifically for the task, such as AHCS, Herdfinder and the AIM database.

- AIM is live at markets, export points and slaughterhouses. Through linkage to AHCS AIM provides information in real time before sale/slaughter on animal status, TB test data and movement/export eligibility, information including an animal's compliance with identification, Animal Health requirements and eligibility for sale/slaughter. In particular, certification of live animals for export may only be completed if all checks on AIM confirm full eligibility.
- AHCS is live at all but the smaller slaughterhouses. This ensures prompt recording of detection of suspect TB granulomas, notification of detections to RVOs and thereby ensures prompt restriction of supplying herds pending laboratory examination of the detected granuloma.
- Linkage of AHCS and the Laboratory Information System (LIMS) at the CVRL ensures that samples submitted to the laboratory from smaller slaughterhouses, under contract to the FSAI (see section 4.2.3) or other locations will be notified to RVOs so that supplying herds may be restricted as appropriate. This linkage also ensures that RVOs may monitor the progress of samples through the laboratory.
- Linkage of Veterinary Practitioners electronically to AHCS is designed to facilitate herd profile production (download) immediately preceding testing and prompt upload of test results to DAFM RVOs.
- 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, allows greater analysis of data, trace-onward/back and epidemiological investigation tracking.
- The Geographic Information System based 'Herd Finder' programme, incorporating mapping data as submitted by farmers to support claims for payment under EU funded support schemes, is used to rapidly locate and identify herds that may be, or may have been, at risk of exposure.
- 'TB leaders' in RVOs who have received specific training in TB programme management, including familiarisation with DAFM computerised systems, epidemiological investigation, PVP supervision techniques etc., serve as a local resource to others involved in the BTBEP.
- Additionally, resources have been allocated to continue to provide intensive laboratory analysis, including culturing and strain typing at DAFM's CVRL.
- Furthermore all systems are under continuous review and upgrade to ensure that they perform optimally and ensure full compliance with both legislation and the programme.

A series of dedicated and specific periodic reports are produced, via the above systems, as a routine to monitor programme implementation and delivery on an on-going basis as well as trends in the incidence of the disease, quality control of testing veterinarians etc. These reports are examined in the context of regular meetings of the ERAD Management Committee. Further data generated by the programme are analysed so as to determine specific risk factors, as required by Decision 2008/341/EC, that may militate against disease eradication or where modification of the programme would be indicated e.g. Clegg, T.A., Good, M., Duignan, A., Doyle, R., More, S.J. (2011). Longer-term risk of *Mycobacterium bovis* infection in Irish cattle following an inconclusive diagnosis to the single

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intradermal comparative tuberculin test. Preventive Veterinary Medicine. 100:147-154. doi:10.1016/j.prevetmed.2011.02.015

4.4.12. Dissuasive action in the case of non-compliance:

Where farmers fail to comply with the requirements of the TB eradication scheme, a number of actions can be taken ranging from warning notices and restriction of the herd, to requiring farmers to pay for testing otherwise payable by the Department, to sanctions on or non-payment of compensation, to penalties on payments under other EU funded schemes and, ultimately, to prosecution. (Report SANCO 2010-8408-13).

### 5. Benefits of the programme

*A description is provided of the benefits of the programme on the economical and animal and public health points of view.*

*Describe*

- progress expected compared to the situation of the disease in the previous years, in line with the objectives and expected results
- cost efficiency of the programme including management costs

*(max. 32000 chars):*

The agriculture, food and the marine sector continues to make a significant contribution to the Irish economy and the most recent figures available suggest it accounts for 7.2% of GVA at factor cost, 8.4% of employment and 12.7% of all goods exported. Within agriculture, approximately 70% of output value is from 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 approx. €60m per annum (including staffing costs) will yield significant benefits, in terms of improving (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.

