EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food chain, stakeholder and international relations

Unit D4 - Food safety programmes, Emergency funding

Programmes for eradication, control and surveillance of animal diseases and zoonoses submitted for obtaining EU financial contribution

Annex I.b: Programme for the eradication of bovine tuberculosis, bovine brucellosis or sheep and goat brucellosis (*B. melitensis*)

Member States seeking an EU financial contribution for national programmes of eradication, control and surveillance shall submit online this document completely filled out by the 31 May of the year preceding its implementation (Art. 2 of Decision (EU) 2015/2444 and Art. 12 of Regulation (EU) No 652/2014).

For multiannual programmes already approved, this document shall also be filled out and submitted after selection of the options:
This programme is multiannual:
"YES"
"Funding request for subsequent year of already approved multiannual programme"

If encountering difficulties:

- concerning the information requested, please contact SANTE-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Instructions to complete the form:

1) You can attach documents (.doc, .xls, .pdf, etc) to complete your report using the button "Add attachments" on the last page of the form.
2) Before submitting this form, please use the button "Verify form"(bottom right of each page). If needed, complete your pdf document as indicated.
3) When you have finished completing this pdf document, save it on your computer.
4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf

document will be sent to our server. A submission number will appear on your document. Save this completed document on your computer for your record.

5) For simplification purposes you are invited to submit multi-annual programmes.
6) You are invited to submit your programmes in English.

Member state : IRELAND

Disease
Bovine tuberculosis

Species : Bovines

This program is multi annual : yes

Type of submission : New multiannual programme

Request of Community co-financing from beginning of : 2017 To end of 2018

1. Contact data

Name :

Rosanne Greene

Phone : 00353-1-5058869

Email : rosanne.greene@agriculture.gov.ie

Your job type within the CA :

Submission Date

Wednesday, September 21, 2016 11:53:3

Submission Number

1474455218

244-9495

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

2. Historical data on the epidemiological evolution of the disease

Provide a description on the target population (species, number of herds and animals present and under the programme), and the main results in the last 5 years (incidents, prevalence, qualification of herds and animals). The information is given for distinct periods if the measures were substantially modified.

(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., Lesslie, 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 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 BTBEP 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 BTBEP 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 BTBEP 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 1960-2015.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 and H-herds following de-restriction prior to testing, the restriction of inconclusive reactors, which pass the re-test, to the holding of disclosure and use of Interferon-γ as a routine in larger TB outbreaks).

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 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 – 2016
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, focused badger population control measure 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 Table referred to above and attached at Annex 2 (Cattle Population Trends and TB incidence 1960 -2015.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 3.37% in 2015, the lowest level since the programme started in the 1950's. Reactor numbers also fell from approximately 45,000 animals in 1999 to 15,137 in 2015.

The 2015 BTBEP was the fifth year of a 5 year eradication programme covering the period 2011-2015. Herd incidence during the 5 years of the current programme fell by 27.5% between 2010 and 2015. Within this period, herd incidence fell by 20.9% between 2012 and 2015, slightly in excess of the target of 20% set down by the EU Commission for Ireland in SANCO 10181 2014 Rev2 . In Ireland's view, this demonstrates the effectiveness of the programme. We believe that the programme currently in place is effective and, if amended from time to time in light of on-going scientific developments and research, that it is capable of eradicating the disease by 2030 (biological extinction). This target has been incorporated as a strategic objective in DAFMs vision for agriculture to 2025.

Scientific analysis of data gathered during the implementation of the Irish BTBEP has been used to develop a model which shows that TB is not self-sustaining within the cattle population and that it is the measures provided for in the Irish BTBEP to address a major source of the disease (badgers) that have been and continue to be a key factor in bringing about the substantial improvement in the incidence of the disease.

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 . It is noteworthy that a study by Gallagher et al. (2013) 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).

The improvement in the situation has carried into 2015, with herd incidence falling by 13% compared with the same period in 2014. The TB Task force in 2014 acknowledged the progress made but noted that their visit had taken place before the end of the 5 year plan had "been given a chance to give results, which makes the numbers difficult to assess but the results are according to the predictions given in the plan, or better". The 5 year plan that finished in 2015 successfully exceeded planned targets.

McGrath et al (2014) presents a number of methods using GIS systems to visually portray the improvement in the levels of bovine tuberculosis over the 15 years 1998-2012. The TB reactor density maps for 1998, 2005, 2012 presented in Annex 4 shows that the TB high risk areas where reactor density occurred at >1.5 reactors/km2 in 1998 (dark red) are no longer identifiable by 2012. This demonstrates that the Irish policy of combining focused testing of high risk herds, their contiguous herds and badger removal where implicated in breakdowns, is effective.

The reactor density map for 2014, utilising the same scale i.e. 0.5 and 1.5 reactors/Km2, also demonstrates further improvement and also that the same areas do not necessarily show higher TB prevalence in successive years. Note that the time interval to 2014 is only 2 years compared to the 6-8 year time intervals in the reactor density maps for 1998 to 2012.
These maps visually confirm that the intensity of disease at an animal level is progressively continuing to decline and that the measures included in the Irish programme are demonstrably effective.

The progressive decline in the incidence of bovine TB in Ireland demonstrates that the programme is being implemented effectively. In addition, as noted by the TB Task force in its report on the 2014 visit, "The Irish programme has an evidence-informed approach and commitment to risk-based management" and "Ireland is continuously improving the programme". In line with this approach, Ireland has introduced number of measures into the bTB eradication programme over the last number of years so as to accelerate the eradication of bovine tuberculosis. These measures include the restriction of inconclusive reactors to the holding of origin and the restriction of herds which are contiguous to a high risk breakdown pending a herd test (see par 4.4.5.4 for more detail).

In addition, as detailed in the programme for 2016-2018, additional controls on animal movement from high risk herds are planned (see paragraph 4.4.5.4) in line with the recommendation of the Task Force. Furthermore, Ireland is already making greater use of Interferon-γ assay and this will continue into the 2016-2018 programme. At the end of 2015, the number of samples submitted for Interferon-γ assay had risen 305% over the number submitted in 2014 (32,226 as compared with 7,966), notwithstanding a continued decline (13%) in the number of infected herds detected. Despite this additional testing and the removal of additional reactors as a consequence, the total number of reactor animals has declined by 5% . This demonstrates that the measures being implemented and the additional measures introduced during 2014 and 2015 are having an impact and accelerating the eradication of M. bovis in Ireland. However, the impact of such measures does not manifest immediately and requires time to take effect before it is reflected in evident improvement. In fact, the effect of additional Gamma testing is to increase the number of reactors in the short-term but will result in reduced numbers of reactors and shorter restriction periods in the medium to longer term.

Research has demonstrated that the badger is the primary upstream driver of TB infection in Ireland. In view of this and with a view to making sustained progress toward the final eradication (biological extinction) of M. bovis in Ireland, our priority is to develop and advance a sustainable method to limit badger-to-cattle transmission as quickly as possible. To this end, the authorities and research community in Ireland, together with those in the U.K. and France, are collaborating to complete the necessary studies on oral vaccination so as to complete a dossier in order to be in a position to apply for a Marketing Authorisation (MA) under EU legislation. The current projected timeline for oral badger vaccination development is pictured in Annex 5.

Ireland is not currently planning to introduce additional measures at the present time but, as measures are identified through scientific analysis of the programme data that are likely to improve the programme further, they will be added to the suite of measures currently in the programme.

With regard to stakeholder involvement in the programme, the position is that Irish stakeholders have been involved in the design and implementation of the bTB eradication and research programmes to a very significant extent for many years. Since 1980, they have contributed some 40% of the total cost of the programme indirectly through the payment of disease levies on production and by directly engaging and paying an approved veterinarian to test their herd each year. In 2013, for example, they

contributed some €30m of the total €75m cost of the programme (of which €24m in testing fees, reduces the amount eligible to be reclaimed under EU co-funding by approximately €12m annually). Stakeholders participate in the local Animal Health groups operational in each RVO area to examine and address local disease issues and programme implementation. They have also engaged nationally with the Minister for Agriculture and in particular with ERAD team in respect of policy development and programme operation matters. Having regard to the very considerable financial contribution which farmers make towards the programme and additional cost borne by farmers in the event of a disease outbreak, farmers have a strong commitment to the acceleration of the disease eradication programme.

In view of the ambitious objectives set out in the 2016-18 programme, the latest national strategy for the Irish agri-food industry provides for the establishment of a national forum on Bovine TB which will include all relevant stakeholders. The role of the forum will be to review the strategic programme on an ongoing basis, facilitate agreement on appropriate new programme measures and targets and ensure the constructive participation by all parties in sustaining progress towards eradication.

