



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2014-7055 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE UNITED KINGDOM

FROM 15 TO 26 SEPTEMBER 2014

IN ORDER TO EVALUATE THE EFFECTIVENESS OF AND PROGRESS MADE BY THE PROGRAMMES CO-FINANCED BY THE EUROPEAN UNION TO ERADICATE BOVINE TUBERCULOSIS

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

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office in the United Kingdom from 15 to 26 September 2014.

The main objective of the audit was to evaluate whether the programmes co-financed by the European Union during 2013 and 2014 to eradicate bovine tuberculosis in England and Wales were implemented effectively as approved by the Commission.

The report concludes that the competent authorities of England and Wales have taken significant steps forward in relation to the strategic planning and incorporation of new well-informed measures to the bovine tuberculosis eradication programme, which is implemented in accordance with the one approved by the Commission. The competent authorities have taken into account most of the recommendations included both in the Food and Veterinary Office's report of 2011 and in the report issued in 2012 by the Task Force for Monitoring Animal Disease Eradication after their last visit to the United Kingdom.

Despite a considerable effort, progress in tackling bovine tuberculosis spread is still slow in areas with a high incidence of the disease in England (South West and West Midlands) and Wales (various areas in the South and the North East), and the authorities still face important challenges inherent to the eradication programme in those countries, in particular:

- The current uncertainty in relation to the extent and geographical distribution of infection in wildlife, and the sociological and technical constraints hindering the decision-making process to select effective policy options to address that problem, such as culling and vaccination of badgers.*
- The complexity of animal trade networks and the risks associated to a very mobile cattle population, including considerable involvement of animals from restricted herds. Even though those risks are increasingly mitigated with reinforced control measures and the use of pre-movement testing, evidence still shows that they can contribute to increase the level of environmental infection with *M. bovis* and facilitate the transmission of bovine tuberculosis.*

In the context of the new strategies for eradication of tuberculosis in England and Wales, the United Kingdom is submitting a new multi-annual eradication programme to the Commission for the period 2015-2020, which aims at consolidating and reinforcing the implementation of the measures already in place. Therefore, the effectiveness in the mid- and long-term of all those measures, which will likely be reinforced with expected improvements in relation to the challenges mentioned above, will have to be further evaluated in the near future in order to confirm that they actually materialise in a progressive reduction in the annual levels of bovine tuberculosis herd incidence throughout England and Wales.

The audit team did not consider it necessary to issue recommendations to the authorities in United Kingdom.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AHVLA	Animal Health and Veterinary Laboratories Agency
bTB	Bovine tuberculosis
bTB breakdown	A bTB incident in a previously OTF herd
CA	Competent authorities
CCA	Central competent authority
CTS	Cattle Tracing System
DEFRA	Department for Environment, Food and Rural Affairs
EU	European Union
FVO	Food and Veterinary Office
HRA	High Risk Area
IFN-gamma	Gamma-interferon assay
Infected herd	Herd where infection with bTB has been confirmed
LRA	Low Risk Area
<i>M. bovis</i>	<i>Mycobacterium bovis</i> , the causative organism of bTB
OTF(-S or -W)	Officially bTB free (suspended or withdrawn) status
PAFF Committee	Standing Committee on Plants, Animals, Food and Feed – Section Animal Health and Welfare
Previous FVO report	Report DG(SANCO) 2011-6057 – MR Final, of an audit carried out in the United Kingdom from 5 to 16 September 2011 in order to evaluate the operation of the bovine tuberculosis eradication programme
Pre-(Post-)MT	Pre-(Post-)movement testing
PVP	Private veterinary practitioners
Restricted herd	Herd with the OTF status suspended or withdrawn
SICTT	Single intra-dermal comparative tuberculin (cervical/skin) test
SOP	Standard operating procedures
TF	Task Force for Monitoring Animal Disease Eradication
UK	United Kingdom

1 INTRODUCTION

This audit took place in the United Kingdom (UK) from 15 to 26 September 2014 and covered England and Wales. 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, during the second week, two other officials from the Commission services in Brussels. The audit team was accompanied throughout the audit by:

- Representatives of the Department for Environment, Food and Rural Affairs (DEFRA), which is the central competent authority (CCA) within the scope of this audit and the competent authority (CA) responsible for planning and overall verification of the bovine tuberculosis (bTB) eradication programme in England.
- Representatives of the Welsh Government, which is the CA responsible for planning and overall verification of the bTB eradication programme in Wales.
- Representatives of the Animal Health and Veterinary Laboratories Agency (AHVLA), which is an executive agency working on behalf of DEFRA, the Scottish Executive and the Welsh Government, and is the CA responsible for implementation of the bTB eradication programme in the field in England and Wales¹.
- Representatives of the Food Standards Agency, as the CA responsible for surveillance for bTB related to *post-mortem* inspection of carcasses of cattle slaughtered in England and Wales.

An opening meeting was held on 15 September 2014 with the CCA and representatives of other CA involved in official controls in relation to bTB. 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

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 2013 (by Commission Implementing Decision 2012/761/EU) and from 1 January to 31 December 2014 (by Commission Implementing Decision 2013/722/EU).

Insofar as they were incorporated in the approved programmes mentioned above, the audit included follow-up of actions taken by the CA in response to the recommendations contained in the previous FVO report that covered the same topic and to those made by the Task Force for Monitoring Animal Disease Eradication (TF) in 2012 (see section 4.1 for further information).

¹ In their comments to the draft report, the CA clarify that the AHVLA has become the Animal and Plant Health Agency since 1 October 2014.

In pursuit of the audit objective, the following sites were visited and meetings held:

Meetings/visits		Comments
Competent authorities	7	Opening and closing (debriefing) meetings with the CCA and representatives of other CA. Additional meetings with staff of the AHVLA regional offices visited, four in England and one in Wales (Preston, Stafford, Gloucester, Exeter and Carmarthen).
Animal holdings	5	Three cattle farms (LRA, Edge Area, Wales) and two approved finishing units (HRA, Wales).
Other establishments	2	One slaughterhouse and one cattle market.
Other stakeholders	5	Meetings with representatives of the cattle industry in England (at the four AHVLA regional offices) and in Wales (South Wales Regional bTB Eradication Delivery Board).

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, and
- Article 10 of Council Directive 77/391/EEC, introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle.

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 PREVIOUS FVO AUDITS AND OTHER RELATED INFORMATION

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 2014, 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:

http://ec.europa.eu/food/animal/diseases/docs/wd10181-2014-rev2_guidelines_for_union_cofunded_programmes.pdf

The FVO regularly audits the implementation of eradication programmes to evaluate their effectiveness and to assist the Commission services in deciding whether EU co-financing is justifiable or not. The most recent audit carried out by the FVO in the UK in order to evaluate official animal health controls in the context of the bTB control and eradication programme was carried out in September 2011 (ref. DG(SANCO) 2011-6057 – MR Final). The report of that audit (hereafter, the previous FVO report) and the current state of the FVO follow-up process can be found at the following links:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2830

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

The TF 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 TF held a meeting in the UK in March 2012. During that meeting, the experts of the TF 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 TF meeting can be found on the the following link:

http://ec.europa.eu/food/animal/diseases/docs/tb_subgroup_uk_2012_en.pdf

While acknowledging the many important steps taken by the CA 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 CA 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 CCA. Those recommendations are considered in the body of this report.