The objective of the programme is the eradication (biological extinction) of bTB (*M. bovis*) in Ireland. The existence of bTB in the country results in significant income losses to farmers in terms of (i) reduced productivity, restrictions on trade (ii) testing costs and (iii) levies on production. In addition, the existence of the disease involves considerable public expenditure on disease eradication measures, thereby imposing a heavy burden on the Irish taxpayer. The significant reduction in the incidence of the disease which has taken place since 2008 has significantly reduced the financial burden arising from these losses/costs to farmers and taxpayers. In fact, the cost of the programme has fallen from €80m in 2008 to €58m in 2014. The number of herds restricted due to bTB has also been reduced by over 50% during the past 10 years, thereby ameliorating the economic impact of this disease on cattle farmers. A value for money review of the programme which was completed in 2008 concluded that the public expenditure on the programme has enabled the Irish Livestock industry to maintain and develop exports markets for cattle and beef. In addition, it found that the net impact of the Programme has been to facilitate the growth of the Irish cattle industry by creating and enhancing export opportunities and by improving the productivity of cattle rearing. The export trade in beef, was worth €3.055 billion in 2014, is dependent on the effective implementation of the eradication programme. The benefit of improved market access accrues to the farmer producer and to the processing sector in the first instance, while the benefits of improved animal productivity and public health accrue primarily to the farmer producer. Society at large also benefits from the Programme's impacts in these three areas to the extent that the improved

## Standard requirements for the submission of programme for eradication, control and monitoring

economic performance of the farming industry spills over into the wider economy and to the extent that the Programme contributes to enhanced public health. In addition, any improvement in the disease situation will reduce the burden on the national exchequer and, accordingly, the taxpayer.

The disease statistics reported by Ireland exaggerate the incidence of actual disease in the country. This arises from the fact that there are approximately 1,000 herds, each year in Ireland, where reactors are identified and removed but TB is not confirmed. This is as a consequence of the Specificity (Sp) of the Single Intradermal Comparative Tuberculin Test (SICTT) which is in the region of 99.985%. As Ireland is a country that has bTB it is not possible to determine the precise Sp of the SICTT. However, even with a Sp of 99.985%, there will be false positive reactors ~15/100,000 tests. At current level of testing in Ireland (~8M individual animal tests) some 1,200 animals will test positive, even if there was no actual infection, and a ~1% herd incidence consequently is to be expected. If, as it has done to date, Ireland continues to report every herd with a test reactor, regardless of TB confirmation or not, (and the test is done accurately) herd incidence will not decline below 1% and thus this base line 1% is factored into the expected decline in herd incidence and has to be taken into account in assessing achievement of the target set.

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### 7. Targets

The blocks 7.1.1, 7.1.2.1, 7.1.2.2, 7.2, 7.3.1 and 7.3.2 are repeated multiple times in case of first year submission of multiple program.

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

##### 7.1.1 Targets on diagnostic tests for year: **2016**

Region	Type of the test	Target population	Type of sample	Objective	Number of planned tests
Ireland	Tuberculin Skin Test	Bovines	SICTT	Programme Implementation	8 500 000 <b>X</b>
Ireland	Gamma Interferon Assay	Bovines	Heparinised Blood	Programme Implementation	25 000 <b>X</b>
Ireland	Bacteriological	Bovines	Tissue	Programme Implementation	2 427 <b>X</b>
Ireland	Strain typing	Bovines	Culture	Programme Implementation	1 000 <b>X</b>
<b>Total</b>					8 528 427
<b>Add a new row</b>					

# Standard requirements for the submission of programme for eradication, control and monitoring

## 7.1.1 Targets on diagnostic tests for year:

**2017**

Region	Type of the test	Target population	Type of sample	Objective	Number of planned tests
Ireland	Tuberculin Skin Test	Bovines	SICTT	Programme Implementation	8 500 000
Ireland	Gamma Interferon Assay	Bovines	Heparinised Blood	Programme Implementation	25 000
Ireland	Bacteriological	Bovines	Tissue	Programme Implementation	2 913
Ireland	Strain typing	Bovines	Culture	Programme Implementation	1 200
<b>Total</b>					8 529 113
<b>Add a new row</b>					

## 7.1.1 Targets on diagnostic tests for year:

**2018**

Region	Type of the test	Target population	Type of sample	Objective	Number of planned tests
Ireland	Tuberculin Skin Test	Bovines	SICTT	Programme Implementation	8 500 000
Ireland	Gamma Interferon Assay	Bovines	Heparinised Blood	Programme Implementation	25 000
Ireland	Bacteriological	Bovines	Tissue	Programme Implementation	3 495
Ireland	Strain Typing	Bovines	Culture	Programme Implementation	1 400

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		<b>Total</b>	8 529 895
		<b>Add a new row</b>	