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 BTBEP 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) . 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 bTB 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 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 Single Neucleotide Polymorphism (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. Aznar et al., have developed a mathematical model http://library.wur.nl/WebQuery/ wurpubs/495403 to understand the maintenance and transmission of M. bovis as a multiple host diseases as well as to assess the impact of control measures. Two simple mathematical models were built to separately estimate the reproduction ratio R for bTB transmission between cattle and between badgers in Ireland with the current control strategies in place (Rcc and Rbb). If Rcc is <1 then eradication in cattle will be possible if the transmission matrix is "disjunct", otherwise, if the transmission matrix for the system is "separable", bTB eradication in cattle will only be possible if Rbb is also reduced <1. Using data gathered during the implementation of the Irish programme the model shows that TB is not self-sustaining within the cattle population and that it is the measures provided for in the Irish programme to address a major source of the disease (badgers) that have been and continue to be a key factor in bringing about the substantial improvement in the incidence of the disease.

3. Description of the submitted programme

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 BTBEP 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 submitted is a 2 year programme covering the years 2017 and 2018. 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 is set at 1.5 non-TB granulomas submissions/1000 slaughtered (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-γ 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,

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

- 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,
- Computerised system for organising, recording and follow-up of tests; control of animal movements; traceback and trace forward of epidemiologically linked animals,
- 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.),
- Use of strain typing in local epidemiological investigations and studies,
- Maintenance of the local badger population at reduced levels (within the constraints of the Berne Convention) where associated with bTB breakdowns and following epidemiological linkage to bTB outbreak in cattle, for a minimum of 3 years before moving to a vaccination regime,
- Badger vaccination and ecological studies to address questions of efficacy of badger vaccination for bTB and optimise vaccine delivery methodology,
- On-going research into optimum vaccination methods,
- 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),
- Wildlife (badger) oral vaccination – conditional on a Marketing Authorisation in compliance with EU legislation being 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 bTB 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 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.

Wildlife Policy

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

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

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 published and reported on during 2016. Other studies underway or in prospect are designed to assess the impact of badger vaccination on the incidence of bTB 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 in cattle since 2008. There has also been a very substantial reduction in the level of TB in badgers in recent years. In 2015, TB prevalence in badgers removed as a consequence of focal culling under the programme was 14.7% compared with the 36.6% 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 (i.e. badgers) 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. This provides the rationale underpinning Ireland's case for co-funding of the vaccination and badger culling elements of the programme.

The effect of proactive badger culling has been observed two separate studies, in Ireland including the East Offaly Project [Eves 1998, Ó'Máirtín D, et al. 1998] and the Four Area Project [Griffin, et al. 2005a, b]. In each of these studies, cattle TB incidence was reduced following badger removal, providing irrefutable evidence of the role of badgers in the epidemiology of bovine TB. Kelly et al., (2008) reviewed the impact and effect of these removal projects up to 2004 and has provided further evidence of the importance of badgers in the epidemiology of bovine TB in Ireland; demonstrated that proactive badger culling during these two projects was associated with a significant and sustained decrease in disease risk in associated cattle herds, relative to reactive culling with the risk, overall, decreasing with time and that, there was no evidence of increased disease risk in cattle at the interface between areas of proactive and reactive badger removal .

Murphy et al. (2010, 2011) demonstrated that the prevalence of TB in cattle reflects the prevalence of TB in badgers in Ireland and that where badgers are removed in response to tuberculosis (TB) breakdowns in cattle herds (focal culling) 36–50% of badgers were infected with M. bovis whereas the infection prevalence in badgers, in areas where there had been historically a consistently low prevalence of infection in cattle, was at 14.9% significantly lower ($P < 0.001$). There was, however, no significant difference in the distribution of infection within the badger in the two studies.

Ní Bhuachalla et al (2015) and Corner et al (2011) review papers provides an overview of the role of badgers in the epidemiology of TB and irrefutable scientific evidence that badgers are a reservoir of M.

bovis infection and are implicated in the transmission of infection to cattle.

The potential of Wild Deer as a vector for TB for Irish cattle and/or wildlife.
Wild deer in on the island of Ireland are largely found in upland areas where forestry and/or amenity lands predominate. For both historical and cultural reasons, there is no functional deer management system operating nationally but it is generally agreed that deer numbers are rising in Ireland and encroaching on agricultural (grazing) land. Responsibility for wild deer in Ireland rests with the National Parks and Wildlife Service (NPWS), which is part of the Department of Arts, Heritage and the Gaeltacht and wild deer species are protected under the Wildlife Acts. Deer may be legally hunted during defined seasons and may also be hunted out of season under licence from NPWS where deer are causing damage to farmland or commercial forests. By definition, wild deer are free roaming and as local populations increase the areas over which they roam increases proportionately. Deer are being seen as a growing problem where they are encroaching into new areas where they were absent from previously. Fencing wild deer either into or out of defined locations is impractical and is not an economically viable option generally. In East Wicklow, land is equally divided between farmland (~30%), forestry (~30%) and publicly owned National Parks (~30%). This range of ownership and user interests in areas of high deer abundance makes assigning responsibility for implementing management strategies problematic.

International studies (USA, UK and New Zealand) have concluded that wild deer are normally only spill-over hosts of TB only becoming maintenance hosts when density is high and only significant in transmitting TB to cattle when both species co-mingle at feeding/meeting locations where forage is shared. In response to concerns about bovine TB levels in Wicklow, DAFM recently carried out a survey of 103 deer shot in a 70 Km2 area of East Wicklow that has had persistently high levels of TB in bovines relative to the national situation (7.2% versus 2.97% herd incidence 2015 to date). Of the 103 deer examined, 5 had gross lesions of TB indentified and 16 were positive on culture. Strain typing results for isolates are not yet available. The interface where cattle and deer overlap in Ireland is more complex in that badgers also forage in these habitats and in the same area as the deer and thus deer may also be a source of infection in badgers and vice versa. In March 2015, The Irish Deer Management Forum, comprising representatives of all stakeholders interests, namely the various government bodies with responsibilities in the areas of animal health, public health, forestry, management of public lands and conservation, and also farming, hunting and the private forestry industry, was launched. The forum will advise Government on how best to organise and implement deer management strategies. The composition of the forum ties in, in a concrete way, both the involvement and the active responsibility of the stakeholders in the design and the implementation of the national strategy to manage the future abundance of wild deer across the Irish countryside. The Department will carefully consider any recommendations made by the Forum.

There is currently no map of TB spoligiotypes available for Ireland. Since the late 1990s studies have been conducted into the use of strain differentiation methods for M.bovis as an aid to epidemiological investigations. RFLP and spoligotyping was used on isolates from multiple species. The prevalent RFLP and spoligotypes were identified in isolates from all animal species tested and had a wide geographic distribution. The same range and geographic distribution of strains were found for the majority of isolates from cattle, badgers, and deer suggesting that transmission of infection between these species is a factor in the epidemiology of M. bovis infection in Ireland. However, on a geographical basis a significant proportion of isolates (approximately 20%) exhibit a common strain type, limiting the value of strain typing methods as an epidemiological tool. Attempts were made to use additional tools to provide greater discriminatory power. A comparison in 2010 of the different methods available demonstrated that a combined spoligotyping and MIRU-VNTR (4-loci) would maintain a high level of strain differentiation. A 2013 collaborative trial with regions of the U.K. has revealed that that the same

lineage of M. bovis is present throughout Ireland and the U.K. The dominance of this lineage is unique within Europe, and suggests that in the past the populations were homogenous. Comparison of approximately 500 strains isolated in 2005 from each region by spoligotype and 5 locus VNTR profiling, revealed distinct differences in the genotype frequencies and sublineage makeup between each region. We concluded that whilst each region shared the same major phylogenetic lineage of M. bovis, more recent evolution had resulted in the development of region-specific populations. Regional differences in the M. bovis populations suggest that it may be possible to identify the movement of strains from one region to another. Most recently Furphy et al (2012) reported on spoligotyping and variable number tandem repeat (VNTR) analysis of M. bovis isolates from badgers, representing a wide geographic area, with different tuberculosis prevalence levels. The results of the typing show that there is no geographic clustering of strain types associated with prevalence. Spoligotyping and VNTR analysis also provided evidence of multiple infections of individual badgers with different M. bovis strains. The VNTR profiles from a large sample of cattle isolates showed that the profiles are not unique to infected badgers (unpublished results). In infected badgers, the high prevalence of lung infection strongly supports the lungs as the principal site of primary infection and that inhalation of infectious aerosol particles is the principal mode of transmission. The results of this study provide further evidence of extraterritorial movement of badgers and the discrimination of strains by spoligotyping, and VNTR analysis demonstrates that the interactions between badgers can result in coinfections of individual badgers with different strains.

