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 report describes the outcome of an audit carried out by the Food and Veterinary Office in Northern Ireland (the United Kingdom) from 1 to 5 June 2015.

The objective of the audit was to evaluate whether the programmes co-financed by the European Union during 2014 and 2015 to eradicate bovine tuberculosis in Northern Ireland were implemented effectively as approved by the Commission.

The eradication programme is applied largely in accordance with planned arrangements but the herd incidence rate has stagnated at levels above 6%, which is not what would be expected with an effective eradication programme in place.

The audit team identified a number of strengths in the implementation and verification of the programme that contribute to disease eradication by increasing detection and elimination of infection with M. bovis. A comprehensive and well-targeted research agenda has provided the competent authorities with relevant evidence to reinforce the implementation of the available control and eradication measures.

The main factors holding back progress in the eradication of the disease can be grouped under five broad categories:

- There is ineffective implementation of some measures to stop disease transmission between cattle and between cattle and badgers (e.g. controls on animal movements and biosecurity measures).
- There is a need to further optimise the sensitivity of some components of surveillance for bovine tuberculosis to accelerate detection of persistent infection with M. bovis.
- The ineffective policies to clear-up chronically infected herds and to understand and contain levels of infection in the badger population, lead to a significant contribution of residual infection to the maintenance of the disease and to its unsuccessful elimination from the cattle and badger populations.
- The effectiveness of the measures contained in the eradication programme is not regularly evaluated to define and adapt disease control strategies to the epidemiological situation of bovine tuberculosis.
- The engagement and commitment of key stakeholders to the eradication programme are still insufficient to ensure its future success.

The competent authorities have decided to develop a future strategy to eradicate bovine tuberculosis based on a proposal by an independent panel of experts and representatives of the industry. The audit team concludes that the new strategy (with subsequent action plan and its implementation), if accepted and co-owned by all relevant stakeholders, provides a good opportunity to bring the programme to a level where the final target of accelerated eradication becomes realistic and achievable.

The report makes a number of recommendations addressing areas in which further improvements are required to secure future EU funding.
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## Abbreviations and Definitions Used in This Report

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<th>Explanation</th>
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<tbody>
<tr>
<td>AFBI-VSD</td>
<td>Veterinary Sciences Division of the Agri-Food and Biosciences Institute</td>
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<td>APHIS</td>
<td>Animal and Public Health Information System</td>
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<td>bTB</td>
<td>Bovine tuberculosis</td>
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<tr>
<td>bTB breakdown</td>
<td>A bTB incident in a previously OTF herd</td>
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<tr>
<td>bTB task force</td>
<td>bTB Subgroup of the Task Force for Monitoring Animal Disease Eradication</td>
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<tr>
<td>bTB WD</td>
<td>Working Document on Eradication of bTB in the EU (Document SANCO/10067/2013)</td>
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<td>CA</td>
<td>Competent authority</td>
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<td>DARD</td>
<td>Department of Agriculture and Rural Development of Northern Ireland</td>
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<td>DVO</td>
<td>Divisional Veterinary Office</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>FVO</td>
<td>Food and Veterinary Office</td>
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<tr>
<td>IFN-gamma</td>
<td>Gamma-interferon assay</td>
</tr>
<tr>
<td>Infected herd</td>
<td>Herd where infection with bTB has been confirmed</td>
</tr>
<tr>
<td>M. bovis</td>
<td>Mycobacterium bovis, the causative organism of bTB</td>
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<tr>
<td>OTF(-S or -W)</td>
<td>Officially bTB free (suspended or withdrawn) status</td>
</tr>
<tr>
<td>PAFF Committee</td>
<td>Standing Committee on Plants, Animals, Food and Feed – Section Animal Health and Welfare</td>
</tr>
<tr>
<td>Pre-MT</td>
<td>Pre-movement testing</td>
</tr>
<tr>
<td>PVP</td>
<td>Private veterinary practitioner</td>
</tr>
<tr>
<td>Restricted herd</td>
<td>Herd with the OTF status suspended or withdrawn</td>
</tr>
<tr>
<td>SICTT</td>
<td>Single intra-dermal comparative tuberculin (cervical/skin) test</td>
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<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>VO</td>
<td>Veterinary Officer</td>
</tr>
<tr>
<td>VS</td>
<td>Veterinary Service</td>
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</table>
1 INTRODUCTION

This audit took place in the United Kingdom (UK) from 1 to 5 June 2015 and it covered Northern Ireland. The audit was undertaken as part of the planned audit programme of the Food and Veterinary Office (FVO).

The audit team comprised two auditors from the FVO and a national expert from a Member State.

The audit team was accompanied throughout the audit by representatives of the Veterinary Service of the Department of Agriculture and Rural Development of Northern Ireland (VS of the DARD), which is the competent authority (CA) responsible for planning, implementation and overall verification of the majority of the measures included in the bovine tuberculosis (bTB) eradication programme in Northern Ireland. In addition, other relevant CAs were represented during the opening and closing meetings:

- The central competent authority within the scope of this audit in the UK; i.e. the Department for Environment, Food and Rural Affairs.
- The central policy group of the DARD, which is responsible amongst other things to bring forward, in cooperation with the VS, bTB policy and legislation in Northern Ireland in order to maintain equivalent controls in that respect across the UK.
- The Food Standards Agency, which is the CA responsible for setting standards and auditing meat hygiene in Northern Ireland, including aspects related to the post-mortem inspection of carcasses of cattle carried out by staff of the VS.

An opening meeting was held on 1 June 2015 with representatives of the CAs above mentioned. At this meeting, the audit objectives and itinerary were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 OBJECTIVES AND SCOPE

The audit assessed the operations related to the eradication of bTB. The objective of the audit was to evaluate whether the programmes for eradication of bTB have been implemented effectively and as approved for the periods:

- From 1 January to 31 December 2014, by Commission Implementing Decision 2013/722/EU, mainly in relation to its outcome and how the CAs have evaluated the results in order to enhance effectiveness of the programme in the future.
- From 1 January to 31 December 2015, by Grant Decision approving national programmes and associated funding of 30 January 2015 (Decision Number SANTE/VP/2015/UK/SI2.700838).

Insofar as they were incorporated in the approved programmes mentioned above, the audit included follow-up of actions taken by the CAs in response to the conclusions and
recommendations made by the bTB Subgroup of the Task Force for Monitoring Animal Disease Eradication (hereafter, the bTB task force) in 2012 (see section 4.1 for further information). The bTB task force is in charge of providing guidance for disease eradication to the Member States and assists the Commission in evaluating national eradication programmes.

The principal audit criteria, against which fulfilment of the above objective was assessed, comprise the specific legal texts listed in each of the 'legal requirements' sections below. In addition, the Commission published in 2013 a Working Document on Eradication of bTB in the EU which was accepted by the bTB task force (Document SANCO/10067/2013; hereafter, the bTB WD). The main purpose of that document is to provide guidelines for the design and operation of bTB eradication and surveillance programmes and a basis for decision-makers to determine appropriate measures adapted to the local epidemiological situation of the disease in order to enhance the effectiveness and efficiency of those programmes. The criteria laid down in the bTB WD are fully taken into consideration by the bTB task force during their evaluations and are the main pillars on which their conclusions are based. Likewise, those criteria are taken into account by the Commission during the approval and evaluation of the implementation of the bTB eradication programmes. The bTB WD can be found through the following link:


The table below lists sites visited and meetings held in order to achieve the audit objective.

<table>
<thead>
<tr>
<th>Meetings/visits</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent authorities</td>
<td>Opening and closing (debriefing) meetings with the VS and representatives of other CAs. Additional meetings with staff of six Divisional Veterinary Offices (Newry, Newtownards, Enniskillen, Omagh, Ballymena and Coleraine)</td>
</tr>
<tr>
<td>Cattle herds</td>
<td>One cattle farm</td>
</tr>
<tr>
<td>Other establishments</td>
<td>One slaughterhouse and one cattle market</td>
</tr>
<tr>
<td>Other stakeholders</td>
<td>Meeting with the members of the bTB Strategic Partnership Group of Northern Ireland</td>
</tr>
</tbody>
</table>

3 **LEGAL BASIS**

The audit 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 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- Article 27(9) of Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field (applying to the programme approved for 2014);
- Article 37 of Regulation (EC) No 652/2014 of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council


Full legal references are provided in the Annex to this report. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 TARGETS AND INDICATORS AT EU LEVEL

Eradication programmes have been co-funded by the EU since 1977, when acceleration of eradication programmes was first set as an objective in Council Directive 77/391/EC. Criteria for the eradication plans were first established by Council Directive 78/52/EC and more recently, by Commission Decision 2008/341/EC. In addition to the bTB WD, the Commission has issued in recent years a number of other important documents in relation to the control, surveillance and eradication programmes for animal diseases which are co-funded by the EU:

- A Working Document on Indicators for animal disease eradication, control and surveillance programmes published in 2012 (Document SANCO/12915/2012 Rev.2), which provides further guidance on indicators to be used in the context of bTB eradication and which can be found through the following link:
  

- Points 5 and 6 of the Annex to Commission Implementing Decision of 16.10.2014 on the adoption of the financing decision for the year 2015 for the implementation of Union co-funded programmes for the eradication, control and surveillance of animal diseases and zoonoses, set out the objectives and expected outcomes of national veterinary programmes from 2015 (Document C(2014)7437 final). The operational objectives and expected outcomes with regard to eradication of bTB include the decrease of herd incidence and prevalence and the reduction in the number of bTB breakdowns. This document can be found through the following link:
  

- A Commission Working Document on Guidelines for the Union co-funded programmes of eradication, controls and surveillance of animal diseases and zoonoses for the years 2015-2017 (Document SANCO/10181/2014 Rev.2) sets indicative minimum targets for
2015 and 2017 for the various programmes covered by this EU policy. This document can be found through the following link:


4.2 PAST EVALUATIONS OF THE PROGRAMME

In recent years, eradication of bTB in Northern Ireland by the DARD has been subject to a number of external evaluations and reviews.

The last audit carried out by the FVO in Northern Ireland in order to evaluate official animal health controls in the context of the bTB control and eradication programme was carried out in November 2004 (ref. DG(SANCO)/7251/2004 – MR Final). The report of that audit can be found at the following link:

http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=1273

The task force for monitoring animal disease eradication is in charge of providing guidance for disease eradication to the Member States of the EU and assists the Commission in evaluating national eradication programmes. The bTB task force held a meeting in the UK in March 2012. During that meeting, the experts of the bTB task force and the Commission received detailed information on all aspects related to the bTB control and eradication programmes in the UK, while they provided expert advice to the CA on how to improve the programme and accelerate the eradication of the disease. The report of that meeting can be found on the following link:


While acknowledging the many important steps taken by the CAs since 2009 in order to enhance the effectiveness of the bTB eradication programme, the conclusions of that report highlighted the need for a long-term strategy from the CAs in order to ensure continuity for that process and accelerate eradication of the disease. In that context, a number of recommendations were issued to the central competent authority in the UK. Some of those recommendations were relevant for the bTB eradication programme in Northern Ireland and are considered in the body of this report.

After several years of field work and extensive consultations with the DARD, in March and June 2009 the Northern Ireland Audit Office and the Public Accounts Committee of the Northern Ireland Assembly published their respective reports as a result of an extensive review of the control of bTB in Northern Ireland. The reports stressed the fact that incidence of the disease remained significantly high and that progress made by the DARD to control the disease had been too slow. The reports contain a number of recommendations addressed to the DARD in order to enhance the cost-effectiveness of the bTB eradication programme. In particular, they ask the DARD to adopt a much more strategic approach, with a clear focus on eradication of the disease rather than mere containment. Besides, the reports already acknowledged and subscribed to the undertaking provided by the DARD in 2008 to introduce
a new, agreed Government/industry strategic approach to move towards the eradication of bTB in the most cost-effective way and in a realistic timeframe. The reports have been made available through the following links:


In November 2012, the Committee for Agricultural and Rural Development of the Northern Ireland Assembly published a report on the review of bTB in Northern Ireland that they had started in March 2012. The Committee asked the DARD for immediate action to tackle the increasing incidence of the disease. The report has been made available through the following link:


As part of their contribution to the review of bTB carried out by the Committee for Agricultural and Rural Development, the DARD provided an updated action plan to address the recommendations of the report presented in 2009 by the Public Accounts Committee of the Northern Ireland Assembly. This information can be found through the following link:


Finally, in order to address the recommendations of the previous report, on 17 September 2013 the Minister for Agriculture and Rural Development of Northern Ireland announced that she intended to establish a Government/industry strategic partnership to develop a long term strategy to eradicate bTB from the cattle population in Northern Ireland. The relevant information can be found through the following link:


4.3 CURRENT PROGRAMME, STRATEGIES AND REPORTS

The 2014 and 2015 approved programmes for the eradication of bTB in the United Kingdom, including the specific arrangements that apply to Northern Ireland, can be found through the following links:


According to the eradication programme approved for 2015, information on the DARD strategy in relation to bTB can be found in a number of strategic documents.

The DARD strategic plan 2012-2020, includes as a key action to increase participation in, and ownership of, the eradication programme by stakeholders in order to agree on a long-term strategy to eradicate bTB.


The Agri-Food Strategy Board of Northern Ireland, i.e. the leaders of the agri-food industry, acknowledged in their document 'Going for Growth' published in April 2013 that an agreed strategy in cooperation with the DARD was paramount to deliver a significant reduction (and the ultimate eradication) of bTB.


The DARD business plan 2013-2014 included an undertaking to strengthen the bTB eradication programme before the end of 2013 in response to the aforesaid report of the Committee for Agriculture and Rural Development.

The Government/industry bTB Strategic Partnership Group was established in October 2014 after the Chair for the group and the independent members were appointed by the Minister for Agriculture and Rural Development of Northern Ireland. Their mandate was to develop an all-embracing long-term strategy to eradicate bTB in Northern Ireland. That development process will follow a number of steps, such as:

- The Group has to consult with all relevant stakeholders and to obtain adequate scientific advice on all aspects related to bTB eradication.
- The Group intends to present their proposal in June 2015 to the Minister for Agriculture and Rural Development of Northern Ireland and to the Northern Ireland Assembly.
- Afterwards, after a new broad consultation with stakeholders, the panel will prepare an action plan that will have to be translated into an implementation plan by the DARD, adopting the measures proposed as part of the bTB eradication programme.

The DARD published the first bTB eradication programme annual report to provide a descriptive overview of the implementing measures of the programme approved for 2013. The report has been made available through the following link:


At the time of this audit, the VS was in the process of analysing the situation after implementation of the 2014 bTB eradication programme in order to prepare the next annual report. In the meantime:

- Statistics on the implementation of the bTB eradication programme in Northern Ireland since 2007, as well as monthly updated data on the implementation of the programme in 2014 and so far in 2015, are available through the following link:
Maps showing the evolution of the geographical distribution of bTB breakdowns detected in Northern Ireland from 2006 to 2013 are available through the following link:


4.4 DEMOGRAPHIC FACTORS

According to data provided by the DARD, there are 1.6 million cattle in Northern Ireland kept in some 23,000 herds, of which some 66% have less than 50 animals. The southern half, and notably the south east of Northern Ireland, is one of the few very highly densely populated cattle areas of the UK. There are other specific agricultural production features that have been recognised as occurring alongside the epidemiological evolution of bTB in Northern Ireland:

- Cattle graze mainly during summer and early autumn months, but a significant percentage of farmers do not own enough grazing land to cater for the needs of their cattle. Those needs, which increase in parallel to the growth of the production sector, keep driving the demand for land upwards. Thus, according to data provided by the DARD, some 30% of grazing land is not owned by the users, but rented.
- Cattle herds using rented land have become more and more fragmented, with animals moving regularly between numerous parcels during their productive lives. All those movements, which can represent significant distances between the parcels, are considered movements within the same registered herd.
- In recent years, there has been a downward trend in the professionalization of cattle herds in Northern Ireland. The majority are family owned, approximately two thirds are operating as a part-time business and there is an increasing trend to use external contractors to run them.

The factors above mentioned have a direct impact on the willingness of, and possibilities for farmers to invest in, and adhere to the additional biosecurity measures considered necessary to control the levels of environmental infection with *M. bovis* (e.g. investments to mitigate risks related to infection in badgers, spreading of slurry) and the risks of cattle-to-cattle transmission of bTB (e.g. double fencing in parcels they do not own).

5 FINDINGS AND CONCLUSIONS

5.1 IMPLEMENTATION OF THE bTB ERADICATION PROGRAMME

Legal requirements

Commission Implementing Decision 2013/722/EU (programme for 2014) and Grant Decision Number SANTE/VP/2015/UK/S12.700838 (programme for 2015).


Findings

1. Comprehensive information on the general organisation of the CAs involved in management and implementation of the bTB eradication programme in Northern Ireland is provided in the FVO country profile for the UK and in the Multiannual National Control Programme 2013-2015 for the UK (updated in 2014), which can be found, respectively, at:

   http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=GB

5.1.1 Progress made with the eradication programme

2. UK authorities informed the Commission and the Member States of the bTB situation in Northern Ireland through several presentations made to the Standing Committee on Plants, Animals, Food and Feed - Section Animal Health and Welfare Committee. The latest update was provided by the central competent authority during the Committee meeting held on 5 June 2015; this presentation has been made available through the following link:


3. Up until now, the bTB eradication programme has not been as effective as expected in accelerating or intensifying the eradication of the disease, as required by Directives 77/391/EEC and 78/52/EEC.

