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FINAL REPORT OF A MISSION

CARRIED OUT IN

IRELAND

FROM 03 TO 11 NOVEMBER 2010

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN PLACE IN RELATION TO BOVINE TUBERCULOSIS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

The objectives of the mission were to assess the application of the national programme for eradication of bovine tuberculosis approved and co-funded by the European Union (EU), and compliance with EU rules related to this disease.

Official controls related to bovine tuberculosis remain a high priority for the Competent Authorities.

Some herds are exempted from eradication measures, a feature which is not indicated in the approved programme. Although the animals from these herds move only to slaughter, the risk they represent for environmental contamination is not adequately addressed.

The approved programme is otherwise largely applied. Quality assurance has been developed for the detection of infected animals. However, the programme gives a lot of leeway for adaptation of the controls at local level (including derogations for not testing some animals in the herds, or f or movements from, into and between restricted herds), which is not monitored or sufficiently controlled from the higher level to ensure consistent effectiveness throughout the country.

Measures to prevent re-infection from other sources focus on the risk presented by wildlife (badgers). Measure to prevent infection of and from the environment (cleaning and disinfection, manure and slurry, transport of animals) are given insufficient attention, and are not in line with EU requirements.

The system for certification of bovine animals for intra Union trade (IUT) does not ensure that all relevant checks are performed when the certificate is issued. The possible transit of such animals to markets and dealers premises after leaving their holding of origin is not in line with EU requirements, and the risk it represents must be evaluated in the light of the insufficient measures related to the environmental contamination.

Recommendations were made to the CA of Ireland to address the shortcomings described in this report.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AHCS	Animal Health Computer System
CA	Competent Authority
CCA	Central Competent Authority
CVRL	Central Veterinary Research Laboratory
DAFF	Department of Agriculture, Fisheries and Food
DVO	District Veterinary Office
ELISA	Enzyme linked Immunoassay
ERAD	Eradication of animal disease board
EU	European Union
FVO	Food and Veterinary Office
GIS	Geographic Information System
IUT	Intra-Union Trade
LAVS	Local Authorities Veterinary Services
MANCP	Multi-Annual National Control Plan
Market	Assembly centre for national trade (mart)
MS	Member State
OTF	Officially tuberculosis free
PM	*Post Mortem*
PVP	Private Veterinary Practitioner
SOP	Standard Operating Procedure
SVI	Superintending Veterinary Inspector
TB	Tuberculosis
TVI	Temporary Veterinary Inspector
UCD	University College Dublin
VI	Veterinary Inspector (full time official veterinarian)
VPHI	Veterinary Public Health Inspectorate

1 Introduction

This mission took place in Ireland from 3 to 11 November 2010, as part of the Food and Veterinary Office (FVO)'s planned mission programme.

The mission team comprised 2 inspectors from the FVO. The mission team was accompanied throughout the mission by a representative of the Central Competent Authority (CCA).

2 Objectives Of The Mission

The mission was intended to assess the application of the EU approved and co-funded programme for eradication of bovine tuberculosis (TB), and compliance with EU rules related to this disease.

In pursuit of this objective, the following sites were visited:

Central competent authority	1
Local competent authorities	3
Laboratories	1
Holdings	3
Private veterinary practice	1
Markets and assembly centres	1
Milk establishments	1
Slaughterhouses	2

3 Legal Basis for the Mission

The mission was carried out under the general provisions of EU legislation and, in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council;
- Article 10 of Council Directive 77/391/EEC, introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle;
- Article 27(9) of Council Decision 2009/470/EC on expenditure in the veterinary field.

The EU legislation relevant to this mission is listed in the Annex. In each case, the reference is to the latest amended version.

4 Background

4.1 Bovine tuberculosis eradication

Bovine TB is one of the three diseases for which Council Directive 64/432/EEC (on animal health

problems affecting intra-Community trade in bovine animals and swine) harmonises surveillance and control measures to be applied by all Member States (MS). Council Directive 77/391/EEC requires MSs in which cattle populations are infected with bovine TB to draw up plans for accelerating its eradication. The same Directive also foresees the possibility of EU financial contribution. Council Directive 78/52/EEC establishes the minimum criteria to be applied by the national eradication plans in order to qualify for 'Community' financial contribution.

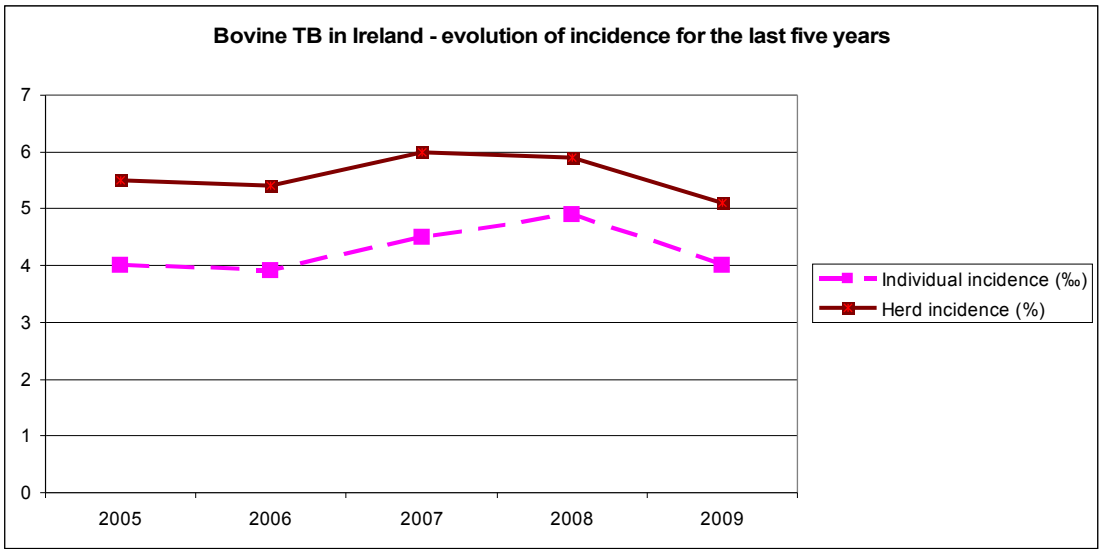
Plans for the accelerated eradication of bovine TB in Ireland have been approved for the years 2009 and 2010 by Commission Decisions 2008/897/EC and 2009/883/EC respectively. The EU financial contribution has been fixed at a maximum of 14 million Euros for 2009, and 12,5 million Euros for 2010. Before these years, the last period during which the Irish eradication programme for bovine TB was approved and co-financed with 'Community' (EU) funds was between 2000 and 2004.

The last FVO mission on bovine TB in Ireland was performed in 2007 (DG(SANCO)2007-7366).

4.2 Statistical data

The registered population of cattle in Ireland is around 6 millions (data for 2009, Source: Department of Agriculture). Cattle in Ireland are subject to many registered movements, either direct from farm to farm (850 000 in 2009) or through local markets (1.6 million in 2009). In addition, close to 290 000 animals (of which 180 000 were older than 6 weeks of age) were sent in 2009 to other MS. In the same year, around 1.5 million cattle were sent to large throughput slaughterhouses in the country, and 76 000 to local abattoirs.

Cattle in Ireland are kept in more than 117 000 herds. In 2009, around 5 % of herds (6 000) were identified as newly TB infected; this figure does not differ much from the total portion of herds which were infected at some stage during the year (5.1% incidence, against 5.3% prevalence). Close to 24 000 animals were identified as TB reactors in 2009, and a further 3 000 (non-reactor) cattle were identified as TB infected during routine post-mortem examination in slaughterhouses. The evolution of the disease incidence over the last five years is represented in the graph below:



5 Findings And Conclusions

5.1 Competent authorities

5.1.1 Requirements

Regulation (EC) No 882/2004 of the Parliament and the Council lays down the general rules for official controls to ensure the verification of compliance with feed and food law, including animal health and welfare requirements.