A study of Tuberculosis of wildlife and cattle in East Wicklow involving strain typing is currently underway. A previous study found that infection levels in badgers were higher than in deer, that there was strong evidence of inter-species transmission and that M. bovis infection in the two wildlife species are inter-related rather than independent of each other.

As stated earlier 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 bTB in Ireland and the likely contribution of vaccination of badgers in the future, we believe that the costs associated with vaccination (both the cost of the vaccines and the cost of distribution/ administration) and badger culling should be co-funded, as recommended in the recent Court of Auditors report. Accordingly, Ireland is applying under this programme for co-funding in respect of the costs relating to vaccination, which are eligible for co-funding under Article 11(e) of Regulation 652/2014, and for badger culling under Article 11(h) 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).

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

4. Measures of the submitted programme

4.1 Summary of measures under the programme

Duration of the programme : 2017 - 2018

First year :

Eradication

Testing

Slaughter of animals tested positive

Vaccination

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

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

The specific objective of the BTBEP 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 BTBEP currently in place is an effective programme and is capable of eradicating the

disease by 2030. The estimated date for achievement of both biological eradication of bTB and OTF status is 2030. It is anticipated that by this date the number of confirmed infected herds will not have exceeded 0.1% of the total numbers for six consecutive years.

The operational objective of this 2 year programme, 2017-2018 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), 3 (2014) and 5 (2015) [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. Descrive the responsabilities of all involved stakeholders. Explain which actions are taken to actively involve the stakeholders in the implementation of the programme.

(max. 32000 chars) :

4.2.1. Programme and Policy

The initiation and drafting of the BTBEP 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 Chief Veterinary Officer (CVO). In consultation with ERAD HQ, the BTBEP 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.

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-γ 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, and under Service Contract to 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, has a permanent staff complement of c. 54 veterinary inspectors and 183 technical staff and engages some 610 private veterinarians on a part-time basis. All cattle presented for slaughter in the State undergo an ante-mortem and post-mortem inspection under the control and supervision of the VI in charge of the 32 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 also conducted under contract to the FSAI (Food Safety Authority of Ireland). All granulomas detected at slaughter, from either DAFM or Local Authority Veterinary Services (LAVS) approved beef slaughter plants 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. 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 BTBEP 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, directly contributing some €30M towards the total running cost for the BTBEP of €76M (including staff), ensures that they are significant stakeholders in the programme and who by their contribution reduce the cost burden on both the Irish exchequer and the claims made 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 bTB and procedures when a

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

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 bTB 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. Targeted selections of samples are taken for correlation with IFN-γ 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.

Consistent application of the test in compliance with national and international requirements is critical to the success of the eradication programme and to providing security to importing countries. In Ireland, supervision and quality checks on skin tests conducted by field veterinarians consist of on the spot supervisory checks and administrative checks (Duignan and Good 2012) .

In summary a specialist report (ER13A) is generated on the Animal Health Computer System (AHCS) was introduced in 2008 to monitor the performance of each field veterinarian in delivery of the SICTT. This report captures all data relevant to testing by each veterinarian and concentrates on measuring key deliverables that affect the quality of both administrative and disease detection performance. The key measures of performance are critical control points are objective and readily measurable and therefore enable comparison of performance over time and between peers.

The measures evaluated include numbers of herds and animals tested, non compliances with advance itinerary, late test report submission, disease detection rates, backtraced confirmed lesions in abattoir and back-traced reactor detection (both of which relate to animals tested by the field veterinarian within the previous six months) and amendments to test details subsequent to test report certification. Field veterinarians are ranked alongside their peers, both at national and local level, according to the key performance indicators, using a numerical risk-based weighting for each value measured on the report. It is therefore possible to give considerable attention to the standard of SICTT application on an objective basis. It is also possible to apply performance based sanctions based on analysis of the specialist reports.

- ERAD HQ centrally generates ER13A reports six monthly and annually on AHCS.
- Field Veterinarians have access their own individual ER13A reports on AHCS and are instructed to apply

corrective action in cases of non compliance and unsatisfactory disease detection.

- ERAD HQ caries out risk based analysis of ER13A reports and select lists for follow up action on a six monthly basis.
- ERAD HQ selects a number of the poorest performing field veterinarians for supervision by members of

a specialist regional inspection team which will report directly to the Regional Senior Superintending Veterinary Inspector. Selection for supervision is risk based on the analysis of ER13A reports and previous history.

- ERAD HQ select a further number of PVPs for field supervision by local Regional Office Veterinary inspectors based on risk analysis of the ER13A reports.
- A file is circulated to Regional Offices which includes:

1. A list of the performances of all field testers for the period.

2. An individual list for each Regional Office of veterinarians selected for field supervision based on performance analysis.
3. A random selection from all testing veterinarians for field supervision.

- Regional Veterinary Offices additionally conduct supervisions following adverse reports, on an opportunistic basis (e.g. if visiting farm during the conduct of a test), on foot of observations at ER06/09 inspections of reactors/testing facilities and including outcome of Interferon-γ assay on reactors or balance of cohort group/herd. This procedure ensures that any field veterinarian may be scheduled for supervisions during the calendar year. The number of PVPs assigned inspection from HQ has been reduced to facilitate targeting of those field veterinarians whose ER13A reports indicate below normal standards and a random selection.
- Each Whole Time Temporary Veterinary Inspector is supervised twice annually.
- Regional Superintending Veterinary Inspectors schedule further supervisions for all new applicants for approval so as to ensure satisfactory proficiency.
- Regional Offices are also required to carry out unannounced random, opportunistic and targeted supervisory inspections on field testers in addition to the checks conducted during routine herd inspections, breakdown herd visits and 'desktop' checks via AHCS (ER13A reports).
- A Standard Operating Procedure for field supervisions includes strictly unannounced inspection. Checks include; biosecurity, equipment, test technique, test interpretation, recording and follow up reporting.
- Field supervision reports are kept in the individual field veterinarian files at the Regional Offices. Copies of unsatisfactory supervision reports or other non-compliances and follow up action are sent to ERAD HQ.

Unsatisfactory reports are followed up with disciplinary measures, as appropriate, laid out in a procedures policy document "Protocol for the assessment and quality control of Private Veterinary Practitioners and Whole time Temporary Veterinary Inspectors under the Bovine Tuberculosis Eradication Programme" .

Disciplinary measures are proportionate to the seriousness of the deficiencies found and range from verbal or written warning to re-inspection, retraining, suspension, referral to The Veterinary Council of Ireland or even prosecution.

RVOs are also instructed to impose a charge on non compliant field veterinarians to cover additional costs incurred by the competent authority in accordance with EU Dir 882/2004.

Training: Regular theoretical and practical training courses are conducted at which attendance is mandatory for new applicants for approval for testing and on those deemed in need of retraining. A new TB test training DVD was produced by DAFM in 2014 and circulated to all testing veterinarians and official veterinarians, which demonstrates application of the SICTT in compliance with EU 64/432.

The quality control system was examined in the context of the FVO audit of 2014 and the Task Force visit in 2014andwhen it was commented on favourably.

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 informs 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 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 Office (RVOs) units serve the 26 counties and 29 District Veterinary Office (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, a Regional Assistant Principal (R/AP) and an Area Superintendent (AS), covering the North and South of the country. These AMTs liaise with ERAD HQ in relation to implementation of the BTBEP. The table at Annex 3 attached shows the herds under the programme etc. in each county for 2015.

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 > 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 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 article 14 of Regulation EU No 652/2014 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

Please detail also the rules existing for transhumance and common grazing areas, if any.

(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.

The maximum amount of time that can elapse before a herd's OTF status is suspended on AHCS, where an annual round test is overdue, is 25 days. In practice it is normally less than this. Additionally, animals may not be traded via markets or farm-to -farm on the annual anniversary of their previous test and thus effectively the status of such animals is de-facto suspended immediately. Veterinary Practitioners, legally, have 7 days to submit reports of tests where there are no reactors disclosed. Herds that have not had their annual round test completed and signed off on AHCS by the testing Practitioner, five days after the due date of the test has passed are issued with a letter instructing them to test within 14 days. In cases where an advance itinerary giving the planned date of test has been submitted, the letter instructing them to test within 14 days will not issue until 10 days after the due date of the test has passed if the test has not been completed and signed off by the testing Practitioner. Any herd which has not had its round test completed and signed off by the testing Practitioner 5 days after the expiry of the 14 days will have its OTF status suspended automatically by the AHCS computer system. Where consequential type tests are concerned, i.e. tests related to a disease breakdown, because of the higher risk involved, where the test has not been completed and signed off by the testing Practitioner 5 days after the test due date, AHCS will automatically suspend the herd's OTF status.