   - The evolution in recent years of the bTB herd and animal incidence and prevalence in Northern Ireland can be seen on the charts below. Herd incidence declined slightly after a peak in October 2012, reaching an annual herd incidence rate of 6.03% for 2014, but the trend had started to reverse from mid-2014, increasing to 6.44% by March 2015. That figure equals the annual herd incidence rate for 2013.
   - The animal incidence rate followed a very similar pattern. It had declined in 2013 after its peak in 2012, but it increased again slightly from 0.511% in 2013 to 0.550% in 2014.
   - Similarly, after reaching their latest peak in October 2012 and having declined afterwards, levels of herd and animal prevalence have followed an upwards trend since mid-2014.
The following map shows the geographical distribution of bTB breakdowns in 2014, differentiating those already active at the beginning of the year (i.e. chronic) from those newly detected during 2014 contributing to the annual herd incidence rate. According to data provided by the VS, 1,606 bTB breakdowns were confirmed in 2014, a slight decrease compared with the 1,648 confirmed in 2013.
4. No specific target has been set with regard to eradication of bTB for the period 2011-2015 in the programme for government of the current Northern Ireland Executive. As a result, and unlike it was the case with regard to the eradication of bovine brucellosis, the DARD did not have to set out any specific series of actions in a delivery plan to be fulfilled within a specific deadline.

5. A conservative estimate of annual decrease of 0.5% in the herd incidence rate has been assumed for future target prediction by representatives of the VS, assuming that current bTB control measures are adequate to drive the incidence down (although they stressed the fact that there are disease drivers that are currently outside the control of the DARD). This estimate will be modified to an annual decrease of 0.1% once the herd incidence rate falls below 5%, given that past experience would indicate that control measures have not attained a lower level than this.
Conclusions on progress made with the eradication programme

6. The bTB eradication programme has not made satisfactory progress toward eradicating the disease, as shown by the evolution of the epidemiological indicators in recent years and as pointed out to the CAs by previous evaluations (see section 4.2). Due to the perception that current measures will not be able to carry the eradication process to a successful conclusion as rapidly as possible, the medium to long-term targets for the programme, such as the expected outcomes with regard to the decrease of herd incidence and prevalence, are rather unambitious.

5.1.2 Surveillance for bTB – detection and confirmation of the disease

5.1.2.1 On-farm tuberculin testing – quality controls

7. The recent improvements to the quality assurance of the single intra-dermal comparative tuberculin test (SICTT) have brought this area more into line with the recommendations of the bTB task force and the guidelines laid down in the bTB WD.

8. Approval of private veterinary practitioners (PVPs) for bTB testing ensures that approved testers have the necessary competence to undertake their duties:

- The authorisation of PVPs to carry out the SICTT is subject to training and since 2013, to enhanced on-the-spot verification of their required level of competence carried out by experienced veterinary officers (VOs) of the Divisional Veterinary Offices (DVOs).
- Standards of on-the-spot verification are very demanding and require a fully satisfactory performance by the PVPs.
- After that, PVPs are granted a temporary authorisation until they attend a comprehensive training on all aspects of the bTB eradication programme.

9. Testing is carried out according to comprehensive and regularly updated documented procedures:

- The audit team could see that adequate and regularly updated official instructions are available both for PVPs (responsible for 80% of the official SICTT) and VOs also responsible for bTB testing.

10. The effectiveness of testing is continuously monitored by using audits and data analysis.

- Since October 2012, staff from central level responsible for audits is joined by VOs selected from the ten DVOs throughout the country, in order to carry out the audits on bTB testing.
- They have been specifically trained for that purpose and the selection process, including for the specific audits each of them has to perform, ensures that they are independent from the PVPs and the other VOs they audit.
- In addition, the level of detail of those audits has increased significantly.
As part of their quality control system, since October 2009 the VS has been providing statistics on the performance of the PVPs to their supervisors in the veterinary clinics employing them.

PVPs and their supervisors can access that information at any time through a specific module made available to them by the DARD in the Animal and Public Health Information System (APHIS).

11. The bTB WD indicates that data collection and management should facilitate evaluation of performance and trends in the context of the quality control of the bTB testing procedure. At the time of the audit, the CAs did not have any specific procedure to evaluate the data available in order to target the audits according to the risk of non-compliance with the documented procedures laid down in the official instructions for the performance of the SICTT.

- The VOs responsible at central level for the audits make the selection of the PVPs who are going to be audited. At the time of the audit, beyond referral from field staff, not necessarily based on the evaluation of the available data on PVP performance; no formalised targeting mechanism based on the evaluation of performance indicators for each PVP was yet in operation.
- According to staff of the DVOs visited and compliance VOs met, the audit programme is designed to cover all PVPs on a multi-annual routine and no selection is made yet on the basis of the statistics available.
- Senior staff of the VS responsible at central level for the fine tuning of the quality control programme advised the audit team that some performance indicators are going to be introduced to the system, in order to facilitate the selection of PVPs and of VOs to be audited, depending on their personal statistics.
- The latter initiative will bring the system more in line with the guidelines provided by the bTB WD.

12. The audits are carried out according to documented procedures which are regularly updated and improved, taking into account the recommendations of the bTB WD.

- The standard operating procedures available to the compliance VOs ensure that the required minimum standards for the performance of the SICTT are checked during the audits. They include adequate guidance on how to interpret those standards according to a number of parameters and determine whether the outcome for each of them is satisfactory or not.
- In addition, where the result is not acceptable, the procedures describe the process to follow in order to immediately address the situation.
- The audit team was informed that more technical details were going to be added to the standard operating procedures shortly in order to make the evaluation of some parameters more objective.

13. A report is produced after each audit and the results are analysed in order to address any deficiency or any non-compliance with the official instructions.
• The reports of the audits describe the evaluation of the parameters established in the standard operating procedures against a series of targets that cover the testing performance from all angles.
• Amongst other things, these include standards of good hygiene practices, the detailed process of applying (and, later, reading the reaction to) the tuberculins, and the communication process with farmers.
• Staff from central level responsible for audits has to introduce their reports into APHIS; then, the results of these reports are submitted to, and may be discussed with one of the managers of the bTB programme at central level.

14. The managers of the bTB programme at central level must take a decision on how to address any non-compliance identified and they have the powers to temporarily suspend or withdraw the authorisation of PVPs to carry out the SICTT. The audit team was informed that the latter case had happened on five occasions in 2011 and once in 2013, but most situations are solved with additional targeted training and the support of the PVP supervisors in the veterinary clinics.

15. Staff of the VS provided the audit team with data on the number of audits carried out since 2011, their results, and the ensuing measures taken and their follow-up. Levels of compliance have been high in general (over 91% for 2013 and 2014) but the percentage of fully satisfactory audits has decreased during the first months of 2015 (just below 74%, out of 57 audits), and seven of the audited PVPs needed special attention from senior managers of the bTB programme. The audit team was informed that this increase in non-compliances is considered temporary and is attributed mainly to the special importance given during this year to the quality of the reading of the SICTT, in order to further optimise the sensitivity of the surveillance.

16. Staff of the Veterinary Sciences Division of the Agri-Food and Bioscience Institute (AFBI-VSD), which is responsible for confirmation of bTB in reactors to the SICTT, advised the audit team that in excess of 45% of the reactors are confirmed by histopathology or bacteriology. The latter is always carried out if the former gives negative results. According to the guidelines laid down in the bTB WD, this (not too high) confirmation rate may be a result of the high sensitivity of the SICTT, as detected animals will have been recently infected and be difficult to confirm by post-mortem investigations. They added that in excess of 96% of samples from reactors with visible lesions at post-mortem are confirmed positive, whereas 8% are confirmed from those without visible lesions. According to the guidelines laid down in the bTB WD, the latter percentage is of importance as it also indicates detection of bTB at an early stage of infection.
Conclusions on on-farm testing

17. The current quality controls on the application of the SICTT in the field are contributing to optimise the sensitivity of the testing scheme. This is further validated by disease confirmation rates showing that the SICTT is performing well at detecting animals at early stages of infection. Further improvements are underway providing additional confidence with the high standard of testing.

5.1.2.2 Slaughterhouse surveillance

18. Slaughterhouse surveillance is in place and continuously detects new cases - which are missed by the inherent limitations of on-farm testing – as recommended in the bTB WD:

- During 2014, 372 herds had animals with confirmed bTB that were detected by slaughterhouse surveillance and not disclosed as tuberculin skin test reactors (381 in 2013). A proportion of these were animals which would have initiated a breakdown in an officially bTB free herd (OTF herd) through lesions found at routine slaughter.
- All those cases were found in animals coming from OTF herds, had visible lesions compatible with bTB infection identified at routine slaughter and were confirmed by laboratory diagnosis.
- These breakdowns represent around 23% of the total number of breakdowns detected annually in Northern Ireland, a percentage that has remained stable in recent years.

19. Post-mortem inspection is carried out according to documented procedures in compliance with EU requirements on performance of official controls on meat hygiene and following standards set by the Food Standards Agency.

- Official veterinarians of the Veterinary Public Health Programme of the VS are responsible for overseeing daily implementation of post-mortem inspection carried out by meat inspectors in the ten cattle slaughterhouses in operation.
- Specific sampling instructions describe how to inspect animals with a higher risk of bTB; e.g. reactors to the SICTT and the Gamma-interferon assay (IFN-gamma).
- When lesions are not found at post-mortem inspection in those animals, samples are still taken from a maximum of five animals per affected herd for further laboratory examination to increase the probability of isolating *M. bovis* if the disease is still at an early stage.
- All samples are submitted to the AFBI-VSD for histopathological and/or bacteriological investigation.
- The staff instructions lay down detailed protocols to be followed when lesions compatible with bTB are found in non-reactor animals. Samples from these are taken and sent to the AFBI-VSD, where both histopathological and bacteriological tests are conducted.
• According to staff of the AFBI-VSD, just below 70% of samples from lesions found in non-reactor animals are confirmed positive. Besides, 94.5% of the animals that are positive to the IFN-gamma and have visible lesions are confirmed as bTB positive.

