Communications with Defra via Freedom of Information Requests and follow on communications.

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Letter form Defra RFI 4469 Dated 1st Feb 2011 sic.

To: Mick Griffths
mickgriffthsnow@tiscali.co.uk

Dear Mr Griffths

Cattle Vaccine for Bovine TB Freedom of Information Request

Thank you for your request received on 4 January 2012 asking for documents relating to the way Defra describes the availability of cattle vaccine for bovine TB. As you know we have handled your request under the Freedom of Information Act 2000 (FOIA).

In the September 2010 consultation on badger control we said:

“Defra had invested £18 million by the end of the last financial year on the development of cattle vaccines and associated diagnostic tools. **We aim to have a licensed cattle vaccine by**
This vaccine is BCG (Bacille Calmette-Guérin, the human TB vaccine) which sensitizes cattle to the mandatory tuberculin skin test for some time after vaccination and can lead to a positive result when an animal is not infected with *M. bovis* (a “false positive”). Therefore Defra is also developing a diagnostic test to differentiate infected from vaccinated animals (known as a “DIVA” test) that could be used alongside the tuberculin skin test, where necessary, to confirm whether the animal is indeed infected. Our aim is also to have the DIVA test approved by 2012.

But we also made clear in paragraph 63 of the same documents that...

“...Once a licensed cattle vaccine and effective DIVA test are available, the basis for declaring herds tuberculosis-free will need to change. As part of the ongoing consultation on the new EU Animal Health Law, we will be using the strong scientific and technical evidence on the efficacy and safety of the cattle vaccine and the role of a DIVA test to request the necessary changes to EU legislation to lift the requirement for the skin test to be the only test to confer OTP herd status. Due to the need to change EU legislation, which is a lengthy process, we anticipate that a cattle vaccine and DIVA test could not be used in the field before 2015 at the earliest....

By the time we came to publish the TB Eradication Programme in July 2011 we were aware that a TB cattle licence could not be issued by the Veterinary Medicines Directorate until the ban on vaccination had been lifted...and we said this in the Eradication Programme. As I have explained above, we had already said in the consultation that deployment for use in the field could not be before 2015 at the earliest. When we came to publish the Eradication Programme it was clear that significant technical and regulatory challenges remained and this led us to conclude that the 2015 date should be dropped until matters had been clarified. We still do not have a fixed date by which we expect cattle vaccine to be deployed in the field. However, the details underpinning these uncertainties as requested in your freedom of information request are withheld under exemptions 27 (international relations) and 35 (formulation of government policy) of the Freedom of Information Act.

You also asked what steps the government has taken to change EU law to allow vaccination in anticipation of licensing. In brief we are continuing with the work described in paragraphs 83-88 of the TB Eradication Programme for England see [http://www.defra.gov.uk/publications/files/pb13601-bovinetb-eradication-programme-110719.pdf](http://www.defra.gov.uk/publications/files/pb13601-bovinetb-eradication-programme-110719.pdf)

In keeping with the spirit and effect of the Freedom of Information Act 2000, all information is assumed to be releasable to the public unless exempt.

I attach Annex A, which explains the copyright that applies to the information being released to you.
I also attach Annex B giving contact details should you be unhappy with the services you have received.

If you have any queries about this letter please contact the Customer Contact Unit at the email address below.

Yours sincerely
Defra TB Programme
From: Mick Griffiths

To: TBADMIN (FFG)

Sent: Thursday, February 09, 2012 7:36 PM

Subject: Re: Freedom of Information request RFI 4469

Thank you for your response to my FOI request RFI4469

Your reply has raised a number of questions which I have marked below in red against your response.

“....Once a licensed cattle vaccine and effective DIVA test are available, the basis for declaring herds tuberculosis-free will need to change. As part of the ongoing consultation on the new EU Animal Health Law, we will be using the strong scientific and technical evidence on the efficacy and safety of the cattle vaccine and the role of a DIVA test *1 to request the necessary changes to EU legislation to lift the requirement for the skin test to be the only test to confer OTF herd status. Due to the need to change EU legislation, which is a lengthy process, we anticipate that a cattle vaccine and DIVA test could not be used in the field before 2015 at the earliest....

*1 This indicates such evidence exists and is of a robust and substantial nature. Please provide a copy of this evidence.

"By the time we came to publish the TB Eradication Programme in July 2011 we were aware that a TB cattle licence could not be issued by the Veterinary Medicines Directorate until the ban on vaccination had been lifted… and we said this in the Eradication Programme."

What measure or authority stops licensing preceding legislation?

Why was this not known before, and when the badger cull consultation was published?

Even if a license cannot be issued until the ban is lifted, why can the licensing process not be otherwise completed and an announcement to that effect made?

"As I have explained above, we had already said in the consultation that deployment for use in the field could not be before 2015 at the earliest. When we came to publish the Eradication Programme it was clear that significant technical and regulatory challenges remained "

What were the: a) regulatory and b) technical challenges. And why were they only now apparent?

It would appear from this response that:

A vaccine and DIVA test cannot be licensed unless and until the ban is lifted.

The ban cannot be lifted until, (from para 86 of http://www.defra.gov.uk/publications/files/pb13601-bovinetb-eradication-programme-110719.pdf) a vaccine is available i.e. licensing has occurred.

Or arguably until information on efficacy is available, which Defra imply above (see “the strong evidence”) is now available This means the ban can be lifted NOW.
Lifting of the ban and licensing can be simultaneous, if the preparation for legislating is carried out simultaneously with preparation for licensing.

Please advise which is the case and why you have made the following statement. "and this led us to conclude that the 2015 date should be dropped until matters had been clarified."

Please advise if or when will "matters" be clarified.

If matters are so confused and uncertain that no date can be deduced or estimated or even set as a target, a full disclosure of the problem needs to be made, inter alia so that interested and expert parties can propose solutions. Please advise if this will happen. If not why not?

"We still do not have a fixed date by which we expect cattle vaccine to be deployed in the field. However, the details underpinning these uncertainties as requested in your freedom of information request are withheld under exemptions 27 (international relations) and 35 (formulation of government policy) of the Freedom of Information Act."

This seems to extend the meaning of S 27 and 35.

It is hard to see how it relates to formulation of Government policy when there is no question of formulating such policy - the Government has already declared the relevant policy specifically to “request” a specific change in EU legislation. The exemption therefore expires under S35 (2) a of the Act.

Alternatively there is an overriding public interest in disclosure as the information relates to a consultation (badger cull) which while now closed was conducted on false information.

Notwithstanding the above the full reasons for arguing that S27 and 35 apply must be advanced and appealed.

You also asked what steps the government has taken to change EU law to allow vaccination in anticipation of licensing. In brief we are continuing with the work described in paragraphs 83-88 of the TB Eradication Programme for England see http://www.defra.gov.uk/publications/files/pb13601-bovinetb-eradication-programme-110719.pdf

This states at 88

88. Changing EU legislation is a lengthy and uncertain process and preliminary discussions with the EU Commission have indicated that a change to the legal framework on vaccination and DIVA testing cannot be considered until sufficient evidence of their effectiveness is available. This is likely to take some time and as a result we anticipate that a cattle vaccine and DIVA test will not be available for use in the field for many years.

What is the scope of "sufficient evidence"?

What is the programme timeframe to compile such evidence.
Has this programme started, is it on target and what is the expected completion date?

Has the EU Commission given a timescale for the change to the legal framework after submission of the evidence?

At 84 this document states: The necessary regulatory studies are nearing completion and we intend to submit an application for a marketing authorisation for a BCG cattle vaccine later this year. While the Veterinary Medicines Directorate (VMD) will be able to confirm whether it is satisfied with the safety, quality and efficacy data provided, it will not be able to grant a marketing authorisation for the product while cattle TB vaccination is prohibited in EU legislation.

Please advise if and when an application was made and when a response is expected from VMD.

Thanking you in anticipation

Michael Griffiths
Dear Mr Griffiths

Cattle Vaccine for Bovine TB Freedom of Information Request

Thank you for your follow up request asking for additional information about a cattle vaccine for bovine TB, an oral badger vaccine, DIVA test and steps the government has taken to change EU law to allow vaccination.

You have challenged the use of exemptions set out in the original correspondence for why documents are not being released to you. As referred to in Annex A of our previous letter, if you are unhappy with the service you have received in relation to an FOI request and you wish to make a complaint or appeal against our decision you should 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 are on our website.

The remainder of the points you’ve raised are not FoI matters.

Your first issue concerns evidence. You may have already seen the latest addition to the Defra website concerning cattle vaccines. http://www.defra.gov.uk/animal-diseases/a-z/bovine-tb/vaccination/cattle-vaccination/ This briefly explains the challenges faced in licensing this vaccine and provides a small number of references suitable for web page presentation.

But you are of course right and BCG has been used in numerous vaccine studies since 1911 in cattle – see Annex C. 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).

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’s Animal Health and Veterinary Laboratories Agency and these data have been included in the recently submitted licensing application to the Veterinary Medicines Directorate (the UK’s regulatory body for veterinary medicines) for assessment. Provided it is satisfied with the safety, quality and efficacy data, VMD would be able to confirm that requirements to obtain a marketing authorisation have been met/fulfilled. If circumstances remain unchanged and the EU prohibition of the vaccination of cattle against TB is then lifted, the Secretary of State would be able to grant the marketing authorisation for the product. The safety, efficacy and quality data in the marketing authorisation dossier is commercial in confidence and cannot be released at the present time.

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%.

However, to put BCG in cattle into context: as with BCG in other species it is not 100% effective in preventing TB. Rather, it provides a spectrum of protection:

- Some cattle will be fully protected;
- Some cattle will benefit from reduced disease;
- Some cattle will get no protection from vaccination; and
- As far as we know BCG does not have a therapeutic effect in already infected animals.

BCG vaccination of cattle could be a valuable tool when used alongside other TB control measures in the UK.

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.

Your second group of questions concerned the licensing process to which the answers are as follows: We already knew that the ban on vaccination would have to be lifted before vaccination could go ahead and that was clear in the consultation document. A license can only be granted because there is a statutory power to do so. In the case of a cattle vaccine against TB the EU ban on vaccinate precludes the issue of such a license. A license application has been made and if there is an agreement in principle that will be announced.

Thirdly, you ask about the regulatory and technical challenges. These include lifting the EU ban on cattle vaccination, see above and; the amount and quality of evidence required by VMD and the European Commission and other Member States before lifting the ban. These challenges were discussed in the original cattle vaccines policy paper published by Defra in 2008 see http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/tb/documents/vaccine_cattle.pdf As you say, the vaccine and DIVA test cannot be licensed until the legal ban is lifted. We hope that the period between the lifting of the legal ban on use of vaccine and the granting of a licence for its use can be kept very short. But the first is a pre-requisite of the second.
Fourthly you ask when matters related to the date will be clarified, when the application to VMD was made and when we expect to hear back. An application to VMD for an ‘in principle’ decision on licensing was made on 20 January and we would normally expect to know the outcome in 9-12 months. Indications from the European Commission are that their proposal for an EU Animal Health Law will be put to the European Parliament and Council of Ministers later this year. It is unclear how long it will take before these can be adopted, or what their final form will be. In the meantime we will be doing all we can to ensure the evidence produced in support of the cattle vaccine and DIVA test is sufficient to persuade the European Commission and Member States to lift the present ban. The pathway to what we hope will be a licensed and effective vaccine is clear. It is just the timing that remains unclear, since it depends on the actions of a number of institutions, including the European Commission, Parliament and Council of Ministers.