Official controls must be carried out regularly on a risk basis, with appropriate frequency. The CA designed by the MS must have legal power to carry out official controls, and have sufficient number of suitably qualified staff. CA shall carry out official controls in accordance with documented procedures, with information instructions and guidelines for staff. They shall have procedures in place to verify the effectiveness of official controls. They shall have contingency plans in place in the event of an emergency. They shall ensure impartiality, quality and consistency of official controls at all levels. Efficient and effective coordination and cooperation shall be ensured between different units. CA shall have transparent audits carried out, and take appropriate measures in the light of their results. Laboratories for analysis of samples taken during official controls must operate and be accredited in accordance with the ISO 17025 standard. The MS shall draw up an integrated multi-annual national control plan (MANCP), promoting an integrated approach to official controls. In case of non-compliance, actions shall be taken to ensure that the situation is corrected. Sanctions must be effective, proportionate and dissuasive in case of infringement.

5.1.2 Findings

The organisation of the CA is described in the MANCP[1]. The Department of Agriculture, Fisheries and Food (DAFF) is the CA in charge of the TB eradication programme. The programme is managed by the Eradication of Animal Disease Board (ERAD), a central twin division. The veterinary part of ERAD is under the responsibility of the State Veterinary Service (SVS), whereas the policy and administrative part of ERAD is under the responsibility of the Assistant Secretary General, reporting directly to the DAFF Secretary General. An ERAD management committee co-ordinates both parts on a regular basis. Each service (veterinary and administrative) has an internal audit unit.

The Centre for Veterinary Epidemiology and Risk Analysis (CVERA) is a national structure, managed jointly by DAFF and the University College of Dublin (UCD) which provides scientific and epidemiological support to the ERAD division. Contrary to what is stated in the MANCP, CVERA is not responsible for verification of compliance with the rules and effectiveness of delivery.

Official controls are performed by the Animal Health Inspectorate of the SVS whose field organisation has been substantially modified from that described in the control plan[2]. The number of regions has been reduced from 4 to 2, and the number of District Veterinary Offices (DVOs) has been reduced from 28 to 16. The CCA explained that this move included a reduction of administrative staff, justified by the increase in automatic electronic transmission of information.

The Veterinary Public Health Inspectorate (VPHI, from the SVS) supervises large throughput slaughterhouses and milk pasteurisation establishments.

1 http://www.fsai.ie/uploadedFiles/Legislation/Food_Legisation_Links/Official_Control_Of_Foodstuffs/national_control_plan_2007_2011.pdf

2 In their response to the draft report, the CA indicated that the MANCP is currently due for review, and that it will be sent to the Commission in due course.

The Local Authorities Veterinary Services (LAVS) are responsible for supervision of low throughput slaughterhouses. They report to Local Authorities, which are autonomous bodies generally related to either a county or a city.

The Dairy Produce Inspectorate is responsible for official controls in milk establishments of limited production capacity. It reports to the Agricultural Inspectorate, which is a DAFF division, independent from the S VS.

The Central Veterinary Research Laboratory (CVRL) is the only laboratory performing TB diagnostic tests on samples taken in slaughterhouses. This laboratory also performs ELISA (Enzym linked immunoassay) tests on serological samples. Another laboratory, in the University College of Dublin (UCD), has been designated by the CA to perform gamma interferon tests.

Observations:

- The attribution of responsibilities between the sections of ERAD was not clearly delineated, but ample evidence of close coordination and cooperation was available, either through minutes of meetings or issuance of circulars.
- The TB eradication programme states that up to 50% of human resources of the Animal Health Inspectorate are allocated to TB related measures. This proportion was even greater in the DVOs visited by the mission team;
- The CCA indicated that the reduction in staff did not significantly affect the performance in the field. However:

    ◦ One DVO visited lacked supervisory staff: it had no district superintending veterinary officer (SVI) (not replaced), and had been for the last two years without Higher Executive Officer (HEO, in charge of administrative and staff matters). Poor supervision and enforcement was observed in this DVO.

    ◦ Significant delays in notifying IUT movements were explained by the staff in charge (at the DVO level) as due to the limitation of human resources.

- Official controls have been reorganised on a risk / priority basis. Targets are set by the central level, in view of developing an auditable control system. Some of them (eg.: visit to restricted herds) can explicitly be modified temporarily according to availability of staff at DVO level; other targets are defined by their upper limit only. The mission team asked an account of the DVOs' performances regarding these targets: these were not available, and a SVI indicated that they were not requested to monitor them. The CCA indicated that they monitor staff allocation according to the work output, but monitoring of staff allocation compared to the number of outbreaks at DVO level was not available.
- The frequency of the quarterly regional meetings (indicated in the MANCP, between the CCA and DVOs/ regions) has been reduced, with three meetings in 2009, and two so far in 2010. Minutes of these meetings indicate that they are a forum for clarification, and exchanges of experiences, but review of implementation of targets of official controls were not included, contrary to what is foreseen in the MANCP.
- Weak enforcement of the rules, either for identification and movement of bovine animals, or related to TB eradication, was observed in several instances (see below for details).

- Internal audits were carried out in 2007 and 2009, on matters related to TB eradication (on payments to transporters and private veterinarians, and quality controls related to the latter category). Recommendations were made and followed.
- Documented procedures, guidelines, detailed instructions, were available for the Animal Health and Veterinary Public Health Inspectorates, as well as for the LAVS. They were reviewed, updated, and used in the field. In addition, official controls benefit from the sophistication, integration and widespread availability of the electronic databases (for herd registration, identification and movement of bovine animals, animal health updates), at many levels (DVOs, PVPs, CVRL, markets, slaughterhouses). A comprehensive quality assurance programme is conducted on PVPs official tasks.
- Annual local meetings between DVOs and the LAVS, foreseen in the MANCP, were not systematically held, and in both cases observed by the mission team, problems related to notification of suspect lesions from LAVS were not adequately dealt with (see chapter 5.4.2.1.).
- Coordination between the SVS and the Dairy Produce Inspectorate, in the event of an outbreak of TB in a dairy herd, is not covered in the MANCP. The CCA indicated that appropriate coordination is organised at central level, bu no evidence was presented, and the level of awareness of the operation of this Inspectorate was low from the ERAD/SVS staff encountered during the mission at central level (see also chapter 5.4.2.3.).
- The TB section of the CVRL has not yet been accredited. Accreditation is expected for mid 2011, and the laboratory is actively revising and documenting its activities for this reason. TB diagnosis may be made on the basis of histopathology Bacterial isolation will be performed when no lesion is present, or when the lesions do not allow a definitive diagnosis. Quality elements are already in place, and the CVRL participates in international ring-trials with the British national laboratory (on histopathology and bacterial isolation). Validation data for the ELISA test were not reviewed by the mission team. The UCD laboratory performing gamma interferon tests was not accredited either.

5.1.3 Conclusions

Official controls related to bovine TB, which are of high priority for the CA, are in general managed according to the principles of Regulation (EC) No 882/2004, with the valuable support of sophisticated tools and quality system.

Impact of the reduction of staff, and consequently the field presence of the CA in charge of the TB eradication programme, is mitigated by the automation of tasks and the reorganisation of official controls on a risk basis. However, the level of implementation of official controls is insufficiently verified to ensure their effectiveness throughout the country. This verification is all the more necessary in the execution of the TB eradication plan as a lot of latitude is given for the DVO to adapt many requirements to local circumstances as deemed necessary. Confidence in the quality and consistency of official controls is further undermined by indications of weak enforcement actions.

Coordination with authorities in charge of public health was efficient in relation to large throughput slaughterhouses and dairy plants pasteurising milk, but was insufficiently developed in relation to low capacity slaughterhouses and dairy establishments selling raw milk or manufacturing products made from raw milk.

The laboratory analysing samples taken during TB official controls is not formally accredited, but had elements of quality assurance in place. In addition, the diagnostic path followed enhances the sensitivity of the analyses.

5.2 Holding registration, animal identification, movement controls

5.2.1 Requirements

Article 14.3.C of Council Directive 64/432/EEC requires each MS to establish a computerised database, registering details of all holdings and identity details of bovine animals, able to give lists of bovine animals present in each holding and the movement history of each animal.

Article 13 of Directive 64/432/EEC requires dealers to be registered and approved, with an approval number, and the premises to meet structural and hygienic requirements.

Regulation (EC) No 1760/2000 requires each MS to establish a system for the identification and registration of bovine animals, including, in addition to the database, double ear-tags to individually identify the animals from birth, animal passports, and individual up-to-date holding registers kept on each holding. Each animal keeper with the exception of transporters must keep up-to-date registers. More detailed rules are given in Regulation (EC) No 911/2004. No animal may be moved without being identified, and must be accompanied by its passport. Each keeper must complete and sign the passport on arrival.