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 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 bTB 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 bTB 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.

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 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) 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 bTB rather than for administrative reasons) are required to have been tested with negative results within the 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 BTBEP 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 (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 (see 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.

There are no exemptions to movement restrictions other than those already covered in paragraphs 4.4.5.2 and above. There is no such category of herd in Ireland as an 'approved fattening unit'.
The minimal exemptions to Directive 64/432/EEC as set out in the preceding paragraphs are necessary to address and prevent animal welfare arising from the restriction of herds. This has been recognised in the recent Task Force Report which stated: "For herds with separate units/farms for e.g. rearing and milking, where movements must be allowed for animal welfare reasons (no milking facility in replacement unit, no room for rearing calves in milking unit etc.), such movements must lead to restrictions on all epidemiologically linked units/farms." These moves involve very small numbers of animals e.g. in 2014

(a) 3 Restricted (OTF withdrawn) herds moved 108 animals into 3 feedlots with existing OTF-withdrawn status - all moves occurred in late autumn/early winter because there was insufficient winter housing and feed to accommodate all animals on the restricted farm and all 3 feedlots remained restricted for the lifetime of the moved in animals and (b) with respect to animal moves, between linked herds (i.e. units with animals under same ownership) 517 animals moved between 14 restricted herds - noting that as per Task force recommendation if the holding from which the animals moved was restricted then the holding into which the animals move is also restricted, regarded as the same epidemiological status and tested accordingly.

With regard to the risk of the spread of TB due to animal movements, numerous studies in Ireland have demonstrated that the risk to spread bovine tuberculosis is not increased in Ireland by the high number of movements of animals between herds. In addition, observations on the reports of TB from

destinations to which Irish animals are exported demonstrate that there is minimal risk of moved animals confirming as infected e.g. 144,218 animals were exported to mainland Europe in 2014: of these 44,957 went to Spain and no case of a TB detection was notified to Ireland; similarly 126,472 were exported in 2013, with 97,172 going to Spain of which there was one single TB detection post-mortem notified to Ireland. In total therefore, of 270,690 Irish animals exported to mainland Europe in 2013 and 2014, there was a single TB detection notified over a 2 year period.

Clegg et al (2015) also examined this question and detected little change in Ireland in the estimated proportion of restrictions attributable to introduced cattle between 2003 and 2004 (Clegg et al., 2008) and 2012 data. Therefore, although between-herd movement of cattle in Ireland is common, introduced cattle as a source of infection remains relatively uncommon.
A 'Feedlot' herd designation exists solely in the context of a TB diagnosis in the herd, withdrawal of OTF status and restriction. A Feedlot is merely a subset within those herds that operate a beef fattening enterprise. Only a small number of beef herds meet the criteria for designation as a feedlot when diagnosed with TB.

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, and 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 function as a commercial entity while complying with animal health legislation and practice. Such herds are not exempted from testing, reactor removal or disinfection requirements.

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 i.e. must not have any neighbour contacts either through cattle being confined exclusively in yards/building or if intending to graze cattle the grazing block of land is secured so there can be no contact with cattle e.g. surrounded by tillage, residential/ industrial/recreational units or impenetrable rivers, roads or walls
or
(iii) the boundaries are walled, double fenced or equivalent so as to prevent any direct contact with cattle on contiguous lands/premises/holdings
and
there must be no evidence of within herd acquisition or spread of TB (i.e. Low risk).
Thus a Feedlot herd, is a herd that poses minimal risk of infecting other cattle because of effective isolation from other herds. Such herds are allowed, when restricted, to continue to acquire animals for fattening so as to maintain a viable enterprise.

In addition the following conditions apply:

- Only one parcel/fragment may be designated as the 'feedlot'.
- A Feedlot, being de-facto a TB restricted herd (OTF-withdrawn), is not permitted to sell cattle on the open market other than directly to slaughter.
- Permission to move animals into the herd will only be activated when the keeper has signed, dated and
returned an application agreeing to the conditions of authorisation and after it is countersigned by the SVI/VI and has been entered on the Animal Health/Animal Identification and Movement Control database.

- The permit to move animals in may be cancelled if disease situation or enterprise type is being altered.

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

- Feedlot' herds that fatten females must have the capability of rearing any unplanned calves until slaughtered or OTF status has been restored under Directive 64/432/EEC.
- When bTB is diagnosed, the restriction notice specifies conditions with respect to disinfection of premises and equipment and also storage and spreading of manure/slurry that must be respected.
- The restriction notice (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).
  - Manure/slurry may not be spread on ground to be grazed within the succeeding 4 weeks.
  - Animal Identification and Movement Notification procedures must be complied with.
  - Animals may only be sent to slaughter while the herd is within 12-months of its herd test.

An animal may only be sent to slaughter if it is within 18 months from its previous test.

  - Permission to test animals >18-months since its previous test for movement to slaughter must be sought from RVO before test and the test will be at keeper's expense.
  - Timing of routine tests will be as agreed with the RVO. In any event if animals are being put on grass,

the herd must be tested before 'let out'. Only animals that pass this test are allowed on pasture.

  - When test reactors or suspect TB lesions are detected the RVO assesses the epidemiological situation

with special reference to consideration of the animals having acquired infection within the feedlot.

  - Test reactors must be removed under permit and within the timeframe specified (ER30) by the RVO.
  - Suspension of inward movement permission and tests in addition to those pre-agreed may be required

by the RVO as dictated by the epidemiological situation pertaining at any time and in particular to evidence of within herd disease spread (previous point refers). Normal rules and timeframes for test completion shall apply to all such tests.

  - Inconclusive reactor animals that are being slaughtered before re-test must be moved to slaughter on

foot of a movement permit to ensure they are subject to appropriate post mortem examination.

  - Any animals moving in from another restricted herd on welfare grounds must have been TB tested in the 30 days prior to movement.

Feedlot herds that continue to acquire and finish cattle while restricted are ineligible for compensatory payments for test reactors acquired while restricted.

Herds that are designated feedlot normally source animals from OTF herds in the open market under permit from the RVO 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.

With regard to de-restriction of these herds, as stipulated in the Directive, the OTF status of the herd is restored only if all the animals are free from clinical signs of tuberculosis, cleansing and disinfection of the premises and utensils has been completed and all animals on the holding have reacted negatively to at least two consecutive tuberculin tests, the first no less than 60 days and the second no less than four months and no more than 12 months after the removal of the last positive reactor. This stipulation in

the Directive also applies to animals, with OTF suspended or withdrawn status from their herd of origin, that move on permit into a feedlot. OTF status will only be restored to a restricted feedlot herd in full compliance with Directive 64/432/EEC. When the OTF status is restored to an erstwhile feedlot designated herd no additional controls apply over and above any other OTF status herd.

Ireland has no plans to phase out the feedlots as they currently operate. Feedlots currently must meet a number of strict criteria/conditions (see above) before approval and are subject to annual review. Furthermore, as with all OTF status withdrawn herds whenever an infected animal is detected in or from such herds the area VI will epidemiologically assess the likelihood of within herd acquisition and spread of infection and take appropriate action.

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 (bTB 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.

The current minimum size of the contiguous testing area is all herds with any lands within 25m from the boundary of the index herd. Contiguous herd lists are compiled dynamically using data from the Departments iMap system. The AHCS system is populated from Herdfinder with a preliminary list from this data and this is validated prior to the initiation of a contiguous programme. The preliminary ER 35 gives a herd profile of TB and eligible animals and a phone number where known, of each of the contiguous herdowners that have submitted a map for the Basic Payment Scheme (BPS). This information is updated daily from the iMap system. The list is generated for herds 150m from the index herd and those herds >25m are marked for testing.

Where badgers have been implicated in a breakdown and it is clear that badger paths extend from the holding of the index herd to one or more other farms outside the 25m contiguity list then such farms will be added to the contiguous testing programme.

Where there is an area with a cluster of TB-infected herds, all herds within the area are managed as at risk and testing co-ordinated so that all lands within the area are accounted for and on a contiguous programme so that no potentially exposed herds and stock are omitted from the testing regime.