The Commission has issued in recent years a number of important documents in relation to the control, surveillance and eradication programmes for animal diseases which are co-funded by the EU. The following are of relevance in the context of evaluating the progress made with the implementation of bTB eradication programmes:

- 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:

http://ec.europa.eu/food/animal/diseases/docs/sanco-12915-2012_en.pdf

- A Working Document on Eradication of bTB in the EU published in 2013 and accepted by the bTB subgroup of the TF (Document SANCO/10067/2013). This document provides guidelines for the design and operation of bTB eradication and surveillance programmes, and also 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. Those guidelines are fully taken into consideration by the TF during their evaluations and are the main pillars on which their conclusions are based. It can be found through the following link:

http://ec.europa.eu/food/animal/diseases/eradication/tb_workingdoc2006_en.pdf

Comprehensive information on the general organisation of the CA involved in management and implementation of the bTB eradication programme in England and Wales is provided in the previous FVO report (see link above), and also 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

<https://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/ukmancp-updated2014.pdf>

4.2 PROGRESS IN ERADICATION OF bTB

4.2.1 General information

The 2014 approved programme for the eradication of bTB in the UK can be found through the following link:

http://ec.europa.eu/food/animal/diseases/docs/adopted_2013_722_eu_bovine_tuberculosis_uk_en.pdf

The programme was submitted to the Commission for approval in the context of the current strategic frameworks for the eradication of bTB in England and Wales, which were set out respectively in 2014 and 2012 in the documents that are accessible through the following websites:

<https://www.gov.uk/government/publications/a-strategy-for-achieving-officially-bovine-tuberculosis-free-status-for-england>

<http://wales.gov.uk/topics/environmentcountryside/ahw/disease/bovinetuberculosis/bovinetberadication/tbstrategicframework/strategicframeworkfortberadication/?lang=en>

The Commission and the Member States have been kept informed of the bTB situation in the UK *inter alia* 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 CCA during the Committee meeting held on 6 May 2014; this presentation has been made available through the following link:

http://ec.europa.eu/food/committees/regulatory/scfc/ah/animal_health/docs/20140506_bovine_tuberculosis_uk_en.pdf

The following is worth being highlighted:

- In England, a new eradication strategy was promoted since 2014 by the bTB eradication Advisory Group operating under the Animal Health and Welfare Board for England created in 2011. The strategy was informed by a number of expert reviews and research studies, and established as a result of extensive consultations with all relevant stakeholders. It sets out clear initial targets, and provides indicators for monitoring their evolution and a time scale for their achievement. Since January 2013, the strategy relies - amongst other things - on the establishment of three bTB management regions or zones in England:
 - A High Risk Area (HRA), covering the South West, West Midlands and East Sussex, that traditionally have shown a high bTB herd incidence;
 - a Low Risk Area (LRA), including large parts of the North and East, that have shown a very low bTB herd incidence for many years now,
 - and a buffer zone in between (Edge Area), spanning counties or parts of counties with a low, but increasing bTB prevalence and with a high risk of becoming new endemic areas. Definition of the boundaries for the Edge Area took into consideration, amongst other factors, the observed and potential range of spread of *M. bovis* genotypes originating from the HRA.
- The exact geographical distribution of these areas, and details on the main targeted control principles and measures to be applied in each of them can be found on the document laying down the bTB eradication strategy for England mentioned above.
- In relation to the bTB eradication programme in Wales:
 - Actions implemented since 2012 within the current strategic framework were

informed by a comprehensive scientific review of the evidence available in that respect. The document produced as the main outcome of that review can be found through the following link:

<http://wales.gov.uk/docs/sacw/publications/130201tbreporten.pdf>

- The programme is overseen by the bTB Eradication Programme Board, that provides overall direction and management of the programme for Wales bringing together representatives of the Welsh Government and all relevant stakeholders. In addition, a bTB Eradication Programme Technical Advisory Group brings together scientific, veterinary, social science, agricultural economics and public health expertise who advise on the design and delivery of the programme. Finally, three Regional bTB Eradication Delivery Boards, established in 2008, have as their objective ensuring that the delivery of the programme is effective and reflects local conditions.
- In that context, the UK has submitted in 2014 a new multi-annual programme to the Commission for the period from 2015 to 2020. This programme plans both to intensify the implementation of the measures gradually introduced in the programmes approved for 2013 and 2014, and to adapt them. It also plans introducing new ones, according to the epidemiological evolution of the disease in the various regions involved. The CAs of England and Wales stressed and demonstrated during this audit, the major role of the latter approach in shaping up the bTB control measures depending on the prevailing epidemiological drivers of the disease in each region of both countries.
- In England and Wales, a bTB breakdown can cause suspension or withdrawal of the officially bTB free status of the affected herd (OTF-S and OTF-W herds, respectively):
 - In the case of a OTF-W herd, additional evidence of *M. bovis* infection has been identified in at least one slaughtered bovine animal, i.e. *M. bovis* identified in a cultured tissue sample and/or lesions detected in the carcass of a single intra-dermal comparative tuberculin test (SICTT) or a test reactor to the Gamma-interferon assay (IFN-gamma).
 - In an OTF-S herd, there is only a suspicion of the infection being present; i.e. no *M. bovis* and/or lesion has been found yet. In general, the de-restriction process for these herds is carried out in accordance with EU requirements, but stricter rules than those requirements apply in England to OTF-S herds that are contiguous to OTF-W herds, that have been OTF-W herds within the previous three years or that are in the Edge Area. In England, those OTF-S herds need to have at least two consecutive clear SICTT in order to recover their OTF status (in Wales, they are considered OTF-W herds).

4.2.2 *Epidemiological situation of bTB in England and Wales*

Comprehensive statistics on the implementation of the bTB eradication programme in England and Wales during 2012 and 2013, as well as monthly updated data on the implementation of the programme in 2014, are available on the following websites:

<https://www.gov.uk/government/collections/bovine-tb>

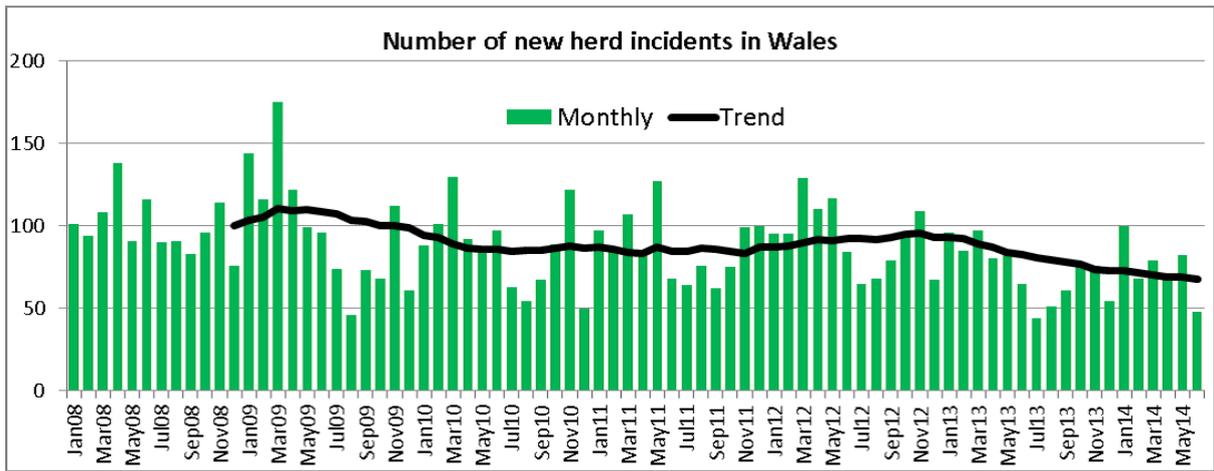
<http://wales.gov.uk/topics/environmentcountryside/ahw/disease/bovinetuberculosis/background/annual-surveillance-report/?lang=en>