Regulation (EC) No 494/98 lays down the minimum administrative sanctions to be applied in the field of identification and registration of bovine animals. Movement restriction should be imposed on animals which do not fully comply with identification requirements, or on the whole herd if these represent more than 20% of the herd. If the keeper cannot prove the identification of an animal within 2 days, it must be destroyed without compensation.

Article 6.1. of Directive 64/432/EEC stipulates that bovine animals sent to other MS for breeding and production must have remained in their holding of origin for 30 days, but may transit through an approved assembly centre.

5.2.2 Findings

5.2.2.1 Holding registration

The holding registration system, for epidemiological purpose, registers herds rather than holdings. All animals on a holding are treated as one epidemiological unit, and only one herd number is issued per holding.

An alternate holding registration system is in place for single farm payment claim purposes. This system is coupled to a geographic information system (GIS), which identifies all “fragments” or separated pieces of land belonging to the same person.

The CCA is reviewing its herd registration system for epidemiological purpose. All herds which have “distant fragments” (greater than 32 km) are being assessed to evaluate the desirability of

issuing new herd numbers for these fragments.

Observations:

- The system of registering herds rather than holdings does not provide for registration of rented lands (which is a common practice in Ireland, at least on temporary basis). Movements of animals to these rented lands are not registered in the movement database[3].
- The current review of herd registration system was amended following consultation with the farming organisations, in order to outline the circumstances where there is no need for a new herd-number to be issued. Farmers are asked to declare whether they meet any of these circumstances. One such circumstance is that the keeper visit or inspect the livestock on the distant fragment frequently.
- The approval of one dealer with premises was reviewed by the mission team. The only license available was given for 6 months in 2002, asking the dealer to upgrade structural conditions. Although the dealer included a map of the proposed geographic location to be used as dealer's premises, the approval did not limit or refer to the location[4] (the dealer also had seven further registered locations with cattle, used as "feed-lot").
- The GIS did not identify separately the two activities of this owner. The CCA indicated that difficulties have arisen for ERAD regarding electronic information on locations related to holdings (as defined under the single farm payment) comprising separate herdnumbers

5.2.2.2 Animal identification

Bovine animals are identified and registered with double ear-tags and a passport, and registered in a herd register on farm, and in a national database. The identification of bovine animals was part of the scope of another FVO mission which took place shortly before this one (DG(SANCO)/2010-8508).

Observations:

- In addition to dedicated official controls, a further check of identification of animals is performed by the veterinarians during TB testing. In case of insufficient identification, the veterinarian may refuse to test the herd (but this has not occurred in the last three years), or can add a temporary (brass) identification tag to the non-identified animals. 3 500 such tags were used in 2009.
- Farmers are allowed to purchase several full sets of replacement ear-tags at the same time, and to replace them without official control[5]. On one farm visited, the farmer explained that it was cheaper to order replacement ear-tags by pair. He had at his farm sets of pairs of replacement ear-tags for animals which were no longer in his farm.
- Another farm was visited, where significant non-compliances with identification and movement have been identified by the CA since 2007. These included animals with no ear-tags, animals in the herd which have never been reported to the central database, and animals no longer present in the herd for which no movements were reported.

3 In their response to the draft report, the CA indicated that changes of the original holdings must be registered into the single-farm payment GIS, and therefore, any fragment added can be identified. For those who are not eligible to single farm payment, alternate databases for holding information are also accessible to the CA.

4 In their response to the draft report, the CA indicated that following the mission, additional documentation was found since, on the central files or at the local office.

5 In their response to the draft report, the CA indicated that unusually high levels of replacement tag orders viz. a viz. herd size will be included as a risk criteria for selection of herds for inspection from 2011 onwards.

- Movement restriction had been imposed by the DVO on this herd in March 2009, which were not respected by the owner. These restrictions were lifted in November 2009 in order to allow the registration of animals moved into the herd, then reinstalled in December 2009 (no sanction was taken). The owner still received animals into his herd after restriction, and sent animals to slaughter (no restriction was applied to this category of movements).
- A cross-compliance check, instigated by ERAD, had been performed in early 2010, which led to a reduction in his single farm payment (of about 6 000 €).
- The herd owner indicated that he recently re-identified, at the same time, several animals which had no ear-tag, based on his recollection of identities.
- 82 animals had been TB tested in October 2010: 18% of the animals registered in his holding were not present at the last TB test a month ago. On the other hand, 12% of the animals tested were not registered as being in his herd. The herd had not been subject to inspection by the SVS since.
- The CA at the DVO indicated on the day following the mission team visit that they would demand progeny testing to be performed on the animals recently re-tagged, in order to verify their identity, and ensured that they would not enter the food chain if the result is not conclusive.

5.2.2.3 Movement controls

Cattle must be moved together with their passport, or with a special permit from the CA; movements of cattle are registered in the national database. All local markets have an on-line access to the database, in which they record movements in and out. Similarly, all VPHI-controlled slaughterhouses have access and record movements on-line. Farmers may also register on-line births, deaths and movements related to their herd.

Observations:

- The system for on-line registration of movements was efficient in the market and in the slaughterhouse visited. Identification was checked by the operators, and official controls were performed on these checks and registration.
- Cattle intended for IUT for fattening or production purpose are still allowed to transit through markets and dealer's premises (where the TB test may be performed) before being dispatched to other MSs, as outlined in report DG(SANCO)/2007-7366. The guidelines for certification indicates that the 30 day residency in the holding of origin prior to loading "*is interpreted as meaning that the animal has been resident on the holding of origin at some stage during the 30 days prior to loading*." The CCA indicated that they do not intend to change this interpretation, but that they will inform the Commission of their official position regarding this non-compliance with the requirement of Directive 64/432/EEC[6].

5.2.3 Conclusions

The CA is aware of the weaknesses of their current definition of herd/holding for epidemiological purpose, but the current review process will not significantly clarify the situation.

6 In their response to the draft report, the CA indicated that they wrote to the Commission seeking their views on possible approaches.

Herds are registered, and tools are available to identify their possible location(s), but movements to some (temporary) holdings are not registered.

Additional controls on identification of cattle are performed at the herd TB tests, but the case seen where serious shortcomings had been identified for years and not adequately dealt with, undermines confidence in the system. The lack of official supervision in case of re-identification of groups of cattle represents a significant gap in the traceability of the animals. This confirms the findings and conclusions of the FVO mission DG(SANCO)/2010-8508.

Apart from these shortcomings, the movement of cattle between herds and through markets was efficiently registered. Registration of movements through dealers was not checked by the mission team. The deficiencies in the approval of one dealer indicate a low level of attention to this category.

The conclusions on the decision of the CA not to respect the conditions of residency for cattle for IUT set out in Article 6.1 of Directive 64/432/EEC have to be seen in the context of the official supervision and biosecurity considerations (see next chapter) in the intermediate places through which these animals may transit.

5.3 Routine surveillance

5.3.1 Requirement

Article 3 of Council Directive 77/391/EEC requires the eradication plan to be so devised that, on their completion, herds are classed as officially tuberculosis free (OTF), in accordance with Directive 64/432/EEC.

Annex A to Directive 64/432/EEC indicates that bovine herds will retain OTF status if all animals of more than 6 weeks are subjected to routine tuberculin testing in accordance with Annex B, at yearly intervals.

Annex B to Directive 64/432/EEC describes the test procedures and standard for tuberculin, for the routine tuberculin test. The CA is responsible for official testing of tuberculin.

Article 3 (2) of Directive 96/93/EEC indicates that certifying officers must not certify data of which they have no personal knowledge or which cannot be ascertained by them. Article 4(3) of the same Directive requires the CA to keep a copy of each certificate.

Article 4 (2) of Council Directive 90/425/EEC requires the CA to notify through TRACES the details of certification of animals for IUT, on the day the certificate is issued. Article 4(2) of Directive 90/425/EEC requires the CA of the MS of origin to communicate TRACES information to the CA of the MS of destination on the day of issuance of the certificate.

Section I, Chapter II of Annex I to Regulation (EC) No 854/2004 indicates that particular attention must be paid to the detection of zoonotic diseases during ante- and post-mortem inspection. Section IV, Chapter I of the same Annex details the post-mortem procedures to be followed.