Recent restoration of OTF-status following a high risk breakdown: Irish research has shown, over many years, that herds that have experienced a H-breakdown (2 or more infected animals with infection acquired and/or transmitted within the herd) are at increased risk of having further TB breakdowns and that the longer an animal remains in such a herd following a clear test the greater the likelihood of

infection in that animal. This risk is however relatively low and reducing. The breakdown rate at the first test post de-restriction for such herds in 2015 was at 5.5% in comparison to 8.14% in 2008. Following on from recommendations made by the TB-Task force in 2014, 'trade restriction' movement controls were introduced, in 2016, on the movement of stock out of such herds limiting the movement 'window' by imposing a trade restriction at 3-months post OTF status restoration. High Risk herds, as before under the Irish bTB eradication programme, have to undergo 3 herd tests post-de-restriction before having a default risk (D) status restored however the first test may now take place at a time of the farmer's choosing between 3 months after de-restriction but no later than 8 months after de-restriction. AHCS has been programmed to prompt the scheduled date of the first of the 3 tests at 3 months from the date of the clearance test. The trade restriction will remain in place until the first full herd test is completed, between 3-8 months post-OTF status restoration; unless that test is superseded by a test of higher priority (N.B. while restricted the herd is not eligible for pre-movement test permission on individual animals). The herd may move animals out for a maximum of 3-months before the herd is automatically trade restricted with trading status suspended. To be trade restricted means that the herd may acquire cattle but may not dispatch cattle (other than calves under 6 weeks of age) except directly to slaughter from the date the restriction is applied. 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. After the first test is completed, if clear, the herd must complete 2 further tests at 6 monthly intervals before reverting to D-risk.

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 per region, animal coverage in each herd, interpretation rules of the test,...)

For bovine tuberculosis, please detail how the quality/reliability of the skin-testing is ensured/verified (training and supervision of field veterinarians, recheck of some officially-free herds by the official veterinarians, quality insurance system in force if any, etc. ...) Please detail also how the surveillance of bovine tuberculosis is monitored in slaughter houses (Training of vets, monitoring of the lesions submission rates and positivity rates, link with the field vets in case of positive results, etc. ...)

(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 (Single Intradermal Test) is, at best, between 92 and 94% as demonstrated by O'Reilly and Mac Clancy , 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 2009 and 2012 (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 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 (bTB) is not confirmed, and not epidemiologically suspected, still count in the statistical output for the BTBEP.

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 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.

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-γ assay is employed with a view to removing all potentially infected animals in as short a time- frame as possible.

Ireland complies fully with Directive 64/642/EEC. Instructions are provided annually to Practitioners by means of the ER4 and annual acknowledgement of this document is a precondition of renewal of approval to test under the programme. The most recent ER4 document applicable for the 2016 programme is available on the Department's website and is thus available to all stakeholders.

Section 9.6.1.2 page 21of the ER4 gives instructions to practitioners on test interpretation. Furthermore the appropriate interpretation level is programmed into AHCS, this will download to the testing practitioner with the test listing and thence to the handheld computer used at testing by practitioner. AHCS will highlight any deviation from the interpretation levels laid down in the first instance to the testing veterinary practitioner (97% of tests are reported electronically) and in the second instance to the Veterinary Inspector interpreting the test. Normal standard interpretation of the tuberculin test results is as laid down in Directive 64/642/EEC Annex B 2.2.5.2 with respect to Interpretation of reactions and
2.2.5.3 with respect to test interpretation in routine surveillance, low risk test situations.

Interpretation levels in herds with reactors on test or for herds listed for high risk test types is more severe than laid down in the Directive. The interpretation level for high risk test types is the so called

severe interpretation – high risk test types are all test types other than a type 1 (annual round test) and 3 (inconclusive reactor retest) or a test listed for a herd categorised as Atypical (see page 11 of handbook for a description of test types, page 31 for a description of an Atypical herd and page 23 of the ER4 for a description of severe interpretation).

A copy of the Handbook is available on line to stakeholders and the general public. The ER4 instructions to practitioners lay down (page 22) that where 2 or more standard interpretation positives are found in a 'clear' herd (i.e. clear 'OTF' status before the test) standard interpretation inconclusive reactors must be identified as reactors and recorded on the test report - unless instructed by the RVO to the contrary. The RVO may instruct to the contrary in so called atypical herds i.e. that subset of herds that behave in an atypical manner in that they produce unusually large numbers of no visible lesion (NVL) unconfirmed reactors; and experience repeat 'reactor' episodes and where a potential NSI problem must be suspect. Such herds are treated in accordance with Article 3A (b) of Annex A.I of the Directive. See page 31 of the handbook.

The ER4 instructions to practitioners also lays down (page 22) that Where the herd is undergoing a contiguous test, all standard interpretation inconclusive reactor animals must be identified for removal as reactors unless specific instructions in respect of the herd and interpretation have been received from the VI.

Severe interpretation of the tuberculin test results is laid down on page 23 of the ER4.

Positive: - a positive or inconclusive bovine reaction which is greater than the avian increase.
Inconclusive: - a positive or inconclusive bovine reaction, which is equal to, or 1 to 2mm less than, the avian reaction.
Negative: - a negative bovine reaction, or a positive or inconclusive bovine reaction, which is more than 2mm less than a positive or inconclusive avian reaction.
Animals displaying reactions to tuberculin, which cause them to be classified as reactors or inconclusive reactors must be identified and recorded as such in all cases.

All veterinary practitioners approved to test under the programme are given a copy of the interpretation chart a version of which is reproduced in the ER4 (page 23). Veterinary Inspectors are instructed that interpretation of tests carried out on herds in a breakdown should be based on the level of interpretation on the severity of the breakdown and epidemiological findings (See Section 7 page 15 of the Handbook) and that they are ultimately responsible for the official test interpretation. Under Section 7 and 8 and more recent instructions on the use of the IFN-γ assay, Veterinary Inspectors are also required as part of the epidemiological assessment of a breakdown to review the herd/area test history and the animals within or originating from the infected group and in addition to give consideration to removal of additional animals on the basis of current or previous test measurements, IFN-γ assay, ELISA and/or epidemiological considerations including depending on the extent of the infection, removal, as reactor, of animals 'inconclusive' to the severe interpretation chart or positive at the bovine site (straight bovine i.e. as if the Single Intradermal Test was conducted). In 2014, 9,261 standard interpretation reactors were removed under the programme (57% of the total animals removed) and a further 2,560 (15% total) reactors had standard inconclusive reactor readings (as per the Directive) and the balance of 4,324 (28% of total) removed with a more severe interpretation.

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-γ assay has been used more widely in the programme since the beginning of 2014. During 2015 Ireland 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. ≥4 reactors). Early in 2016 the incubation phase of the assay was extended to an additional regional laboratory in the South-West of Ireland which relieved the logistical issues attendant on the use of the Interferon-γ assay and the necessity to have samples submitted for incubation within 6-hours, in that area. There are now 3 locations, Sligo, Cork and Dublin, where the incubation phase of the assay is conducted.

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.

Circular ER04/2015 Protocol for Strategic applications of the IFNg assay in reactor herds) sets down the criteria and protocols for Strategic applications of the IFN-γ assay in TB restricted herds. This circular noted that it is stipulated in Directive 64/432/EEC and recommended by the TB Task Force and by the FVO that the IFN-γ assay should be carried out in addition to the tuberculin test in order to improve the detection of the maximum number of infected and diseased animals in infected herds,. The Circular advised the RVOs that sampling for IFN-γ assay should be promptly undertaken in herds with TB- outbreaks in or from which 4 or more reactors/infected animals have already been disclosed in order to ensure that, in so far as is possible, all infected animals are disclosed, removed and the TB-outbreak is brought speedily under control. The circular goes on to instruct that sampling must be conducted where:
- there are four(4) or more infected animals in a breakdown: note: this will include a combination of skin reactors, factory lesions and/or back-traced reactors/factory lesions, and
- there is disclosure of further skin reactors and/or factory lesions at a third and/or any subsequent reactor retest.

This has resulted in additional samples being submitted for IFN-γ assay during 2015 and 2016.

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 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, 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 BTBEP.

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 3-8 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 bTB), 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 approximately 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, 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 4.4.6.3). In 2015, 552,883 male animals and 504,998 female animals moved herd within 30 days of a TB test. In addition, some 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. 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 BTBEP 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 BTBEP. 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 11.2 in 2015, which shows a continuing declining trend. Analysis of the results of tests conducted following detection of a TB granuloma at slaughter indicates that in only 14-16% of herds is there an active TB-outbreak ongoing as demonstrated by the detection of reactors to the SICTT. Studies on herds where there is no evidence of within-herd transmission indicates that the detected animal was a case with latent TB infection. The main risk factors for animals presenting with a latent bTB lesion at slaughter were: previous bTB exposure history, previous inconclusive-reactor result at the SICTT, the number of herd movements and herd type/size and with very limited (none) evidence that these animals could have been detected any earlier. The study advocated a need to reconsider (stress) the importance of abattoir surveillance during the latter stages of an eradication campaign. In addition it should be considered if the timing of tests following the detection of a bTB lesion at slaughter should be modified so as to encourage performance of an immediate test in order to detect the sub-set of herds actually experiencing a bTB outbreak earlier without penalising those where the case was latent by requiring them to conduct 2 further herd tests in order to comply with Directive 64/432/EEC as amended.

