



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Directorate F - Food and Veterinary Office

Ares(2012)259064

DG(SANCO) 2011-6057 - MR FINAL

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
THE UNITED KINGDOM
FROM 05 TO 16 SEPTEMBER 2011
IN ORDER TO EVALUATE THE OPERATION OF THE BOVINE TUBERCULOSIS
ERADICATION PROGRAMME

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

Executive Summary

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

Official controls related to bovine tuberculosis, and the operation of the programme have been given a high priority by Government (it represents over 40% of the DEFRA animal health budget). Nonetheless, despite efforts to date, the disease situation overall in GB is at best static and may be deteriorating in England.

While the approved eradication programme is broadly applied as described, the audit identified a number of potential weaknesses. These include numerous movement derogations, pre-movement test exemptions (including extended time intervals between testing and movement), the operation of "linked" holdings over large geographical areas, incomplete herd testing and the operation of specialist units under restriction, which lacked the necessary bio-security arrangements. Furthermore, despite efforts by the CA – some of their key targets could not be met in relation to the removal of reactors from breakdown herds and the instigation of epidemiological enquiries.

There is a fragmented system of controls, involving a number of responsible bodies. This combined with a lack of co-ordination (particularly with Local Authorities) makes it difficult to ensure that basic practices to prevent infection/spread of disease (such as effective cleaning and disinfection of vehicles and markets) are carried out in a satisfactory way.

Many of the weaknesses have been identified by the CA, and enhanced controls have been incorporated into a pilot area (intensive action area in Wales) where the CA has removed movement test exemptions, "broken" links, increased test frequencies and sought to improve biosecurity by formal education of animal keepers. The CA will assess the lessons learned from this area, to determine whether the measures could be applied more widely in Wales and England.

Measures to prevent re-infection from other sources focus on the risk presented by wildlife (badgers). The CA maintains that the delay in implementing the proposed wildlife controls (i.e. a managed cull of badgers), which is a significant element of the approved eradication programme, remains the major obstacle to progress.

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

Table of Contents

1	<u>INTRODUCTION</u>	1
2	<u>OBJECTIVES</u>	1
3	<u>LEGAL BASIS</u>	1
4	<u>BACKGROUND</u>	2
4.1	<u>BOVINE TUBERCULOSIS ERADICATION</u>	2
4.2	<u>STATISTICAL DATA</u>	2
5	<u>FINDINGS AND CONCLUSIONS</u>	3
5.1	<u>COMPETENT AUTHORITIES</u>	3
5.1.1	<u>REQUIREMENTS</u>	3
5.1.2	<u>FINDINGS</u>	3
5.1.3	<u>CONCLUSIONS</u>	5
5.2	<u>HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND MOVEMENT CONTROL</u>	5
5.2.1	<u>REQUIREMENTS</u>	5
5.2.2	<u>FINDINGS</u>	5
5.2.3	<u>CONCLUSIONS</u>	8
5.3	<u>ROUTINE SURVEILLANCE</u>	9
5.3.1	<u>REQUIREMENTS</u>	9
5.3.2	<u>FINDINGS</u>	9
5.3.3	<u>CONCLUSIONS</u>	11
5.4	<u>MEASURES FOLLOWING IDENTIFICATION OF SUSPECT OR INFECTED ANIMALS</u>	12
5.4.1	<u>REQUIREMENTS</u>	12
5.4.2	<u>FINDINGS</u>	13
5.4.3	<u>CONCLUSIONS</u>	20
6	<u>OVERALL CONCLUSIONS</u>	21
7	<u>CLOSING MEETING</u>	21
8	<u>RECOMMENDATIONS</u>	22
	<u>ANNEX 1 - LEGAL REFERENCES</u>	24

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AHVLA	Animal Health Veterinary Laboratories Agency: executive agency working on behalf of DEFRA, Scottish Government and Welsh Government
AFU	Approved Finishing Unit
AQU	Approved Quarantine Unit
BCMS	British Cattle Movement Service
(C)CA	(Central) Competent Authority
CPH	County Parish Holding – a unique holding number issued by the RPA
CTS	Cattle Tracing System
DEFRA	Department for Environment, Food and Rural Affairs
DNA	Deoxyribonucleic acid
EC/EEC	European Community/European Economic Community
EFU	Exempt Finishing Unit – established to provide beef producers a route to finish animals without the need for a pre movement test.
EU	European Union
FBO	Food Business Operator
FMD	Foot-and-Mouth Disease
FSA	Food Standards Agency
FVO	Food and Veterinary Office
g-IFN	g- interferon - (measured in a diagnostic blood test for bovine TB)
GB	Great Britain
ISO	International Standards Organisation
LA	Local Authority
MS	Member State
OIE	World Organisation for Animal Health
OTF(S)(W)	Officially Tuberculosis Free (Suspended) (Withdrawn)
OV	Official Veterinarian
PrMT	Pre Movement Test
RPA	Rural Payments Agency
SANCO	Directorate General for Health and Consumers
SIT	Short Interval Test
SICCT	Single Intradermal Comparative Cervical Tuberculin test

SOA	Sole Occupancy Authority - allowing the movement of FMD susceptible livestock within and between grazing and premises under single ownership or rental without triggering a 6-day movement standstill. A SOA is recognised as a single farming unit even where more than one CPH numbers are involved.
TB	Tuberculosis
UK	United Kingdom
V/NVL	Visible/Non Visible Lesion, on carcasses of TB reactor animals.
WG	Welsh Government

1 INTRODUCTION

This audit took place in the United Kingdom (UK) from 5 to 16 September 2011, as part of the Food and Veterinary Office (FVO)'s planned programme.

The audit team comprised 2 inspectors from the FVO and an observer from SANCO G. The team was accompanied by a representative of the Central Competent Authority (CCA).

2 OBJECTIVES

The objective of the audit was to assess the application of the European Union (EU) approved and co-funded programme for eradication of bovine tuberculosis (TB), and compliance with EU rules related to this disease in England and Wales.

In 2009 Scotland was recognised as an Officially TB-Free (OTF) region of the UK, reflecting the low and stable incidence of bovine TB in Scottish herds.

A separate plan has been submitted in respect of Northern Ireland.

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

Central competent authority	2	Welsh Government (WG) Office & Department for Environment, Food and Rural Affairs (DEFRA)
Regional offices	3	Worcester, Exeter, & Carmathen (Animal Health and Veterinary Laboratory Agency - AHVLA)
Laboratories	1	AHVLA Regional Laboratory
Holdings	7	5 Farms, including an Approved Quarantine Unit (AQU) and an Approved Finishing Unit (AFU).
Private veterinary practice	2	
Markets and assembly centres	1	
Milk establishments	1	
Slaughterhouses	1	

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;
- Article 10 of Council Directive 77/391/EEC, introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle;
- Article 27(9) of Council Decision 2009/470/EC on expenditure in the veterinary field.
- The EU legislation relevant to this audit is listed in the Annex. In each case, the reference is to the latest amended version.

4 BACKGROUND

4.1 BOVINE TUBERCULOSIS ERADICATION

Bovine TB is one of the three diseases for which Council Directive 64/432/EEC (on animal health problems affecting intra-Union trade in bovine animals and swine) harmonises surveillance and control measures to be applied by all Member States (MS). Council Directive 77/391/EEC requires MSs in which cattle populations are infected with bovine TB to draw up plans for accelerating its eradication. The same Directive also foresees the possibility of EU financial contribution.

Council Directive 78/52/EEC establishes the minimum criteria to be applied by the national eradication plans in order to qualify for 'Community' financial contribution. Plans for the accelerated eradication of bovine TB in the UK have been approved for the years 2010 and 2011 by Commission Decisions 2009/883/EC and 2010/712/EU respectively and a financial contribution from the Community is foreseen, up to a maximum of 10 million Euros for 2010, and 23 million Euros in 2011. Following the amendment of Commission Decision 2009/883/EC by Commission Decision 2010/732/EU¹, further funding was allocated to the UK, increasing the amount for 2010 to 27 million Euros.

The last FVO mission on bovine TB in the UK was performed in 2004 (DG(SANCO) 2004-7251).

Government and Ministers have given the TB eradication programme a high priority (in Wales it was the only animal health issue cited in the Government manifesto). It represents more than 40% of the total animal health budget and in 2008/9, £84 million was spent on TB controls in England alone. While acknowledging that it will take a number of years for any measures to have a significant impact, they are committed to using a package of measures, which include wildlife controls to eradicate the disease in the long term.

4.2 STATISTICAL DATA

The registered population of cattle in GB is around 8.5 million cattle and calves on 81,000 holdings (data for 2010: source DEFRA Livestock team).

The trend of TB cattle incidence in England and Wales (South West and West Midlands of England and South/Mid-Wales) has been rising for 25 years, which has been accompanied by a steady increase in the number of new TB herd breakdowns (particularly since the disruption caused by the Foot-and-Mouth (FMD) epidemic in 2001).

In general terms, after a peak in 2008 the annual herd and animal incidence of bovine TB (and the total proportion of herds with OTF status suspended or withdrawn during the year) started to fall in 2009, in both England and Wales. That declining trend continued in Wales throughout 2010, whereas in England it stabilised towards the second half of the year but it appears that the disease situation may be worsening again in England.

National Statistics on the incidence of TB in cattle in Great Britain to the end of June 2011 were released on 14 September 2011, according to the arrangements approved by the UK Statistics Authority. In brief, the provisional statistics pointed to a 3.8% increase in the number of new TB incidents in January - June 2011 compared to the same period in 2010. In this reporting period, approximately 7% of herds were under restriction because of a TB incident. Detailed statistics (by country and county) are available at:

<http://www.defra.gov.uk/statistics/foodfarm/landuselivestock/cattletb/national/>

DEFRA is to replace the two current sets of monthly statistics with a single consolidated notice.

¹ OJ No. L 315, 01.12.2010, p. 43

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

5.1.1 Requirements

Regulation (EC) No 882/2004 of the Parliament and the Council lays down the general rules for official controls to ensure the verification of compliance with feed and food law, including animal health and welfare requirements. Official controls must be carried out regularly on a risk basis, with appropriate frequency. The CA designated by the MS must have legal power to carry out official controls, and have sufficient number of suitably qualified staff. CA shall carry out official controls in accordance with documented procedures, with information instructions and guidelines for staff. They shall have procedures in place to verify the effectiveness of official controls. They shall have contingency plans in place in the event of an emergency. They shall ensure impartiality, quality and consistency of official controls at all levels. Efficient and effective coordination and cooperation shall be ensured between different units. CA shall have transparent audits carried out, and take appropriate measures in the light of their results. Laboratories for analysis of samples taken during official controls must operate and be accredited in accordance with the ISO 17025 standard. The MS shall draw up an integrated multi-annual national control plan, promoting an integrated approach to official controls. In case of non-compliance, actions shall be taken to ensure that the situation is corrected.

5.1.2 Findings

The organisation of the CA is described in the multi-annual national control plan². DEFRA is the central competent authority for TB in the UK. However, the control, monitoring and eradication of bovine TB, is the responsibility of national Devolved Administrations in the UK, and for this audit in England and Wales, included DEFRA and the WG respectively.

There is a close liaison between the devolved structures at the UK level through the UK TB liaison Group to ensure a consistency of approach. The GB Strategic Framework (2005) provides a further structure for the co-ordination of the respective programmes.

However, England, Scotland, Wales and Northern Ireland each have legislative responsibility for their areas and can implement policies to reflect their own circumstances. Thus, while there are certain common elements within the various Orders made under sections 32 and 34 of the Animal Health Act 1981 (notification of disease, compulsory testing, valuation, and restriction of the movement of affected herds), significant differences exist.

In relation to the implementation of the TB eradication programme there are a number of organisations involved in the operation/delivery of the programme in England and Wales. These include AHVLA – GB-wide, Rural Payments Agency (RPA) incorporating British Cattle Movement Service (BCMS) /Rural Payments Division in Wales, the Food Standards Agency (FSA) – GB-wide (incorporating the former Meat Hygiene Service), Local Authorities (LAs) and the Department of Health incorporating the Health Protection Agency.

The AHVLA is the executive agency primarily responsible for implementing DEFRA and WG policy in England and Wales. They undertake routine surveillance and testing and are also responsible for administration of TB restrictions and (in England) compensation payments. AHVLA

² http://ec.europa.eu/food/fvo/msm_en.cfm?co_id=GB

have a Service Level Agreement with the FSA to undertake TB sampling and surveillance in slaughterhouses in England, Scotland and Wales for all red meat species. Enforcement falls primarily to LAs, with animal disease control policies (including TB) enforced through Trading Standards Departments, and food safety and hygiene legislation (e.g. dairy products) enforced through Environmental Health Departments. The other significant element of TB controls (animal identification) falls both to LAs, the RPA (also providing the British Cattle Movement Service) and the Rural Payments Division (Wales).

Information is recorded on a number of IT systems (e.g. VetNet) developed for AHVLA. Reports are regularly extracted from data supplied providing results for both national and local requirements. Operational reports are produced on a monthly basis for a range of targets. A quarterly Performance report is produced detailing the various targets which is reported to Food and Farming Group in DEFRA and to the Devolved Administrations.

AHVLA publish extensive general guidance on their website to assist farmers and officials: <http://animalhealth.defra.gov.uk/about/publications/advice-guidance/bovine-tb.html>

Laboratories within the AHVLA network are accredited ISO 17025 and the scope of accreditation covers *M. bovis* culture and genotyping (spoligotyping).

Observations:

- The Tuberculosis (Wales) Order 2010 includes additional requirements to those applicable in England under the Tuberculosis (England) Order 2007, and includes Veterinary Improvement Notices (giving AHVLA in Wales the legal authority to issue farmers with a notice to take certain actions to reduce the risk of spreading TB either within their own herd or to others) and compensation reductions under specific circumstances. The Wales TB Order (2011) introduced further controls on non bovines.
- Extensive documented procedures were available in the form of manuals for AHVLA, the FSA and Official Veterinarian (OVs - approved for TB testing).
- Co-operation exists between the AHVLA (through their "regulatory hub") and the LAs, with routine contact via automated notifications sent from the AHVLA "print desk". These notifications are not routinely acted upon by the LA (i.e. The LA may or may not contact a dairy farmer placed under TB restrictions to check that he has notified his first milk buyer).
- LAs are not systematically updating their central enforcement database (AMES - Animal Health and Welfare Management and Enforcement System) citing a reduction in direct funding and the end of Framework Agreements in March 2011 as contributory factors.
- There are revised funding arrangements from April 2011, and LAs may determine how spending is allocated within their animal health programme. However, this is against a background of overall budget reductions from Central Government following the Comprehensive Spending Review in 2010.
- AHVLA is seeking to reduce the reliance on a number of old "unstable" IT systems through the development and implementation of new software (linking the main bodies responsible for TB controls, including the laboratory network). In relation to TB controls, the roll out of the new TB module for the AHVLA system "SAM" release 6 scheduled for 5 September 2011 was postponed. During the audit, it was noted that case management was impeded due to the incomplete/delayed access to information during this transitional period. Some case officers maintained paper files for important dossiers.
- At present culture for *M. bovis* is limited to 6 weeks which is not in line with the OIE Terrestrial Manual 2009.

5.1.3 Conclusions

Official controls related to bovine TB, are in general managed according to the principles of Regulation (EC) No 882/2004 while taking into account the differing legislation and policy commitments in the devolved administrations (e.g. Wales has sought to take additional measures to England to "bear down" on the disease).

Enforcement of animal disease control policies is fragmented across a number of bodies and weaknesses have been identified – particularly in relation to co-ordination between AHVLA and the LAs.

The delivery of the programme is being undermined at present by resource constraints (particularly in LAs), the seriousness of the disease situation and inefficiencies caused by the delayed roll out of the new TB software.

The laboratories analysing samples taken during TB official controls are formally accredited, albeit that one element of *M. bovis* isolation is not in line with the OIE diagnostic manual.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND MOVEMENT CONTROL

5.2.1 Requirements

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

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

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

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

5.2.2 Findings

5.2.2.1 Holding registration

Registration of holdings was part of the scope of another FVO mission which took place shortly before this one (DG(SANCO)/2011- 6023). In brief, it was concluded that a system was in place covering the registration of bovine holdings.

The keeper (the person responsible for cattle but not necessarily the owner) must register their holding with BCMS using a County Parish Holding (CPH) number (allocated by the RPA) and a herd mark number (allocated by AHVLA); they must keep their holding details up-to-date. The CPH number is, in principle, a meaningful identifier of animal location.

Observations:

- At present, a complex arrangement may exist whereby a large farming enterprise can be issued a CPH number covering a number of other farms and parcels of land (either rented or owned). The outlying farms may have their own CPH number, which can be active or "dormant" on the central Cattle Tracing System (CTS) database.
- The "home" farm/holding, may extend beyond a radius of 10 miles and lie in (a number) of different parishes (the administrative division routinely used for establishing TB testing frequency).
- There may be one central herd register at the "home" farm covering all premises/herds, or separate registers for each premises/herd. A CPH number can be permanent or temporary.
- Holdings may comprise a number of premises/unit/herd types and include exempt finishing units (EFU), AFUs, AQUs, dealers herds, heifer rearers, bull hirers and city farms. Specific rules apply to movements between some of these premises/herds which are described in the relevant section of the report.
- Holdings may be linked together under a "Sole Occupancy Authority (SOA)" or by a British Cattle Movement Service (BCMS)/CTS - link. A SOA allows owners or keepers to move animals between different premises under the same management and control without triggering a "standstill" or the need for a pre-movement test (PrMT). A linked holding is an administrative arrangement with BCMS, which enables a farmer to move cattle to and from specified holdings under his management without the need to notify the movement to them.
- A "Separate premises" may be established within a holding under restriction subject to CA approval and a risk assessment (to allow movement of animals for management reasons or allow the lifting of restrictions on part of a premises). Thus restrictions may be limited to part of a holding under the same CPH number.
- One registered holding visited had opted to divide the farm into 3 premises (the main farm and two AQUs) each with its own CPH number. These premises were collocated and the electronic herd register did not discriminate between the premises, thus making it impossible to see movements between them.

5.2.2.2 Animal identification

The identification of bovine animals was also part of the scope of the FVO mission DG(SANCO)/2011- 6023. In brief, it concluded that bovine animals are identified and registered with double ear-tags and a passport, and registered in a herd register on farm, and in a national database.

Notification of birth of bovine animals to the CA may be made within a maximum period of 27 days of the event occurring (tagged within 20 days and notification within 7 days after tagging). For dairy cattle, at least one of the ears must be fitted within 36 hours of birth.

LA surveys provided evidence that some cattle farmers may have been illegally swapping cattle ear tags (i.e. retaining TB positive animals in their herds and sending less productive animals to

slaughter in their place). From mid-April 2011 cattle testing positive for TB were to be tagged by the OV during herd TB testing a sample of DNA retained by AHVLA. These samples are to be cross-checked at random, or where fraud is suspected, against the DNA of animals sent to slaughter.

Observations:

- DNA tagging was observed on-the-spot (during a TB test reading) with the collection of sample in tamper-proof bags as described by the AHVLA.
- During a slaughterhouse visit it was noted that not all reactors had been tagged in this way as foreseen.
- Current AHVLA instructions do not require a permanent mark during test reading, where tags are missing. It is adequate to provide a temporary mark (by clipping or indelible marker) at the time of testing, and the owner must inform the CA when the animal is correctly marked³.

5.2.2.3 Movement controls

Cattle must be moved together with their passport, or with a special permit from the CA. Movements of cattle are registered in the national database unless there is a BCMS-link which enable farmers to move cattle to and from specified holdings without the need to notify the movement to BCMS (albeit movements should be recorded within 36 hours in the herd register). Nor do movements need registering for cattle moving between holdings under a “home” farm or “umbrella” CPH. Markets have an on-line access to the database, in which they record movements in and out. In 2010 there were 4,862,185 reported movements in England and 773,560 in Wales (the actual number of movements is approximately half this number as keepers must report movements on and off their holding).

Observations:

- At the market visited it was explained that the operator could help farmers by recording all movements (i.e. off farm, on/off market and on to the farm of destination).
- For the sale selected, it was found that all the data linked to that day had not been uploaded onto CTS. This was rectified by the LA (trading standards) officer before the end of the audit.
- Many cattle movements are paper based (i.e. only recorded in a farm register).
- In the AFU visited, many of the calf passports were incomplete (date of movement onto the farm had not been recorded). See also section 5.4.2.10 on the movement conditions for stocking an AFU.

5.2.2.4 Pre and post movement TB testing

Pre-movement testing regimes in England and Wales are broadly the same, with both requiring that cattle of 42 days of age and over moving from 1- and 2-yearly tested herds be tested clear for TB (using the single intradermal comparative cervical skin test (SICCT)) within the 60 days prior to movement to another herd. The Government-funded routine TB herd tests can be used as a PrMT if carried out up to 60 days prior to the movement, otherwise the farmer has to make arrangements

³ In their response to the draft report, the CA of UK stressed that at reading, all reactors are identified with the DNA plastic tag.

with his own OV (although the Government pays for the cost of the tuberculin used). Post movement tests and isolation of animals is obligatory if the PrMT requirement is not respected.

A range of PrMT exemptions exists and these include: cattle moving direct to slaughter or to slaughter markets, cattle moving directly to approved (exempted) finishing units or markets for animals not pre-movement tested, cattle moving directly to approved TB finishing units for cattle under movement restrictions for TB or approved TB collection centres, cattle moving from markets, cattle movements within premises sharing rights of common and cattle moving between holdings within the same SOA.

The responsibility for monitoring PrMT is held by AHVLA with a dedicated Pre-Movement Testing Monitoring Unit established in Gloucester in January 2007. This unit uses the BCMS CTS data and Data Warehouse data from Vetnet to assess compliance on a monthly basis.

Between 1 March 2006 and 30 June 2010, 1970 reactors were identified in 1133 herds from dedicated PrMT in England and Wales, and a further 3086 inconclusive reactors were also identified.

Observations

- A number of changes to the PrMT exemptions in Wales were introduced by the Tuberculosis (Wales) Order 2010. This legislation removed two exemptions, and include cattle moving off premises within 30 days of arrival and cattle moving to housed shows or ones that last more than 24 hours. Further changes can be done administratively and would not require legislative amendments to the 2010 Order⁴.
- The Pre-Movement Testing Monitoring Unit works 2 months in arrears to give time for information to be uploaded into the 2 different systems, and does not allow an immediate intervention. Furthermore it matches movement numbers and not individual animals.
- Proof of PrMT (i.e. obligation to carry test certification or a passport record) is not required. However, a TB PrMT Passport Sticker Project in North Wales has introduced a system whereby a sticker (completed by the farmer) is placed in the passport indicating the date of the PrMT. A survey found that the information recorded by the animal keepers was accurate.
- The CA pointed out the fact that only positive test results are recorded on the Vetnet electronic database and this limits the analyses that can be performed. Vetnet cannot record a PrMT and a Routine or Whole Herd Test for a single premises on the same day.

5.2.3 Conclusions

A system is in place covering the registration of bovine holdings, as required by Article 14.3.C of Council Directive 64/432/EEC. However, one or more herds may be managed under the same CPH number and complex links are possible, potentially extending the effective range of the "home" premises well beyond a 10 mile radius.

A new system of animal identification for reactor cattle is largely in place.

While movements between holdings are recorded in the central database as required by Article 7(1) of Regulation (EC) No 1760/2000, there are derogations allowing "paper based" farm records of animal movements between certain "linked" premises.

Incomplete passport (movement) data on one AFU, made it difficult to reliably ascertain how long the calves had been present on the holding.

⁴ In their response to the draft report, the CA of UK indicated that England is planning to abolish exemptions in 2012.

The current system of PrMT for “non-restricted” holdings (see section 5.4.2.4 for “restricted” holdings) has numerous exemptions (albeit fewer in Wales) and allows testing more than 30 days in advance of movement. This is not in line with point I(1)(c) of Annex A to Directive 64/432/EEC (for herds to remain OTF, animals introduced over 6 weeks of age, should be tested within 30 days of movement (when such PrMT is required)). Furthermore, compliance checks by the CA lack precision and are retrospective (preventing real time interventions).

5.3 ROUTINE SURVEILLANCE

5.3.1 Requirements

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

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

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

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

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

According to Article 12 of Directive 64/432/EEC, transporters are required to keep registers of their activities, including details of places, dates and time of collection and delivery, and disinfection, for transports of more than 65 km.

5.3.2 Findings

5.3.2.1 Compulsory testing

The primary screening test within the routine surveillance programme for bovine TB in GB is the SICCT, using 0.1 ml of bovine (3,000 international units (IU)/ml) and avian (2,500 IU/ml) Purified Protein Derivative tuberculins, manufactured under a 3 year supply contract awarded in December 2009. The gamma interferon (g-IFN) test is used in specific situations as an ancillary parallel test to enhance sensitivity.

The herd owner is responsible for arranging scheduled tests under the routine surveillance programme, which will be paid for by government. AHVLA give herd owners advance notice of the 2-3 month period in which the test must be completed by their nominated OV practice. Test notification letters are sent centrally from AHVLA to ensure consistency of notification. OVs will also be notified by AHVLA of the test due dates for their client's herds. From February 2005, there has been a requirement for immediate suspension of OTF status in all herds with an overdue TB test (zero tolerance).

All herds in England have a testing frequency of either 1,2,3 or 4 years based on TB incidence in

their area, while herds in Wales continue to be subject to annual testing in 2011.

A core area across the whole of South West and the West Midlands of England is placed on annual TB testing, since this represents the TB endemic area and risk in England broadly associated with a local wildlife reservoir. No pockets of less frequent routine testing remain within this core annual testing area. The northern and eastern edges of this endemic core are separated from the low TB incidence and risk regions of England by a continuous "buffer" area of 2 yearly testing interval (established in 2010, and expanded in 2011), so that the core annual and 4 yearly testing areas do not adjoin. In addition, a small area in the South East of England along the East Sussex coast, which has sustained a low but endemic TB incidence linked to badger infection, has annual testing with a buffer zone.

Observations:

- AHVLA Veterinary Officers and Lay Testers are approved to undertake SICCT following training and are to receive field audits to ensure satisfactory standards are maintained.
- Private Official Veterinarians (OVs) working for AHVLA are also appointed and paid under the conditions of a memorandum of conditions of appointment (dated 1994) between the British Veterinary Association and DEFRA. However, they have not been subject to an official auditing programme.
- A one retest policy on inconclusive reactors was introduced on 1 March 2009 in Wales, and on 1 January 2010 in England.
- According to data provided by the CA, AHVLA had taken measures in GB for 93.3% of overdue tests for the year to date (target 94.5%) within 90 days of the test becoming overdue. Herd restrictions are imposed and OTF status is suspended by AHVLA if a test becomes overdue. At the end of May 2011, there were 3,308 overdue TB tests in England, and 555 in Wales⁵.
- The CA is developing risk based testing intervals and a "spatial unit" to replace parish testing intervals by 2013.
- At present, routine test results are not routinely provided to the keeper (although foreseen under point 10(1) of the Tuberculosis (England) Order 2007), unless it is a PrMT arranged by the keeper.
- In farms within 2 and 3 year test interval parishes a Routine Herd Test is performed, rather than a Whole Herd Test. In these cases not all animals over 42 days of age are tested (e.g. exclusion of home bred non breeding females and any non breeding bulls).
- The CA does not at present test the potency of the tuberculin, however, a batch release protocol is reviewed by the Veterinary Medicines Directorate and a certificate of approval for release onto the UK market is issued.

5.3.2.2 Intra union trade

All cattle imported into GB from non-OTF EU MSs and other parts of the UK (Northern Ireland, Isle of Man and Channel Islands) must comply with the TB certification conditions set out in Council Directive 64/432/EEC (as amended). Cattle from Northern Ireland and the Isle of Man are subject to PrMT within 30 days of departure using the SICCT. Additionally, post movement skin testing of cattle from Northern Ireland, Ireland and Isle of Man and any non OTF MS is conducted

⁵ In their response to the draft report, the CA of UK indicated that these data include tests carried out but not reported on time.

60 to 120 days after arrival in GB, unless destined for direct slaughter.

Observations:

- Post-movement tests are not required for animals moving within/between England and Wales, even if coming from "high risk" areas with endemic disease.

5.3.2.3 Examination in slaughterhouses

The Food Standards Agency (FSA) OV needs to be present at slaughterhouses processing cattle throughout ante- and post-mortem inspection. Meat Hygiene Inspectors may carry out post-mortem checks and apply the health mark, subject to regular monitoring by the OV.

AHVLA regard slaughterhouse inspection of cattle from unrestricted herds is a key additional tool in the GB surveillance strategy for TB. In 2010, a total of 1,012 tuberculous carcasses were notified to AHVLA by meat inspectors, out of approximately 2.6 million cattle slaughtered in the country. These slaughterhouse cases now account for approximately 22% of all new confirmed TB breakdowns disclosed in GB during the year.

Where suspect lesions are identified in cattle from non-restricted herds, AHVLA is to trace and issue movement restrictions on the herd of origin within 2 working days of receipt of notification from the FSA, and the OTF status is suspended pending the results from the laboratory.

Observations:

- In March 2011 the FSA updated the manual of official controls on TB and provided training.
- Data from the CA report that the number of suspect cases of TB in England and Wales initially identified during routine meat inspection of cattle carcasses in abattoirs ("slaughterhouse cases") increased from 312 in January-April 2010 to 495 in the same period in 2011 (462 in England, 33 in Wales).
- Post mortem inspection in relation to TB was carried out in compliance with the general requirements of Section I, Chapter II and the specific requirements of Section IV of Annex I to Regulation (EC) No 854/2004.
- The inspection point for abdominal viscera (green offal) in the slaughterhouse visited was poorly located and had inadequate lighting for inspection purposes.
- In a new breakdown the CA culture up to 3 visible lesions (VL), up to 10 non visible lesions (NVL) and all atypical lesions. In an ongoing breakdown it is generally only atypical lesions that are cultured. Approximately 90% of VLs are due to *M. bovis*, whereas there is an isolation rate of approximately 5% in NVLs.

5.3.3 Conclusions

Routine surveillance is performed according to the eradication plan, is broadly in line with targets set by the CA and, increasingly, using risk based testing intervals covering areas larger than a Parish. The eradication plan permits the exclusion of certain categories of animal (in 2 and 3 year test interval herds) from testing and foresees the discriminatory post movement testing of animals originating in certain parts of the UK and non OTF MSs.

Surveillance in slaughterhouses has been a useful tool in identifying further TB cases and post mortem inspection is comprehensive, albeit the facilities were found to be inadequate at one inspection point in the slaughterhouse visited.

5.4 MEASURES FOLLOWING IDENTIFICATION OF SUSPECT OR INFECTED ANIMALS

5.4.1 Requirements

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

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

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

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

Point 3B of section I of Annex A to Directive 64/432/EEC states that the OTF status of the herd must be withdrawn in case of confirmation of the presence of tuberculosis. In such cases, tracing and checking must be performed on epidemiologically related herds. The status is to be withdrawn until cleansing and disinfection of the premises and utensils is completed, and two clear tests of the herd are obtained, not less than 60 days and four months after removal of the last reactor.

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

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

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

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

5.4.2 Findings

5.4.2.1 Suspension – withdrawal

Where test reactors are identified or disease is suspected clinically or at slaughter, enhanced measures may be applied such as g-IFN testing. Herd restrictions will be imposed (OTF status suspended) – by service of a “TB2” notice.

Herds where disease has not been confirmed by post mortem analysis but have previous disease history, or where there is presence of TB in the area, will be placed under restriction for longer periods and may be required to pass further skin tests.

Post mortem examination of all reactors and "direct contacts" is carried out, with tissue culture of selected animals. Where demonstrable evidence of *M. bovis* is found in at least one reactor (typical macroscopic lesions and/or isolation of *M. bovis*) the OTF status of the herd is withdrawn. The OTF status may also be withdrawn for epidemiological reasons.

Observations:

- In some cases the OV depends on the farmer to identify the various premises/land occupied by his herd (although previous TB test sheets and Integrated Administration and Control System data may be used as a guide) prior to serving the restriction notice. Wording may vary, and the veterinary officer may refer to the farm address and associated CPH with the words "as above and associated grazing".
- The audit team noted a case where two restriction notices were in force concurrently.
- Restriction notices may be served on whole premises (CPH number provided) and then lifted on part(s) of this premises where there is a discrete group of animals adequately separated by management/location. Similarly, a request can be made for the separation of cattle (TB155) for the purpose of removing TB restrictions, which is assessed by a veterinary officer having taken into account the biosecurity arrangements.

5.4.2.2 Epidemiological investigation

Epidemiological enquiry includes molecular typing of *M. bovis* isolates and the identification of a "home range" – i.e. the likely geographical origin. There is a risk based approach to source/spread tracings – check testing of origin herds and testing of individual animals at herds of destination where at-risk movements have been identified.

In every TB breakdown disclosed, at least one reactor will be sampled for bacteriological culture and molecular typing. In newly detected breakdowns, tissue will be submitted from up to three representative reactors with visible lesions. If no reactors show any tuberculous lesions at post mortem then NVL reactors will have samples submitted from those with the biggest bovine-avian reaction difference.

Observations:

- The audit team was presented data on "enhanced surveillance" following an outbreak in Cumbria (a region recognised as having a low TB incidence). This included a detailed epidemiological enquiry, testing within a 3 km radius and a wildlife survey within the hotspot. No clear source of the outbreak was established but animals were identified on a neighbouring farm that had been moved into the area from the South West of England on a BCMS-link (i.e. not recorded in the BCMS database).

- Detailed Disease Report Forms (TR 150) are in use which emphasise that all premises, units and groups with a reasonable degree of separation should be identified which could lead to the alteration of their individual TB2 status.
- A number of key AHVLA targets were not met at the time of the audit, and in particular completion of Disease Report Forms (at first visit following breakdown) within one month of the loss of OTF status (GB total of 56.8% against target of 89.5%). The CA explained that staff resource issues meant that some of these visits (were postponed, had not been done, were conducted over the telephone or undertaken by an animal health officer rather than a veterinary officer. A remedial action plan has been put in place to "catch up" during 2011.
- In Wales from January 2011 all OTF suspended/withdrawn premises are to be visited by a Veterinary Officer. It was noted that this was not to be applied retrospectively.

5.4.2.3 *Isolation and restriction of milk*

If the breakdowns involve dairy herds, AHVLA is to notify the LA to ensure compliance with food hygiene regulations, including withholding any milk produced by any reactor cows from the human food chain. This is accomplished by an automated letter sent from a central "print desk".

Observations:

- The TB2 restriction notice lays down requirements in relation to public health protection action to be taken on a dairy herd. However, in one case a keeper had not isolated reactor cattle or excluded their milk from the bulk tank (subsequently rectified by an AHVLA dairy inspector).
- At the dairy visited, they did not maintain a complete set of data based on the farmer notification (i.e. number of reactors and confirmation that milk has been withheld).
- The LA officer confirmed that they had an incomplete file for the automated notifications and did not now follow these up systematically. The Food Business Operator (FBO) also confirmed that they had only been contacted by one of the many LAs covering their collection area.
- While in this particular FBO all the milk was being pasteurised, the CA acknowledged that controls on the FBOs processing milk without pasteurisation (permitted in England) could be improved.

5.4.2.4 *Movement prohibition*

Whilst an investigation is being carried out, the herd will be placed under official surveillance and movement restrictions will be put in place prohibiting any animal being moved into or out of the herd.

The CA has provided guidelines on the movements that may be allowed off restricted premises under certain circumstances and conditions (including a licence issued by the local AHVLA office). These include movements between linked holdings, direct to slaughter (if necessary via an approved slaughter gathering), to an approved AFU/AQU, other restricted premises (including isolation units), and to summer grazing. If going to slaughter they must be accompanied by an identification document, a movement licence, a notice of proposal to slaughter (if a reactor or direct contact) and the food chain information form (TB 104). DEFRA provide a list of abattoirs approved to accept such cattle.

Observations:

- The passport remains in the possession of the animal keeper during herd restrictions & cannot therefore be used as an additional tool to prevent unauthorised movement. In the AQU visited, most of the passports did not have movement data entered.
- Many movements are permitted on a "specific" licence (TB16) between or on to restricted holdings. Potentially there are multiple moves possible (e.g a move between restricted herds, followed by sale through a "TB market" into an AFU and then on to slaughter).
- A number of licensing errors were noted and included the proposed movement of cattle from a restricted farm on to an AQU that had gained OTF status and other incidents where animal had been moved, in error, outside of the validity period for the licence or because a (General) licence had not been revoked (e.g. when a herd became 90 days overdue for a "short interval test" - SIT).
- While movement on to restricted premises is generally licensed after the first clear SIT, this is not always the case. One farm selected by the audit team on account of the amount and regularity of compensation claims, had restocked with cattle of OTF origin (including animals obtained through intra-community trade), with some subsequently becoming infected and then slaughtered with compensation. The CA acknowledged that in another instance a large farm in Wales (with "umbrella" CPH) had restocked despite not having a licence to do so.
- PrMT apply to animals of more than 42 days of age moving on/off restricted premises, with the basic principle that animals destined for slaughter should be tested with negative results within 90 days of the movement (e.g. animals from restricted holdings going direct to slaughter or through an AFU/slaughter market), whereas those destined for production should be tested with negative results within 60 days of the movement (animals from restricted holdings moving onto another restricted holding, to a TB isolation unit, an AQU direct or through a "TB market").

5.4.2.5 Marking, removal and slaughter of reactors

All reactors and inconclusive reactors are required to be isolated from contact with any other cattle, reactors for immediate slaughter and inconclusive reactors for further testing. Rapid removal of reactors is required within 10 working days of disclosure to an abattoir or animal by-products approved collection centre/disposal site.

Observations:

- AHVLA have "designated" 22 abattoirs where reactor cattle can be sent for processing. FSA staff in these abattoirs receive the TB110 form detailing the reactor animals to be processed and whether samples are required or not. Details of the type and location of the lesion are recorded on the TB110 which is emailed to AHVLA local office and printed and signed to accompany samples to one of three AHVLA laboratories.
- Not all cattle are isolated on farm (particularly if there are large number of reactors/inconclusive reactors).
- In GB, the removal of reactors is below the target of 90% in 10 days as of July 2011. The CA provided figures to show that a significant number of animals in England (1005 cattle over the period January to July 2011) had not been removed within 30 days.
- The audit team noted the arrival of animals at a designated abattoir with the relevant

documentation and identification. Not all reactors were "DNA tagged", but the OV confirmed that the level of compliance was improving.

5.4.2.6 *Compensation*

In accordance with domestic legislation, AHVLA arranges removal of all SICCT and g-IFN reactors and direct contacts to slaughter or disposal with compensation paid. All reactors and direct contacts are to be valued before being removed. In England, the Cattle Compensation (England) Order 2006 sets out the detailed rules for the table valuation based compensation system. In a small number of cases, animals are valued individually.

In Wales a consultation on compensation arrangements took place in 2009 and the Tuberculosis (Wales) Order includes measures to link compensation to best farming practice (including appropriate biosecurity measures). Compensation payments to farmers who do not adhere to regulations, do not follow advice provided in Veterinary Improvement Notices or allow their TB test to become overdue may be reduced.

Observations:

- The table valuation system in England does not take account of all animal categories (e.g. all dairy cattle irrespective of age, receive the same value).
- In Wales, compensation is based on an individual valuation and average valuations are significantly higher for animals in Wales compared to England (£1658 compared to £1114 at the time of the audit).
- Data was provided to show that this gap was closing, due to a gradual average reduction in individual valuations in Wales. Average compensation values have fallen from around £2000 (since the peak 2 years ago) to approximately £1600. In particular, the average pedigree animal has fallen from a peak of around £5000 to just over £2500.
- While the average salvage received per animal has increased (£282) this only represents approximately 17% of the compensation value.

5.4.2.7 *Cleaning and disinfection, manure and slurry*

As part of general TB control requirements, the keeper will be required to comply with legislation with regard to the transport of animals set out in the Transport of Animals (Cleaning and Disinfection) (England) and (Wales) (No 3) (Amendment) Order 2003 (as amended). After unloading the animals, vehicles must be fully cleaned and disinfected as soon as reasonably practical, before they are used again and in any case within 24 hours of unloading.

In accordance with the Tuberculosis (England) Order 2007 and the Tuberculosis (Wales) Order 2010, a Cleaning and Disinfection Notice will be served on the owner immediately following the removal of any reactors or "affected" animals for completion of cleaning and disinfection. This will include thorough disinfection of all parts of the premises where reactors were housed or yarded (since isolation) and ensuring that any pastures previously used by cattle should be left vacant for a minimum period of 60 days after such use if new stock are to come on. There are also rules for the disposal of manure on TB infected farms (cited in BT05).

Observations:

- While a notice is served on restricted farms requiring cleaning and disinfection (BT05), and

stipulates an "approved disinfectant" listed in the Diseases of Animals (Approved Disinfectants) Order 1978, it does not make reference to a disinfectant active against bovine TB and the keepers questioned were not aware that the disinfectant selected should specifically cover TB and were unclear about the parts of the premises for treatment. The AQU visited (collocated with another AQU and the main farm premises) did not have designated/clearly separate areas for isolation of reactors or storage of manure should it be necessary.

- Cleaning and disinfection of farms and the disposal of manure/slurry was not supervised (a declaration is provided by the keeper). The CA acknowledged that there is no practical way for the CA to enforce the leaving of pastures vacant for 60 days on a routine basis.
- In the slaughterhouse visited (designated to accept TB reactor cattle) there was no cleaning and disinfection protocol available for vehicles, and the staff member responsible for the vehicle wash area could not demonstrate how the disinfectant was made up to the correct dilution. The disinfectant for cleaning the slaughter hall and processing areas was not on the "live list" of approved disinfectants published on the DEFRA website: http://disinfectants.defra.gov.uk/Default.aspx?Module=ApprovalsList_SI
- Vehicles that has not been cleansed and disinfected following the delivery of animals to the designated slaughterhouse, completed a declaration in the lairage office to say where they will take the vehicle for cleaning and disinfection. This declaration was forwarded by the slaughterhouse operator to the LA (Trading Standards) for enforcement. However, the LA representative acknowledged that they did not follow these up as a routine.
- The market visited that held sales of cattle from TB restricted herds did not have adequate disinfection equipment available (one knapsack sprayer) for a multiple vehicle wash area.

5.4.2.8 *Supplementary blood tests, depopulation*

In GB the g-IFN test is to be used as an ancillary parallel test, alongside the SICCT in specified circumstances. The use of the g-IFN test in GB is mandatory under prescribed circumstances (e.g. in England to aid in the prevention of disease in low incidence areas, or in Wales, since January 2010, in areas where TB is not attributed to wildlife and not considered endemic).

It is specifically used on ISCCT negative cattle in severe confirmed TB breakdowns to inform decisions on partial/complete depopulation.

Observations:

- Problems were identified with blood sample quality for the g-IFN test and the collection from animals within the required time-scale (91% met the target). Improvements have been made in collection techniques and storage. Furthermore, samples are to be rejected if outside the permitted temperature range.
- Even when TB is widespread within a herd, total or partial depopulation is rarely carried out (no more than approximately 6 herds over the course of a year in England and Wales) and in endemic areas, depopulation will only be contemplated in very severe TB incidents.
- Depopulation is primarily confined to heavily infected herds in low incidence areas (those with 3 or 4 yearly testing intervals and in specific areas of Wales) to prevent the development of a new potential "hotspot".

5.4.2.9 Official measures to prevent re-infection from other sources

The CA apply a risk based approach to the testing of herds contiguous to cattle holdings with TB breakdowns. In 3 and 4 year testing areas and in specific areas of Wales, an enhanced surveillance strategy will be instigated for new, confirmed TB breakdowns where the cause cannot be attributed to recently purchased cattle. This is to comprise increased testing of cattle in the area together with a survey of the wildlife in the area (to check whether or not TB has become established in wildlife).

The eradication plan includes the intention by DEFRA and the WG to continue to develop approaches to tackle TB in badgers as they are regarded as the main wildlife reservoir. The CA believes that a "science led" managed badger cull is one of a package of measures needed to bear down on the disease, as the cattle measures deployed to-date have not controlled the spread of disease.

A badger vaccine deployment project has been launched in England to start using an injectable vaccine in summer 2010 following the issue of a licence for the badger vaccine in March 2010.

Observations:

- In England, a consultation on badger culling was ongoing at the time of the audit (scheduled to end 20 September) and if a decision was taken to go ahead, culling would only take place in 2 pilot areas by early autumn 2012. Furthermore, a representative of the National Farmers Union indicated that although farmer uptake was adequate to meet the licence conditions (70% uptake in the proposed areas) there may be further legal obstacles linked to the ownership of land where control areas are to be established.
- A maximum of 10 licences will be granted in any year.
- In Wales, an intensive action area covering approximately 300 square kilometres has been established in North Pembrokeshire where additional control measures are already in place (six monthly test intervals, withdrawal of SOA and BCMS-links and individual farm biosecurity assessments by trained private veterinarians using a "biosecurity scoring tool"). A managed badger cull was to be part of the control measures. However, the proposed cull has been suspended by the WG while they await the outcome of an independent scientific review with a report expected in the autumn. Their first meeting took place during the audit.
- The lessons learned from the intensive action pilot area will be assessed by the CA in order to determine whether the measures could be applied more widely in Wales and England.
- A badger vaccine was licensed in 2010 and has been shown to reduce severity, progression and excretion of TB. It is being used in a scaled down badger vaccine deployment project in one area.
- £20 million pounds have been committed to vaccines research and development (cattle and badgers) over the next 5 years.

5.4.2.10 De-restriction

If the presence of TB is not confirmed in any slaughtered reactor, OTF status can be regained if there is a clear test of all animals within the herd at 60 days after the isolation/removal of the reactors. In higher risk herds, two consecutive tests are required. Where *M. bovis* infection is confirmed, two clear consecutive tests are required. Additionally, a more severe re-interpretation of the skin tests is introduced if there is demonstrable evidence of *M. bovis* infection found at post mortem examination/culture.

Follow-up testing of OTF withdrawn herds 6 and 18 months after restoration of its OTF status is required (and a follow up test of OTF suspended herds) including PrMT of any cattle moved to other herds.

AFUs have been introduced to provide an outlet for the fattening and/or finishing clear tested cattle from TB restricted holding lacking such facilities. They must have an individual CPH number allocated and must not have any SOA or BCMS link. They are placed under restriction and tested every 6 months (without grazing) or every 90 days (with grazing). However, if the intake of cattle ceases and if all the cattle are housed (without grazing), the keeper can opt to regain OTF status. In brief, this requires compliance with certain biosecurity conditions, treatment of manure and two consecutive SITs tests at least 60 days apart with negative results.

AQUs have been introduced to provide an outlet for calves from TB restricted holdings lacking facilities for rearing. AHVLA has developed an approval system for the purposes of removing restrictions and the sale of these animals. Conditions for lifting restrictions are as for the AFUs, subject to testing of cattle at 60 day intervals, the unit being filled by the keeper within 6 weeks and the CA notified.

Observations:

- De-restriction of herds was performed according to the classification status and taking into account herd history and local disease conditions.
- In the AFU visited (without grazing), there were delays introducing the individual CPH number and updated TB2 notice (original approval October 2010, new CPH number April 2011 and updated TB2 notice & movement licence – September 2011), and the owner was not aware that as part of his approval, he could not keep cattle from his main holding at this premises (these were subsequently tested and removed). The owner regarded the facility as wildlife secure despite the presence of an open feed store. There was no biosecurity plan and there had been a recent change in supervising VO.
- No further follow up testing is required in the guidance notes (TB131), should an AFU obtain OTF status following the two SITs.
- In the AFU visited, pen walls were in a poor state of repair and boundaries were not well defined. The keeper could not demonstrate the management separation of the units on his electronic herd register (it covered three premises) and in one case the AQU had not been filled within the 6 week time-frame. Biosecurity could not be ensured as both approved AQUs and the main premises were collocated, i.e. the two AQUs were not discrete self-contained cattle units clearly isolated from other cattle herds. Nonetheless, the keeper was in a position to obtain OTF status for these units subject to fulfilling the test obligations.

5.4.2.11 TB in other species (sheep and goats)

Passive surveillance is carried out on domestic livestock other than cattle (farmed deer, sheep, pigs, camelids and goats) mainly by meat inspection in animals going through licensed abattoirs and necropsy of clinical cases at Regional laboratories i.e. a "scanning surveillance". A case file was presented for an outbreak in goats, with tracing to Wales and West of England. If bacteriological tests confirm infection with *M. bovis* in non bovine animals, where appropriate, movement restrictions will be imposed by AHVLA and usually only lifted following 2 clear tuberculin tests. The extent and impact of *M. bovis* infection in some of these species is currently being reviewed to consider whether or not any additional TB controls are needed.

Observations:

- There is no surveillance testing or control programme in place in GB for TB in non bovines.
- Suspicion of disease in non bovine species is notifiable, and there is a requirement to notify suspect lesions and positive cultures of *M. bovis*.
- In England there are no statutory powers to test non bovines (other than deer) and as no compensation is payable, the CA cannot compulsorily impose slaughter on reactors. Owners are asked to sign an agreement for the removal of reactors before any testing is carried out (an ex gratia payment is payable to owners of camelids). Examples were provided where this had been applied.
- Goats, camelids and deer are subject to TB testing (or restrictions) if co-located on premises with infected cattle or contiguous to an OTF-withdrawn herd.
- In Wales, the Tuberculosis (Testing and Powers of Entry)(Wales) order 2008 allows for testing of all mammals, and the Tuberculosis (Wales) Order 2011, allows for compensation and powers to test in camelids, goats and deer.

5.4.3 Conclusions

The suspension of OTF status is ensured following the disclosure of TB reactors or the identification of lesions at the slaughterhouse. However, due to the extent of some "home premises", the CA cannot always guarantee that all relevant premises/land are covered by the restriction notice(s).

The possibility to lift restrictions progressively means that a premises may have more than one status (e.g. OTF, and OTF-suspended/withdrawn).

The CA requires detailed epidemiological follow up. However, significant delays have occurred due to the availability of veterinary officers and the delayed roll out of the information system module "SAM release 6".

While a system is in place to remove reactor cattle rapidly, those awaiting removal are not always effectively isolated and CA controls have not ensured that milk from reactor cattle is excluded from collection.

The dairy visited did not maintain full records in relation to their supplying farms, and emphasised the fact that all milk was pasteurised. The LA confirmed that they provided limited supervision, while the CA acknowledged that they had inadequate controls on the Food Business Operators (FBOs) processing milk without pasteurisation.

A complex movement licensing system is in place, allowing multiple movements between restricted and non restricted premises. The potential to spread disease is exacerbated by testing animals up to 90 days before movement and the possibility of restocking herds before all animals have had at least one satisfactory whole herd test. Cattle passports are not withdrawn following herd restrictions, removing a means of movement control from the CA.

The CA has put in place a system for marking, removal and slaughter of reactor cattle in dedicated premises with a documented protocol. Most, but not all cattle (particularly in England) are removed within the target of 10 days or not later than 30 days following notification of the results (as foreseen in Article 15 of Council Directive 78/52/EEC).

The compensation systems function as described, but leads to anomalies between England and Wales, as differing values may be assigned for the same category of animal.

Weaknesses exist in cleaning and disinfection (including type and dilution of disinfectant) at farm, vehicle, market and slaughterhouse level, exacerbated by the lack of adequate supervision by the CA (particularly in relation to transport vehicles).

Supplementary tests for elimination of infected animals are used in line with the approved eradication programme, as herd depopulation is rarely used as a TB control option.

Significant attention is placed on the measures taken to prevent re-infection, albeit that the main tool foreseen by the CA (a science led managed badger cull) may only be implemented in a limited way, by early autumn 2012.

De-restriction of conventional herds is in accordance with the approved programme and Union legislation. However, new categories of "higher risk" premises such as AFUs and AQUs, potentially formed from multiple (restricted) sources can obtain OTF status with only 2 SITs, despite weaknesses in biosecurity arrangements and operation in the premises visited.

The CA provided evidence for the passive surveillance carried out on domestic non bovine livestock and indicated that they raised awareness among meat hygiene inspectors in all red meat abattoirs. However, the owners of non bovine susceptible species (e.g. sheep, goats, pigs and camelids) are not part of the national TB eradication programme.

6 OVERALL CONCLUSIONS

The official controls related to TB remain a high priority for Government and the approved programme is largely applied. Despite efforts to date, the disease situation overall in GB, is at best static and may be deteriorating in England.

The audit identified a number of potential weaknesses in the programme, which includes the option to make one or more moves between restricted premises (occasionally prior to a first clear test), movement between linked premises and within extensive "home" premises (in some cases avoiding registration on CTS), PrMT derogations (including extended time intervals between testing and movement), incomplete herd testing and the operation of specialist units under restriction (e.g. AFUs/AQU), which lacked some of the necessary biosecurity arrangements.

Furthermore, the enforcement arrangements are fragmented across a number of bodies, which combined with a lack of co-ordination (particularly with LAs) makes it difficult to ensure that basic practices to prevent infection/spread of disease (such as effective cleaning and disinfection of vehicles and markets) is carried out in a satisfactory way.

Most of the weaknesses are already known to the CA, as new legislation and the operation of pilot areas (such as the intensive action area) have already removed certain movement test exemptions, "broken" links, increased test frequencies and sought to improve biosecurity by education of animal keepers.

However, while the CA acknowledges many of these weaknesses, they maintain that the delay in implementing the proposed wildlife controls (i.e. a managed cull of badgers) which is a significant element of the approved eradication programme, remains the major obstacle to progress.

7 CLOSING MEETING

A closing meeting was held on 16 September 2011, where the main findings and preliminary conclusions of the audit were presented to the national authorities.

8 RECOMMENDATIONS

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

N°.	Recommendation
1.	Ensure effective co-ordination/co-operation between the AHVLA and the Local authorities as foreseen in Article 4(3) of Regulation (EC) No 882/2004, particularly in relation to official controls over a) cleaning and disinfection of vehicles/markets and b) dairy establishments;
2.	Ensure that the disinfectants used and their concentrations are those officially authorised by the CA as foreseen in Article 16(3) of Council Directive 78/52/EEC;
3.	Ensure that cultures for <i>M. bovis</i> are incubated for a minimum of 8 weeks (and preferably for 10–12 weeks) at 37°C with or without CO ₂ in line with chapter 2.4.7 of the OIE Terrestrial Manual 2009;
4.	Ensure that movements are promptly recorded in passports as required by Article 7(2) of Regulation (EC) No 1760/2000;
5.	Consider the revision of a) how holdings are managed/classified, given that the County/Parish/Holding number (CPH) may at present cover large geographical areas and comprise multiple premises and herd registers and b) consider reviewing the use of "links" so that all movements between holdings can be registered in the central (British Cattle Movement Service) database, as required by Article 7(1) of Regulation (EC) No 1760/2000, and the place where cattle are kept, held or handled can be readily identified. In the light of points a) and b) consider revising the conditions for the placing of partial holding restrictions and the operation of "separate" premises;
6.	Ensure that where pre movement testing is required, animals have passed an intra dermal test within 30 days prior to movement as required by either point I(1)(c) of Annex A to Directive 64/432/EEC or Article 19(ii) of Council Directive 78/52/EEC;
7.	Ensure that post movement testing is carried out in a non discriminatory way and on a risk basis as foreseen in Article 3(1) and (6) of Regulation (EC) No 882/2004;
8.	Continue the adjustment of compensation so that breeders are appropriately compensated throughout the UK as foreseen in Article 3 of Council Directive 78/52/EC;
9.	Ensure that herds may retain their officially tuberculosis free status only if animals on

N°.	Recommendation
	the holding are subject to routine tuberculin testing (i.e. a whole herd test in 2 and 3 year testing parishes), as required by point I(2)(c) of Annex A to Directive 64/432/EEC;
10.	Ensure that herds are not restocked until all eligible animals have passed one clear TB test as foreseen in Article 17 of Directive 78/52/EEC;
11.	In order to accelerate the eradication of tuberculosis in cattle, limit where possible exemptions from requirements for the movement of animals from restricted premises as foreseen in Articles 17 of Council Directive 78/52/EEC;
12.	Ensure that Approved Finishing Units (AFU) and Approved Quarantine Units (AQU), meet all the Animal Health – Veterinary Laboratory Agency (AHVLA) conditions for approval, particularly in relation to biosecurity, given that they are allowed to purchase bovine tuberculosis restricted cattle from multiple sources;
13.	Ensure that adequate controls are placed on Food Business Operators processing milk without pasteurisation and in particular that the provisions of Section IX, Chapter I, I, points (3) and (4) of Annex III to Regulation (EC) No 853/2004 are applied.

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=2011-6057

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. 494/98	OJ L 60, 28.2.1998, p. 78-79	Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals
Reg. 1760/2000	OJ L 204, 11.8.2000, p. 1-10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Reg. 1082/2003	OJ L 156, 25.6.2003, p. 9-12	Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

Legal Reference	Official Journal	Title
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 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
Reg. 911/2004	OJ L 163, 30.4.2004, p. 65-70	Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards eartags, passports and holding registers
Dec. 90/638/EEC	OJ L 347, 12.12.1990, p. 27-29	90/638/EEC: Council Decision of 27 November 1990 laying down Community criteria for the eradication and monitoring of certain animal diseases
Dec. 2003/467/EC	OJ L 156, 25.6.2003, p. 74-78	2003/467/EC: Commission Decision of 23 June 2003 establishing the official tuberculosis, brucellosis, and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds
Dec. 2004/292/EC	OJ L 94, 31.3.2004, p. 63-64	2004/292/EC: Commission Decision of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC

Legal Reference	Official Journal	Title
Dec. 2009/883/EC	OJ L 317, 3.12.2009, p. 36–45	2009/883/EC: Commission Decision of 26 November 2009 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2010 and following years
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dec. 2008/940/EC	OJ L 335, 13.12.2008, p. 61-90	2008/940/EC: Commission Decision of 21 October 2008 laying down standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Community
Dec. 2010/712/EU	OJ L 309, 25.11.2010, p. 18-30	2010/712/EU: Commission Decision of 23 November 2010 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 2011 and following years