20. The Veterinary Epidemiology Unit of the VS has made a preliminary analysis of slaughterhouse surveillance data from 2011 to 2013. The results indicate that:

• There is considerable variation in the submission rates of lesions detected in non-reactor animals at slaughterhouses between the ten slaughterhouses studied – with some significantly low rates, indicative of underperforming surveillance.

• The bTB confirmation rates of the submissions also vary between slaughterhouses, ranging from 57.9% to 72.9%. According to representatives of the CA, the lower levels in some cases could be related to the fact that they encourage their staff in the slaughterhouses to keep a high submission rate, which sometimes operates to the detriment of a high confirmation rate.

• A number of critical factors are likely to contribute to these differences, such as:
  • The speed of the slaughter line.
  • The intensity of light.
  • Factors related to the performance of the meat inspectors, such as experience, motivation, interest in their jobs and workload.

21. The initiative mentioned above is going in the right direction according to the bTB WD, which recommends regular monitoring of the contribution of post mortem inspection to surveillance for bTB using a number of key indicators, such as submission rates of suspected lesions and detection rates of animals with confirmed tuberculous lesions. Senior management of the bTB programme had started to follow-up the findings and recommendations of the preliminary analysis, but this had not (at the time of the audit) materialised yet into concrete corrective actions or improvements (see also sections 5.2.1 and 5.2.2).

22. The audit team could verify that the VO responsible for the herd of origin is immediately informed upon detection of lesions compatible with bTB at slaughterhouse level. A message is sent to the DVO responsible for the herd and a request for the follow up appears as a task on APHIS for the VO. The VO must then inform the herd keeper as soon as possible in order to impose the relevant movement restrictions and organise additional bTB tests and, as appropriate, begin with the epidemiological investigation of the breakdown (see sections 5.1.3.1 and 5.1.3.2). This is in accordance with provisions laid down in the approved eradication programme and in compliance with relevant EU requirements.
Conclusions on slaughterhouse surveillance

23. This component of surveillance for bTB is contributing to the detection of new breakdowns by accelerating the bTB detection process in cattle herds that are subject to bTB herd testing only once a year, and by increasing the sensitivity of the overall surveillance system by detecting herds with animals that are anergic to the SICTT and with silent persistent infection.

24. While improvements in relation to quality control of this component of bTB surveillance have started recently and are under further development, evidence shows that optimisation of the sensitivity of this component of surveillance for bTB is still far from being accomplished. This is undermining its potential to accelerate detection of infected animals that are not uncovered by the testing scheme in the field.

5.1.2.3 Contribution of molecular epidemiology to the control of bTB

25. The VS are using molecular epidemiology in order to better determine the sources of infection and spread of the disease as recommended in the bTB WD.

26. All positive bacteriological cultures are subject to further analysis to confirm the presence of *M. bovis* and DNA typing is carried out afterwards on all *M. bovis* isolates with a specific assay developed by the AFBI-VSD. DNA typing has been done since June 2009 for more than 40,000 samples originating from more than 10,000 herds. The same analyses have been carried out on 228 *M. bovis* isolates from badgers. As a result, 344 different DNA strain types were identified – out of those, the 30 most common types cover 95% of the samples.

27. The AFBI-VSD has developed a comprehensive database containing data on the geographical distribution of all *M. bovis* isolates – from both cattle and badgers. This information is used by the DVOs during their epidemiological investigations after bTB breakdowns.

28. In addition, this has allowed the VS to identify a number of geographically defined home ranges for the most prevalent DNA strain types. In some cases, in particular when isolates were found outside of their home range, this has contributed to explain the possible cause of the initial disease incursion (e.g. animal movements from an area within the home range) and the possible routes of spread in the newly affected area (e.g. inadequately fenced neighbouring parcels of grazing land that facilitate cattle-to-cattle transmission, detection of badgers infected with the same DNA strain type).
Conclusions on molecular epidemiology

29. The adequate use of molecular epidemiology is contributing to increase the knowledge about the dynamics of bTB in the cattle and badger populations in Northern Ireland, while facilitating the evaluation of the possible local pathways of transmission of *M. bovis* and the tailoring of preventive and eradication measures accordingly.

5.1.3 Measures after detection and confirmation of bTB

5.1.3.1 Herd restriction and de-restriction measures

30. Restrictions after positive test results are applied in accordance with Annex B of Directive 64/432/EEC.

31. A bTB breakdown is followed by either suspension or withdrawal of the OTF status of the affected herd (OTF-S and OTF-W herds, respectively):

- If additional evidence of *M. bovis* infection has been identified in at least one slaughtered animal, i.e. a bacteriologically positive sample and/or lesions detected in the carcass of a reactor or a positive animal to the IFN-gamma; the herd is classified as OTF-W.
- Alternatively, the OTF-W status is always applied when more than five reactors to the SICTT are detected during the course of a breakdown and in exceptional situations when – as a result of the epidemiological investigation of a breakdown – the risk is considered very high.
- If no *M. bovis* and/or lesion have been found yet and five or fewer reactors to the SICTT have been detected during the course of a breakdown, the herd is classified as OTF-S; i.e. there is only a suspicion of the infection being present, without confirmation.

32. Movement restrictions out of OTF-S and OTF-W herds are in accordance with EU legal requirements and with the guidelines laid down in the bTB WD:

- Restriction of animal movements out of the herd other than to slaughterhouses under official permission applies immediately to all OTF-S and OTF-W herds.
- This information is entered in APHIS so that any possible intention to move an animal from those herds will be immediately flagged as not possible in the system.
- In exceptional circumstances, authorisation can be granted to move animals to other herds (with an OTF-S or OTF-W status, as appropriate) due to animal welfare reasons, but this happens rarely and under strict official control.

33. The testing regime applied for de-restriction of OTF-S herds is slightly stricter than the EU requirements laid down in point 3A of Annex A to Directive 64/432/EEC:
• All animals present in the herd, regardless of their age, must have a clear SICTT at least 42 days after the removal of the reactor(s).

34. Upon confirmation of bTB, staff instructions describe a number of measures that are compulsory for OTF-W herds, as explained in the approved eradication programme and in accordance with provisions laid down in point 2.2.5.3.5 of Annex B to Directive 64/432/EEC.

• All animals in the herd must pass two clear SICTTs before derestriction can be applied and the OTF status regained.
• At least one of the SICTT must use a more severe interpretation, as described in detail in the staff instructions.
• In the DVOs visited, these requirements were applied as instructed.

35. VOs have the discretion to apply stricter interpretations of the SICTT in other situations according to the evaluation of the case. The audit team could see examples in this respect applied to heavily infected herds and herds with recurrent bTB breakdowns. Decisions in this respect are left to the VOs, who must do so on the basis of the general guidance provided in the staff instructions and register the type of interpretation of the SICTT in APHIS.

### Conclusions on herd restriction and de-restriction measures

36. The testing, restriction and de-restriction measures applied after detection of bTB – in many cases stricter than EU requirements – are likely contributing to eliminate further infected animals and to reduce the potential spread of disease from herds where the presence of bTB has been confirmed.

#### 5.1.3.2 Epidemiological investigations

37. According to the approved eradication programme, VOs have to carry out epidemiological investigations on bTB breakdowns. The guidelines of the bTB WD are taken into account in order to identify possible epidemiological links that could need additional investigation.

• Examples discussed at the DVOs visited demonstrated that the VOs were extremely dedicated to that task and carried out detailed investigations of the cases selected.
• Animals potentially at risk are usually identified through backward and forward tracing. Those animals are always subject to a SICTT, unless they had passed one recently.
• Data provided by the VS show that herds with animals subject to a SICTT as a result of backward tracing have a fourfold higher probability to be disclosed as a bTB breakdown than herds subject to the routine annual SICTT (with a twofold higher probability for those identified through forward tracing).
• All herds with any parcel of land neighbouring any of the parcels used by restricted herds after its last clear SICTT, and even earlier (e.g. the previous grazing season), are also identified. After a strict evaluation of the possible risk of bTB, these herds are flagged for additional testing, but no movement restriction policy is applied on them.

• Data provided by the VS show that neighbouring herds have a threefold higher probability to become a bTB breakdown than herds subject to the routine annual SICTT.

38. The objective underlined in the bTB WD in relation to the performance of epidemiological investigations, i.e. that they are fundamental to the control of bTB in infected herds and to the provision of descriptive and analytical information for the assessment of risk factors useful in adapting future eradication strategies, has not been fully achieved, because:

• The files of the breakdowns checked by the audit team contained extensive amounts of information and documentation. However, there was no specific document or file to explain the conclusions on the possible causes of the breakdowns. Very limited documentation was available to explain or facilitate the selection of measures to prevent recurring breakdowns.