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

Ireland does not normally perform bacteriological cultures of tissue from slaughtered reactors out of OTF status withdrawn herds. To attempt to confirm disease in what are regarded as TB-infected animals having previously failed either a SICTT or Interferon-γ assay or both and epidemiologically likely to be infected is considered an inefficient use of resources. Bacteriological cultures are routinely performed on tissues from animals coming from OTF herds where visible lesions are found at regular post mortem inspections, in Singleton Protocol herds, herds being considered for status restoration under Article 3A (b) of Directive 64/432/EEC or where there is a doubt as to the agent infecting the herd.

General:
The programme as submitted includes a range of measures aimed at accelerating detection, the elimination of infected animals and avoiding recurrence of disease. These are as follows:

(i) Gamma blood testing
(ii) Contiguous herd testing
(iii) Early removal of reactors
(iv) Cleansing and disinfection (compensation is subject to confirmation in the case of high risk breakdowns)
(v) Removal of badgers where they are deemed to be the source of infection
(vi) The post clearance testing regime and movement controls.
(vii) Restriction of inconclusive reactors
(viii) Application of severe interpretation
(ix) Group or batch removal.

In essence, the focus of the current controls is (i) on the holding where bTB has been identified (the "Index herd") where the herd occupying the holding is immediately restricted, (ii) on the herds adjoining (or 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 bTB levels in sympatric badgers where they are implicated in bTB outbreaks using a combination of population control and BCG-vaccine by injection. The position is that bTB 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

Explain also how the vaccination coverage is monitored by the official authorities

(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. The field stage of this trial was completed in 2014, laboratory and data analysis is expected to be completed in 2015 with results published in peer reviewed journals in 2016. 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 bTB 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.

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

Please detail also the situation as regard to this disease in the wildlife, and explain the surveillance and control measures in wildlife if any, and the coordination between the stakeholders involved (hunters, farmers, official service labs, vets, etc ...)

(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 bTB breakdown, leaflets, publicity etc. A statutory disinfection notice is issued to all infected holdings (ER24). A veterinary Inspector will inform the herdowner/keeper, using the ER 24, what is to be disinfected and that the disinfectant used must be from the Departments list of the approved disinfectants. The herdowner/keeper must return a declaration to the RVO informing DAFM that he/she has completed the Cleansing and Disinfection procedure together with copies of invoices relating to the purchase of an approved disinfectant or invoices from 3rd parties who completed the task for him/her) or that he/she wishes to defer cleaning and disinfection. Prior to the de- restriction of an infected holding a check is carried out to ensure the required declarations have been received by DAFM. This check is prompted by the Animal Health Computer System. In addition, in herds 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. As a control on the basis of risk assessment and random selection, 20% of farms are subjected to a field compliance check. A guidance note as how this should be implemented at RVO level is available to RVO staff as are the risk criteria for the selection of holdings (ER06/09). 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.

Farmers are reminded at least annually via the notification to test letters that they need to be aware of the necessity to adopt good biosecurity practices to avoid the entry to and the spread of disease on their holdings. In particular they are reminded to:

- maintain the security of boundary fences

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

- minimise contact between their herd and neighbouring or other cattle

- quarantine cattle entering their holding either from another holding or on return from a mart or show etc.

- isolate sick animals

- observe good general good hygiene measures with, for example

a. the provision of disinfection footbaths and overalls for personnel visiting their premises

b. providing clean drinking water

c. securing feedstores to prevent access by livestock, wildlife or vermin

d. providing secure clean feeding troughs not accessible to wildlife and

e. rodent control measures.

As stated already 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 bTB breakdown. Such advice includes: the above plus, if the VI suspects badgers are involved in the outbreak the identification of badger setts and latrines on or accessible to grazing ground so that these may be fenced to keep cattle away. In addition, advice is provided on not feeding meals and/or minerals to cattle at grass and especially along hedgerows where such feed/minerals might be contaminated by wildlife.

In relation to biosecurity measures to reduce contact between cattle and wildlife and suggestions of compensations penalties where farmers have failed to apply adequate biosecurity measures recent papers have demonstrated that badgers preferred habitat and feeding ground is on improved pastureland i.e. grazing land. However, spread of disease is unlikely to happen as a result of direct contact either at pasture or by infected but apparently healthy badgers coming into cattle sheds and contacting cattle directly . It is more likely to happen as a result of cattle coming into contact with infected dead/dying badgers perhaps behaving abnormally or infected badger products/excretions contaminating the environment and which could remain infective in pasture for several months. There is generally a lack of information on the distribution and magnitude of environmental reservoirs of M. bovis. Infected badgers may intermittently shed M. bovis in sputum, faeces and urine (Clifton Hadley et al., 1993). In 2015 French researchers reported finding environmental samples positive for the presence of M.bovis strains within the Côte d'Or region in a restricted area in the environment of farms affected by bovine TB where shared genotypes of M. bovis circulate in a multi-host system including cattle, badgers, wild boar and deer. Detection persistence over an eight month-period, despite absence of the supposed source of infection, suggested that the DNA detected could belong to viable cells. The detection of positive signals in 10% of water samples from naturally occurring water springs and accompanying flowing water in pastures where both cattle and wildlife had access is supportive of a role for water in environmental dissemination and in animal contamination perhaps even by the formation and inhalation of bioaerosols. The average prevalence in badger sett soil and badger latrines was 7.3% and 7% respectively. These were the highest prevalences detected amongst 356 environmental samples assessed (Barbier et al 2015). Similar work in the U.K. (King et al., 2015) had earlier assessed that correlations between badger social group TB prevalence as determined by the qPCR assay of faecal samples from latrines and individual or combined diagnostic test results from trapped badgers

suggested that spring was the optimum latrine sampling period, with autumn an acceptable confirmational back up with 100% and 80% sensitivity respectively. The study demonstrated that badger faecal contamination may create potential infection hotspots and a substantial and a seasonally variable environmental reservoir that may be responsible for a proportion of transmission amongst badgers and onwards to cattle. Summer had the highest detected shedding rates of M. bovis from badgers overall and summer would also have the highest rates of cattle presence on pasture. Research at Warwick University, with qPCR of faeces and culture performed in parallel on samples taken from badgers in areas in the Republic of Ireland with high levels of TB breakdown in cattle, indicates that faecal shedding is a good proxy for respiratory shedding (Travis et al 2014). Bearing in mind that Ghodbane et al (2014) demonstrated that M. bovis can be cultured from mice fed soil in which M. bovis had been persisting for months, thus demonstrating the viability of M. bovis over a prolonged period, it is probable that pasture contaminated with M. bovis shed by badgers may remain a source of infection to cattle for quite some time. It is not possible for farmers to exclude access to pasture by badgers and, at this time, no satisfactory biosecurity measure available to farmers to prevent exposure of cattle at pasture to this potential source of infection. As a result, it would be very difficult to suggest appropriate measures that farmers might take to protect their cattle and which would be effective to counteract this type of spread.

In addition to bTB specific advices and procedures, the Department is a 50% stakeholder in Animal Health Ireland (AHI). AHI was constituted as a Company Limited by Guarantee in 2009. AHI functions as a partnership between private sector organisations and businesses in the agri-food sector and the Department of Agriculture, Food and the Marine. AHI provides benefits to livestock producers and processors by providing the knowledge, education and coordination required to establish effective control programmes for non-regulated diseases of livestock. The advice provided by AHI is developed by a number of Technical Working Groups whose major outputs and policy advice, wherever possible, are published in international peer-reviewed journals. AHIs mission is to contribute to a profitable and sustainable farming and agri-food sector through improved animal health. AHI is tasked with pursuing effective control strategies for economically important diseases of livestock which are not subject to international regulation.

AHI fulfils a role compatible with one of the 2014 task force recommendations namely “The risk presented by animal movements should be regarded as a part of biosecurity that all farmers must be aware of and this should be continuously emphasised to farmers by all parties involved in advising them on various issues”. It is a not-for-profit organisation which receives no guaranteed income from the State; government funding is provided on the basis of strict matching with private sector contributions up to an agreed limit, meaning that the organisation depends entirely on its ability to attract investment from the private sector. Since its inception, AHI has concentrated solely on bovine issues and accordingly the stakeholders in and funders of AHI are the same stakeholders as for the Bovine TB eradication programme. AHI is a collaborative organisation committed to delivering outcomes of real and quantifiable value to stakeholders which continually engages with stakeholders to maximise their contributions to all aspects of the work programmes and to ensure that these are aligned with their requirements. Their objective is to base practices, including the design and development of programmes, on research, robust analysis, technical expertise and international best practice.