Finally, you asked in connection with the international ban on vaccination what was ‘sufficient evidence for lifting the ban’ and the timescales involved. Sufficient evidence will involve at least an agreement in principle on the part of the VMD to license the vaccine; international certification by the OIE of the evidence regarding the DIVA test; and validation by the European Food Standards Agency (EFSA) of vaccinating cattle against TB. On the basis of this the EC and Member States may seek further evidence. As far as timescale is concerned, the process has started and will be subject to discussions that have yet to take place with OIE and EFSA. These are planned for later this year. However, it would be wrong to guess at a completion date, but we’re doing all we can to influence others to move things on as soon as possible. The Commission has not given a timescale because the necessary legal framework is not yet in place. The Commission has however indicated that they plan to put their proposal on a new AH Law to the European Council and Parliament in the autumn but it is unclear how long this process will take to achieve completion.

In keeping with the spirit and effect of the Freedom of Information Act 2000, all information is assumed to be releasable to the public unless exempt.

I attach Annex A, which explains the copyright that applies to the information being released to you.

Annex B giving contact details should you be unhappy with the services you have received.

Annex C listing published studies re BCG cattle vaccination.

Annex D listing published studies towards development of a DIVA test.

If you have any queries about this letter please contact the Customer Contact Unit at the email address below.

Yours sincerely

Defra TB Programme

Email: ecu@correspondence@defra.gsi.gov.uk
Email from Defra July 31st 2012

Dear Mr. Griffiths,

Thank you for your email.

The studies described to generate validation data from AKVLA’s prototype DIVA test in BCG-vaccinated experimentally-challenged cattle were completed and analysed by Easter 2012. The OIE was asked to evaluate the test but because there was no data from the field (since TB vaccination of cattle in this field is prohibited by EU law) but rather (by necessity) the test performance had been evaluated in a limited number of experimentally vaccinated cattle they could not accept this validation. We have subsequently put the dossier to experts at a number of international reference laboratories seeking their views on our results and our approach to validation and are awaiting their advice. This will be used to inform what other experimental and field studies would be needed for the OIE to accept validation of the test. As things currently stand the UK would need a derogation to undertake field trials in England or any field studies would need to be carried out in non-EU countries. The latter would not be ideal for validation of the DIVA test since ordinarily these studies would be carried out under the field and environmental conditions of the intended country of use.

I hope this answers your questions.

Regards,

Defra TB Programme

Department for Environment, Food and Rural Affairs (Defra)

This email and any attachments is intended for the named recipient only. If you have received it in error you have no authority to use, disclose, store or copy any of its contents and you should destroy it and inform the sender. Whilst this email and associated attachments will have been checked<bn>for known viruses whilst within Defra systems we can accept no responsibility once it has left our systems. Communications on Defra’s computer systems may be monitored and/or recorded to secure the effective operation of the system and for other lawful purposes.
Please see attached acknowledgement for your FOI request (FOI 5088).

Many thanks

Bovine TB Programme
Defra

From: Mick Griffiths [mailto:mickgriffithsnow@btiscali.co.uk]
Sent: 28 October 2012 19:57
To: Tbadmin (FFG)
Subject: Validation data from AHVLA's prototype DIVA test

Freedom of information request.
Please can you provide answers to the following:
Re your email below. You say “We have subsequently put the dossier to experts at a number of international reference laboratories seeking their views on our results and our approach to validation and are awaiting their advice. This will be used to inform what other experimental and field studies would be needed for the OIE.”
1. Did you ask the OIE what other experimental and field studies would be needed for them to accept validation of the test?
  If yes what was their response and if not why not?
2. Provide a list of international Reference Laboratories to which you sent the dossier.
3. What responses did you receive from these Laboratories?
4. A list of any experimental and/or field studies planned as a result.
5. Dates by which any studies in 4 above are planned to be completed.
6. When you expect to have International Certification of the DIVA test.
Thanking you in anticipation
Michael Griffiths
To: Michael Griffiths

Your ref: FOI 5088

Date: 5th December 2012

Dear Mr Griffiths

REQUEST FOR INFORMATION: REFERENCE OF THE CATTLE DIVA TEST TO INTERNATIONAL LABORATORIES

Thank you for your request for information which we received on 28th October 2012 and I am sorry for the delay in responding. Your latest request related to an earlier reply in which we had said:

“We have subsequently put the dossier to experts at a number of international reference laboratories seeking their views on our results and our approach to validation and are awaiting their advice. This will be used to inform what other experimental and field studies would be needed for the OIE.”