## 7.1.2 Targets on testing herds and animals

### 7.1.2.1 Targets on testing herds

#### 7.1.2.1 Targets on the testing of herds for year: **2016**

Region	Animal species	Total number of herds	Total number of herds under the programme	Number of herds expected to be checked	Number of expected positive herds	Number of expected new positive herds	Number of herds expected to be depopulated	% positive herds expected to be depopulated	Target indicators		
									Expected % herd coverage	Expected period herd prevalence	% new positive herds Expected herd incidence
Ireland	Bovines	115 000	115 000	113 390	3 742	3 515	30	0,8	98,6	3,3	3,1
	<b>Total</b>	115 000	115 000	113 390	3 742	3 515	30	0	98,6	3,3	3,1
									<b>Add a new row</b>		



# Standard requirements for the submission of programme for eradication, control and monitoring

## 7.1.2.1 Targets on the testing of herds for year : **2017**

Region	Animal species	Total number of herds	Total number of herds under the programme	Number of herds expected to be checked	Number of expected positive herds	Number of expected new positive herds	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
Ireland	Bovines	114 700	114 700	113 094	2 940	2 878	30	1,02	98,6	2,6	2,54
<b>Total</b>		114 700	114 700	113 094	2 940	2 878	30	1	98,6	2,6	2,54
<b>Add a new row</b>											

## 7.1.2.1 Targets on the testing of herds for year : **2018**

Region	Animal species	Total number of herds	Total number of herds under the programme	Number of herds expected to be checked	Number of expected positive herds	Number of expected new positive herds	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
Ireland	Bovines	114 400	114 400	112 798	2 481	2 368	30	1,21	98,6	2,2	2,1
<b>Total</b>		114 400	114 400	112 798	2 481	2 368	30	1	98,6	2,2	2,1



## Standard requirements for the submission of programme for eradication, control and monitoring

Region	Species	Total number of animals	Number of animals under the programme	Number of animals expected to be tested	Number of animals to be tested individually	Number of expected positive animals	Number of animals with positive result expected to be slaughtered or culled	Total number of animals expected to be slaughtered	Expected % coverage at animal level	% positive animals (Expected animal prevalence)
Ireland	Bovine	6 500 000	6 500 000	6 370 000	5 987 800	14 500	14 500	15 500	98	0,23
<b>Total</b>		6 500 000	6 500 000	6 370 000	5 987 800	14 500	14 500	15 500	98	0,23
<b>Add a new row</b>										

### 7.1.2.2 Targets on the testing of animals for year : **2018**

Region	Species	Total number of animals	Number of animals under the programme	Number of animals expected to be tested	Number of animals to be tested individually	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	Expected % coverage at animal level	% positive animals (Expected animal prevalence)
Ireland	Bovine	6 500 000	6 500 000	6 370 000	5 987 800	13 000	13 000	14 000	98	0,2
<b>Total</b>		6 500 000	6 500 000	6 370 000	5 987 800	13 000	13 000	14 000	98	0,2
<b>Add a new row</b>										

## Standard requirements for the submission of programme for eradication, control and monitoring

### 7.2 *Targets on qualification of herds and animals*

#### *Targets on qualification of herds and animals*

### 7.2 *Targets on qualification of herds and animals for year: 2016*

		Targets on the status of herds and animals under the programme												
		Expected not free or not free from disease				Expected free or officially free from disease status suspended				Expected free from disease				
		Last check positive		Last check negative		Expected free or officially free from disease status suspended		Expected free from disease		Expected officially free from disease				
Region	Animal species	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals			
Ireland	Bovines	115 000	6 500 000	1 100	128 000	800	92 800	180	21 600	0	0	112 900	6 257 600	<b>X</b>
<b>Total</b>		115 000	6 500 000	1 100	128 000	800	92 800	180	21 600	0	0	112 900	6 257 600	
												<b>Add a new row</b>		

### 7.2 *Targets on qualification of herds and animals for year: 2017*

## Standard requirements for the submission of programme for eradication, control and monitoring

Targets on the status of herds and animals under the programme																
Region	Animal species	Total number of herds and animals under the programme		Expected not free or not free from disease				Expected free or officially free from disease status suspended		Expected free from disease		Expected officially free from disease				
		Herds	Animals	Last check positive		Last check negative		Herds	Animals	Herds	Animals	Herds	Animals			
				Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals			
2017	Bovines	114 700	6 500 000	0	0	880	102 400	640	74 240	144	17 280	0	0	113 000	6 306 080	<b>X</b>
<b>Total</b>		114 700	6 500 000	0	0	880	102 400	640	74 240	144	17 280	0	0	113 000	6 306 080	
<b>Add a new row</b>																