Within AHI, the Technical Working Groups (TWGs) comprise experts and experienced practitioners from a variety of fields who are tasked with drawing up factual resources, the development of decision-making tools, and the identification of areas for further Research and Development. Furthermore, in areas in which AHI is developing disease control and eradication programmes of national scope, the TWGs, in conjunction with the relevant Implementation Group (IG), are responsible for the development and implementation of these programmes. By giving of their time free of charge, these experts enable

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

AHI access the technical resources required to develop its various programmes at a fraction of the true commercial cost of such expertise.

To raise awareness of biosecurity in general AHI has created a series of helpful information publications which are available to download as a PDF and they actively engage with farmers by conducting workshops, running road-shows, attending and presenting at various farmer meetings, agricultural shows and exhibitions. The Biosecurity series of information leaflets produced by AHI for farmers, advisors and veterinary practitioners aims to provide science-based, practical advice and guidelines on bio security and disease control that are easily implemented on farm and include leaflets entitled i) Puchasing Stock: Reducing Disease Risks, ii) Bioexclusion, iii) Understanding Infectious Diseases and most recently iv) Preventing Disease Spread within your Farm – Biocontainment.

The terms of reference of the TWG for Biosecurity 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
3. raise awareness of biosecurity.

Achievement of these objectives will support informed decision-making by Irish farmers and the broader livestock industries. All these outputs will feed into national disease control programmes in the future. Bioexclusion: One of the key messages from the TWG is on the biosecurity risks associated with added animals. Added animals include animals bought in (whether imported from abroad or from Irish farms), returning from sales, shows, out-farms, communal grazing or housing and 'borrowed' stock, e.g. a bull. These animals represent the greatest biosecurity risk to the resident herd livestock. Mitigation of these risks requires implementation of bioexclusion practices before, during and after animal movement.

In this manner AHI has raised awareness amongst stakeholders as to their role in promoting good herd health practices and disease controls including the necessity for biosecurity and biosecurity measures that are applicable to the introduction (bio-exclusion) and spread (bio-containment) of diseases in general and are equally applicable to bovine TB as to other diseases.

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

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

A description is provided of the measures as regards positive animals and detailed reference 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. Detailed information should also be provided as regard the epidimiological investigations done, and the additional laboratory tests foreseen (culture, PCR, IFGamma, etc ...). Please mention if national guidelines are available.

(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 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). 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.

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 bTB infected herds are scheduled for test between 3 and 8-months post status restoration and, following this test after a high risk breakdown, herds are placed on a 6-monthly herd-testing regime for the succeeding year. Ireland places herds which have experienced a high risk breakdown on an approximately 6 month testing regime over an 18 month period after the herd tests clear of bTB 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 . Following the recommendation by the EU TB Task Force, in 2016, 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 heretofore) 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.

The holding will be de-restricted where the criteria for eligibility continue to be met: bTB 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 bTB) 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 bTB 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 (see Section 4.4.6.3 Post-mortem Surveillance).

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 bTB 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.

Depopulation

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

Depopulation is a normal part of disease eradication in Ireland where it featured very significantly in the eradication of Brucellosis and BSE. The intention of the depopulation for TB is that, following restocking, these farms would be capable of attaining and retaining a bTB free status. In the past, analysis demonstrated that depopulation alone was insufficient to ensure that the re-stocked herd would attain or retain an officially free bTB status (OTF) as defined by Directive 64/432/EEC and recommended that the elimination of other on-farm sources of M. bovis was essential to protect the reconstituted herd. A depopulation that fails to meet its objective is ultimately of no benefit to the farmer, the neighbourhood, DAFM or ultimately bTB eradication. The introduction of a programme of testing in contiguous herds and the implementation of badger culling together with use of the Interferon-γ assay now means that the vast majority of the circa 3,000 herds expected to be restricted for TB during any year are cleared of infection over the course of one or two tests (i.e. then pass two consecutive tests). In addition, the number of reactors disclosed in TB breakdowns is relatively small. For example, based on 2013 figures,
<600 herds will have 4 or more reactors removed over the course of a breakdown and <200 herds will have >10 reactors removed in 2015. In essence, the measures under the programme have considerably reduced the necessity for full herd depopulation. Nevertheless depopulation of a herd or group within a herd is always considered for larger breakdowns where more than 30% of the herd or group has tested positive whereas if 50% of the herd or group are reactors then depopulation must be considered in conjunction with the SVI for the RVO and the local AMT SVI/SSVI. 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.

Ireland is satisfied that depopulation as a tool is fully exploited where it will provide a control benefit.

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 the keeper. 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 as if they were not affected by disease, but is subject to legislative 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.

Compensation payable under the Bovine TB Eradication Scheme is legislated for under the Animal Health and Welfare Act 2013 (No.15 of 2013) and Animal Health and Welfare (Bovine Tuberculosis) Regulations 2015 (S.I. No 58 of 2015) and in line with other criteria laid down by the Minister.

- The On-Farm Market Valuation Scheme is the principal compensation measure available to herdowners. Under this scheme animals identified as TB reactors are slaughtered and the herdowner is compensated for the market value of the animals up to maximum limits.

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

-Depopulation Grants may be payable to herdowners whose herds are depopulated (totally or partially) in the interest of disease control, during the rest period. Such grants are conditional on the holding, or depopulated portion thereof, remaining free of stock. Grants are generally paid for each animal removed and for those removed as reactors from the time the holding was restricted. There are strict conditions on the payment of this grant and the herdowner must agree to depopulate at the time specified by the RVO.

-Income Supplement is payable in cases where disease breakdown results in the removal of more than 10% of animals in a herd in the relevant restriction period and where depopulation is not deemed appropriate. Payment is in respect of each animal removed as a reactor from a herd, subject to a maximum of 100 animals.

-Hardship Grants) are also available, subject to the herdowner meeting strict eligibility conditions. This grant is designed to alleviate the additional feed costs incurred by some herdowners whose holdings are restricted on foot of a herd retest and where animals are retained and fed during periods of restriction. The eligibility period runs from 1 November to 30 April.

The measures outlined above are designed to compensate farmers for the replacement cost of removed animals, income loss (e.g. lower milk sales) arising from their removal, and for additional costs associated with feeding animals during the winter months over a prolonged restriction period.

The amounts payable in these measures have remained unchanged since 1995 and are now being reviewed. Farm organisations have long campaigned for increases in these amounts which they claim are inadequate and do not reflect the income losses borne by farmers who suffer a bTB breakdown. Their own research also suggests that farmers are fearful of the financial consequences of a bTB outbreak.

In addition, it should be noted that payment of compensation is subject to strict compliance with;

- All cleansing and disinfection requirements
- Compliance with the provisions of the legislation relating to the TB eradication programme,
- Compliance with the Animal Remedies legislation,

-Compliance with movement, identification, and other controls laid down under disease eradication schemes, including other National/EU legislative requirements and controls.

Animals that are not in compliance with legal requirements whether introduced to a holding or otherwise are ineligible for compensation under the bTB eradication programme and further sanctions may be applied.

In view of the fact that the transmission pathways between badgers and cattle are not clear, the mounting evidence of environmental contamination by infected wildlife and the effectiveness of bio-security measures, which can be quite expensive are not proven and are unlikely to be effective, the Department has not made compensation conditional on the adoption of bio-security measures by farmers with respect to segregation of wildlife and cattle. There is no legally defensible or scientifically sustainable argument to support such a linkage (see Section 4.4.8 above).

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

Please indicate also when the last FVO audit has taken place and provide a table listing the recommendations and the actions taken by the national authorities to this regard.
Please mention if a Task Force subgroup visit has taken place and the state of play as regards the implementation of the recommendations suggested if any.

(max. 32000 chars) :

Control and implementation of the programme rests with the Competent Authority at headquarters in conjunction with the AMTs 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, bTB 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 bTB 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.
- Veterinary Inspectors 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 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 BTBEP, 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.

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 managenent 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 7.6% of GVA at factor cost, 8.5% of employment and 10.8% 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. €55m 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 implementation of the programme has conferred considerable benefits on Irish farmers and has significantly reduced the cost to the Irish exchequer. As indicated earlier, the incidence of the disease has fallen 42.6% since 2008 and by 20.9% since 2012. The improvement in the situation has considerably reduced the financial burden arising from these losses/ costs to farmers (the number of herds restricted due to bTB has been reduced by over 50% during the past 10 years). The cost of the programme has fallen from €80m in 2008 to €55m in 2015. 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, worth €2.41 billion in 2015, 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 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 bTB 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 bTB 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.