According to Article 12 of Directive 64/432/EEC, transporters are required to keep registers of

their activities, including details of places, dates and time of collection and delivery, and disinfection, for transports of more than 65 km.

5.3.2 Findings

5.3.2.1 Compulsory testing

The system in place is as described in FVO report DG(SANCO)2007-7366. All herds must be tested at least on an annual basis, and the frequency may be increased for some herds based on risk evaluation (high risk herds, contiguous herds). All TB tests performed are intradermal comparative tests.

Both avian and bovine tuberculins are purchased by the CCA from a sole commercial manufacturer, and are registered. According to the manufacturer's indications, each dose (=0.1 ml) of avian tuberculin contains 2 500 IU, and each dose of bovine tuberculin contains 3 000 IU.

The integrated animal health Computer System (AHCS) database generates automatic notification when herds are due for testing. Animals cannot move to other herds or markets if they have not been tested within the previous 12 months. Formal suspension of the TB status may be performed after reminder letters sent by the DVO. This suspension may or may not include movement restriction to direct slaughter.

Routine testing can be performed by full-time veterinary inspectors (VI), but most are performed by private veterinary practitioners (PVPs): around 1 150 PVPs are currently under contract for this task. They are chosen by the farmers, and are required to ensure absence of conflict of interest. They are usually in charge of the routine care of the herds they test.

PVPs have the possibility to access the AHCS, which is coupled to the animal identification and movement database. They can download herd composition, and record the reading of the skin fold thickness with a portable electronic device. These data are then transferred automatically to the AHCS, which processes them and sends the relevant notification to the DVO.

The dates of clear herd tests are also recorded in each individual passport by the testing veterinarian, in order to allow a cross-check of the eligibility of animals for movements.

A quality assurance programme has been developed by the CCA. It includes training of newcomers, a full set of detailed instructions on the standards to be applied, and reporting channels. The PVPs must be subject to annual unannounced inspections by the DVOs while testing, and the quality of the data they transmit is subject to desk review. This quality system was subject to a specific internal audit in 2009.

Observations:

- According to data provided by the CA, in 2009, in the frame of routine surveillance, 41% of the herds were tested within 12 months, and 76% were tested within 14 months. In addition, herds considered to be at some level of risk were tested as high priority. At the end of 2009, only fewer than 2% of the herds had not been tested. The CCA issued instructions in 2010 in order for the DVOs to enforce the 12 months rules for all type of herds.
- Since mid 2010, new rules have been introduced, relaxing the compulsory testing of all animals within 12 months: if 80% of the animals have been tested within that time-frame,

non-tested animals may be sent to slaughterhouses and no restriction is applied to the holding.

- The markets only accept animals tested within the last 12 months. They perform a double check, on the passport of the animals, and by registering the movement of the animal in the movement database, which would flag any movement from a restricted herd. The CA confirmed that all markets have access to the electronic database.
- Although the vast majority of PVPs use the electronic recording device to register the result of the test, some are still using paper records. Deficiencies were identified in two such cases. In one case, the PVP tested 182 animals for which in each case the skin fold measurement was exactly the same 72 hours after the initial one. The herd test was reported as being complete, whereas no reading was recorded for two animals at the second visit. The report of the test was received 14 days after completion of the test, whereas the PVPs are required to report within seven working days[7].
- There is no rules governing whether herds must be tested by a VI or a PVP. In one DVO, when inconclusive reactors were disclosed, these were systematically re-tested by a VI. In another one, a PVP re-tested animals identified as inconclusive by a VI. The CCA indicated that they did not find evidence that the performance of such re-test would be affected by the attribution to one or the other category of tester.
- The adequacy of each of the tuberculins is ensured through manufacturer's tests, and additional official controls. These include official documentary checks on each batch delivered, annual inspection visit of the manufacturer, and official occasional potency tests. The CCA indicated that they check the potency of commercial tuberculin on four to six batches every year. These checks are not performed on guinea pigs, which is the method prescribed in point 2.1.5 of Annex B to Directive 64/432/EEC, but on naturally infected bovines, following the advice of the World Animal Health Organisation.

5.3.2.2 Private testing and Intra-Union Trade

Additional skin tests may be requested by keepers. All tests must be first authorised by the CA, and must be intradermal comparative tests. The eradication programme states that "keepers are encouraged to acquire pre-movement tested animals as part of their overall herd health strategy".

Instructions to PVPs (ER4, veterinary handbook) contain specific rules to be observed for testing for IUT. TB test must not be performed if it falls within 42 days of any previous TB test.
Observations:

- The total number of voluntary pre- or post- national movement testing is not recorded or monitored by the CA. The total number of private tests for 2009 was 260 000. However, this number also includes private pre-movement testing of animals for IUT, and of animals not tested within the last 12 months. It is therefore not possible to estimate the extent of voluntary application of the "pre-introduction" TB testing as a biosecurity rule.
- Instructions to PVPs ("Veterinary handbook") indicate that IUT certificates will not be issued when inconclusive reactors are in the herd (in line with point 2.2.5.3.3. (c) of Annex

7 In their response to the draft report, the CA noted that the incomplete and late test report had not been evaluated by a veterinary inspector and so had not had the opportunity to address the issue. The report was returned to the submitting veterinarian for clarification.

B to Directive 64/432/EEC). They do not refer to the condition in 2.2.5.3.4. (no increase of skin-fold thickness of more than 2 mm) for the eligibility for IUT. The CCA indicated that this point is automatically checked by the database, when the movement of the animal is notified. The guidelines for certification of live animals do not mention such a check. They state that the database will automatically check that the test has been performed at least 42 days after the previous one (a condition which is not required for other private tests). They do not indicate that the certificate should be issued only when the movement has been entered into the database. In one DVO, the VI indicated that he would sometimes enter the movement in the database the day following the issuance of the certificate.

- Copies of IUT certificates from the previous months were not systematically retained in one DVO. The CA makes available certificate templates on the intranet system, which are generally used as alternatives to those available on the TRACES system. TRACES notifications were subsequently entered either by a VI, or non-veterinary administrator. In the latter case the name of the administrator was entered as an official inspector. Many incorrect statements were entered on such occasions, and the dates of last testing and identification of animals were frequently missing. TRACES notifications were frequently entered several days (or weeks) after the actual movement took place.
- In response to a recommendation from the FVO mission DG(SANCO)2007-7366, the CCA indicated that they have discontinued the systematic testing of animals coming from other MS. The rule is that these animals are not given a passport until they are tested for the first time with the rest of the herd. If the farmer wants to move this animal before, then he has to arrange a private test. In 2009, 4 000 cattle came into Ireland from other MS for a purpose other than immediate slaughter.

5.3.2.3 Examination in slaughterhouses

In all slaughtering plants, the presence of temporary veterinary inspectors (TVI, private veterinarians under contract with the relevant CA) or a VI is required throughout ante-mortem and post-mortem (PM) inspection.

Instructions and documentation on the management of TB suspect lesions identified during routine PM inspection are available both for DAF and LA -supervised slaughterhouses. In 2009, 5 652 suspect lesions were sent for analysis from routine PM inspection. A survey has been performed and published by the CCA in order to compare the performance of notification of suspect lesions in large throughput slaughterhouses.

Observations:

- The CCA is considering the possibility to develop a quality control programme of PM inspection performance, at the inspector or at the slaughterhouse level.
- SOPs in slaughterhouses indicate that PM examination must be carried out in accordance with Annex I, Section I, Chapter I of Regulation (EC) No 854/2004. However, the veterinary procedure notice for the PM inspection of TB reactors indicates, in relation to mesenteric lymph nodes, that particular attention must be paid to their visual inspection, whereas the Regulation stipulates that they must be palpated. At the slaughterhouse visited by the mission team, the TVIs were palpating these lymph nodes. However, they were not palpating the gastric lymph nodes, and the VI in charge of the slaughterhouse confirmed that

it was not required. At the final meeting, the CCA disputed that this is a requirement of the Regulation.

5.3.2.4 Biosecurity related to routine movements

At national level, transporters are required (S.I. 574 of 2007) to wash, clean and disinfect the vehicle and equipment used, after each transport. Slaughterhouses, ports and markets are required to have adequate facilities for cleansing and disinfection of vehicles.

