Cabinet Secretary for Environment and Rural Affairs

Climate Change, Environment and Rural Affairs Committee

This paper sets out the background to Bovine Tuberculosis (TB) Eradication in Wales and outlines historic and current activities within the Bovine TB Programme, which is part of the Environment and Rural Affairs portfolio, in advance of the scrutiny session on bovine TB with the Committee on 14 December.

TB has a significant financial and social impact on farm businesses and the wider rural community, and a huge emotional impact on many farming families. It is a disease which is also very costly to the Welsh Government in terms of payment for TB testing, breakdown management and compensation to keepers whose animals are slaughtered because of TB (£25.9m was spent by Welsh Government alone in the financial year 2015-2016).

Mycobacterium bovis (M bovis) the cause of bovine TB can infect all mammals. TB is a zoonosis which means it can be transmitted from animals to humans. Although the risk to public health is kept low because of regular testing of cattle, milk pasteurisation and inspections at abattoirs, it is important to mitigate against any threat of bovine TB to the public. A commitment to TB eradication is also important to support our trade both within the EU and globally.

TB eradication is a long-term goal for the Welsh Government and the TB Eradication Programme was established in 2008. Our programme is based on the four basic principles of infectious disease control:

- Keep it out
- Find it quickly
- Stop it spreading
- Stamp it out

The Eradication programme is continually improved, building on the latest evidence in order to better inform policy development. As part of that we collaborate with other UK administrations as well as those further afield. Our programme is reviewed on an annual basis as part of the submission of the UK TB Eradication Plan to the European Commission (EC) and has received endorsement by the EC for the last seven years. The UK Plan covers Wales, England and Northern Ireland. Scotland achieved Officially TB Free Status as recognised by the EC in 2008.

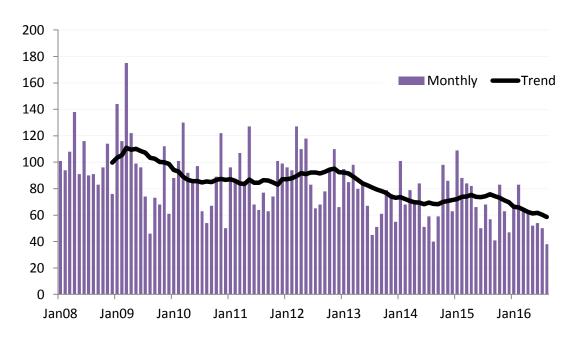
Up to 2008, the testing frequency of herds ranged between annual testing and four-yearly testing and was determined by the proportion of herds in each parish which had previously been infected. At the start of our Eradication programme we delivered "TB Health Check Wales (HCW)" where all cattle herds in Wales were tested over a shortened timeframe of 15 months (October 2008 to December 2009) to give us a better understanding of the disease situation across the country. The results of HCW led to the

introduction of annual herd TB testing across the whole of Wales from the start of 2010 to maintain a high level of surveillance.

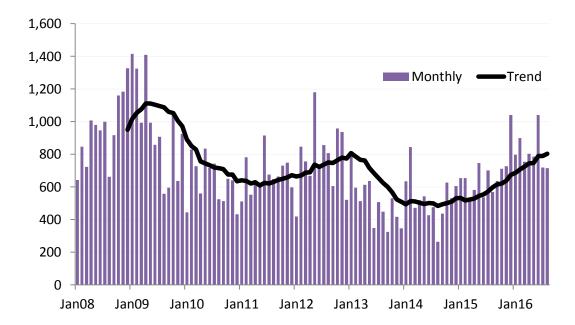
In 2012 we published a 4 year Strategic Framework for bovine TB Eradication which set out our agenda for achieving eradication. We are currently reviewing our strategy with a view to refreshing our approach to TB eradication, building on the progress made to date.

The programme has been monitored by tracking TB incidence (the number of new breakdowns) and the number of cattle slaughtered and these basic statistics are published monthly. More recently we have started to publish a more sophisticated dataset through a quarterly TB Dashboard that presents data in an understandable and visual way, charting the journey to TB eradication. The latest TB Dashboard can be found at Annex 1.

New TB herd incidents - 2008 to 2016



Increasing the frequency of testing resulted in an initial anticipated peak in incidence which has fallen substantially since then (note that the series is characterised by periods of rising and falling trends, with a long-term downward trajectory). As at August 2016, the number of new incidents had fallen by 47% since the high-point in 2009).



The trend in animals slaughtered has tended to follow the trend in new incidents though recently the two have diverged with an increase in the number of cattle slaughtered. This is primarily due to increased targeted interferon gamma-testing, which has a higher level of sensitivity than the standard skin test and thus discloses a higher number of the infected cattle in a herd. This more sensitive test is used to help clear infection in persistent and recurrent breakdown herds.

The TB Eradication Programme is a comprehensive approach aimed at dealing with all risk factors for disease spread:

- Cattle
- Non-bovine domestic species (e.g. goats, llamas and alpacas)
- Wildlife including badgers and deer
- Fomites (e.g. spread via farm visitors, and farming practices that involve sharing equipment).

Cattle

The main components of the programme are aimed at limiting and mitigating against the spread of infection between cattle. This includes the following surveillance and control measures:

- Each herd in Wales is tested at least once a year to identify infected cattle as early as possible
- Cattle are required to have a Pre-Movement Test (PrMT) before they
 can be moved from a farm (although there are some exemptions) to
 minimise the risk of the disease spreading
- Post-mortem inspections are performed on all cattle carcases.

Removing infected cattle as early as possible reduces the chance of them infecting others. When a herd containing an animal suspected of having TB is identified it is placed under movement restrictions and investigations are carried out to confirm or rule out the presence of TB. Until the outcome of these investigations are known:

- There is no movement of cattle into or out of the herd unless licensed by the Animal and Plant Health Agency (APHA). Cattle can leave the herd to move straight to slaughter or to slaughter via an Approved Finishing Unit (AFU).
- No restocking is allowed until the cattle remaining have completed one or more TB test.
- Any suspect animals must be isolated from other cattle within the herd.

The Tuberculosis (Wales) Order 2010 (as amended) is made under the Animal Health Act 1981. It confers powers relating to the prevention of the spread of bovine TB in cattle. It sets out the controls and requirements which are in place as well as how compensation is paid for any cattle slaughtered.

Domesticated non bovine species

In Wales, TB surveillance in domesticated non-bovines is risk based, for example, where disease is identified in cattle on contiguous premises. There is no intention at this time to introduce regular TB testing, or compulsory premovement testing, of non-bovine animals.

The Tuberculosis (Wales) Order 2011 provides APHA with the powers it needs to deal effectively and quickly with incidents of TB in certain non-bovine animals (camelids, goats and deer) similar to those available in relation to cattle.

The Order also provides for statutory compensation for any of these non-bovine animals that are removed and slaughtered as TB reactors. These are set compensation figures (up to £1,500) rather than individual valuations as in the case of TB reactor cattle.

Wildlife

There has been evidence of a link between TB in badgers and cattle since the discovery of an infected badger carcass in Gloucestershire in 1971. It has been proven experimentally that badgers can transmit bovine TB to cattle (Little 1982).

There is also evidence that other wild mammals can become infected with M bovis but most are regarded as "spillover hosts". A study undertaken in 2007 (Delahay et al) to survey for prevalence in other wild mammals and assess the relative risk to cattle, examined the carcasses of 4715 mammals collected across the South West of England. Infection was confirmed in range of wildlife species. Although most species presented a relatively low risk, higher values

and uncertainty associated with muntjac, roe, red and in particular fallow deer, suggest they require further investigation. The results suggest that deer should be considered as potential, although probably localised, sources of infection for cattle.

Since autumn 2014, Welsh Government has been promoting the surveillance for TB in wild deer culled by stalkers. Training in sampling techniques and the provision of sampling kits has been made available through the Deer Initiative Scheme. To date, 994 samples suitable for testing have been received with 17 testing positive for M.bovis, 972 negative with 5 results pending.

A survey of badgers found dead in Wales in between 2005 and 2006 found of the 457 carcasses tested, 61 (13%) were positive for M bovis. Also the geographical distribution of molecular types of M bovis found in badgers was similar to those found in cattle.

A further all Wales survey is currently being undertaken. Provisional results indicate of the 650 badger carcasses we have collected and tested to the end of October 2016 43 (6.62%) were positive. As found in 2005/06, it is expected there will be great regional variation.

The survey sample size is small so caution should be taken in interpreting these results although it gives us useful data which can help us identify areas where badgers may be contributing to the transmission of disease.

It is most likely cattle pick up infection by coming into close contact with other infected cattle. Little is known about how TB spreads between cattle and wildlife such as badgers.

Research has shown that badgers visit farm buildings and come into close contact with housed cattle. A number of studies have been undertaken to examine the interaction between cattle and badgers at pasture, and all conclude that direct contact is a very rare occurrence. It is more likely that the disease is transmitted in both directions by indirect means through environmental contamination.

The Randomised Badger Culling Trial (RBCT) provides the best evidence for the impact of badger culling. The RBCT showed that proactive badger culling as conducted in the trial resulted in an overall beneficial effect on confirmed bTB cattle herd breakdowns compared with 'survey only' (no cull) areas. This beneficial effect was still in evidence 5 years after the final annual proactive cull (Jenkins *et al*, 2010) but wanes gradually over time towards the incidence seen in the control areas.

The Bovine TB Science Review (22011) concluded, "There is a general consensus based on expert opinion that eradication of bTB in cattle will require the simultaneous use of a range of measures aimed at the control of infection in cattle and in wildlife reservoirs. No single measure will lead to eradication".

Vaccination

A field trial (Chambers et al 2010) demonstrated that vaccination of badgers, that were uninfected prior to administration of BCG, led to a 74% reduction in the incidence of new cases in the vaccinated group compared to an unvaccinated control group. Studies have also shown that risk of unvaccinated badger cubs testing positive decreased significantly as the proportion of vaccinated individuals in their social group increased. When more than a third of their social group had been vaccinated, the risk to unvaccinated cubs was reduced by 79%.

BCG vaccine used in badgers, as with other species, is not 100% effective in preventing infection. It is not necessary for all individuals to be immune for vaccination to deliver a benefit. Vaccinating a proportion of a population stops a disease from spreading as there are fewer individuals who can be infected. This is known as 'herd immunity'.

A model (Fera 2010) of control strategies in England predicted that vaccination of badgers in a high incidence area (17% TB prevalence in the badger population, 70% trapping efficacy and 70% probability of the vaccine to give full protection) could produce a reduction in confirmed herd breakdowns. In a 150km² area, the model estimated vaccination could reduce confirmed cattle herd breakdowns by 9% after five years of repeated vaccination, 28% in the five years following vaccination with an overall reduction of 19% over 10 years within the core area.

The Intensive Action Area (IAA) in Wales was established in 2010 as an area where increased measures would be implemented to tackle all sources of bovine TB, in both domestic and wild animal species. It is approximately 288km² and is primarily located in north Pembrokeshire. A badger vaccination project in the IAA began in May 2012 and over 5,500 doses were administered over four years alongside additional cattle surveillance and controls and enhanced biosecurity measures.

In the IAA we have seen a falling trend in the number of open breakdowns. This is encouraging but more time is needed before we can see if there are any meaningful differences in trends. However, any changes we see will be as a result of all the measures we have introduced to reduce the level of infection within all species in the area and we cannot draw any conclusions regarding the role of badger vaccination alone in reducing TB incidence in cattle.

The vaccination of badgers was halted due to a global shortage of BCG vaccine available for use in humans. We continuing to explore the possibility of obtaining human BCG from a different supplier and have remained in close contact with Defra and together we are monitoring developments relating to the availability and supply of vaccine.

Research continues into the feasibility of utilising BCG in Oral Bait as a tool to control the spread of Bovine TB. Simultaneous studies are ongoing to produce fermenter grown vaccine to sufficient strength, monitor the level of

bait take up by badgers, and possible adverse effects on non-target species and the environment.

Badger vaccination remains an important tool which should be used where appropriate.

Programme refresh

On the 18 October 2016 we published a consultation document entitled 'A Refreshed TB Eradication Programme' where we ask for industry views on a number of policy changes that will help us move forward as we continue the fight against TB. As part of the consultation we are asking for comments on –

- Measures to be applied to support the regional approach to the eradication of TB with three categories of areas based on the epidemiological evidence of the disease situation in each area.
- A standardised online biosecurity package to help farmers identify the risks on their farm and implement improvements.
- New policies for preventing overvaluation and reducing the compensation cap to £5,000.
- Reducing compensation for within herd movements, where there is an increased risk of disease spreading, to incentivise farmers to minimise movements between separate units in a herd under restrictions.
- To promote positive behavioural changes and adherence to the requirements, we would like to link compliance with Common Agricultural Policy (CAP) scheme subsidy payments (or any other payment scheme that the industry receives subsidy from in the future).
- The concept of mandatory Informed Purchasing (Risk Based Trading) to ensure that cattle keepers disclose the disease status of the herd at the point of sale.
- Proposals to realign the location and makeup of the regional TB eradication boards to be consistent with our new TB areas.

Approximately 10% of TB breakdowns are characterised as "Persistent" (i.e. herds which have been under TB restrictions for 18 months or more). These chronic breakdown herds remain particularly difficult to resolve.

We are now working with the individual farmers and their vet to develop bespoke plans for each of the persistent breakdown farms and where we believe badgers contribute to disease in these chronic breakdown herds, we have to be innovative in finding ways to break the transmission of infection. This may include removal of infected individual or groups of animals.

This refreshed TB Eradication Programme will put us in a stronger position to ensure we continue to make progress towards a TB Free Wales. The consultation closes on the 10 January 2017.

Annex 1

TB testing

There are two different official cattle tests which are approved for use within European Union (EU) Member States:

- the single intradermal comparative cervical tuberculin (SICCT) test for bovine tuberculosis (known as the skin test)
- the interferon-gamma blood test (known as the gamma test).

These tests detect an immune response to M bovis and can identify infection before cattle show any clinical signs of disease.

The skin test is used as the main screening test. It is good at finding infected herds and its high specificity means is very good at correctly identifying uninfected cattle. The tuberculin skin test is known to be approximately 80% sensitive at standard interpretation. Its specificity is 99.98% or higher. After identifying infection in a herd a stricter interpretation of the next test result is used which increases the test's sensitivity and ability to identify any remaining infected cattle. The gamma test is used to complement the skin test and can detect infection earlier. It has a higher sensitivity which means that, when used alongside the skin test, it improves the likelihood that infected cattle will be identified. Gamma tests are most commonly used in:

- Low TB incidence areas, to help stop TB from becoming established
- Chronic herd breakdowns, to help clear infection from herds
- Other herds on an ad-hoc basis.

Definitions

- **Sensitivity:** Probability that the test will give a positive result in the presence of disease = 80%. Equally this means that we may have a rate of 20% of false negative results, i.e. miss 20% of infected animals in the herd. In general terms it is probable that 80% of infected animals will test positive to the skin test reactions to bovine tuberculin can sometimes be triggered by exposure to bacteria of the *M.avium* complex and other non-pathogenic *Mycobacteria*. However, fewer than 1 in 5,000 animals will be wrongly classified as a reactor. The measure of correctly identified animals is the test's **specificity**
- **Specificity**: Probability that the test will give a negative result in the absence of disease (false positives) = 1 in 5,000. Equally this means that 99.98% animals classed as a reactor following application of the comparative skin test will be infected with *M.bovis*.

Wales TB Dashboard

The Wales TB dashboard filters a vast range of available data into a handful of key measures. It illustrates the disease situation across Wales and demonstrates the progress our eradication programme has made.