### 7.2 Targets on qualification of herds and animals for year: **2018**

Targets on the status of herds and animals under the programme																
Region	Animal species	Total number of herds and animals under the programme		Expected not free or not free from disease				Expected free or officially free from disease status suspended		Expected free from disease		Expected officially free from disease				
		Herds	Animals	Last check positive		Last check negative		Herds	Animals	Herds	Animals	Herds	Animals			
				Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals			
Ireland	Bovines	114 400	6 500 000	0	0	704	81 290	512	59 392	115	13 824	0	0	113 100	6 345 494	<b>X</b>
<b>Total</b>		114 400	6 500 000	0	0	704	81 290	512	59 392	115	13 824	0	0	113 100	6 345 494	
<b>Add a new row</b>																

## Standard requirements for the submission of programme for eradication, control and monitoring

### 7.3 Targets on vaccination or treatment

#### 7.3.1 Targets on vaccination or treatment

##### 7.3.1 Targets on vaccination or treatment for year: 2016

Region	Animal species	Targets on vaccination or treatment programme									
		Total number of herds in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Number of herds in vaccination or treatment programme	Number of herds expected to be vaccinated or treated	Number of animals expected to be vaccinated or treated	Number of doses of vaccine or treatment expected to be administered	Number of adults expected to be vaccinated	Number of young animals expected to be vaccinated		
Ireland	Bovines	0	0	0	0	0	0	0	0	0	X
<b>Total</b>		0	0	0	0	0	0	0	0	0	
<b>Add a new row</b>											

##### 7.3.1 Targets on vaccination or treatment for year: 2017

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



## Standard requirements for the submission of programme for eradication, control and monitoring

Region	Square km	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
Ireland Vaccine	3 900	1 442	1	1 442
Ireland Population Control	3 900	6 450	1	6 450
<b>Total</b>		7 892		7 892
<b>Add a new row</b>				

### 7.3.2 Targets on vaccination or treatment of wildlife for year: **2017**

Targets on vaccination or treatment programme				
Region	Square km	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
Ireland Vaccine	4 200	1 730	1	1 730
Ireland Population Control	4 200	6 500	1	6 500
<b>Total</b>		8 230		8 230
<b>Add a new row</b>				



# Standard requirements for the submission of programme for eradication, control and monitoring

## 7.3.2 Targets on vaccination or treatment of wildlife for year: **2018**

		Targets on vaccination or treatment programme			
Region	Square km	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	
Ireland Vaccine	4 400	2 595	1	2 595	<b>X</b>
Ireland Population Control	4 400	4 000	1	4 000	<b>X</b>
<b>Total</b>		6 595		6 595	
<b>Add a new row</b>					

## Standard requirements for the submission of programme for eradication, control and monitoring

### 8. Detailed analysis of the cost of the programme

#### 8.1 Costs of the planned activities for year: **2016**

The blocks are repeated multiple times in case of first year submission of multiple program.

To facilitate the handling of your cost data, you are kindly requested to:

1. Fill-in the text fields IN ENGLISH
2. Limit as much as possible the entries to the pre-loaded options where available.
3. If you need to further specify a pre-loaded option, please keep the pre-loaded text and add your clarification to it in the same box.

1. Testing	Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
Cost of analysis	Tuberculin		Individual animal sample/test	8 500 000	0.3	2 550 000	yes <b>X</b>
Cost of analysis	Tuberculin test Fees		Individual animal sample/test	2 260 000	4.21	9 514 600	yes <b>X</b>
Cost of analysis	Gamma-Interferon test		Individual animal sample/test	25 000	15.23	380 750	yes <b>X</b>
Cost of analysis	Bacterial culture		Individual animal sample/test	2 427	38	92226	yes <b>X</b>
Cost of analysis	Strain typing		Individual animal sample/test	1 000	38	38000	yes <b>X</b>
Cost of sampling	Domestic animals Gamma-Interferon		Individual animal sample/test	25 000	2.54	63500	yes <b>X</b>
						<b>Add a new row</b>	
2. Vaccines							