Official controls of markets include controls on disinfection. They are performed on a risk basis, with 20% of markets visited monthly by a technician, and on an annual basis by a VI.

Observations:

- Transporters are not required to keep a log-book of their activities, nor of the disinfection they carry out, for routine animal transportation. The CCA indicated that Article 12 of Directive 64/432/EEC has not been specifically transposed into Irish legislation.
- The disinfectants to be used as a routine in markets and slaughterhouses must be approved disinfectants, but they are not restricted to disinfectants that are active against TB.
- At the market visited, the VI had identified the absence of disinfectant in her previous visit, and had followed up with corrective action. At the time of the visit of the mission team, disinfectants approved against TB were available at the market. However, the containers presented as being used for the premises were either out of date, or the validity label was not longer present on the containers. The disinfection device for transporters was not working at the time of the visit[8]. The person in charge of preparation of the disinfectant solution for the lorry washing area, who had no access to procedure or veterinary instruction on the matter, indicated a quantity to be added to the water tank that would make an insufficient final concentration of disinfectant.

5.3.3 Conclusions

The quality system applied to veterinarians carrying out TB tests enhances the level of confidence in the quality and consistency of the TB test of the animals, when fully availing of the electronic system. The introduction of a system with a similar aim for routine PM controls at slaughterhouses will have the same effect.

Effective TB status check is performed on cattle moved through markets. However the classification of herds as OTF does not necessarily respect the condition required Annex A, I. (2) (c) of Directive 64/432/EEC, as the CA introduced the possibility for some animals in the holding not to be tested at yearly intervals without imposing restriction on the rest of the herd (or changing its TB status).

Procedures and guidelines for certifying cattle for IUT have been issued to ensure that animals have been adequately tested. However, they lack the details and clarity of information necessary for

8 In their response to the draft report, the CA noted that the device was not operational for a short period only.

cattle being certified to ensure their eligibility. Notifications of movements to other MS were not in line with EU requirements.

The fact that cattle for IUT may transit through markets or dealers represents a non-negligible risk because of the lower level of official supervision in these holdings (compared to approved assembly centres), and the weaknesses in the application and control of biosecurity measures at the holdings or related to transport. These weaknesses are all the more significant in the light of the transport of some TB reactors outside the officially controlled reactor collection system (see below section "feed-lots").

Procedures and guidelines for PM examination in slaughterhouses lack clarity on the requirements for palpation of gastric and mesenteric lymph nodes. Considering the findings of the previous mission (on mesenteric lymph nodes), and the observation during this one (on gastric lymph nodes), the current system in place does not ensure that adequate PM examination is performed.

Official testing of tuberculins were not entirely in line with provision of point 4.1. of Annex B to Directive 64/432/EEC, but no point was identified that could raise doubt on their adequacy.

5.4 Measures following identification of suspect or infected animals

5.4.1 Requirements

Annex B to Directive 64/432/EEC describes the interpretation of reactions to the skin test (positive or reactor, inconclusive, or negative).

Point 3A of section I of Annex A to Directive 64/432/EEC states that the OTF status of a herd must be suspended if a reactor is identified, or in case of suspicion at PM examination. Reactors must be removed and slaughtered, and undergo laboratory and epidemiological investigations. If the disease is not confirmed, a further clear test of the herd, performed at least 42 days after the removal of the reactor, must be performed before lifting the suspension.

The same point states that the health status of the herd must be suspended when animals with an inconclusive test are identified. These animals must be isolated, and their status clarified either by a further testing 42 days later or PM and laboratory examination.

Article 14 of Directive 78/52/EEC states that in the presence of an eradication programme, prohibition of movement into or out of the herds must be applied when suspected of tuberculosis, unless for direct movement to slaughter under authorisation of the CA.

Point 3B of section I of Annex A to Directive 64/432/EEC states that the OTF status of the herd must be withdrawn in case of confirmation of the presence of tuberculosis. In such cases, tracing and checking must be performed on epidemiologically related herds. The status is to be withdrawn until cleansing and disinfection of the premises and utensils is completed, and two clear tests of the herd are obtained, the first no less than 60 days and the second no less than four months and no more than 12 month after the removal of the last positive reactor.

Articles 14, 15 and 16 of Directive 78/52/EEC lists measures to be taken when TB is officially confirmed in the frame of an eradication programme. They include the same movement prohibitions, isolation of reactors and suspect animals (and marking of the former), slaughter of infected animals within 30 days, immediate clinical examination of cattle for TB, prohibition of use or delivery of milk from infected cows for human consumption (and heat treatment in case of use for animals), treatment with disinfectant of manure (unless covered with uninfected manure or earth) and storage for at least 3 weeks in a place inaccessible to farm animals and disinfection of liquid waste (including slurry). Cleaning and disinfection must be performed under official supervision, in accordance with instructions, and prior to restocking. Cleaning and disinfection must also be performed of all means of transport and containers after the transport of animals or materials from infected herds.

Section IX, Chapter I, I(3)(a) of Annex III to Regulation (EC) No 853/2004 states that raw milk from non-reactor cows of non OTF herds may be used for human consumption only if it is suitably pasteurised.

Article 17 of Directive 78/52/EEC gives the possibility to relax movement prohibitions on the herd after elimination of infected cattle, and a first clear test of the herd.

Section 1, Chapter III (7) of Annex I to Regulation (EC) No 854/2004 stipulates that the CA is to determine the conditions under which animals subject to a specific scheme for eradication of tuberculosis may be slaughtered, and the official veterinarian is to impose the conditions under which animals are to be dealt with, in order to minimise contamination of other animals or meat from other animals.

5.4.2 Findings

5.4.2.1 Suspension - withdrawal

As mentioned in mission report DG(SANCO)2007-7366, a number of requirements go beyond the minimum requirements of Directive 64/432/EEC. One of the most significant requirements is the direct withdrawal of OTF status for all herds disclosing reactors, if they do not meet the criteria for the “singleton protocol”.

Following the discovery of a TB compatible lesion at routine PM examination in slaughterhouse, a sample is sent to the CVRL, and the DVO responsible for the herd of origin is notified. The CVRL and DVO are informed electronically or by post and/or by fax. The DVO suspends the OTF status until a laboratory diagnosis is available. If TB is confirmed (either by histopathology, or by culture), the OTF is withdrawn. If a different diagnosis is made, the status is restored, and if no definite conclusion is reached, the status is maintained as suspended until further testing of the herd.

Observations:

- Official information sent to the keeper does not specify whether the OTF is suspended or withdrawn. However, a distinction is made in the electronic database, automatically triggering the relevant testing regime.
- Most notifications of reactors or lesions are performed electronically (more than 97% of testing PVPs, all slaughterhouses supervised by the SVS, and some of those supervised by

LAVS).

- Most official restriction notices following disclosure of test reactors were issued within a few days.
- Deficiencies were identified by the mission team in relation to suspension of TB status when suspect lesions were identified in LAVS supervised abattoirs:
  - In one case, the DVO was not informed by the LAVS. The CVRL acknowledged reception of the sample, and the herd was eventually restricted one month after the slaughter of the animal.
  - In another case, the DVO was incorrectly informed (with an inadequate form), and did not suspend the status of the herd. The laboratory cultured the sample more than one month after slaughter.

5.4.2.2 Epidemiological investigation

Herds with disclosure of reactors are automatically drawn to the attention of the DVO by the AHCS database. Herds with up to 2 standard reactors are usually attributed to a technician; these represent around 70% of the outbreaks. Those with 3 or more reactors are attributed to a VI, unless the SVI decides otherwise.

A preliminary desk analysis is performed, with information generated by the database. Testing and movement history is automatically generated for reactors. If the reactors came from another herd, the DVO of the herd of origin is informed and may decide, upon assessment, to suspend the status of this herd, and to require disinfection and a clear herd test to be completed.

A full investigation report is required for herds assigned to VIs. A more thorough desk analysis is performed, including a trace-forward exercise. A list of animals moved from the infected holding since the last clear test, or the last 12 months, is automatically generated for these cases. The VI must mark the animals which he believes are of higher risk of being infected. These animals, or the total herd of destination, must be tested, and the herd restricted. Contiguous herds must also be identified. The epidemiological investigation includes enquiries on movements between fragments of the herd, or to rented pastures.