According to data provided by the AHVLA for surveillance for bTB carried out in 2013:

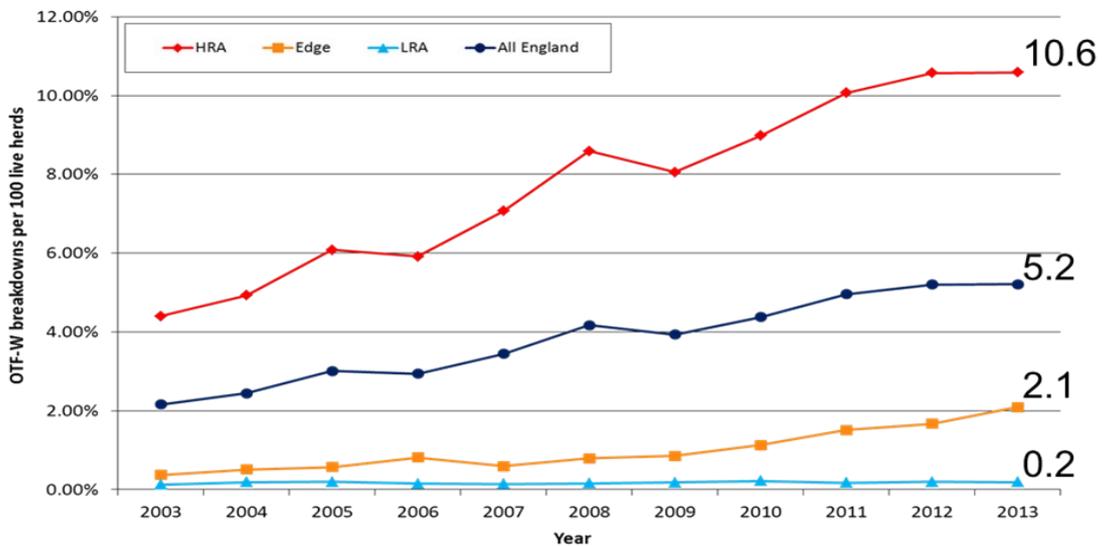
- The proportion of cattle herds on annual testing areas in England (i.e. in the HRA and the

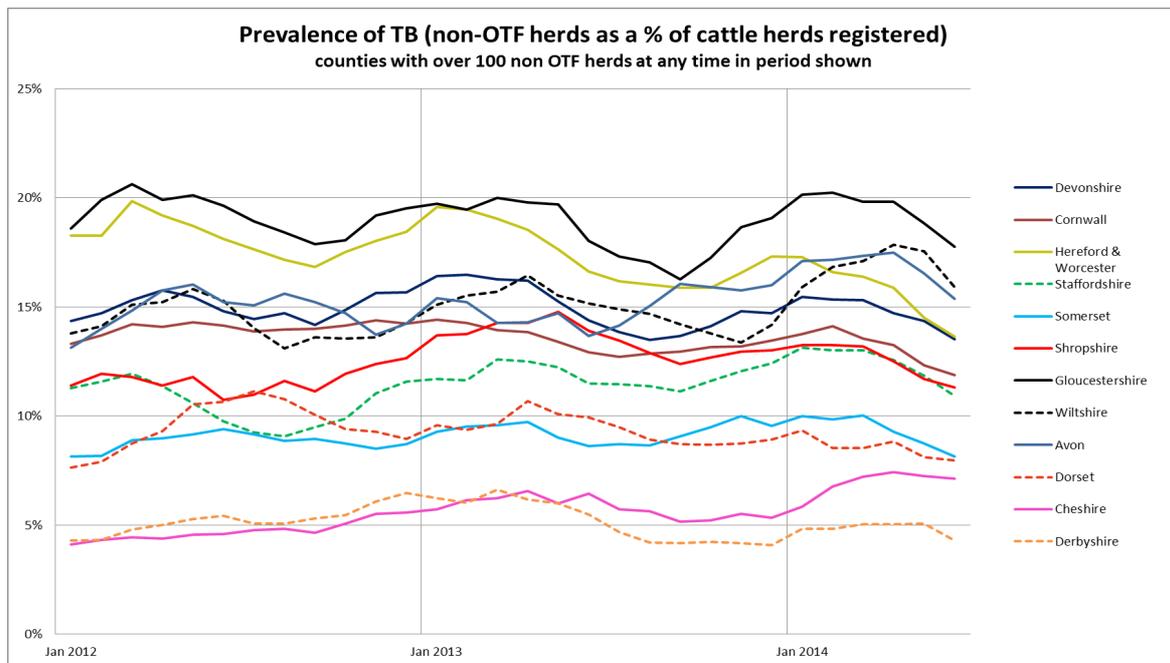
Edge Area) increased from 48.5% in 2012 to 60.3% in 2013, as a result of placing all cattle herds in the Edge Area on annual testing from 1st January 2013.

- The rest of the cattle herds in England are those in the LRA which, in normal circumstances (i.e. OTF herds without any bTB restriction applied on them), are tested once every four years. Nevertheless, as an example of the adaptive control policy mentioned above, some 12% of those herds were on annual testing since they were targeted because of their high bTB risk profile (proximity to bTB breakdowns, high-risk animal movements, intensified public health controls related to milk production, etc.).
- The total number of new breakdowns increased by 2.9% in England relative to 2012. There were 3,460 new breakdowns in the HRA (3,437 in 2012), 320 breakdowns in the Edge Area (229 in 2012), and 105 in the LRA (109 in 2012):
 - Some 35% of bTB breakdowns were detected with the routine annual SICTT and another 30% with post-breakdown SICTT in risk-targeted/contiguous herds.
 - More than 92% of all OTF-W herds were found in the HRA, whereas 40% of cattle herds in the HRA have not had any breakdown for the last 10 years.
 - According to representatives of the AHVLA, the higher number of bTB breakdowns detected in the Edge Area is attributed to the intensification of surveillance for bTB since January 2013, with all herds in this area now subject to the annual SICTT (30% increase in bTB testing in 2013), and to mandatory Pre-MT for all cattle from the Edge Area moved other than to slaughter.
 - Of the 105 new bTB breakdowns detected in the LRA, only 40 were culture or lesion positive; i.e. were considered as OTF-W herds.
- All herds in Wales have been subject to the SICTT annually since January 2010. There were 867 new breakdowns in 2013 (1,091 in 2012; i.e. there has been approximately a 20% decrease) of which 442 (547 in 2012) were classified as OTF-W herds. The largest clusters of breakdowns were found in the South West and in the geographical areas along the Welsh/English border.
- In England and Wales, *M. bovis* was isolated, respectively, from 95% and 97% of samples submitted from slaughterhouses from animals with visible lesions, and from 5.5% and 3% of samples submitted from animals with non-visible lesions.
- There has been an increasing trend in England in the proportion of recurrent bTB breakdowns, both for OTF-S and OTF-W herds. On the contrary, in Wales the proportion of recurrent breakdowns has been decreasing since 2011 (6% decline for OTF-S herds, 11% decline for OTF-W herds, and an 8% decline in total).
- According to representatives of the Welsh Government, the declining trend in Wales for the number of breakdowns, in particular for the recurrent ones, suggests that implementation of the new eradication strategy and of measures applied for a number of years - including intensive tightening of controls on and around bTB breakdowns - is already paying clear dividends and proves their fitness for purpose. The following picture depicts that positive trend:



- In relation to the current situation in England, representatives of the bTB programme in DEFRA stressed the fact that the new battery of measures intensified since 2013 will have to be implemented for a few years before solid improvements can be seen in the evolution of the epidemiological indicators both in the HRA, where the annual herd incidence seems to have stabilised, and in the Edge Area, where it has increased just temporarily owing to the more intensive testing and targeted control measures carried out now.
- The first graph below shows the evolution since 2003 of the annual incidence of new OTF-W herds in the three areas of England. The second graph depicts preliminary data for the first half of 2014 showing a declining trend for the overall herd incidence and, with some exceptions, for the majority of the counties that historically had a higher bTB risk:





5 FINDINGS AND CONCLUSIONS

5.1 IMPLEMENTATION OF THE bTB ERADICATION PROGRAMMES

Legal requirements

Commission Implementing Decisions 2012/761/EU and 2013/722/EU (approval of the eradication programmes).

Council Directive 64/432/EEC (general and specific measures on bTB).

Council Directive 77/391/EEC (specific measures on bTB eradication programmes).

Findings

5.1.1 Regular management of the eradication programme – adaptation of measures

The CA in England and Wales have put in place integrated animal health information management tools, including very active epidemiological analysis teams. They allow their staff to constantly evaluate the results of surveillance for bTB and the local epidemiological intelligence about the disease and tailor control measures accordingly. The audit team saw the application of this approach in various areas visited. The following are some examples worth being highlighted:

- Due to the persistent high incidence of bTB in some parts of the Edge Area and as a result of local epidemiological analysis, surveillance for bTB has been extended since January 2014 to three kilometres radial areas around new OTF-W herds in the Edge Areas of Cheshire and Derbyshire (counties which straddles the HRA and the Edge Area). Herds included in that extended surveillance are re-checked six months after the initial SICTT, as a follow-up to the initial post-breakdown targeting before they revert to the normal annual testing interval. In addition, plans were in place to replace annual herd testing and radial surveillance with a routine six months SICTT interval policy for all herds in the Edge Area part of Cheshire on

1 January 2015.

- The sensitivity of the surveillance has been increased in the Edge Area in OTF-S herds before they can recover their OTF status. In order to achieve that, they have to pass two SICTT at short intervals and under severe interpretation of the test, which has contributed to detect additional OTF-W herds. This is in accordance with the recommendations of the TF.
- Radial testing is applied in the LRA, as well as a more intensive use of IFN-gamma as an ancillary test. Both options are used in all OTF-W breakdowns. In addition, severe bTB breakdowns are subject to partial or full depopulation, which is better informed thanks to the use of the IFN-gamma. According to the results obtained in 2013 and so far in 2014, it appears that bTB is not spreading within the LRA:
 - 41 of the 105 bTB breakdowns found in the LRA in 2013 were OTF-W herds. Based on bTB molecular typing, animal movement data and local epidemiological investigations, 21 of those breakdowns were clearly attributable to introductions of infected cattle with no evidence of secondary spread to other herds.
 - In the first six months of 2014, 20 OTF-W cases were disclosed, with a similar geographic distribution and causal pattern to those found in 2013. Only one case was detected as a result of radial testing.
 - The audit team could verify examples of the comprehensive use of those measures while in the LRA.
- Both in England and Wales, but particularly in the latter, more OTF-S herds are immediately considered as OTF-W herds on the basis of the epidemiological background of the herd or the local area (e.g. previous breakdowns, recurrent infection in contiguous herds, etc.). According to representatives of the Welsh Government, they were considering the policy of automatically considering all bTB breakdowns as OTF-W herds (now, some 80% of all new breakdowns are considered OTF-W herds), but no specific time-line could be provided for that option to be introduced. Both options follow the recommendations of the TF, with the latter being considered more effective at eliminating residual infection and preventing re-occurrence of bTB².
- In Wales, a specific project, the Wales bTB 'Epidemiology Project', was carried out from April 2013 to April 2014. It studied the epidemiological drivers of bTB in six areas of the country that were selected on the basis of their differences in bTB incidence, disease transmission risks and cattle production practices. The CA anticipated that these areas would need different control and prevention approaches in order to reduce their respective bTB situations and that this diversity of options would enrich the bTB control policy in Wales as a whole.
 - The team responsible for the study provided the Welsh Government with comprehensive individual reports for each area that include details of the evolution of surveillance for bTB over the years and an analysis of the factors that are likely modulating the epidemiology of bTB in each one, as well as a number of tailor-made recommendations to address their specific situations. The audit team confirmed that for each of the six reports.
 - Representatives of the Welsh Government stated that they were in the process of studying those reports and the overall outcome of the project in detail, in order to better shape up and adapt their bTB control policy country-wide.

² *In their response to the draft report, the CA noted that in England, subject to the results of a public consultation expected to be launched in early 2015, DEFRA is considering adopting a policy of treating all new bTB breakdowns in the HRA as OTF-W by default later in 2015.*

- Special projects are under way in both England and Wales in order to address persistent bTB breakdowns. More detailed epidemiological investigations and analysis are carried out in those cases to be able to introduce individually tailor-made measures to tackle that problem. The audit team checked a few cases; in general, this approach was well implemented and additional disease prevention and management measures were adequate to increase the chances of eliminating the infection in those cases (e.g. additional testing, including use of IFN-gamma, partial depopulation, enhancement of biosecurity measures). Representatives of the CA acknowledged that additional time will be needed to confirm the overall effectiveness of this initiative in the current disease control environment where limited action can be taken in respect of the levels of infection in wildlife.

5.1.2 *Surveillance for bTB – detection and confirmation of the disease*

5.1.2.1 *Application of the SICTT*

There have been important improvements in quality assurance of the application of the SICTT in both England and Wales. The authorities took steps to reduce the impact of variable levels of quality in its application by private veterinary practitioners (PVP) who have been authorised by the AHVLA to act as official veterinarians for the performance of that specific task. These initiatives are undoubtedly increasing the sensitivity and effectiveness of this component of surveillance for bTB.

- Adequate and regularly updated official instructions are available for both PVP (responsible for 95% of the official SICTT) and AHVLA veterinary officers or approved lay testers (responsible for the other 5%). The authorisation of PVP to carry out the SICTT is subject to training and to the on-the-spot verification of their required level of competence carried out by AHVLA experienced veterinary officers. Besides, all PVP, or their employers, as appropriate, must ensure that they participate regularly in training activities organised by, or under supervision of AHVLA, which also requires that PVP pass one practical field test every two years.
- AHVLA introduced in 2012 in Wales and in 2013 in England field audit programmes in order to spot-check the performance of PVP:
 - Standard operating procedures (SOP) for those audits ensure that the required minimum standards for the performance of the SICTT are checked by AHVLA veterinary officers. Thanks to the centralised database available to AHVLA staff that keeps all details on all authorised PVP and on the SICTT they plan to carry out; unannounced audits can be planned easily.
 - Selection of the PVP to be audited is both targeted, on the basis of updated data on their regular activities (e.g. number of herds and animals tested, percentage of reactors detected, cases detected in slaughterhouses from herds they test, etc.) and random. The first approach has been the one privileged in England, whereas in Wales the process evolved from a more random-basis selection initially to a more targeted one in 2014.
 - Detailed results, including indication of what measures need to be taken in case of non-compliance with the official instructions, are communicated to the PVP directly or to their supervisors in the veterinary clinics employing them. The audit team verified several examples in the AHVLA offices visited.
- Both in England and Wales some 20% of the audits found non-compliances, which in most

cases were considered minor. In the very few cases where a major non-compliance was found, the authorisation of the PVP had been withdrawn and further professional disciplinary sanctions had been considered.

5.1.2.2 *Surveillance for bTB in slaughterhouses*

The audit team found improvements in relation to surveillance for bTB in slaughterhouses, that keeps contributing significantly to the detection of new bTB breakdowns in England and Wales as a means to: a) accelerate the bTB detection process in-between annual bTB herd testing, b) increase the sensitivity of the overall surveillance system by detecting herds with animals anergic to the SICTT and silent persistent infection, and c) identify infected herds in areas with very low prevalence and longer inter-annual bTB herd testing regimes, such as the LRA in England.

- This component of surveillance for bTB had been significantly improved in both England and Wales between 2009 and 2011, which was largely attributed to additional training organised by the Food Standards Agency for official veterinarians responsible for routine *post-mortem* meat inspection of cattle carcasses. The submission rates nearly doubled in comparison with the situation up until 2009. In addition, in 2012 and 2013:
 - The submission rates and the contribution of this surveillance component to detection of bTB breakdowns have stabilised. At the same time, there has been a slight decrease in the percentage of submissions that are confirmed.
 - There are differences in both the submission rates and the percentage of confirmed cases between the surveillance areas in England and Wales, with slaughterhouses in the HRA consistently offering higher values, those in the Edge Area being on the increase, and those in the LRA and Wales with a decreasing contribution. Nevertheless, this component of surveillance for bTB still detected 50% of new breakdowns found in 2013 in the LRA and the submission rates for Wales are still considered adequate (some 0.60 submissions per 1,000 animals slaughtered).
 - The CA have commissioned a research initiative to analyse more in detail this component of surveillance for bTB and better ascertain the role of the epidemiological factors that may explain the correlation between the submission/confirmed rates and the evolution of bTB in the various areas of Great Britain.
- During 2013, surveillance for bTB in slaughterhouses identified 15.8% of all new breakdowns in England (90% of them in the HRA) and 20.7% of the OTF-W herds. In Wales, some 8% of the new breakdowns were disclosed in the slaughterhouse, with 65 of the total of 70 found turning out to be OTF-W herds (with 14.7% of all OTF-W herds detected this way). According to representatives of the AHVLA, the lower contribution of slaughterhouse surveillance to the overall detection of new breakdowns in Wales, compared with the HRA in England and even if submission rates are still considered satisfactory, is due to the more intensive use of the SICTT in all herds in Wales since 2010, which has accelerated the detection of infected animals before they are sent to slaughterhouses.
- Comprehensive SOP on implementation of surveillance for bTB in slaughterhouses have been prepared by the Food Standards Agency and are fit-for-purpose to ensure consistency in implementation of this component of the bTB eradication programme. The SOP were available to, and followed by official veterinarians met in the slaughterhouse visited in Wales. The Food Standards Agency has in place an auditing system which regularly verifies the activities of official veterinarians in slaughterhouses; these audits, as seen in the slaughterhouse visited, include verification of adherence to the SOP mentioned above.

- The operations manual of the AHVLA lays down detailed instructions on how to proceed when suspect lesions of bTB are detected by Food Standards Agency staff in the slaughterhouses. The notification immediately initiates the trace-back procedures for the herds of origin and (at the very least) the OTF-S herd status must be in place within 48 hours. The audit team could verify the process in the slaughterhouse visited and check information kept on slaughterhouse cases in the national bTB database.
- Staff of the Food Standards Agency and AHVLA hold quarterly meetings to discuss key performance indicators for the operation of surveillance for bTB in slaughterhouses. On the basis of their outcome, additional follow-up of the activities performed in some areas, or specific slaughterhouses, have been undertaken to better ascertain the reasons behind variations in those indicators.
- Detailed information on surveillance for bTB in slaughterhouses in Great Britain can be found through the following link:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376705/tb-pub-surveport-slahou-09-13-19nov14.pdf

5.1.2.3 *Contribution of molecular epidemiology to the control of bTB*

There is an extensive use of genotyping after bTB confirmation to better understand the geographical dynamics of the disease and contribute to ascertain the probable cause of infection. Spatial and temporal mapping of the range of spread of *M. bovis* genotypes provides a very valuable insight into the transmission patterns of the disease and significantly contributes to shape up prevention and control policies in the various bTB management areas in England and Wales.

- More than 90,000 isolates are kept from confirmed bTB cases found since the year 2000, with 3,500 to 4,000 genotyping tests carried out each year.
- This has contributed to confirm and explain the geographical clustering of most genotypes, and the home-range maps drawn for each of them provide very relevant information to AHVLA staff about the importance of local routes of transmission and their local persistence. 83% of cattle cases and 91% of genotypes isolated from badgers were found to be within their home-range.
- In addition, detection of genotypes out of their home-range immediately triggers additional investigations by AHVLA staff to find out the origin of the infection, which has been specially important in relation to new breakdowns confirmed in the LRA (related to animals moved from home-range areas in the HRA or the Edge Area) and to understand the expansion routes of the disease in the Edge Area from the HRA.

5.1.3 *Management of bTB risks associated to animal movements*

The CA have taken decisive action to tighten up control measures, and gradually eliminating provisions for some derogations and exemptions in relation to animal movements. Thus, they are further mitigating the risks of transmission of the disease in accordance with the recommendations of both the previous FVO report and the TF.

- As described in the approved eradication programme, after acknowledging that they undermined the effectiveness of the bTB eradication programme, the CA both in England and Wales took measures to remove most derogations to the compulsory notification of cattle movements that could be used by farmers that have geographically separated land fragments and/or holdings linked in the Cattle Tracing System (CTS) of the British Cattle

Movement Service (see the previous report for further details on both options).

- Since July 2012 and November 2013 in England and Wales respectively, no applications are granted to constitute new sole occupancy authorities and no new holding can be added to the existing ones.
- The WG and DEFRA have undertaken to initiate in 2015 and 2016 respectively, a two-year transition period to gradually abolish the system of CTS links and sole occupancy authorities throughout Wales and England. In the meantime, in England the CA have already removed all CTS links between holdings which are in different bTB risk areas; i.e. those movements need now to be notified to the CA.
- A number of Pre-MT exemptions that were in place when that testing policy was introduced in 2006 have gradually been phased out. For instance:
 - In England, Pre-MT is mandatory since July 2012 for movements between holdings within a sole occupancy authority that are in different bTB risk areas and, from October 2014, for all movements within any sole occupancy authority in the HRA and the Edge Area. An exception is made to movements between holdings of a sole occupancy authority where all holdings are within a 10 miles radius and are within the same bTB risk area.
 - In Wales, all cattle movements, except some made by holdings that are part of a sole occupancy authority and that take place within a 10 miles area of the main holding (which also has to meet other risk mitigation criteria), need to comply with mandatory Pre-MT since 2013.
- In relation to animal movements from OTF-S and OTF-W herds, the rules were applied as described in the approved eradication programme, in particular:
 - The limited types of movements allowed from restricted herds; i.e. directly to slaughter, to slaughter through a dedicated or 'exempted' market, or to an approved finishing unit (outlet for the fattening and/or finishing clear tested cattle from bTB restricted holding lacking such facilities), can only take place within a 30 days window after the last Pre-MT for the animals concerned.
 - According to data provided by the AHVLA, 95% of these movements occur in the HRA in England and in the high incidence areas of Wales, and the majority of the movements from restricted herds to approved finishing units are done without passing through cattle markets.
 - The CA increased significantly the official controls on approved finishing units, both in relation to the tightening of the rules to be complied with in order to obtain the operation licence and to the performance of more frequent inspections. The audit team verified comprehensive information on the many inspections carried out, including details of the non-compliances found (in some 10% of them), the follow-up carried out in some cases, and the temporal withdrawal of the licences pending the addressing of the non-compliances encountered.
 - The approved finishing units and the market visited complied with the required biosecurity measures and kept good records of their activities.
- Upon checking of a number of cases, the audit team found that, in general, Pre-MT was used in accordance with the rules laid down in the approved eradication programme as explained in detail in the AHVLA operations manual.
 - Specific checks are carried regularly to verify that these rules are respected by

farmers, approved finishing units and animal markets. Some examples were provided of cases of recurrent non-compliances where enforcement measures had been taken by the local authorities. In less serious cases, the AHVLA requires, at the very least, that post-movement testing (Post-MT) is performed on the animals moved.

- The few remaining derogations to the use of Pre-MT (e.g. movements to approved finishing units from OTF herds, movements within the LRA) are also strictly controlled to ensure that they are used in accordance with the rules.
- As a positive side effect to its primary objective of preventing transmission of bTB, Pre-MT disclosed 8% of the total number of bTB breakdowns found in England in 2013 and it contributed to the detection of 45 of the 320 breakdowns found in the Edge Area during the same year.
- Representatives of DEFRA provided data on the voluntary use of Post-MT in England during 2013 (11,591 tests were carried out) and for 2014 (4,105 tests). The majority of them have been private tests requested and paid by farmers incorporating new animals to their herds (mostly in the LRA). A small percentage were requested by the AHVLA because Pre-MT had not been carried out as required. They had recently proposed the incorporation of Post-MT as a compulsory measure for cattle movements from the annual testing areas of England and Wales into the LRA. A final decision on that respect was not taken yet at the time of this audit.

5.1.4 Measures after confirmation of bTB

The CA made significant progress with implementation of the rules included in the eradication programme regarding de-restriction, re-stocking and depopulation in bTB infected herds. Thus, they are contributing to further reduce the risks of transmission, persistence and recurrence of bTB in accordance with recommendations of the previous FVO report and of the TF.

- Data provided by the AHVLA indicates that at least 1,500 applications have been made for partial de-restrictions of herds affected by bTB breakdowns since mid-July 2010 (approximately 10% of all breakdowns) and that 391 were granted that possibility after a veterinary risk assessment. DEFRA representatives stressed that, as agreed with the Commission, this policy was going to be officially discontinued from 1 October 2014 and that no application for partial de-restriction was accepted any more.
- The rules on re-stocking for OTF-S and OTF-W herds were tightened after the last FVO audit. Since January 2013, re-stocking of both types of restricted herds is only permitted under licensing following a veterinary risk assessment carried out by the AHVLA and it is only considered after the first official post-breakdown SICTT and the removal of any reactors identified at that test. These requirements are explained in detail in the AHVLA operations manual in accordance with the approved eradication programme.
 - According to data provided by the AHVLA, from 1 January 2013 to 31 July 2014, 2,260 herds were re-stocked at some point during the breakdown after a post-breakdown test, with a total of 8,575 cattle involved. This represents roughly a 30% of the total number of bTB breakdowns found during the same period. The majority of these herds were located in the HRA and Edge Area of England and in the high incidence areas of Wales.
 - A closer analysis of the data shows that over 60% of these movements involved less than three animals, likely allowed to be moved for welfare reasons (e.g. suckler calves to replace dead ones and/or stock bulls). A further 6% of the moves were large

groups of animals (more than 20), most likely moved to re-stock approved finishing units, which are considered OTF-W herds by definition. The audit team could check a few examples related to the two options just described, for which the requirements laid down in the AHVLA operations manual had been followed adequately. According to DEFRA representatives, the rest are likely to be replacement stock for dairy herds that risk missing their production targets for dairy companies in cases where they have lost several milking cattle as reactors.

- The use of partial or total depopulation of OTF-W herds depends on the outcome of a detailed epidemiological investigation carried out by staff of the AHVLA at herd and local level and on the results of additional bTB testing carried out in the herd. Some examples of their use have been already mentioned in section 5.1.1, mainly in relation to tackling of persistent bTB infection and in order to quickly eliminate all possible risks of infection related to sporadic breakdowns in the LRA.

5.1.5 Engagement of stakeholders and application of biosecurity measures

The audit team found excellent levels of commitment and co-participation in the bTB eradication programme from the most relevant stakeholders, in particular from animal keepers and PVP. This can be attributed both to their own perception of the relevance of their ownership of the eradication programme for it to be successful, and also to the relentless efforts made by the CA, in particular in Wales, to get them fully engaged in the strategic policy consultations and during the implementation of the programme. In that context, a lot of importance has been given by the CA, and increasing attention paid by farmers and PVP, to enhance biosecurity policies at farm level in order to prevent new incursions and recurrence of bTB.

- The CA made significant efforts to communicate and transparently discuss and develop its intentions and plans for the current bTB eradication strategy with all relevant stakeholders. Stakeholders have actively participated in the consultation process before it was finally approved. The CA keep these stakeholders regularly informed about all new developments and measures introduced to the programme; in doing that, they try to provide clear details and explanations for the reasoning behind and the added value that those measures bring to the bTB eradication process.
- Many stakeholders, mainly cattle farmers, have organised themselves around regional bTB eradication boards. Even if their participation in the programme is more formalised in Wales, they also play an increasing role in the local management of the disease in the HRA and the Edge Area in England.
- The CA was in a process of gradually delegating more bTB prevention responsibilities to the farming community; the main example was the introduction of a risk-based animal trading policy. The shape up of this policy is driven by both the CA and representatives of the main stakeholders, such as farmers and animal auctioneers. Despite an initial slower uptake by animal keepers and markets, and because of some constraints to the introduction of this policy related to data protection regulations, the CA both in England and Wales stressed that it will become soon a major pillar of the eradication programme. In particular, they believed that it will contribute to further stop transmission of the disease within and from the HRA.
- There were some initiatives already under way in that respect: development of a specific bTB herd accreditation system- with the support of the cattle industry- whose standards should be ready in early 2015 for the system to be rolled out during the same year. The AHVLA has studied the possibility of introducing a system of bTB herd risk profiling to better inform purchasers of cattle, but their representatives stated that additional analysis

was still needed to confirm the impact of this system in farmers behaviour before it can be rolled out.

- The audit team met both in England and Wales various representatives of the cattle farming community and of the veterinary profession directly involved in the bTB eradication programme.
 - The farming community emphasised the need for the CA to better address the levels of bTB infection in the badger population, but all of them acknowledged the major role they can play in enhancing biosecurity and herd health management measures intended to curtail transmission and persistence of bTB.
 - The audit team observed that farming associations, some regional eradication boards in the HRA and the Edge Area, and the Regional bTB Eradication Delivery Boards in Wales have engaged considerably in providing targeted awareness and training sessions to cattle farmers. In the examples seen all the main principles of bTB prevention and biosecurity measures were explained and practically illustrated with excellent material prepared in collaboration with AHVLA staff. The audit team verified in the farms and the market visited that awareness and consciousness about those aspects of bTB control were adequate and that improvements with regard to biosecurity practices were widespread.
 - Amongst the positive initiatives observed, it is worth highlighting the significant importance given by the stakeholders and by the CA in England and Wales to the engagement of the veterinary profession in providing support to cattle farmers and into the development of specific herd biosecurity plans both in OTF herds and in those with a bTB breakdown. An excellent example was observed in Wales: a pilot project called *Cymorth TB* was carried out from October 2013 to March 2014 with the objective of getting PVP supporting the overall bTB prevention and eradication process in herds with a bTB breakdown. According to representatives of the CA and the stakeholders met, the pilot project was a success and the Welsh Government intends to extend it throughout the country during 2015.
 - Finally, the Welsh Government informed the audit team that they intended to make the emphasis on biosecurity more formal and that to further encourage adherence to it by farmers, it will become one of the basic evaluation criteria to take into account during the evaluation of the amount of compensation to be paid to cattle farmers in the event of a breakdown from 2015 .

5.1.6 *Control of bTB in wildlife*

There is limited robust epidemiological information on the extent and geographical distribution of bTB infection in the badger population. As a consequence, its real impact on the dynamics of the disease in the cattle population cannot be fully ascertained and quantified. The CA still face considerable difficulties to introduce badger population investigation and management policies. Availability of feasible and proven effective alternative control strategies - such as badger vaccination - is still limited. Despite the firm commitment of the CA to find solutions to tackle the bTB situation in wildlife, those constraints still constitute a challenge for the potential effectiveness of the bTB eradication programme.

- Representatives of DEFRA, the AHVLA and the Welsh Government explained that, in general, their options for the large-scale study of the bTB epidemiological situation of the badger population in both England and Wales are still limited. Nevertheless:

- On the basis of old data, mostly from the nineties, and limited information obtained from more recent epidemiological investigations of bTB breakdowns and the study of badgers found dead; DEFRA estimates that one third of badgers are infected with *M. bovis* in the HRA. In addition, they added that all those sources of information provide conclusive evidence that they are a significant reservoir of bTB contributing to cause, directly or indirectly, half of the breakdowns in the HRA.
- Scientific evidence gathered between 1998 and 2005 (mostly through the Randomised Badger Culling Trial) had shown that culling a high percentage of the badger population in an infected area could contribute to the long-term control of bTB. On that basis, DEFRA, with the support of the farming community, has tried to develop since 2010 a specific policy to address bTB infection in the badger population, but its implementation has been challenged legally and politically, and it has encountered strong opposition from the general public.
- Despite the possibility to cull badgers under licence when their involvement in bTB spread has been proven, this is rarely done in the context of bTB breakdowns. Therefore, even in cases where there was reasonable evidence in support of the likely involvement of badgers in the local cycle of transmission of bTB, very little, if any investigation could be carried out to confirm it. According to staff of the AHVLA and representatives of the farming associations met, this often makes more difficult and less effective the tailoring at local level of bTB prevention and control initiatives.
- As explained in the approved eradication programme, after considerable controversy and some delays, a four-year culling trial started in 2013 in two selected areas of two counties part of the HRA. The objective is to cull annually a pre-determined number of badgers in each area in order to reduce the population by 70%. In addition, research carried out in parallel tries to ascertain if this policy could contribute to reduce the incidence of bTB in the cattle population in the areas. Results obtained in 2013 were far from satisfactory, as targets were not achieved, in particular in one of the two counties involved. Representatives of DEFRA explained the audit team that on top of the inherent difficulties of studying an animal species like the badger (nocturnal habits, etc.), there had been considerable interferences from activists opposed to the policy. Nevertheless, representatives of DEFRA informed the audit team that the trial continued in 2014 (the second annual one to be finished on 20 October) and that this trial was going to be independently audited³. They added that depending on the outcome of the analysis of this year's culling, DEFRA Ministers are responsible for taking decisions on the extension of the culling policy to new areas.
- In Wales, since 2010 the CA have put special emphasis, among other measures, on trying to control bTB in wildlife in an extensive high incidence area in the West of the country (the Intensive Action Area). The Welsh Government provided some data in that respect showing that 43 found dead badgers were received by AHVLA for examination between June 2012 and April 2013. Of these, 37 were suitable for sampling and *M. bovis* was isolated from seven of them. In addition, representatives of the Welsh Government informed the audit team that they were going to launch a new country-wide initiative in 2015 to promote notification of badgers found dead so that they can be collected and tested.
- At the same time, high expectations are put on the possible availability of effective and feasible vaccination options for the badger population that could be deployed widely all over

³ In their response to the draft report, the CA provided information on the results of the second year of the trial, which can be found in the following link:

<https://www.gov.uk/government/policies/reducing-bovine-tuberculosis/supporting-pages/badgers-and-bovine-tb>

England and Wales, or at least in the areas with the higher bTB incidence. On top of the extensive research promoted and supported by the CA, there are a number of initiatives underway trying to extend the use of currently available vaccines, which require considerable investment and effort mainly owing to the need to inject the vaccine to each individual animal.

- In England, DEFRA has supported privately run badger vaccination projects since 2012, but grants for that purpose have been largely underutilised. In September 2014, DEFRA launched in cooperation with stakeholders a more targeted initiative to support those projects in parts of the Edge Area next to the HRA where the risk of bTB expansion is considered higher. Vaccinating healthy badgers in this way is intended to help create a buffer zone to help prevent the spread of bTB. The package of support includes a funding award of up to 50% of long-term costs for vaccinating.
- In Wales, efforts have been made since 2012 to carry out badger vaccination in the Intensive Action Area, with some 1,400 animals being vaccinated every year. However, the audit team could not see any technical analysis of the possible impact of that initiative in the evolution of bTB in the area and representatives of the CA and the stakeholders met acknowledged that due to the many control and prevention measures included simultaneously, the individual contribution of badger vaccination to the likely reduction of bTB incidence in the mid- and long-term in the Intensive Action Area will be difficult to ascertain.
- According to representatives of the Welsh Government, a country wide initiative similar to the one in the Edge Area in England has started in 2014 to support for the next five years 50% of the cost of privately run badger vaccination projects. They added that seven co-financed projects were already underway and that they were confident that more will follow suit during 2015.

Conclusions

Measures to prevent and control bTB are implemented by the CA in England and Wales in accordance with the bTB eradication programmes approved by the Commission while, at the same time, they address most of the recommendations included both in the previous FVO report of 2011 and in the report issued in 2012 by the TF after their last visit to the UK.

The CA have demonstrated that their new eradication strategies and the current control policies are not only co-owned by the most relevant stakeholders, but are also sufficiently flexible to incorporate and adapt new measures to the needs of the various local epidemiological situations, so that bTB transmission can be further curtailed and bTB infection more effectively eliminated.

While good progress has been made at addressing all the factors that modulate the acceleration of bTB eradication, further steps forward to effectively control the disease in the high incidence areas could still be undermined by:

- The current uncertainty in relation to the extent and geographical distribution of infection in wildlife, and by the difficulties the CA encounter to select and implement effective policy options, such as culling and vaccination of badgers, to address that problem.
- The risks associated to a very mobile cattle population, including animals from bTB restricted herds, which, as demonstrated by the cases detected with Pre-MT and by the non-indigenous breakdowns found in the LRA, can still contribute to increase the level of environmental infection with *M. bovis* and facilitate the transmission of bTB.

5.2 VERIFICATION OF EFFECTIVENESS OF THE IMPLEMENTATION

Legal requirements

Articles 4(6) and 8(3) of Regulation (EC) No 882/2004.

Findings

The AHVLA, and in their areas of responsibility, the Food Standards Agency, have gradually increased audit and verification activities on the various components of the bTB eradication programme. In general, the results of the various initiatives undertaken provide additional evidence of the effectiveness of the majority of the measures implemented in the context of the bTB eradication programme.

- There is a regular monitoring of the spatio-temporal evolution of epidemiological indicators in the various bTB management areas, such as the incidence of OTF-S and OTF-W herds (e.g. using annual rolling averages, comparing monthly rates with previous years', etc.), the (local or regional) frequency of persistent and recurrent breakdowns, the percentage of breakdowns detected as a result of contiguous herds and radial testing (e.g. analysing if that evolution can be consecutive to changes in policy), etc.
 - The regular analysis of the outputs of that monitoring contributes to confirm and sometimes explain a positive trend, to determine if control of well-known risk factors (e.g. Pre-MT from higher risk areas, introduction of specific biosecurity measures to prevent exposure to wildlife) has a positive impact on some of those indicators in a particular geographical area, and it has functioned in some cases as an early warning system for the necessary adjustment of the measures in place (e.g. expansion of the disease in some counties of the Edge Area from the HRA).
- Besides the verification activities already mentioned (on bTB testing and surveillance for in slaughterhouses), since 2010 staff of the AHVLA monitors a other key performance indicators related to implementation of measures incorporated in the eradication programme and to the evolution of outcome targets in the context of their delivery responsibilities to the other CA. The AHVLA ensures that those targets are achieved country-wide and their monitoring facilitates the evaluation of performance of the individual AHVLA offices in relation to all the indicators.
 - Some of the indicators relate to the timely implementation of measures included in the operations manual of the AHVLA for control and management of bTB in the context of a breakdown (e.g. suspension/withdrawal of the OTF status, animal tracing, removal of reactors), other to compliance of other stakeholders with general requirements of the programme, such as timely performance of the SICTT or of the Pre-MT of all animals moving from the HRA.
 - Statistics provided by staff of the AHVLA on the evolution of those indicators show that there has been a gradual improvement in recent years, significant in some cases (e.g. removal of reactors, checks on PVP), and that targets are clearly achieved for all key indicators that have a more direct impact on reducing bTB transmission from infected and high risk herds.
- The AHVLA is developing a new tool within their information management system and quality assurance programme that includes, amongst other components, critical control points, reporting mechanisms and quality metrics specifically adapted to monitor in the near future the delivery of the bTB eradication programme.

Conclusions

The increasing use of adequate verification activities by all CA involved in management of official bTB controls in the context of the approved eradication programme provides for the verification of effective implementation required by Articles 4(6) and 8(3) of Regulation (EC) No 882/2004.

6 OVERALL CONCLUSIONS

The CA of England and Wales have taken significant steps forward in relation to the strategic planning and incorporation of new well-informed measures to the bTB eradication programme, which is being implemented in accordance with the one approved by the Commission. In doing that, the CA have taken into account most of the recommendations included both in the previous FVO report of 2011 and in the report issued in 2012 by the TF after their last visit to the UK.

Despite that considerable effort, progress in tackling bTB spread is still slow in areas with a high incidence of the disease in England (South West and West Midlands) and Wales (various areas in the South and the North East), and the CA still face important challenges inherent to the bTB eradication programme in those countries, in particular:

- The current uncertainty in relation to the extent and geographical distribution of infection in wildlife, and the sociological and technical constraints hindering the decision-making process to select effective policy options to address that problem, such as culling and vaccination of badgers.
- The complexity of animal trade networks and the risks associated to a very mobile cattle population, including considerable involvement of animals from bTB restricted herds. Even though those risks are increasingly mitigated with reinforced control measures and the use of Pre-MT, evidence still shows that they can contribute to increase the level of environmental infection with *M. bovis* and facilitate the transmission of bTB.

In the context of the new strategies for eradication of bTB in England and Wales, the UK is submitting a new multi-annual eradication programme to the Commission for the period 2015-2020, which aims at consolidating and reinforcing the implementation of the measures already in place. Therefore, the effectiveness in the mid- and long-term of all those measures, which will likely be reinforced with expected improvements in relation to the challenges mentioned above, will have to be further evaluated in the near future in order to confirm that they actually materialise in a progressive reduction in the annual levels of bTB herd incidence throughout England and Wales.

7 CLOSING MEETING

A closing meeting was held on 26 September 2014 with representatives of the CCA and other CA involved in official controls on bTB. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team. The representatives of the CA 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 audit team did not consider necessary to issue recommendation to the authorities in United Kingdom.

N°.	Recommendation
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The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2014-7055

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Dir. 77/391/EEC	OJ L 145, 13.6.1977, p. 44-47	Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle
Dir. 78/52/EEC	OJ L 15, 19.1.1978, p. 34-41	Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Dec. 2008/341/EC	OJ L 115, 29.4.2008, p. 44-46	2008/341/EC: Commission Decision of 25 April 2008 laying down Community criteria for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dec. 2012/761/EU	OJ L336, 8.12.2012, p.83-93	2012/761/EU: Commission Implementing Decision of 30 November 2012 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 2013

Legal Reference	Official Journal	Title
Dec. 2013/722/EU	OJ L 328, 7.12.2013, p. 101-117	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