## Standard requirements for the submission of programme for eradication, control and monitoring

Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
Purchase of vaccine/treatment of animal product	BCG	Vaccine dose	1 442	11.6	16727.2	yes <b>X</b>
Distribution costs	Injection of BCG	Vaccine dose	1	1,300,000	1,300,000	yes <b>X</b>
<b>3. Compensation paid to owners</b>						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
Bovines	Slaughtering/culling with salvage value	Animal	16 000	750	12,000,000	yes <b>X</b>
<b>4. Cleaning and disinfection</b>						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested
<b>Add a new row</b>						
<b>5. Slaughtering/culling costs</b>						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
<b>Add a new row</b>						
<b>6. Other costs</b>						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
Compensation	Compensation for income losses	Holding	1	2,520,000	2,520,000	no <b>X</b>
Transport costs	Reactor collection service	Animal	16 000	40.91	654,560	no <b>X</b>

## Standard requirements for the submission of programme for eradication, control and monitoring

DAFM Personnel	Salaries	Personnel	1	25,500,000	25,500,000	no	<b>X</b>
Wildlife Programme	FRS Contractor	Personnel	1	2,082,999	2,082,999	yes	<b>X</b>
DAFM Personnel	Wildlife Programme	Personnel	1	1,316,398	1,316,398	no	<b>X</b>
Supplies	Wildlife Programme	Supplies	1	518,542	518,542	yes	<b>X</b>
DAFM Personnel	Wildlife Programme Travel	Personnel	1	332,944	332,944	no	<b>X</b>
Other general expenses	TB Programme	Supplies	1	4,000,000	4,000,000	no	<b>X</b>
<b>Total</b>						<b>Add a new row</b>	
					62 881 246.2		

### 8.1 Costs of the planned activities for year: **2017**

The blocks are repeated multiple times in case of first year submission of multiple program.

To facilitate the handling of your cost data, you are kindly requested to:

1. Fill-in the text fields IN ENGLISH
2. Limit as much as possible the entries to the pre-loaded options where available.
3. If you need to further specify a pre-loaded option, please keep the pre-loaded text and add your clarification to it in the same box.

1. Testing							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Cost of analysis	Tuberculin	Individual animal sample/test	8 500 000	0.3	2 550 000	yes	<b>X</b>

## Standard requirements for the submission of programme for eradication, control and monitoring

Cost of analysis	Tuberculin test Fees	Individual animal sample/test	2 260 000	4.34	9 808 400 yes	<b>X</b>
Cost of analysis	Gamma-Interferon test	Individual animal sample/test	25 000	15.23	380 750 yes	<b>X</b>
Cost of analysis	Bacterial culture	Individual animal sample/test	2 913	38	110 694 yes	<b>X</b>
Cost of analysis	Strain Typing	Individual animal sample/test	1 200	38	45600 yes	<b>X</b>
Cost of sampling	Domestic animals Gamma-Interferon	Individual animal sample/test	25 000	2.54	63500 yes	<b>X</b>
					<b>Add a new row</b>	
<b>2. Vaccines</b>						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
Purchase of vaccine/treatment of animal product	BCG	Vaccine dose	1 730	11.6	20068	yes <b>X</b>
Distribution costs	Injection of BCG	Vaccine dose	1	1,560,000	1,560,000	yes <b>X</b>
					<b>Add a new row</b>	
<b>3. Compensation paid to owners</b>						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
Bovines	Slaughtering/culling with salvage value	Animal	15 500	750	11,625,000	yes <b>X</b>
					<b>Add a new row</b>	
<b>4. Cleaning and disinfection</b>						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested
					<b>Add a new row</b>	

## Standard requirements for the submission of programme for eradication, control and monitoring

5. Slaughtering/culling costs						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
					<b>Add a new row</b>	
6. Other costs						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested
Compensation	Compensation for income losses	Holding	1	2,520,000	2,520,000	<b>X</b>
Transport costs	Reactor collection service	Animal	15 500	40.91	634,105	<b>X</b>
DAFM Personnel	Salaries	Personnel	1	26,010,000	26,010,000	<b>X</b>
Wildlife Programme	FRS Contractor	Personnel	1	2,082,999	2,082,999	<b>X</b>
DAFM Personnel	Wildlife Programme	Personnel	1	1,342,725	1,342,725	<b>X</b>
Supplies	Wildlife Programme	Supplies	1	518,542	518,542	<b>X</b>
DAFM Personnel	Wildlife Programme Travel	Personnel	1	332,944	332,944	<b>X</b>
Other general expenses	TB Programme	Supplies	1	4,000,000	4,000,000	<b>X</b>
					<b>Add a new row</b>	
	<b>Total</b>				63 605 327	

# Standard requirements for the submission of programme for eradication, control and monitoring

## 8.1 Costs of the planned activities for year:

2018

The blocks are repeated multiple times in case of first year submission of multiple programs.