Each restricted holding must be visited. Detailed attention is given to the presence or possible contact with badgers (a GIS records the location of all badger sets which are identified). When the holding is visited by a VI, other sources of contamination, such as housing, mechanical sources and fragments of land, are investigated, and the VI has to indicate the probable or possible source of infection.

Observations:

- The policy applied is not exactly as presented in the eradication programme: a number of herds described as of higher-risk (two or more standard reactors over the course of an outbreak) are not subject to VI epidemiological investigations.
- The instructions foresee the possibility to adapt rules on visits to restricted herds, according to the availability of officials. Such visits may also be “de-prioritised” if the farmer does not wish to avail of the opportunity of such visit. The CCA indicated that very few holdings did

not avail of the opportunity of a visit, but no data was available on the number of restricted herds that were eventually not visited.

- Neither the epidemiological report nor the instructions detail the elements that should be taken into consideration in order to justify conclusions on possible or probable sources of infection.

5.4.2.3 Isolation and restriction on milk

Keepers receive an instruction (ER20) which stipulates that reactors must be isolated until they are sent for slaughter, and that milk from reactor cows must not be delivered for human consumption. It also indicates (referring to Directive 78/52/EEC) that such milk can be used for animal feeding after suitable treatment.

Keepers must inform the dairy collecting their milk, which is also officially informed by the DVO.

It is uncommon, but not illegal, to sell raw milk or produce dairy products from raw milk in Ireland. Irish legislation (Statutory Instrument No 9/96) indicates that consent from the CA must be obtained.

Observations:

- No operator check or official control is required or performed on the respect of the non-delivery of milk from reactor cows. The dairy is not informed of the number or proportion of milking cows which reacted to the TB test.
- The dairy visited was keeping adequate documentation of notifications of outbreaks of TB among their suppliers, but was not taking any specific action, as it was systematically pasteurising all incoming raw milk. The official checks in the dairy, including those on pasteurisation (a critical control point) were documented adequately, at the prescribed frequency.
- The CCA explained that herds producing raw milk for human consumption or for further processing without pasteurisation are flagged in the AHCS, which will monitor their testing frequency, as such herds should be tested twice a year.
- The organisation of controls in such herds and actions related to raw milk products in case of TB outbreak are not described in the MANCP or in the documentation related to the TB eradication programme. The CCA at ERAD was unaware of any contingency plan covering food safety aspects in case of disclosure of reactors in such herds. The Dairy Produce Inspectorate, which is the CA in charge, has issued instructions, which are currently under review. The current instructions in relation to the detention of dairy products from raw milk in the event of an outbreak, is to consult for guidance.

5.4.2.4 Movement prohibition

If reactors are found at a TB test, the passports are withdrawn from the herd keeper by the testing veterinarian, before the official restriction order is sent by the DVO. Movements are restricted, both

from and into the herd.

However, according to the eradication programme, movements from the restricted herd may be allowed by the DVO, which issues specific permits: these movements include direct movements of non-reactors to slaughterhouses, and also other movements, if the authorising officer is satisfied that they would not result in the spread of TB.

In the case of a herd restricted because of inconclusive reactor(s), a derogation from prohibition may be provided for movements to other herds at national level, availing of the possibility foreseen in point I, 3A (d) of annex A to Directive 64/432/EEC. If more than one inconclusive reactor is identified, the derogation may be applied only if all reactors pass a gamma-interferon test.

Movements into restricted herds may also be allowed by the DVO: these movements may be allowed only after completion of a clear reactor retest, unless the herd had only one reactor (when the risk of exposure of introduced animals is minimal). Further exceptional movements in are also foreseen, in case of replacement calf, or stock bull.

Observations:

- No instructions or guidelines were available on the conditions for derogation of movement from restricted holdings, other than direct to slaughter. The CA acknowledged that these movements could also occur from restricted herds to "feed-lots" with withdrawn status, if approved by the SVI, but could not provide data on the current extent of such movements.
- Circular ER 05/08, setting out the conditions for derogation for movement into restricted holdings, also provides for the possibility to grant a derogation even if the first reactor retest is not clear. In such a case, movement into the holding may be authorised after removal of the reactors if animals to be introduced are intended for slaughter within 6 months[9].
- In the case seen where a suspect lesion was sent from a local abattoir to the CVRL, and the restriction order was imposed more than a month later, 20 animals had been moved from the holding to four other holdings (through a mart) in the meantime. Investigation was performed by the DVO, which concluded that no risk of disease occurred. The documentation of this investigation was not available.

5.4.2.5 Marking, removal and slaughter of reactors

The testing veterinarian must identify reactors with a reactor ear-tag and a red disc. After valuation of the animals, a reactor collection service is organised under official supervision. Reactors are collected by transporters chosen from a list approved by the DVO, which issues a specific movement permit.

For each reactor collection, the DVO issues instructions to the transporter on the number and locations of cattle to be collected (the transporter may collect reactors from various herds before bringing them to the slaughterhouse).

9 In their response to the draft report, the CA indicated that such moved-in animals are not eligible for compensation if they become reactors.

Reactors may only be slaughtered in VPHI-supervised slaughterhouses identified in advance. A notice (VPN 6/2010) updated the measures to be applied when slaughtering reactors. Lesions are recorded, but, as the status of most herds is directly withdrawn when a reactor is disclosed, samples are not usually taken at the slaughterhouse for laboratory examination, unless the DVO so requests (e.g. for the singleton protocol).

The reactor collection service does not apply to reactors detected in "feed-lots", which are sent under private arrangements.

Observations:

- In all cases checked by the mission team, the reactors were removed from the infected herd within 30 days, except in one case where the owner did not agree with the valuation of his animals - the reactors were still in the herd three months after their identification[10].
- Means of transport must meet construction and operation requirements indicated in Article 12 (1)(a) of Directive 64/432/EEC; a slurry collection tank is required on the lorry. A log-book for keeping a disinfection record has been issued by the CA for transporters to record the place and dates of disinfection in relation to transport of reactors.
- The transporter visited by the mission team had a disinfection log-book, with record of disinfections and official controls. However, he had never been instructed to correct his inadequate method of disinfection (sprinkling the disinfection solution by hand from a bucket).
- VPN 6/2010 does not determine the conditions under which reactors must be slaughtered, but leaves this responsibility to the operators, who must develop their own procedures for managing the risk of contamination. The VI must be satisfied that they are adequate, but the VPN does not impose or set minimum conditions.
- Documents accompanying reactors to the slaughterhouse include a special movement permit, and the farmer's food-chain information declaration. These are standard declarations, where the farmer is to declare that the farm is not under disease restriction, and that the cattle had not tested positive for any condition that might render their meat unfit for human consumption. Some of these forms were checked and accepted by the VI, where in addition the slaughterhouse operator indicated that the animals (reactors) were not coming from a restricted holding.

5.4.2.6 Cleaning and disinfection, manure and slurry

Cleaning and disinfection are managed through 2 different standard forms:

- A form to be used in all cases (ER24). This form requires cleansing and disinfection, and possibly orders grazing restriction in some land. This form also specifies the treatment of manure (disinfectant should be sprayed or saturate manure before its removal; manure must be stacked in a place remote from cattle, goats and swine, and not to be spread on pasture land)

10 In their response to the draft report, the CA indicated that this last removal of reactors was enforced the month following the mission.

- In cases where the VI is involved (and further cases where the SVI decides so), further forms are also used (ER64 and ER64A), requiring the keeper to indicate the date he is planning to perform cleansing and disinfection. He then has to return either a proof of purchase of disinfectant, or an invoice from the disinfection company.

The latter outbreaks are to be subjected to official control on a risk basis. Instructions indicated that this control should be performed on up to 20% of such herds.

In addition, the restriction notice (ER22) requires slurry and manure to be stored for at least two months.

Observations:

- Neither ER24 or ER64 links the date of cleansing and disinfection (or treatment of manure with disinfectant) to the removal of animals or a re-testing regime. It has to be performed before de-restriction.
- The restriction notice (ER22) indicates that cleansing and disinfection should be performed in all housing once all "punched" animals are removed. This instruction can be in contradiction with ER24, where the VI or officer may restrict the requirement to some places.
- Slurry is not subject to any official requirement in ER24 or ER64. At an official research farm, the CA was treating cattle slurry (washdown water and effluents (manure, silage) with hydrated lime. One DVO visited was using an old form to require disinfection (ER24B). This form included more detailed aspects (such as "map of the locations to be disinfected to be given to the herd owner, approximate amount of disinfectant), and a detailed section on slurry treatment and storage, but these aspects were no longer followed[11].
- In the DVO where this was checked, the official controls on cleaning and disinfection were performed by technicians or VIs, not using any specific form to report their check. Manure and slurry disposal were not checked. The percentage of holdings subject to official controls is not subject to supervision.
- ER24 recommends to use washing soda (a cleanser), followed by an approved disinfectant. The list of approved disinfectants given to the farmers indicates those which are approved specifically for TB and their concentration, but the CA does not explicitly restrict the use of approved disinfectants to these ones.
- The CA acknowledged that a number of factors could hinder the proper execution of cleansing and disinfection operations (cattle on pasture, impossibility to remove animals from the premises, impossibility to store manure or slurry,...). However, these factors were not subject to specific record (and therefore would be difficult to be taken into account in case of residual infection).

5.4.2.7 Supplementary blood tests, depopulation

As indicated in the approved eradication plan, gamma-interferon and ELISA tests are used as

11 In the response to the draft report, the CA indicated that the section for slurry was intended to be used only in case of brucellosis, and that they will amend the forms and instructions to make it clearer.

supplementary blood tests, or where depopulation would be the only alternative. The latter test aims at identifying anergic animals. The use of these test is proposed by the DVOs, subject to approval from the CCA.

Animals which show positive reaction are flagged as reactors, and are removed under the programme (and subject to compensation). In 2009, around 8 000 gamma interferon and 2 200 ELISA tests were performed (for around 1 500 and 100 positive results respectively).

When the gamma interferon test is not suitable, or when the problem has not been solved with it, partial depopulation is considered; total depopulation will be considered as last resort. Total depopulation is decided by the SVI, with the approval of the hierarchy. As stated in the eradication plan, there is no threshold beyond which depopulation is to be performed. In 2009, 21 herds were fully depopulated; further herds were subject to partial depopulation.

Observation:

- Arrangements were in place in order to ensure that samples would be processed within the time limit, including by authorising a regional veterinary laboratory to perform the initial steps of processing of the samples. Despite this, some areas have difficulties to use this test for practical considerations.
- The CCA indicated that, due to specificity issues, they restricted the gamma interferon test to infected groups of animals within infected herds. No legal basis is in place for the compulsory removal of ELISA reactors.
- After depopulation, the SVI determines the period of rest for the land, which is usually at least four months. These herds are not subject to further specific requirements for cleaning and disinfection. The owner of one depopulated herd treated the slurry with lime, but he was not ordered to do so by the DVO.

5.4.2.8 Official measures to prevent a herd to be re-infected from other sources

The following measures are applied in herds classified as under higher risk.

Contiguous herds are restricted (pending test) if not tested in the previous 6 months. They are then tested every four months until the index herd is cleared.

If the epidemiological enquiry does not establish that the outbreak is probably due to an introduced or residually infected animal, and if badger signs are identified, a survey is performed. Identified sets are computerised in a GIS database, and killing of badgers in the surrounding area is performed under licence from the Department of Environment, Heritage and Local Government.

Observations:

- In addition to extensive research performed on badgers by CVERA, anecdotal evidence was reported by VIs on the badgers as being a source of contamination, particularly when local ecology was disturbed (e.g.: construction of a new road).
- The CCA has reported and published a lot of evidence on the efficacy of the current policy

of killing badgers. In one county the CCA attributed the sharp decline of TB incidence, to both the badger policy and the increased enforcement of all other measures, but in another successful experiment, it was solely attributed to the action against badgers.

- Killing of badgers may only be performed under license from the Department of Environment and with the consent of the landowner. A SVI indicated that some owners with no TB outbreak on their land refused to grant consent, for fear of introducing a risk. As indicated in the eradication plan, a vaccine for badgers is being developed, but is not yet used in the field.

5.4.2.9 De-restrictions

De-restriction of herds is performed according to the classification status: either after one clear herd test 42 days after removal of reactor (for herds with suspended status), or after two clear tests, at least 60 days and four months after removal of reactors (for herds with withdrawn status). These tests and dates are automatically prompted by the AHCS.

For herds which are classified as higher risk, post-derestriction TB tests are performed at increased frequency (three times at 6 months interval).

Observations:

- All TB test sequences leading to de-restriction checked by the mission team complied with the interval requirements.

5.4.2.10 Feed-lots

A Circular issued in 2008 (ER05/08) created a specific category of herds, called "feed-lots", disposing all cattle direct for slaughter. The herds must be tested at least once a year. If a reactor is identified, their TB status is kept as withdrawn, and as such, are legally required to store all manure and slurry on the holding for at least 2 months prior to its spread. The following features of the eradication programme would not apply:

- Reactors are not removed under the removal scheme and the keeper is responsible for the disposal of any reactor. No deadline for removal is set in the circular ("within a reasonable timeframe").

- A minimum of one reactor re-test per year is required, meaning that they may maintain their withdrawn status;

- Once permit conditions for operation as feed-lot are agreed, they are authorised to move animals into their holding.

These herds may be housed or grazing. In the latter case, boundaries must prevent any direct contact

if there are contiguous cattle. They may include female animals and offspring. These herds are not restricted in respect of the cattle they may receive, but they can only send cattle to slaughter.

These herds must be authorised and registered by the DVOs. The CCA indicated that 210 herds are currently registered under this regime.

Observations:

There is no reference to these particular rules for "feed-lots" in the 2009 or 2010 approved eradication plans;

- The circular indicates that reactors may be sent, with "a particular reactor permit", to any "registered premises willing to accept such reactors", which must be on the list of registered premises approved by the Department. The CCA indicated that "premises" referred only to slaughterhouses.
- The authorisation file of one such "feed-lot" was checked by the mission team. The holding consisted of 7 separate fragments of land, in three very separate locations, all grazing or farm land, covering a total area of more than 200 hectares:
    - The approval had been granted in 2008, after a documented visit from a VI. The approval was given on the assurances that the keeper would rectify the shortcomings. No further visit was performed, and the approval was not renewed, but the herd was still on the feed-lot list.
    - The keeper was also registered as a dealer, with dealer's premises. Neither approval referred to the possible risks of the combination of these two activities. No provision was made to ensure the absence of contact of cattle from these two activities.

5.4.2.11 TB in other species

A TB control plan is in place for milking goats and sheep. It applies the requirement contained in Section IX, Chapter I, I(2)(c) of Annex III to Regulation (EC) No 853/2004 (that goats kept together with cows must be tested for TB), requiring goats to be tested at the same frequency as cows, and the "establishment of the TB status"of goats prior to their purchase. It also requires all flock keepers supplying milk to test the flock at least once, and on an annual basis when they are kept outdoors.

Observations:

Although not specified in the TB control plan, the test used in these species is also the comparative tuberculin test, using the same grid of interpretation as for cattle.

5.4.3 Conclusions

Timely suspension of OTF status is ensured following disclosure of TB test reactors or disclosure of lesions in slaughterhouses reporting on-line, but not in the case of lesions found in low throughput slaughterhouses.

The direct withdrawal of the OTF in most cases of TB reactors, and investigation, goes beyond the minimum requirements of Directive 64/432/EEC. The animal health database ensures the respect of number and delays for re-testing until restoration of the OTF status.

A number of arrangements and derogations are foreseen for movement restriction, and left to the decision at DVO level, for which insufficient guidelines are available, and very limited evidence of control performed.

In 70% of the outbreaks, the epidemiological investigation is limited to a desk-based exercise. The requirement for the level of investigations by VIs is less than what is foreseen in the eradication programme, and the level of additional investigations (including farm investigations) is not monitored.

Tracing and checking of herds considered to be epidemiologically related is performed, but the analysis of recent movements of animals is incomplete: most reactors coming from another herd with non-confirmed status (not all, as the research stops at 12 months before disclosure of the reactor) are identified, but recent movements from infected herds are only evaluated when 3 or more reactors are identified. The DVOs have the power to apply restriction measures to these linked herds, but the extent of this application is left to their expert judgement, and is not centrally monitored.

