

## Cattle vaccination against Bovine TB imminent?

Defra has provided the following information, extracted from Freedom of Information requests and other correspondence. This indicates that a cattle vaccine is actually closer to deployment than the Government is admitting.

### **Application for VMD approval has been made**

*“An application to the Veterinary Medicines Directorate (VMD) (the UK’s `regulatory body for veterinary medicines) for an ‘in principle’ decision on licensing was made on 20 January 2012 and we would normally expect to know the outcome in 9-12 months.”*

### **Studies suggest ‘considerable protection’**

*“BCG has been used in numerous vaccine studies since 1911 in cattle. Although studies are sometimes difficult to compare - as a variety of vaccine strains, challenge strains, vaccination and infection routes, and ways to measure protection have been applied - the results of the majority of these studies have demonstrated considerable protection. The results of controlled field studies are more variable but the overall majority also demonstrated protection, including recent studies conducted in Mexico (Lopez-Valencia et al., 2010) and Ethiopia (Ameni et al., 2010).”*

### **Now submitted for assessment**

*“Studies investigating the efficacy and safety of BCG Danish Strain 1331 (a commercially produced strain widely used as human vaccine) required for licensing have been completed by Defra Health and Veterinary Laboratories Agency and these data have been included in the recently submitted licensing application (see above) to the VDM for assessment.”*

### **EU legislation is still holding up field trials**

*“Studies to date cannot provide a definite figure for vaccine efficacy when administered to cattle under field conditions in the UK and it is currently not possible to generate these data in the field because of existing EU legislation prohibiting vaccination of cattle against TB (see below). However, small-scale field studies have been carried out recently in Ethiopia and Mexico and depending on the parameters selected the protective effect of vaccination was between 56% and 68%.”*

### **Moving ahead with the DIVA test**

DEFRA indicate validation and certification of DIVA test, possibly by the end of 2012.

*“Vaccination of cattle with BCG results in a proportion of animals becoming tuberculin test positive (both to the intradermal tuberculin skin test and gamma interferon blood test) and can therefore lead to false positive results in BCG-vaccinated but TB-uninfected cattle. In parallel with developing cattle TB vaccines, AHVLA is also developing a test to differentiate infected from vaccinated animals (so-called DIVA test). This test, based on the gamma interferon blood test, can be used alongside the tuberculin skin test in vaccinated animals where necessary, to confirm whether a skin test positive result is caused by vaccination or TB infection. The studies to generate validation data in vaccinated cattle are expected to be completed and data analysed by Easter 2012. If it is deemed that no further studies are needed, our plan is to make an application to the OIE (World Organisation for Animal Health) in summer 2012 for international certification of the test. Providing the OIE is satisfied with the fitness for purpose of the test, the earliest we could have OIE validation and certification would be the end of 2012.”*

### **Preparing for deployment**

*“As the science becomes clearer Defra will be in a firmer position in the coming months to begin to discuss with farmers, vets and other interested parties about how the vaccine and DIVA test can be used in the field and the likely implications on different types of farm business.”*

Full details on the above are now available at:

[www.defra.gov.uk/animal-diseases/a-z/bovine-tb/vaccination/cattle-vaccination/](http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/vaccination/cattle-vaccination/)