To facilitate the handling of your cost data, you are kindly requested to:

1. Fill-in the text fields IN ENGLISH
2. Limit as much as possible the entries to the pre-loaded options where available.
3. If you need to further specify a pre-loaded option, please keep the pre-loaded text and add your clarification to it in the same box.

1. Testing							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Cost of analysis	Tuberculin	Individual animal sample/test	8 500 000	0.3	2 550 000	yes	X
Cost of analysis	Tuberculin test Fees	Individual animal sample/test	2 260 000	4.47	10 102 200	yes	X
Cost of analysis	Gamma-Interferon test	Individual animal sample/test	25 000	15.23	380 750	yes	X
Cost of analysis	Bacterial culture	Individual animal sample/test	3 495	38	132 810	yes	X
Cost of analysis	Strain typing	Individual animal sample/test	1 400	38	53200	yes	X
Cost of sampling	Domestic animals Gamma-interferon	Individual animal sample/test	25 000	2.54	63500	yes	X
					<b>Add a new row</b>		
2. Vaccines							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Purchase of vaccine/treatment of animal product	BCG	Vaccine dose	2 595	11.6	30102	yes	X

# Standard requirements for the submission of programme for eradication, control and monitoring

Distribution costs	Injection of BCG	Vaccine dose	1	2,340,000	2,340,000	yes	<b>X</b>
					<b>Add a new row</b>		
<b>3. Compensation paid to owners</b>							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Bovines	Slaughtering/culling with salvage value	Animal	14.000	750	10,500,000	yes	<b>X</b>
					<b>Add a new row</b>		
<b>4. Cleaning and disinfection</b>							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested	
					<b>Add a new row</b>		
<b>5. Slaughtering/culling costs</b>							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
					<b>Add a new row</b>		
<b>6. Other costs</b>							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Compensation	Compensation for income losses	Holding	1	2,520,000	2,520,000	no	<b>X</b>
Transport costs	Reactor collection service	Animal	14.000	40.91	572,740	no	<b>X</b>
DAFM Personnel	Salaries	Personnel	1	26,530,000	26,530,000	no	<b>X</b>
Wildlife Programme	FRS Contractor	Personnel	1	2,082,999	2,082,999	yes	<b>X</b>



## Standard requirements for the submission of programme for eradication, control and monitoring

DAFM Personnel	Wildlife Programme	Personnel	1	1,290,587	1,290,587	no	<b>X</b>
Supplies	Wildlife Programme	Supplies	1	518,542	518,542	yes	<b>X</b>
DAFM Personnel	Wildlife Programme Travel	Personnel	1	332,944	332,944	no	<b>X</b>
Other general expenses	TB Programme	Supplies	1	4,000,000	4,000,000	no	<b>X</b>
				<b>Add a new row</b>			
				<b>Total</b>		64 000 374	

### 8.2. Financial informaton

#### 1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursement/payment claim to the EU. Describe the financial flows/circuits followed.

Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

- a) Implementing entities - **sampling**: who perform the official sampling? Who pays? (e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

## Standard requirements for the submission of programme for eradication, control and monitoring

*(max. 32000 chars):*

Staff from the Department sample for the interferon- $\gamma$ -assay. Kits for the sampling are provided by UCD the contracting testing laboratory and the Department pays UCD from the State budget. Bacteriological samples are taken by Department personnel in slaughter plants and are sent to the CVRL (a State Laboratory) for analysis. These costs are borne by the Department.