• The limited analytical information available from the epidemiological investigations does not allow a proper analysis of the situation at local level. Only in a limited number of cases, the DVOs visited could demonstrate how that analysis had been done to inform disease control measures beyond the herd level.

• Some sporadic cases confirmed that gathering adequate information from various herds to carry out the analysis had been very difficult and slow, but once the evidence was collected and analysed altogether, the local approach to bTB eradication had been successful.

• Staff responsible for the bTB programme advised the audit team that they were in the process of developing a new detailed instruction for VOs to enhance the quality of the epidemiological investigations and address the deficiencies aforesaid.
Conclusions on epidemiological investigations

39. The policy of risk-targeting animals and herds for further immediate bTB testing after identifying their epidemiological links with index herds where the disease has been found is proving to be very effective to accelerate detection of silently infected herds.

40. Results and analyses of the epidemiological investigations performed on bTB breakdowns are not sufficiently documented in order to demonstrate how adaptation of eradication and preventive measures is done at herd and local level in accordance with the conclusions reached. They also are not sufficient for contributing to the assessment of risk factors that will be useful in future eradication strategies and changes in the programme.

5.1.3.3 Use of the IFN-gamma

41. The bTB WD recommends the use of IFN-gamma in parallel with the SICTT to maximise the sensitivity of bTB surveillance and accelerate removal of infection with *M. bovis*. Earlier removal of a considerable number of infected animals – with a false negative reaction to the SICTT – would prevent them from remaining unidentified in the herd for an undetermined period.

42. The following data provided by the VS in relation to 2014 indicate that the use of IFN-gamma has – to some extent – achieved the objectives set out by bTB WD:

- 208 herds and some 16,900 cattle were tested (243 herds and a similar number of cattle in 2013), with 7.4% of the animals found positive.
- The percentage of positive results to the IFN-gamma in SICTT-negative animals increased in 2014 (over 83%) with respect to 2013 (over 74%).
- The percentage of cattle positive to the IFN-gamma that were non-reactors to the SICTT and were removed from the herds decreased to 69% from 76% in 2013.
- bTB was confirmed in 8% of the removed cattle that were positive only to the IFN-gamma (over 14% in 2013, with a historical average of 12%).
- Of the IFN-gamma positive animals which had bTB confirmed, about 70% were reactors to the SICTT.

43. Representatives of the AFBI-VSD advised the audit team that, compared with peers with a negative result to the IFN-gamma, animals with a positive result had a higher probability of becoming reactors to the SICTT within five years, and this probability gets even higher within the first 18 months.

44. They also confirmed that some 26% of the animals that are positive to the IFN-gamma and present visible lesions at *post-mortem* examination had not reacted to the SICTT.

45. The approved programme lays down provisions for the use of the IFN-gamma as an ancillary test in herds with a confirmed bTB breakdown.
46. The VS has prepared a protocol for the selection of high risk herds where the IFN-gamma is to be used. The selection is done by staff responsible for management of the programme at central level. Once decided, the use of IFN-gamma requires testing of all animals over six months of age kept in the herd.

47. The test is offered to herds which have had: a) three SICTT with reactors in the past two years and bTB has been confirmed in this period, b) five or more reactors to the SICTT at the last test (they represent between 50 and 60% of the herds selected), or c) confirmed bTB infection identified at routine slaughter within 90 days of the last SICCT.

48. The use of IFN-gamma is limited by certain constraints:

- As a result of limited laboratory capacity, the maximum number of samples that can be processed per day is 220.
- The cost of sampling and analysis, as there are an agreed target number of samples fixed for each year, which do not necessarily match the needs of the eradication measures in the field.
- It is a voluntary non-statutory test requiring herd keepers' agreement. Moreover, the possibility to use the IFN-gamma in case of pedigree herds and animals is very limited.
- Animals with a positive result are not required to be slaughtered unless: a) the SICTT is also positive, or b) the farmer agrees with the slaughter.

49. The audit team could see examples of large herds; i.e. with more than 220 animals, where detection of numerous SICTT on several occasions within a couple of years had not been followed by the use of IFN-gamma due to the large size and the difficulty to process samples within the statutory deadline (eight hours).

50. A herd where the owner has refused slaughtering after positive test results is not selected anymore for the use of the IFN-gamma. In addition, the audit team found conflicting perceptions on the usefulness of the IFN-gamma amongst staff of the VS, which causes difficulties in conveying a consistent message to the farming community.

### Conclusions on the use of IFN-gamma

51. There is evidence that the use of IFN-gamma – albeit limited – has contributed to the elimination of infected animals which would have otherwise remained in the herd. However, due to the current constraints, contribution to the eradication efforts has not been optimised and the potential of the IFN-gamma has not been used to its full extent.

5.1.3.4 Movement controls and related bio-security measures

52. Movements within a holding pose a risk of disease transmission due to the particular structure of cattle farming in Northern Ireland (see section 4.4).
Within holding movements are not controlled – regardless of the distance between parcels owned or rented by the herd keeper.

This applies also to herds with OTF-S or OTF-W status.

Those movements do not need to be entered in APHIS or be recorded in the individual herd registers.

As a consequence and depending on the duration of the restrictions, cattle from an infected herd can be moved to a number of different geographical areas.

53. No requirements or specific policies are in place to ensure that the risk of direct transmission to other cattle (or wildlife) is properly mitigated (e.g. double fencing of the parcels used). Neither are there any requirements in place to ensure that strict cleaning and disinfection practices apply to means of transport used for those movements.

54. According to the approved programme, VOs can impose restrictions on movements into herds where the presence of bTB has been confirmed, depending on the results of an epidemiological analysis. The audit team could verify that no restriction was used in the majority of cases to avoid introduction of cattle to restricted herds before they regain their OTF status, and this happens often at the convenience of herd keepers.

55. The three previous points put together have a significant negative impact on the objectives which Articles 14, 16 and 20 of Directive 78/52/EEC, relevant sections of the bTB WD (3.2, 3.7 and 3.9) and the recommendations of the bTB task force of 2012 are trying to achieve.

56. The bTB WD indicates that movement restrictions on non-OTF herds resulting from the application of EU legislation are not enough when particular epidemiological conditions prevail, such as the particular situation with respect to fragmented herds (see section 4.4). Since those situations make more difficult the application of the standard eradication measures, especially in areas or regions of high prevalence, the bTB WD recommends the use of pre-movement testing (Pre-MT) under those difficult conditions.

57. Pre-MT is not included in the approved eradication programme for movements of animals between OTF herds unless the animal to be moved has not been tested in the past 15 months (except in cases when the movement is directly to a slaughterhouse).

58. According to staff of the VS, wider use of Pre-MT is not considered justifiable, as there are no clearly defined high and low prevalence areas in Northern Ireland and on average cattle herds are subject to short inter-SICTT intervals (maximum of one year, with an average of 8.7 months, based on 2008-2013 figures).

59. The bTB WD highlights that movement of infected, yet undetected, cattle provides a well-established means of spreading bTB from herd to herd. Evidence from Northern Ireland supports this:

- Historical estimates attributed around 20% of bTB breakdowns to movements.
• Around 13% and 7% of recent epidemiological investigations that come to a conclusion of the probable or very probable cause of the bTB breakdown, attribute it to animal movements and residual infection, respectively.
• The higher probability of detecting bTB as a result of backward and forward tracing of animals from new bTB breakdowns indicates that movements do indeed play a role in the spread of the disease (see finding 37).

60. The VS has been advocating for years a risk-based purchasing policy amongst farmers in order to raise their awareness about the relevance of getting information on the bTB historical background from the herd of origin of the animals they buy.

61. The audit team was informed that only a small percentage of professional breeding herd farmers who are conscious of the animal health risks involved in animal trade, are following this advice but that the majority of the farmers, in particular those involved in frequent animal movements for fattening purposes, do not follow this advice.

62. Representatives of the Veterinary Epidemiology Unit of the VS informed the audit team that the decision not to require Pre-MT is further supported by the conclusions of a study they have carried out in 2015. This study looked, amongst other things, at the possible cost-effectiveness of using the Pre-MT (with full cost covered by the DARD):
   • It studied various combinations of risk-based targeting and use of Pre-MT.
   • The main output was the estimated number of new bTB breakdowns detected.
   • The results of the preliminary cost-effectiveness analysis indicated that none of the options offered a satisfactory cost-effectiveness ratio compared to increasing the sensitivity of bTB surveillance in infected herds in order to eliminate infection before de-restriction (see section 5.2.2).

63. Representatives of the Veterinary Epidemiology Unit of the VS informed the audit team that one of the recommendations of the study was to carry out a detailed cost-benefit analysis of the preliminary options they had evaluated. In the meantime, this study did not evaluate in detail the possible long-term impact of:
   • The possibility of transferring the costs to the industry; which was evaluated only preliminarily.
   • The possibility of choosing a risk-based Pre-MT targeting the 5% of chronically infected herds which contribute to 25% of the annual SICTT reactors.
   • The possible change in farmers’ behaviour with respect to the practice of moving animals and, as a consequence, how this may influence disease transmission dynamics.
Conclusions on movement controls and related biosecurity measures

64. The high amount of unregulated frequent movements of cattle that occur within, and into fragmented herds where the presence of bTB has been confirmed is likely contributing to: a) increase the levels of environmental infection with M. bovis and the probability of transmitting bTB to wildlife, b) expose cattle, even in distant geographical areas, to the risk of getting bTB, and c) feed the disease present in infected herds with susceptible animals that can further increase the probability of recurrent breakdowns.