As a result you asked:

1. Did you ask the OIE what other experimental and field studies would be needed for them to accept validation of the test? If yes what was their response and if not why not?

2. Provide a list of International Reference Laboratories to which you sent the dossier.

3. What responses did you receive from these Laboratories?

4. A list of any experimental and or field studies planned as a result.

5. Dates by which any studies in 4 above are planned to be completed.

6. When you expect to have International Certification of the DIVA test.

As you know, we have handled your request under Freedom of Information Act 2000.

For question 1, I can confirm that as we said in our earlier reply, replies from experts will inform the next step.

For question 2, the dossier was sent to the OIE reference laboratories in France, and Argentina, and the EU Reference Laboratory in Spain and details of these laboratories is published and can be found at http://www.oie.int/our-scientific-expertise/reference-laboratories/list-of-laboratories/ and at http://ec.europa.eu/food/animal/diseases/laboratories/index_en.htm.

For question 3 6, an initial analysis of replies recently received from the laboratories consulted has taken place; and we are actively considered options as part of the policy development process. But as yet no decisions have been taken on whether or not to
undertake experimental or field trials. **We have considered the public interest in releasing** this information now but are strongly of the view that to do so could harm both national and international discussion aimed at securing validation of the vaccine and its associated DIVA test; and so the replies from the laboratories and their analysis are withheld under **exemption 35 of the FoI Act.**

I attach an annex giving contact details should you be unhappy with the service that you have received. If you have any queries about this letter, please contact me.

Yours sincerely
Defra TB Programme
Email: ccu@correspondence@defra.gsi.gov.uk

**Annex A**

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 Mike Kaye, Head of Information Standards, Area 1B, Ergon House, Horseferry Road, London, SW1P 2AL (email: requestforinfo@defra.gsi.gov.uk) and he will arrange for an internal review of your case. Details of Defra’s complaints procedure are on our website.

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
Dear Sirs,
Thank you for your response to the above referenced FOI request 5088.

Your reply to question 1, To "Did you ask the OIE what other experimental and field studies would be needed for them to accept validation of the test? If yes what was their response and if not why not?"
You replied "I can confirm that as we said in our earlier reply, replies from experts will inform the next step."
This fails to answer the question. Please answer the specific question asked.

-Your response to Question 2 answered the question Thank you.

Your response to questions 3 to 6 did not provide the information requested. Can you provide a date by which you can provide this information? Dependant on your response I will may appeal against your decision within 40 working days of the 5th Dec 2012 ie the date of your letter. A timely reply would therefore be appreciated.
Thanking you in anticipation

Michael Griffiths.
ps With regard to my question re applying for an extension. Your letter (see below) stated that is what you did. The letter also has incorrect dates by which you planned to reply. Not your finest moment. Best forgotten I think.
Letter from Defra RFI 5189 Dec 19th 2012.

Michael Griffiths
mailto:mickgriffithsnow@tiscali.co.uk

Dear Mr Griffiths

REQUEST FOR INFORMATION: REFERENCE OF THE CATTLE DIVA TEST TO INTERNATIONAL LABORATORIES

Thank you for your request for information which we received on 12th December 2012 about the reply to FOI 5088.

Regarding question 1 of FOI 5088, I can confirm as in my original reply that the data was submitted to the three international laboratories and not to the OIE.

As for question 3 and 6, an initial analysis of replies recently received from the laboratories consulted has taken place; and we are actively considering options as part of the policy development process. But as yet no decisions have been taken on whether or not to undertake experimental or field trials. We have considered the public interest in releasing this information now but are strongly of the view that to do so could harm both rational and international discussion aimed at securing validation of the vaccine and its associated DIVA test; and so the replies from the laboratories and their analysis are withheld under exemption 35 of the FoI Act.

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

If you have any queries about this letter, please contact me.

Yours sincerely

Defra TB Programme
Email: ccu@correspondence@defra.qsi.gov.uk