

Telephone 08459 33 55 77

Website www.defra.gov.uk

Our ref RFI 3725 & RFI 3749

Date 19th January 2011

Dear Ms Hall

REQUEST FOR INFORMATION: Bovine TB: specificity of the tuberculin skin test.

Thank you for your request for further information about the specificity of the tuberculin skin test for bovine TB, which we received on 23^d December 2010. We are dealing with your request under the Freedom of Information Act 2000. This response also covers your Freedom of Information request RFI 3749 of 17th January 2011.

The series of studies performed by Lesslie and co-workers and later published in the Veterinary Record underpinned the changeover in 1975 from 'mammalian' (*M. tuberculosis*) to 'bovine' (*M. bovis*) tuberculin produced by VLA Weybridge. This became, along with avian Weybridge tuberculin, the only antigen used in the detection of cattle infected with *Mycobacterium bovis* in Great Britain until October 2005 (see below). Those studies also enabled the estimation of the specificity of the single intradermal comparative cervical tuberculin (SICCT) test used in the UK bovine TB control programmes.

The formulation of tuberculins at VLA Weybridge remained essentially the same since 1975, i.e. using the same strain of *M. bovis*, same basic tuberculin production method and broadly the same nominal potency as stipulated in the European legislation and Pharmacopoeia (small variations in performance are a normal feature of biological products such as tuberculin, including variation between different production batches).

In the summer of 2005, after difficulties with the production of tuberculin at VLA Weybridge, Defra began to source paired stocks of bovine and avian tuberculins from ID-Lelystad in The Netherlands. These stocks started to be used in herds across GB from October 2005 and were alternated with Weybridge tuberculins for release to veterinarians on a strict temporal basis, dependent on the shelf life of the available stocks from each manufacturer. The alternate use of both tuberculins continued in GB until the production of Weybridge tuberculin at VLA ceased and stocks eventually ran out in September 2009. Since then, Dutch tuberculin from ID-Lelystad (now owned by Prionics) has been the only antigen used in the UK bovine TB testing programme (and it had also been in use in Ireland for many years before it started to replace Weybridge tuberculin in the UK).

Comparative statistical analyses of field test reactor data from British cattle herds tested between January 2005 and June 2009 were carried to monitor the relative performance of Weybridge and Dutch tuberculins. Although the classic test characteristics of sensitivity and specificity could not be compared with surveillance data (because only test reactors are slaughtered and we have no contemporaneous information on TB infection prevalence in test-negative cattle), the analyses indicated that the overall rate of disclosure of reactors and TB herd breakdowns were slightly higher in herds tested with Weybridge than with ID-Lelystad tuberculins. By contrast, confirmation of TB infection by post-mortem examination or culture was higher in reactor animals tested using ID-Lelystad tuberculin. However, the differences between the two tuberculins were small and unlikely to have observable effects in overall trends in bTB surveillance data.

Empirical (field) data from the bovine TB surveillance programme in Great Britain also show that the specificity of the SICCT test remains very high, despite the change of tuberculins. The specificity of a diagnostic test is the converse of the proportion of false positive results. Since (i) the number of false positives cannot exceed the total number of positive test results and (ii) between January and September 2010 (the most recent set of TB test data available) there were 4.1 TB reactors per 1,000 animal tests in GB, this means that, in the worst-case scenario, the SICCT test specificity in GB would be at least 995.9 per 1000 or 99.59%. Given that the majority of skin test reactors detected in GB originated from endemic TB areas of England and Wales and were likely to be infected (regardless of post-mortem findings), a better estimator of the true test specificity would be the converse of the proportion of test reactors observed in a very low TB incidence area such as Scotland, where the majority (but not all) of the test reactors could be expected to constitute false positive test results. Since we had a rate of 0.8 tuberculin skin test reactors per 1,000 animal tests in Scotland in the first nine months of 2010, this means that the test specificity was about 999.2 per 1,000 (or 99.92%).

Therefore, in addition to the field trials carried out by Lesslie et al. in the mid-1970s, the current field data continues to indicate a very high specificity of the SICCT test, despite the gradual replacement of Weybridge tuberculins with ID-Lelystad (Prionics) tuberculins between 2005 and 2009.

Information that you receive and is not subject to Crown Copyright continues to be protected by the copyright of the person, or organisation from which the information originated. You must ensure that you gain their permission before reproducing any third party (non-Crown Copyright) information.

In keeping with the spirit and effect of the Freedom of Information Act 2000/Environmental Information Regulations 2004, all information is assumed to be releasable to the public unless exempt. The information you requested may now be published on our website together with any related information that will provide a key to its wider context.

I also attach an annex giving contact details should you be unhappy with the services you have received.

I hope you find this letter informative. If you have any queries, please contact the Defra Customer Contact Unit at:

CCU 7th Floor
Eastbury house
30-34 Albert Embankment
London SE1 7TL

Email: ccu@correspondence@defra.gsi.gov.uk

Yours sincerely

Defra TB Programme

Annex A: Copyright

The information supplied to you continues to be protected by the Copyright, Designs and Patents Act 1988. You are free to use it for your own purposes, including any non-commercial research you are doing and for the purposes of news reporting. Any other re-use, for example commercial publication, would require the permission of the copyright holder. Most documents supplied by Defra will have been produced by government officials and will be Crown Copyright. You can find details on the arrangements for re-using Crown copyright on OPSI (Office of Public Sector Information) at:

<http://www.opsi.gov.uk/click-use/index.htm>

Annex B: Complaints

If you are unhappy with the service you have received in relation to your request you may make a complaint or appeal against our decision within 40 working days of the date of this letter. Please write to Brendan Walsh, Head of Defra's Information Rights Team at, Area1B Ergon House, Horseferry Road, London SW1P 2AL, (email: informationrights@defra.gsi.gov.uk) who will arrange for an internal review of your case. Details of Defra's complaints procedure can be found at:

<http://www.defra.gov.uk/corporate/policy/opengov/complain/index.htm>

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please note that generally the Information Commissioner cannot make a decision unless you have first exhausted Defra's own complaints procedure. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF