Northern Ireland Assembly

Research and Information Service Briefing Note

Paper 73/13 18th April 2013 NIAR 249-13

Mark Allen

Bovine TB and vaccination update – Spring 2013

1 Bovine TB and DARD

Bovine TB is recognised as a scheduled and notifiable disease under the Diseases of Animals (Northern Ireland) Order 1981[1], and as such farmers are required to inform DARD of any suspected or confirmed cases within their livestock.

The eradication of Bovine TB has been a priority for DARD (and its predecessor departments) since 1964. The disease, which is caused by the Mycobacterium bovis affects the health and welfare of cattle, lowers productivity and fertility and consequently impacts on herd keepers' profitability.

The symptoms of Bovine TB can take months to exhibit in cattle but in the late stages of the disease common symptoms include emaciation, a low–grade fluctuating fever, weakness and lack of appetite.

Within the UK and Ireland, only Scotland is currently recognised as being officially Bovine TB free and the prevention, control and compensation costs throughout the rest of the UK and Ireland continue to be significant.

[1] Diseases of Animals (Northern Ireland) Order 1981

Under internationally defined standards, for a country to be defined as Bovine TB free there must be a herd incidence rate of less than 0.2% for 3 consecutive years.

The level of Bovine TB incidence within herds and individual cattle in Northern is set out in figure 1 below, which highlights the recent rises in both measures over last few years, with 2012 having a herd incidence figure of 12% and an animal incidence rate of 0.663%. Given this data it is however encouraging to note that the data for January 2013 does appear to be showing a decline for both measures.

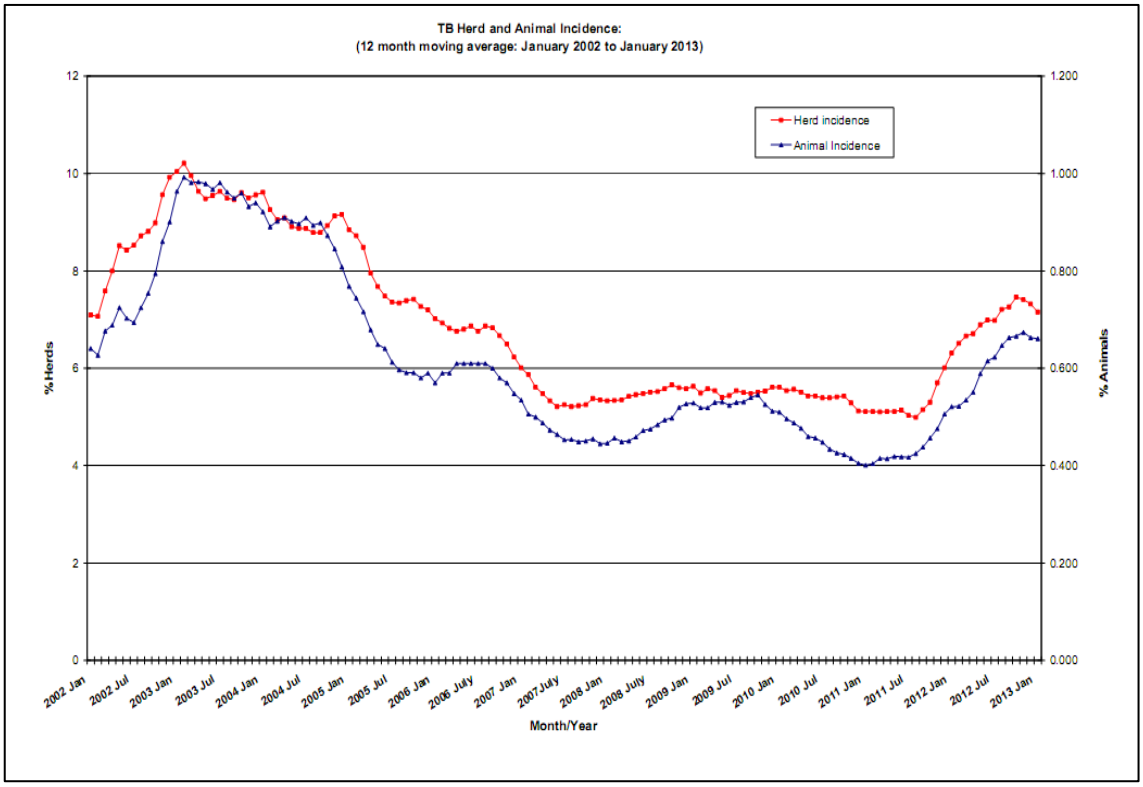

Figure 1: TB Herd and Animal Incidence: (12 month moving average: January 2002 to January 2013)[2]

On an annual basis DARD submits a Bovine TB monitoring, eradication and control programme to the European Commission as a pre-requisite for EU co-financing. This document is a cornerstone of DARD's strategic approach to both the eradication of Bovine TB and the design of the programmes to achieve this objective. The measures that DARD deploys in the effort to reduce and ultimately eradicate Bovine TB within Northern Ireland include:

- **Testing;**
- **Slaughter of TB reactor animals;**
- **Movement controls.**

DARD has also funded or supported ongoing research to address Bovine TB, with notable examples including:

[2] DARD monthly TB statistics - January 2013

- **A biosecurity study in Co Down** - will inform evidence-based biosecurity advice to be provided to livestock farmers and will inform policy decisions in relation to recuing the Bovine TB risk posed by wildlife;
- **Badger vaccine development and trial** - collaborative links with work ongoing in England and ROI;
- **Test and vaccinate or remove (TVR) pilot programme** - involves testing live badgers; vaccinating and releasing the test negative badgers; and removing the test positive ones;
- **Differentiating Infected from Vaccinated Animals** - maintains an interest in ongoing work by Defra on the development of a so called DIVA test which would enable the vaccination of cattle.

2 Vaccinating cattle against TB

At present BCG is identified as the most suitable cattle TB vaccine. Cattle are vaccinated with BCG vaccine from a young age against Bovine TB. Whilst not 100% effective at preventing TB in cattle, recent small scale field trials in Ethiopia[3](13 neonatally vaccinated and 14 control calves) and Mexico[4] (130 calves)have shown that vaccination could protect somewhere between 56% and 68% of the cattle vaccinated.

It is also worth noting that there is no evidence that BCG will have a therapeutic effect in already infected animals.

Within the EU, cattle vaccination is not used, as the BCG vaccine produces a positive reaction to the tuberculin skin test (most common means of establishing TB status) and also interferes with the gamma interferon blood test – making it impossible to determine vaccinated from infected cattle.

Work is ongoing into the development of a so called DIVA (Differentiating Infected from Vaccinated Animals) test which would enable the vaccination of cattle, although this would also require a change in EU law (current EU Directive 78/52/EEC- article 13ii prohibits vaccination[5]) to make vaccination with BCG and the use of a DIVA test legal.

If this work is to progress there are a number of critical and interlinked essential steps that need to be completed at UK, European Commission and World Organisation for Animal Health (OIE) level before vaccination of cattle can be utilised as follows:

[3] Ameni, G., Vordermeier, M., Aseffa, A., Young, D.B., Hewinson, R.G. 2010. Field evaluation of the efficacy of Mycobacterium bovis Bacillus Calmette-Guérin against bovine tuberculosis in neonatal calves in Ethiopia. Clin. Vaccine Immunol. 17: 1533-1538

[4] G. Lopez-Valencia, T. Renteria-Evangelista, M. Munoz del Real, A. De la Mora-Valle, G. Medina-Basulto, J. de Jesus Williamsand A. Licea-Navarro, Field Evaluation of the Mycobacterium bovis-BCG Vaccine Against Tuberculosis in Holstein Dairy Cows, Journal of Animal and Veterinary Advances, vol 8, Issue 11, 2171-2176

[5] 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

- **Need for marketing authorisation for BCG as veterinary product** – this authorisation needs to be issued by the UK's Veterinary Medicines Directorate (VMD) and Defra's Animal Health and Veterinary Laboratories Agency (AHVLA) submitted an application and accompanying evidence in January 2012. To date VMD are continuing to assess the application, but they will only issue a marketing authorisation following the removal of the EU prohibition on vaccinating cattle against TB.
- **Need for World Organisation for Animal Health (OIE) validation of the DIVA test** – OIE will need to be convinced that the DIVA test developed by Defra's Animal Health and Veterinary Laboratories Agency (AHVLA) is both safe and effective. Whilst AHVLA data has been shared with the OIE proving safety and effectiveness may take years.
- **Need to change the existing EU Directive 78/52/EEC- article 13ii –** Defra have initiated discussions with the European Commission on what steps will be required. It is however worth noting that the EU Commissioner for Health and Consumer Policy, Tony Borg, has stated that it is likely to be at least 10 years (2023) at the earliest before issues surrounding the use of cattle TB vaccine within the EU could be resolved[6].

Whilst the completion of these essential steps seems like it will be protracted there may be some hope offered by the development of the new **EU Animal Health Law**. This development will see the creation of a new single regulatory framework for animal health, under the auspices of the EU Animal Health Strategy.

A fundamental and underpinning principle of the Animal Health Law is that **prevention is better than cure**, and as such there may be scope for this new legislation to reduce or remove the current limitations on the use of vaccination. The European Commission is now expected to present the new Animal Health Law during the week beginning the 6th May 2013 as part of the Food and Feed Safety Package.

[6] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/183229/bovinetb-letter-paterson.pdf