65. The narrow scope of the evaluation carried out by the CAs on the possible benefits of introducing Pre-MT under the particular epidemiological conditions present in Northern Ireland does not provide adequate information to ensure that all options for the potential use and effectiveness of this measure to prevent transmission of bTB between OTF herds have been properly considered.

5.1.3.5 Depopulation of herds

66. The CAs are not applying herd depopulation to its full potential in accordance with the bTB WD, which recommends that this measure should be used whenever a control benefit could be derived from it with the aim to reduce the level of residual infection and contribute to the eradication of bTB.

67. The approved programme indicates that there is a well-defined procedure for full depopulation of herds as a means of risk reduction or control by eliminating the infection present in the herd. Staff instructions lay down details on how to evaluate the situation of a herd and take a decision on whether partial or total depopulation is necessary. The main criteria to be used for partial depopulation are:

- Whether the animals considered for depopulation are of a higher risk than the rest of the herd; and
- Whether removal of those animals will reduce the bTB risk to the herd, more than testing and routine controls.

68. Full depopulation has to be decided by senior field managers at the VS. A number of additional factors have to be taken into account to consider full depopulation of a herd and the main rationale for its use is to reduce the risk of infection for new stock.

69. According to staff of the VS, depopulation (partial or full) is unlikely to be beneficial if the probable cause of a breakdown is farmers' purchasing policy or the presence of infected badgers. In addition, due to the high levels of compensation paid, depopulation in large breeding herds is a very costly measure. Therefore, partial and full depopulation are not favoured by the current policy of the VS.
70. The audit team found that partial depopulation is used occasionally when some animals are considered at a high risk of infection despite being negative to the SICTT – for instance in small herds, or when test results are inconclusive.

71. Full depopulation is a very exceptional event (less than 1% of the bTB breakdowns), in particular in large herds. More often it is used when the breakdown occurs in a small herd and, regardless of herd-size, when there is a high-risk profile in the herd (e.g. background information exists on the high risk of residual or recurrent infection) and, on occasion, when a farmer is willing to do that.

72. The audit team could see examples of large herds where despite the high number of reactors to the SICTT within two or three years (e.g. two herds with 65 and 100 positive animals out of some 300), no partial or total depopulation had been carried out. As mentioned above, in those particular cases the high cost of depopulation was mentioned as the main reason for not opting for this measure.

73. The audit team could see that, despite the criteria laid down in the staff instructions, the practical application of depopulation has not been clarified in further guidance (as recommended in the bTB WD) and the decisions on (why) not to use it are not properly documented.

Conclusions on depopulation of herds

74. Implementation of the current policy on herd depopulation is not based on a sound epidemiological evaluation of the long-term benefits for the elimination of infection with *M. bovis*. The high costs and high risk of re-infection are considered as limiting factors at the current level of incidence.

5.1.4 Engagement of stakeholders and application of biosecurity measures

75. The bTB WD highlights that it is essential that all stakeholders involved in the eradication programme, independent of their respective roles and responsibilities, actively commit and contribute to the full implementation of all the measures of the programme.

- According to representatives of the DARD, the bTB stakeholder working group established in 2008 as part of the overall governance of the bTB eradication programme has not yet demonstrated a sufficient level of engagement with regard to the improvements necessary to enhance the effectiveness of the programme.
- For the time being this group has played a rather passive role as they are just receiving information from the DARD on the planning and implementation of the programme and transmitting it to the relevant stakeholders.
- These representatives added that they have also created a bTB partnership group with PVPs in order to improve communication lines on bTB testing between the DARD and these stakeholders.
76. According to the guidelines laid down in the bTB WD, compensation schemes in bTB eradication programmes should be subject to regular review and aimed at modifying the behaviour of farmers in avoiding introduction and further spread of the disease.

- The DARD have proposed several times to reduce compensations paid to affected farmers and to link them to proper application of good biosecurity practices.
- The reports from the Audit Office and the Public Accounts Committee mentioned in section 4.2 highlight the need for the DARD to consider incorporating such policies to the eradication programme.
- These proposals have been rejected by the Northern Ireland Assembly.

77. The bTB WD recommends that effective eradication programmes should include additional tailored measures aimed at addressing the different constraints to eradication in each epidemiological situation.

78. The DARD has promoted a number of studies to collate as much evidence as possible on the importance of herd biosecurity practices to prevent transmission of bTB. These initiatives, both in the form of literature reviews and observational field studies, done by AFBI-VSD, have covered a number of relevant issues, such as:

- Risks related to cattle-to-cattle transmission of bTB.
- The differences in biosecurity practices between herds with bTB and those without.
- The bTB risks associated with spread of slurry;
- The biosecurity practices effective to prevent transmission of *M. bovis* between cattle and badgers.

79. Documentation on these studies can be found through the following link:


80. According to staff responsible for the bTB programme, the information obtained from all those studies is used for various purposes, including:

- Preparation and circulation of informative leaflets for the farming community describing good biosecurity practices to prevent infection with bTB.
- Organisation of informative sessions for farmers and training for PVPs.
- Carrying out epidemiological investigations and providing advice to the affected farmers during bTB breakdowns.

81. The audit team could confirm that the information contained in the leaflets, some of them very recent, provides good general advice on biosecurity practices in order to raise the awareness of the farming community.

82. The audit team found limited evidence of the effectiveness of any training that could have been provided to PVPs and farmers, or of activities organised to encourage the
application of good practices on biosecurity by farmers. Despite the fact that standard documentation provided to affected farmers includes details on bTB ways of transmission and general concepts on biosecurity, the audit team could not find documentary evidence in that respect in the farm visited affected by a bTB breakdown.

83. The bTB affected farmers met by the audit team had not understood the information received in that respect and had a completely biased perception of the possible sources of infection involved in the bTB breakdown of their herd (i.e. the badgers, as they had been told by other farmers).

84. Records and documents seen of the epidemiological investigations carried out in those cases did not describe what aspects related to biosecurity practices could have contributed to the transmission of the disease and which ones could be addressed to prevent it from happening again. This is not in line with the bTB WD, which indicates that advice and guidance – not only awareness, need to be provided to farmers.

**Conclusions on stakeholder engagement and biosecurity measures**

85. To date, the CAs did not get the key stakeholders fully engaged as co-owners of the bTB eradication programme. As a consequence, incorporation into the programme of additional evidence-based measures to tighten up surveillance and eradication measures is still confronted with opposition and good biosecurity practices are not sufficiently adhered to in order to curtail the cycles of transmission of bTB between cattle and between cattle and wildlife.

86. Despite recent efforts made in the right direction, to date the CAs have paid limited attention to giving adequate advice and provide effective guidance to farmers and PVPs in relation to good preventive and biosecurity practices. As a consequence, uptake by these stakeholders of those practices is still low, which undermines fulfilment of their responsibilities to contribute effectively to reduce the spread of bTB.

5.1.5 Control of bTB in wildlife

87. Representatives of the VS provided the audit team with the following updated information on the involvement of badgers in the epidemiology of bTB:

- The current estimate of the total population of badgers is 33,500. This population has remained stable throughout the recent years.
- The density distribution of badger setts across the territory, as depicted in figure 1 below, shows that the suitability of the land in each part of the country, both for badgers and for cattle (i.e. translating into a higher cattle density) has a major impact on that distribution.
- The higher densities of badger setts coincide in many cases with the high densely populated cattle areas (figure 2). According to representatives of the VS, this could
play a major role in the dynamics of environmental infection and in increasing the probability of transmission of *M. bovis* between cattle and wildlife.

- The most recent estimate of bTB prevalence in the population of badgers obtained from testing carried out in animals collected after road traffic accidents, is 15.3%.
- Figure 3 shows the geographical distribution of the results of examinations carried out between 1998 and 2015.
- Only 15% of the epidemiological investigations with conclusions on the probable or very probable cause of a bTB breakdown consider presence of (infected) badgers as the cause.
88. The VS has initiated campaigns to encourage farmers to apply biosecurity measures to prevent transmission of bTB from badgers to cattle, and vice versa, as recommended in the bTB WD (see also section 5.1.4).

89. Considerable uncertainty still exists in relation to the impact of the behaviour and ecology of the badger population on the real dynamics of the cycle of transmission of bTB. In 2014, the VS started an ambitious research project in cooperation with the AFBI-VSD to try to shed light on those aspects, including on the possible impact of selective culling and (injectable) badger vaccination on the reduction of bTB in the geographical area under study.

90. Results will not be available before 2019 and, in the meantime, all representatives of the CAs met agreed with the recommendation laid down in the bTB WD indicating that alternatives to badger vaccination should be implemented without delay so as to allow the progress of the bTB eradication programme.
Conclusions on controls on bTB in wildlife

91. The CAs consider that the estimated level of infection with *M. bovis* in the badger population and the limited availability of measures to reduce it are a constraint for the eradication of bTB in Northern Ireland. However, they lack sufficient evidence to quantify the impact of those factors on the epidemiology of the disease in cattle and on the effectiveness of the eradication programme. Thus, they face difficulties to justify the introduction of control measures on the badger population and to make a well-informed decision on the selection of the possible alternatives to do that.
Conclusions on the implementation of the bTB eradication programme

92. The CAs apply most of the measures to detect and eliminate infection with *M. bovis* largely in accordance with relevant EU requirements and according to the approved eradication programme. At the same time, they have made efforts to address many of the recommendations of the bTB task force of 2012. Despite this broad compliance with minimum requirements, the epidemiological situation has not improved as expected and there is general consensus that additional measures, or adaptation of some of the current ones, are necessary to accelerate eradication of bTB.

93. There is no single point of failure which is preventing the incidence curve from turning down. Instead, a combination of measures – not implemented to their full effect – have the net effect of holding back progress. The measures with sub-optimal implementation can be grouped under the three key components of the bTB eradication programme:

- Detection of the disease – besides the inherent limitations of the SICTT, the overall sensitivity of surveillance for bTB is affected by the sub-optimal use of the IFN-gamma and by insufficient quality control on slaughterhouse surveillance.
- Elimination of infection – the unfavourable epidemiological conditions resulting from the high percentage of fragmented herds, the high frequency of animal movements, and the presence of infection in wildlife, is further exacerbated by the effects of unsupervised intra-holding movements, insufficient bio-security measures and the very cautious use of depopulation – partial or total. Intensification of testing and culling of positive animals, in particular by optimising the use of IFN-gamma, could be more cost-effective than depopulation, but as it is currently used, it does not contribute significantly to accelerate elimination of infection at herd and local level.
- Prevention of disease transmission – the frequency of high risk animal movements within, to and from fragmented herds, the inadequate evaluation of the potential use of Pre-MT, the limited uptake of good biosecurity practices to prevent bTB transmission between cattle and between cattle and badgers, and the deficiencies in the information flow from epidemiological investigations, all have a negative impact on preventing new and recurring bTB breakdowns.

94. The CAs have made efforts to introduce certain improvements into the various components mentioned in the previous point but due to insufficient stakeholder engagement and political commitment these attempts have not been successful up to now.
5.2 VERIFICATION OF IMPLEMENTATION, EVALUATION OF EFFECTIVENESS AND ADAPTATION OF MEASURES

Legal requirements

Commission Implementing Decision 2013/722/EU (programme for 2014) and Grant Decision Number SANTE/VP/2015/UK/SI2.700838 (programme for 2015).

Findings

5.2.1 Verification of implementation

95. The CAs have set up an adequate verification system to ensure that most of the measures planned in accordance with the approved bTB eradication programme are carried out in accordance with established procedures.

96. The VOs with managerial responsibilities in the DVOs have primary responsibility for the regular verification and quality assurance of the activities carried out by staff under their command. Those VOs have access to a comprehensive network of information management tools and integrated monitoring mechanisms that ensure regular management and follow-up of delivery of most of the components of the bTB eradication programme. Those tools include:

- APHIS, as the main repository for data related to the cattle population and the animal health control activities carried out by the VS (e.g. results of all bTB tests and data on post-mortem findings from slaughterhouses).
- A number of key performance indicators adapted to the measures to be implemented by the DVOs as part of the eradication programme and that enable monitoring of the monthly evolution of the outcome targets for each DVO.
- A performance management system for all administrative tasks carried out by staff of the DVOs in relation to the programme (e.g. imposition of herd restrictions, overdue bTB tests to be performed, etc.) that is linked to APHIS. This system provides comprehensive information in response to a number of queries and report formats pre-set in order to enable each VO to regularly manage and follow-up their responsibilities with regard to the local implementation of the programme. In addition, those queries and reports facilitate monitoring by the various layers of verification established within the VS of the consistent delivery by all DVOs (and VOs) of the various components of the bTB eradication programme.

97. Managerial staff of the DVOs holds regular meetings, at least once a month, with local VOs and specifically review all information related to bTB breakdowns to ensure that procedures established in accordance with the bTB eradication programme are adhered to. This activity was confirmed by the audit team during the meetings held at the DVOs visited, where examples of the local evolution of compliance with key performance indicators and of reports from the performance management system were provided and checked.
98. Since 2013, senior management of the bTB eradication programme at central level has received support from the bTB Implementation Team. Members of this team verify regularly the application of bTB control and eradication measures by DVOs and give them technical advice according to the evolution of the epidemiological situation in the area. This system is adequate for ensuring that the tasks allocated to the DVOs are fulfilled in a timely manner and allows the VS to provide a descriptive picture of the implementation of that part of the programme.

99. Limited efforts have been made to verify the operation of surveillance for bTB in slaughterhouses. This does not follow the guidelines on the operation and quality control of bTB surveillance laid down in the bTB WD. The audit team was informed that, at the time of the audit, no special emphasis was put on verification of this component of surveillance for bTB and that the DARD and the Food Standards Agency were in the process of setting up a specific system to do that.

- Regional supervisors of the Veterinary Public Health Programme of the VS are responsible for regular verification of the findings from post-mortem inspection uploaded in APHIS, but they have not been instructed to monitor any particular aspect or trend in relation to surveillance for bTB.
- Up to the time of the audit, neither the DARD nor the Food Standards Agency had considered the use of a system based on specific key performance indicators, as it is the case in England and Wales, to monitor the effectiveness of post-mortem inspection in the context of surveillance for bTB in slaughterhouses.
- Although it is recommended by the bTB WD, the normal patterns of disclosure of non-tuberculous bTB-like granulomatous lesions have not been established as a baseline target for the minimum submission rates of lesions compatible with bTB infection expected from cattle slaughterhouses.
- The Internal Audit Team of the Food Standards Agency audits meat hygiene controls throughout the UK, including post-mortem inspection in slaughterhouses. In recent years, it audited Northern Ireland, but the audits did not focused on verifying whether those official controls are addressing the needs of bTB surveillance.

Conclusions on verification of implementation

100. The use of adequate verification activities by the VS in the context of the bTB eradication programme provides satisfactory guarantees that most of the measures are implemented in accordance with the approved programme. However, verification of the sensitivity of bTB surveillance in slaughterhouses is still insufficient to ensure that it is optimised to contribute more to detect the disease promptly and to accelerate its eradication.
5.2.2 Evaluation of effectiveness and adaptation of measures

101. The bTB WD indicates that measuring progress of a bTB eradication programme concerns more than simply assessing data that are easy to retrieve. It also requires an evaluation of the effectiveness of the measures currently in place in order to reduce the incidence and prevalence of the disease. This was further emphasised in the recommendations of the bTB task force of 2012. So far, the VS has taken limited steps to ensure that the evaluation is carried out regularly.

102. The VS has not used sufficiently the verification system described in section 5.2.1 to follow the recommendations of the bTB WD. It has not evaluated the results of surveillance for bTB and the implementation of disease eradication measures, in order to correlate fulfilment of operational performance indicators with achievement, or the opposite, of improvements in the epidemiological indicators. As a result, some paradoxes were found in DVOs where performance indicators have been fulfilled very well during 2014, but the herd incidence rate had increased during the same period. Staff of the VS advised the audit team that they were developing additional disease indicators to facilitate preparation of more accurate and informative disease situation reports at DVO and country level.

103. The bTB WD recommends that epidemiological data analyses should be an integral part of the continuous assessment of the eradication programme. It also recommends that it is fundamental both for the control of bTB in infected herds and for provision of descriptive and analytical information for the assessment of risk factors that can be useful in adapting future eradication strategies.

- With that aim, analysis of the extensive amount of data and information accessible has been limited. Reports produced in that respect, for instance the one mentioned in section 4.3 on the implementation of the programme in 2013, are mostly descriptive. Nevertheless, the recent preliminary report on the analysis of surveillance for bTB in slaughterhouses is a promising example in the right direction.
- The audit team found evidence of statements made by staff of the Veterinary Epidemiology Unit where they acknowledge the need of deeper analysis of the available information, in particular of the epidemiological investigations that are performed in the context of bTB breakdowns, to ascertain the reasons for a particular localised or temporal increase in bTB herd incidence. Some of the reports seen by the audit team that aimed at explaining sudden increases in herd incidence in some areas could not be conclusive in that respect, mainly because of lack of the right information needed to perform the analysis.

104. The bTB WD recommends that the measures discussed therein should be applied as relevant for the epidemiological situation and ranked in order of priority/effectiveness when allocating the funds available for bTB eradication. The Veterinary Epidemiology Unit and the AFBI-VSD have given the DARD in recent years some evidence-based
recommendations in relation to a number of measures that are worth being reviewed or incorporated into the eradication programme. However, at the time of the audit, most measures had not been added yet to the programme, mainly because of their controversial nature or their cost. In relation to those that have been incorporated, little progress has been made so far with their application.

105. The recommendations mentioned in the previous point align with those of the bTB WD and are covered by the recommendations of the bTB task force of 2012. However, the DARD has not taken full advantage of all that scientific evidence, technical knowledge and epidemiological intelligence in order to increase the sensitivity of surveillance for bTB and adapt preventive and eradication interventions to the dynamics of the disease at herd, local and country level. The measures recommended include:

- **Measures to accelerate the elimination of bTB from the small percentage of chronically infected herds that contribute to 25% of the annual animal incidence rates with residual infection and recurrent breakdowns.** They include:
  - The use of a severe interpretation of the SICTT in all derestriction tests, or using it in parallel to the use of IFN-gamma, in order to increase the sensitivity of bTB surveillance in the herds once the disease has been confirmed, and to accelerate the elimination of infection, and
  - Intensification of surveillance and control measures in the local area as chronic infection is significantly correlated with area-wide high bTB herd prevalence.
- **Increasing the routine use of the severe interpretation of the SICTT,** as mounting evidence shows that it has higher sensitivity than the low one obtained by the standard interpretation (71 to 56%) without losing specificity (both over 99.8%).
- **Recommendations to tighten up restriction measures on high risk herds,** such as decreasing the number of reactors to the SICTT necessary to withdraw the OTF status of a herd (from more than five to just more than one). Thus, additional testing will be required and more time needed to derestrict possibly infected herds which, indirectly, will reduce the levels of residual infection and the circulation of bTB infected animals.
- **A recommendation to identify precisely the factors that could be improved in order to standardise post-mortem procedures and thereby increase the sensitivity of bTB surveillance in underperforming slaughterhouses.** The Veterinary Epidemiology Unit recommended the DARD to increase that sensitivity at the cost of lowering the specificity of the slaughterhouse surveillance for bTB, in order to bring additional benefits to the eradication programme.
- **The need to escalate up the application of biosecurity measures at farm level in order to curtail the cycles of bTB transmission between cattle and between cattle and wildlife.**

106. Representatives of the DARD advised the audit team that they were waiting for the action plan to be put forward by the bTB Strategic Partnership Group in order to adapt
the bTB eradication programme accordingly. The members of the bTB Strategic Partnership Group informed the audit team that amongst the various issues to be considered a priority in their strategic proposal, they will put a major emphasis on the need to ensure stakeholders' engagement, behavioural change at all levels, i.e. both in the industry and in the DARD, and prioritisation of local eradication initiatives in high incidence areas. They added that their mandate goes beyond providing another description of the well-known problems that undermine the bTB eradication programme and, therefore, that they will propose concrete ways to improve the current situation in order to make feasible eradication of the disease in the long term.

**Conclusions on evaluation of effectiveness and adaptation of measures**

107. There is no detailed analysis of the effectiveness of the various measures contained in the bTB eradication programme currently in place, in order to explain the limited progress made with their implementation during recent years and to identify and weigh up the contribution of the various factors intervening in the epidemiology of bTB in Northern Ireland to cause that. Thus, the CAs are in an unfavourable position to adequately inform the design and implementation of future eradication programmes, so that they can achieve the operational objectives and expected results set out by EU requirements on co-funding of disease eradication programmes.

108. The DARD is still reluctant – and constrained by socio-political factors – to incorporate potentially effective measures into the eradication programme that emanate from the evidence- and science-based advice they received. As a consequence, neither the persistence of high levels of infection with *M. bovis* in a number of geographical areas nor the recurrence of bTB breakdowns in a number of herds have been addressed effectively yet.
6  **OVERALL CONCLUSIONS**

The eradication programme is applied largely in accordance with planned arrangements but the herd incidence rate has stagnated at levels above 6%, which is not what would be expected with an effective eradication programme in place.

The audit team identified a number of strengths in the implementation and verification of the programme that contribute to disease eradication by increasing detection and elimination of infection with *M. bovis*. A comprehensive and well-targeted research agenda has provided the CAs with relevant evidence to reinforce the implementation of the available control and eradication measures.

The main factors holding back progress in the eradication of the disease can be grouped under five broad categories:

- There is ineffective implementation of some measures to stop disease transmission between cattle and between cattle and badgers (e.g. controls on animal movements and biosecurity measures).
- There is a need to further optimise the sensitivity of some components of surveillance for bovine tuberculosis to accelerate detection of persistent infection with *M. bovis*.
- The ineffective policies to clear-up chronically infected herds and to understand and contain levels of infection in the badger population, lead to a significant contribution of residual infection to the maintenance of the disease and to its unsuccessful elimination from the cattle and badger populations.
- The effectiveness of the measures contained in the eradication programme is not regularly evaluated to define and adapt disease control strategies to the epidemiological situation of bTB.
- The engagement and commitment of key stakeholders to the eradication programme are still insufficient to ensure its future success.

The competent authorities have decided to develop a future strategy to eradicate bTB based on a proposal by an independent panel of experts and representatives of the industry. The audit team concludes that the new strategy (with subsequent action plan and its implementation), if accepted and co-owned by all relevant stakeholders, provides a good opportunity to bring the programme to a level where the final target of accelerated eradication becomes realistic and achievable.

7  **CLOSING MEETING**

A closing meeting was held on 5 June 2015 with representatives of all the CAs involved in official controls on bTB in Northern Ireland. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team. The representatives of the CAs did not express disagreement with the findings and conclusions presented; they provided additional clarification on a number of issues and they undertook to give due consideration to the points raised by the audit team.
8 RECOMMENDATIONS

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion (‘action plan’), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this audit report.

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| 1.  | To ensure that submission rates of suspected lesions of bTB and detection rates of animals with confirmed tuberculous lesions are adequate to increase the sensitivity of surveillance for bTB in cattle slaughterhouses and detect promptly potentially infected animals.  
  Based on conclusions (24), (93) and (100), and associated findings (20), (21), (99) and (105). |
| 2.  | To ensure that all available evidence supporting a more extensive use of the IFN-gamma in herds where bTB has been confirmed is fully taken into account, and that all necessary arrangements are made to facilitate that use in order to accelerate detection and elimination of infected animals from those herds.  
  Based on conclusions (51) and (93), and associated findings (48), (49), (50) and (105). |
| 3.  | To ensure that results and analyses carried out as part of the epidemiological investigations performed on bTB breakdowns are properly documented and used to: a) substantiate the conclusions reached and the adaptation of eradication measures to the herd and local situation, and b) contribute to the assessment of risk factors necessary for the shaping up of future disease eradication strategies.  
  Based on conclusions (40) and (93) and associated findings (37), (38) and (103). |
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| 4.  | To introduce effective measures to manage the risks of transmission of bTB between cattle and from cattle to wildlife that are associated with movements of animals between land fragments in herds where the presence of bTB has been confirmed.  
   *Based on conclusions (64), (65) and (93) and associated findings (52), (53), (55), (59) and (63).* |
| 5.  | To ensure that movements of susceptible animals into cattle herds where the presence of bTB has been confirmed are prohibited with the exception of those that are authorised by the CAs on the basis of obvious animal welfare reasons.  
   *Based on conclusions (64) and (93), and associated findings (54) and (55).* |
| 6.  | To ensure that decisions on full depopulation of cattle herds with recurrent bTB breakdowns are based on clear guidelines and substantiated by a sound epidemiological evaluation of the possible long-term benefits for the elimination of infection with *M. bovis* in the herd and the local area.  
   *Based on conclusions (74) and (93), and associated findings (66) and (73).* |
| 7.  | To give adequate advice and provide effective guidance to farmers and PVPs in relation to good preventive and biosecurity practices, including on mitigation of risks related to animal movements, so as to encourage their active role as contributors to reduce the spread of bTB.  
   *Based on conclusions (64), (65), (86) and (93), and associated findings (82), (83), (84), (90) and (105).* |
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| 8.  | To ensure that all key stakeholders are fully engaged and committed with the bTB eradication programme and that they assume and fulfil their responsibilities in that respect.  
*Based on conclusions (85) and (94) and associated findings (75) and (76).* |
| 9.  | To ensure that available evidence and epidemiological intelligence that substantiate the incorporation of additional measures into the eradication programme are fully taken into account and acted upon in order to increase the sensitivity of bTB surveillance and adapt preventive and eradication interventions to the dynamics of the disease at herd, local and country level.  
*Based on conclusions (65), (91) and (108), and associated findings (15), (42), (43), (44), (59), (63), (72), (78), (90), (104) and (105).* |
| 10. | To carry out an analysis of the effectiveness of the various measures contained in the eradication programme in order to understand the limited progress made with their implementation during recent years and to adapt them accordingly.  
*Based on conclusions (6), (92), (93) and (107), and associated findings (3), (5), (16), (38), (76), (99), (101) and (102).* |

The competent authority's response to the recommendations can be found at:  
### ANNEX 1 – LEGAL REFERENCES

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
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<tbody>
<tr>
<td>Dec. 2013/722/EU</td>
<td>OJ L 328, 7.12.2013, p. 101-117</td>
<td>2013/722/EU: Commission Implementing Decision of 29 November 2013 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2014 and the following years</td>
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