- b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?  
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

*(max. 32000 chars):*

The bulk of SICTT testing is carried out by private veterinary practitioners and is paid for by farmers. Some tests are also conducted by veterinary inspectors directly employed by the Department while other tests are conducted by Wholetime Temporary Veterinary Inspectors (WTVIs) contracted by the Department solely to carry out TB testing. In principle, farmers pay for one test per annum and the Department pays for all other tests, usually in the context of herds that experience a TB breakdown. The testing arrangements are referred to generally as “Department pay” and “Farmer pay”. The veterinary practitioners employed by the Department are salaried officials while the private veterinary practitioners and WTVIs are paid a fee per test.

The Department supplies and pays for all of the tuberculin used in the testing programme. The Department sources the protein purified derivative (PPD) required for the performance of the TB test through a process of competitive tendering. The current supplier is PRIONICS AG, PRIONICS - Lelystad, in the Netherlands.

Testing of the gamma interferon samples is carried out by UCD which is paid for this service by the Department. The CVRL (a State Laboratory) carries out the bacteriological testing, the cost of which is borne by the Department.

## Standard requirements for the submission of programme for eradication, control and monitoring

- c) Implementing entities - **compensation**: who performs the compensation? Who pays? (e.g. compensation is paid by the central level of the state veterinary services, or compensation is paid by an insurance fund fed by compulsory farmers contribution)

*(max. 32000 chars) :*

Compensation under the On Farm Market Valuation Scheme is paid to farmers who suffer a TB breakdown unless they fail to comply with the rules governing the Diseases Eradication Schemes, with identification regulations and other national/EU legislative requirements and controls relating to bovine animals. This Scheme is designed to compensate herd owners for the loss of animals removed under the eradication programme and compensation is based on the market value of animals which is the equivalent price which might reasonably be obtained for the animal at the time of determination of compensation, from a purchaser in an open market, if the animal were not affected by TB, subject to certain limits applying. The compensation, which is paid by Department to the farmer, is based on the difference between (i) the value attributed to the animal on the farm under the On Farm Market Valuation Scheme and (ii) the salvage paid by the slaughter plant to the farmer for the reactor. Payments are processed and checked by this Department's Regional Veterinary Office staff. Co-ordination and compilation of the claim for EU co-financing is undertaken by ERAD Division.

Animals are valued on the farm by independent valuers included on this Department's approved valuer list. Valuers are monitored by Department staff. Current market prices are monitored by the Department also and are supplied to the valuers. The Department pays the valuers a fee per valuation.

- d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator? (e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

*(max. 32000 chars) :*

The Department provides the vaccine and pays the persons engaged in vaccination.

## Standard requirements for the submission of programme for eradication, control and monitoring

e) Implementing entities - **other essential measures**: who implement this measure? Who provide the equipment/service? Who pays?

*(max. 32000 chars) :*

The Department pays for the restraints used in the removal of badgers. It also pays the private operatives (the FRS) involved in the shooting of the badgers. Some Department officials are also involved in the supervision of the badger removal programme. The Department also pays for the transport of the badger carcasses to the laboratory and for the laboratory tests carried out on the badgers.

### 2 Co-financing rate (see provisions of applicable Work Programme)

The maximum co-financing rate is in general fixed at 50%. However based on provisions of Article 5.2 and 5.3 of the Regulation (EU) No 652/2014, we request that the co-financing rate for the reimbursement of the eligible costs would be increased:

Up to 75% for the measures detailed below

Up to 100% for the measures detailed below

## Standard requirements for the submission of programme for eradication, control and monitoring

### 3. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursement will be claimed are financed by public funds.

yes

no

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# Standard requirements for the submission of programme for eradication, control and monitoring

## Attachments

### IMPORTANT :

- 1) The more files you attach, the longer it takes to upload them .
- 2) This attachment files should have one of the format listed here : **jpg, jpeg, tiff, tif, xls, doc, docx, ppt, pptx, bmp, pna, pdf.**
- 3) The total file size of the attached files should not exceed 2.500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
- 4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD ALL THE ATTACHED FILES.** Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!
- 5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

## List of all attachments

	Attachment name	File will be saved as (only a-z and 0-9 and -_)	File size
	4748_3750.doc	4748_3750.doc	62 kb
	4748_3751.xls	4748_3751.xls	21 kb
	4748_3752.doc	4748_3752.doc	25 kb
	4748_3753.pdf	4748_3753.pdf	46 kb
	4748_3754.xls	4748_3754.xls	27 kb
	Total size of attachments :		181 kb