Official controls on the application of restrictions on milk from reactors are insufficient to ensure that they are correctly applied. Whereas in most dairy plants pasteurisation is systematically applied, which controls the risk, the efficacy of the system in case of use of raw milk is questionable.

Restriction of movements is in principle applied as foreseen in Directive 78/52/EEC, except for the movements from herds with inconclusive reactors. However, there are many options for derogations, with a complex system of conditions to be observed. Instructions for the conditions of granting such derogations are in many instances vague, and in the end left to the judgement of the DVO. Movement of cattle from holdings with suspended or withdrawn status to other holdings (even with a suspended/withdrawn status), are not in line with Directive 78/52/EEC.

In most cases, reactors are swiftly removed from the herds through a supervised system, aiming at controlling the risk of spreading the infection. This system is not applied in all cases, as reactors from “feed-lots” may be removed and sent to slaughter without the same biosecurity requirements.

The animal and public health conditions in place for minimising contamination in case of slaughter of reactor animals are not in line with the requirements of Regulation (EC) No 854/2004, as they are not imposed by the official veterinarians, but left to the responsibility of the business operators.

There are formal instructions for cleansing and disinfection, but these aspects are not considered as covering a significant risk factor by the CA. They are not imposed in a manner consistent with disease control purposes. They may not be supervised or controlled in 70% of the cases, and be subject to check on less than 10% of the outbreaks. The disinfectant to be used is not restricted to the ones active against TB. A system for imposing slurry treatment exists but is not applied. Instructions on manure and slurry are general, and not subject to specific monitoring. When checked, the nature and extent of cleansing, disinfection, manure and slurry treatment is not recorded in a way that can be used for further epidemiological investigations.

Supplementary tests for further elimination of possible infected animals are used in line with the approved eradication programme, when collaboration of the keepers is secured. Their use is hindered by logistic matters in some regions.

Backed by extensive research, a lot of consideration is given to the risk presented by infected badgers, and measures are applied as far as possible to control this source of infection.

The system developed in order to exempt a certain category of "feed-lot" herds from a number of specific provisions for TB eradication, is not included in the approved eradication programme. When the TB status of these herds is withdrawn, most measures foreseen in Directives 64/432/EEC and 78/52/EEC for eliminating the disease and restoring the status of the herds are not applied. This system does not address the risk related to environmental contamination (such as those borne by slurry and manure, transport of animals, wildlife). The nature of the herds of origin (which might include other herds with withdrawn status) and the insufficient controls on the application of structural biosecurity requirements, constitute additional risk factors, which are not adequately monitored.

6 Overall Conclusions

Official controls related to bovine tuberculosis remain a high priority for the Competent Authorities.

Some herds are exempted from eradication measures, a feature which is not indicated in the approved programme. The risk they represent for environmental contamination is not adequately addressed.

The approved programme is otherwise largely applied. Quality assurance has been developed for the detection of infected animals. However, the programme gives a lot of leeway for adaptation of the controls at local level (including derogations for not testing some animals in the herds, or for movements from, into and between restricted herds), which is not monitored or sufficiently controlled from the higher level to ensure consistent effectiveness throughout the country.

Measures to prevent re-infection from other sources focus on the risk presented by wildlife (badgers). Measures to prevent infection of and from the environment (cleaning and disinfection, manure and slurry, transport of animals) are given insufficient attention, and are not in line with EU requirements.

The system for certification of bovine animals for IUT does not ensure that all relevant checks are performed when the certificate is issued, and the possible transit of such animals to markets and dealers premises after leaving their holding of origin is not in line with EU requirements. The risk it represents must be evaluated in the light of the insufficient measures related to environmental contamination.

7 Closing Meeting

A closing meeting was held on 11 November 2010, where the main findings and conclusions of the

mission were presented to the national authorities.

8 RECOMMENDATIONS

The Competent Authorities of Ireland are invited to present an action plan describing the action taken or planned in response to the recommendations of this report and setting out a timetable, and a description of the actions taken to correct the deficiencies identified, within 25 working days of receipt of the report.

N°.	Recommendation
1.	Ensure quality and consistency of official controls related to the TB eradication programme (as required by Article 4 (4) of Regulation (EC) No 882/2004), in particular by developing procedures aiming at verifying the effectiveness of official controls (Article 8(3)(a) of the same Regulation).
2.	Ensure efficient and effective coordination and cooperation with LAVS and Dairy Produce inspectorate for the protection of animal health and food safety in relation to bovine tuberculosis, as required by article 4 (5) of Regulation (EC) No 882/2004, and that corrective action is taken when needed (Article 8 (3)(b) of the same Regulation).
3.	Consider the revision of the definition of herds/holdings so that all movements between holdings can be registered, as required by Article 7 of Regulation(EC) No 1760/2000, and the place where they are kept, held or handled can be identified.
4.	Ensure that all bovine animals sent to other MS comply with all requirements in relation to tuberculosis, including conditions set out in point 2.2.5.3.4. of Annex B to Directive 64/432/EEC; ensure that the competent authority of the Member State of destination receives adequate notification through TRACES on the day the certificate is issued, in accordance to Article 4(2) of Directive 90/425/EEC;
5.	Ensure that the herds may retain their officially tuberculosis free status only if all animals (from 6 weeks old) on the holding are subject to routine tuberculin testing at yearly intervals, as required by point I (2)(c) of Annex A to Directive 64/432/EEC;
6.	As indicated in the approved plan, apply all measures following disclosures of reactors to all herds, in order to consider that the plan is being applied from a veterinary viewpoint, as required by Article 10 of Directive 77/391/EEC;
7.	Ensure that movement prohibitions into or out of the TB herds with suspended or withdrawn status are applied, unless authorised for the purpose of slaughter without delay, as foreseen by Article 14 (1) and (3) of Directive 78/52/EEC, and that the herd is not restocked until all eligible animals have passed one clear TB test, as foreseen in Article 17 of the same Directive; for this purpose, clarify, monitor and report on the conditions and extent of derogations for authorisation of movements from non OTF

N°.	Recommendation
	herds which are not direct to slaughter;
8.	Transpose into national legislation and apply the provisions of Article 12 of Directive 64/432/EEC related to the disinfection requirements and registration of activities and disinfection;
9.	Ensure that requirements in Article 14 of Directive 78/52/EEEC regarding manure and slurry, and Article 16 of the same Directive on cleaning and disinfection, are consistently and efficiently applied;
10.	Ensure the respect of provisions of Section IX, Chapter I, I, points (3)(a) and (4) of Annex III to Regulation (EC) No 853/2004 related to milk from TB reactor cows, and raw milk from non OTF herds;
11.	Ensure that PM examinations are consistently carried out in accordance with Annex I, Section IV, Chapter I of Regulation (EC) No 854/2004, in particular with the provisions of point (B)(6) of this Chapter;
12.	Determine the conditions under which bovine animals sent to slaughterhouse under the TB eradication programme may be slaughtered, and ensure that the official veterinarian imposes the conditions under which they are to be dealt with, as required by Section 1, Chapter III (7) of Annex I to Regulation (EC) No 854/2004;
13.	Ensure effective action in case of non compliance and effective, proportionate and dissuasive sanctions (articles 54 and 55 of Regulation(EC) No 882/2004).

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_ie_2010-8408.pdf

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dir. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Dir. 78/52/EEC	OJ L 15, 19.1.1978, p. 34-41	Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle
Dir. 77/391/EEC	OJ L 145, 13.6.1977, p. 44-47	Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle
Dir. 90/425/EEC	OJ L 224, 18.8.1990, p. 29-41	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Reg. 494/98	OJ L 60, 28.2.1998, p. 78-79	Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals
Reg. 1760/2000	OJ L 204, 11.8.2000, p. 1-10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of

Legal Reference	Official Journal	Title
	226, 25.6.2004, p. 22	animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 911/2004	OJ L 163, 30.4.2004, p. 65-70	Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards eartags, passports and holding registers
Dec. 2008/897/EC	OJ L 322, 2.12.2008, p. 39-49	2008/897/EC: Commission Decision of 28 November 2008 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2009 and following years
Dec. 2009/883/EC	OJ L 317, 3.12.2009, p. 36–45	2009/883/EC: Commission Decision of 26 November 2009 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2010 and following years
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)