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 : 2017

Region	Type of the test	Target population	Type of sample		Number of planned tests	
Ireland	Tuberculin skin test	Bovines	SICCT	programme	8 500 000	X
Ireland	Gamma Interferon Assay	Bovines	Heparinised Blood	programme	25 000	X
Ireland	Bacteriological	Bovines	Tissue	programme	2 913	X
Ireland	Strain Typing	Bovines	Culture	programme	1 200	X
					Total	

7.1.1 Targets on diagnostic tests for year : 2018

Region	Type of the test	Target population	Type of sample		Number of planned tests	
Ireland	Tuberculin skin test	Bovines	SICCT	programme	8 500 000	X
Ireland	Gamma Interferon Assay	Bovines	Heparinised Blood	programme	25 000	X
Ireland	Bacteriological	Bovines	Tissue	programme	3 495	X
Ireland	Strain Typing	Bovines	Culture	programme	1 400	X
					Total	

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 : 2017

ireland	Bovines	114 700	114 700	113 094	2	2 878	30	1,02	98,6	2,6	2,54	X	
T	114 700		114 700	113 094	2 940		30	1	98,6		2,54		

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

Ireland	Bovines	114 400	114 400	112 798	2	2 368	30	1,21	98,6	2,2	2,1	X	
T	114 400		114 400	112 798	2 481		30	1	98,6		2,1		

7.1.2.2 *Targets on testing animals*

7.1.2.2 Targets on the testing of animals for year : 2017

Ireland	Bovine	6 500 000	6 370 000	5 987 800	14 500	14 500	15 500	98	0,23	X
Total		6 500 000	6 370 000	5 987 800	14 500	14 500	15 500	98	0,23	

7.1.2.2 Targets on the testing of animals for year : 2018

Ireland	Bovine	6 500 000	6 370 000	5 987 800	14 000	14 000	15 000	98	0,22	X
Total		6 500 000	6 370 000	5 987 800	14 000	14 000	15 000	98	0,22	

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 : 2017

Ireland	Bovines	6 500 000	0	0	880	102 400	640	74 240	144		0	0	113 000	6 306 080	X
Total		114 700	0	880		102 400	640	74 240	144		17 280	0	113 000	6 306 080	

7 .2 Targets on qualification of herds and animals for year : **2018**

Ireland	Bovines	6 500 000	0	0	704	81 290	512	59 392	115		0	0	113 100	6 345 494	X
Total		114 400	0	704		81 290	512	59 392	115	13 824	0	113 100	6 345 494		

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 : **2017**

Ireland	Bovines	0	0	0	0	0	0	0	0		0	0	0	0	X

T	0	0	0	0	0	0	0	0	

7.3.1 *Targets on vaccination or treatment for year :* **2018**

Ireland	Bovines	0	0	0	0	0	0	0	0	0		X
T	0	0	0	0								

7.3.2 *Targets on vaccination or treatment of wildlife*

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

Ireland Vaccine	4 200	1 730	1	1 730	X
Ireland Population Control	4 200	6 500	1	6 500	X
Total		8 230		8 230	

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

reland Vaccine	4 400	2 595	1	2 595	X
Ireland Population Control	4 400	4 000	1	4 000	X
Total		6 595		6 595	

8. Detailed analysis of the cost of the programme

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.*

Cost of analysis	Tuberculin test	Individual animal sample/test	0.3	2 550 000 yes	X
Cost of analysis	Tuberculin test fees	Individual animal sample/test	4.34	9 808 400 yes	X
Cost of analysis	Gamma-Interferon test	Individual animal sample/test	15.23	380 750 yes	X
Cost of analysis	Bacterial culture	Individual animal sample/test	38	110 694 yes	X
Cost of analysis	Strain Typing	Individual animal sample/test	38	45600 yes	X
Cost of sampling	domestic animals gamma	Individual animal sample/test	2.54	63500 yes	X
				Add a new row	

Purchase of vaccine/treatment ofanimal produ	BCG	Vaccine dose	1 730	27.38	yes	X
Distribution costs	Injection of BCG	Vaccine dose	1	1,560,000	yes	X
					Add a new row	
Bovines	Slaughtering/culling with salvage value	Animal	15 500	750	yes	X
					Add a new row	
					Add a new row	
					Add a new row	
Compensation	Compensation for Income losses	Holding	1	2,520,000	no	X
Transport Costs	reactor collection service	animal	15 500	40.91	no	X

DAFM Personnel	salaries	personnel	26,010,000	26,010,000 no	X
Wildlife Programme	FRS contractor	personnel	2,082,999	2,082,999 yes	X
DAFM Personnel Wildlife	salaries	personnel	1,342,725	1,342,725 no	X
DAFM Personnel Wildlife	travel	personnel	332,944	332,944 no	X
Supplies	supplies	supplies	518,542	518,542 yes	X
Other general expenses	TB Programme	supplies	4,000,000	4,000,000 no	X

Total 63 632 626,4

8.1 Costs of the planned activities for year : **2018**

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:

1.1. Fill-in the text fields IN ENGLISH

1.2. Limit as much as possible the entries to the pre-loaded options where available.

1.3. 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.

Cost of analysis	Tuberculin test	Individual animal sample/test	8 500 000	0.3	yes	X

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

Cost of analysis	Tuberculin test fees	Individual animal sample/test	4.34	9 808 400 yes	X
Cost of analysis	Gamma-Interferon test	Individual animal sample/test	15.23	380 750 yes	X
Cost of analysis	Bacterial culture	Individual animal sample/test	38	132 810 yes	X
Cost of analysis	Strain typing	Individual animal sample/test	38	53200 yes	X
Cost of sampling	domestic animals gamma	Individual animal sample/test	2.54	63500 yes	X
				Add a new row	
Purchase of vaccine/treatment ofanimal produ	BCG	Vaccine dose	27.38	71051.1 yes	X
Distribution costs	injection of BCG	Vaccine dose	1,560,000	1,560,000 yes	X

Bovines	Slaughtering/culling with salvage value	Animal	15 000	750	11,250,000 yes	X

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

Compensation	Compen sation	holding	1	2,520,000	2,520,000 no	X
Transport Costs	reactor collectio	animal		40.91	613,650 no	X
DAFM Personnel	salaries	personnel	1	26,530,000	26,530,000 no	X
Wildlife Programme	FRS contracto	personnel	1	2,082,999	2,082,999 yes	X
DAFM Personnel Wildlife	salaries	personnel	1	1,342,725	1,342,725 no	X
DAFM Personnel Wildlife	travel	personnel	1	332,944	332,944 no	X
Supplies	supplies	supplies	1	518,542	518,542 yes	X
General Expenses	TB Program	supplies	1	4,000,000	4,000,000 no	X

Total 63 810 571,1

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

8.2. Financial informaton

2.1. 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 reimbursment/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.

2.1.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))

(max. 32000 chars) :

Staff from the Department sample for the interferon-y-assay. Kits for the sampling are provided by University College Dublin (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.

2.1.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)

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

(max. 32000 chars) :

The bulk of SICTT testing is carried out by PVPs 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 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 (part of Thermo Fisher Scientific, Wagistrasse 27a, 8952 Schlieren-Zurich Switzerland)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.

2.1.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 herdowners 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 Departments 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 Departments 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.

2.1.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 for the badgers and pays the persons engaged in vaccination of the badgers.

2.1.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 carcases 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

Please explain for which measures and why co-financing rate should be increased to 100% (max 32000 characters)

Ireland is also requesting that the costs relating to the badger control programme (which includes capture and vaccination) should be considered eligible for co-funding under this programme (see table 8 above for a breakdown of the costs involved). Ireland believes that this element of the programme can

3. Source of funding of eligible measures

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

ye

s

no

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, xlsx, 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

Annex 1 Glossary of Terms Used.xls	Annex1GlossaryofTermsUsed.xls	28 kb
Annex 2 Cattle Population trends and TB Incidence 1960 -2015.doc	Annex2CattlePopulationtrendsandTBIncidence1960-2015.doc	64 kb
Annex 3 County Breakdown 2015.xls	Annex3CountyBreakdown2015.xls	27 kb
Annex 4 TB Reactor Density Maps.docx	Annex4TBReactorDensityMaps.doc	352 kb
Annex 5 Oral Badger Vaccine Timeline.docx	Annex5OralBadgerVaccineTimeline.doc	51 kb
Annex 6 Summary table reviewing all the recommendations of the meeting of the subgroup of the Task Force held.docx	Annex6Summarytablereviewingalltherecommendationsofthemeetingofthesubgroupoftheheld.doc	18 kb
	Total size of attachments :	541 kb