TONIO BORG

MEMBER OF THE EUROPEAN COMMISSION

Brussels,
HV/cs/1792649 (13)

Dear Mr Paterson,

Following the meeting between Ms Williams and Mrs Testori Coggi in London on the 21st November 2012, I would like to update you on the bovine tuberculosis (bTB) eradication programme 2013 and the future possible use of vaccine in cattle.

Bovine tuberculosis eradication programme 2013

The UK bTB eradication programme to be implemented in 2013 has been approved by Commission Implementing Decision 2012/761/EU. This programme entails a number of commitments from your authority, in particular:

- the abolition of Approved Quarantine Units (AQUs) by the end of 2013;
- the completion and implementation of the plans for abolishing Sole Occupancy Authorities;
- a commitment to carry out in 2013 a further review of the remaining exemptions to pre-movement testing;
- a thorough review of the arrangements for the implementation in the UK of the concept "holding" as laid down in Union legislation;
- the limitation and phase out by the end of 2014 of the practice of de-restricting certain epidemiologically separate parts of bTB-affected holding.

I very much welcome these commitments and all your efforts to comply fully with EU legislation. My service intends to follow closely the implementation of this programme. I am also confident that all recommendations made by the inspection service of the Health and Consumers Directorate General (Food and Veterinary Office), following their visit in September 2011 have been appropriately addressed.

In the past four years the Commission has allocated considerable funds to support the UK bTB programmes (EUR 116,3 Mio in total). We therefore expect significant improvements in the epidemiological situation in 2013 that show efficient use of Union funds. This is absolutely necessary in view of a further renewal of the EU financial support to this programme.

Mr Owen Paterson
Secretary of State for Environment, Food and Rural Affairs,
UK

RUE DE LA LOI 200 - B-1049 BRUSSELS - TEL.: (+32-2) 295.40.60 - FAX: (+32-2)292.11.80
e-mail: tonio.borg@ec.europa.eu

Future possible use of vaccine in cattle

Vaccination against bTB is explicitly forbidden in the EU legislation on disease control (Council Directive 78/52/EEC) and implicitly also in intra-Union trade legislation, as vaccination is not compatible with the provisions for testing and herd qualification (Council Directive 64/432/EEC). EU legislation is fully in line with OIE standards on international trade and can be changed only by the European Parliament and the Council.

The main reason for the current vaccination ban is due to the possibility that vaccinated animals are not fully protected against bTB infection. Due to the suboptimal protection induced by the available vaccines (live BCG vaccine), vaccinated animals may become infected if exposed to the disease agent and then they cannot be distinguished from the non-infected vaccinated animals, due to the interference of vaccination with existing diagnostic methods (PPD-tuberculin skin test). This would jeopardise current bTB control and eradication policy.

UK has invested considerable resources to develop a candidate vaccine accompanied with diagnostic test(s) that would be compatible with the vaccine (DIVA[1] tests). Apparently only Ireland and New Zealand have shown some interest in this development.

Scientific knowledge on bTB vaccination was reviewed during a recent technical workshop held in Cardiff. The outcome of the workshop clearly indicates that the hypothetical use of the only candidate vaccine (live BCG vaccine) presents still many knowledge gaps, in particular concerning the performance of the vaccine (level and duration of protection, protection from disease or infection), safety (possible shedding of the attenuated live pathogen by vaccinated animals), conditions for use (age of animals, type of herd) and suitability of candidate DIVA test(s).

Fundamental scientific information is not yet available on the reliability and feasibility of cattle vaccination accompanied by use of DIVA test(s) that is fundamental for a possible change in the current EU policy on the control and eradication of bTB. Future studies should also address *food safety concerns* (shedding of vaccine strain in milk), *human health concerns* (BCG is the only vaccine available for humans and its use in cattle may lead to the selection of BCG-resistant strains of bTB that may affect also humans) and *animal health and trade concerns* (proper discrimination between vaccinated and infected animals, costs/benefits of vaccination policy, current policy, acceptability of vaccinated animals in international trade).

However, you can find attached a tentative time line for bTB vaccination of cattle in UK and the EU, showing the series of steps/milestones that will be needed. I would like to underline that under the current circumstances the timeline provided is to be considered as purely indicative.

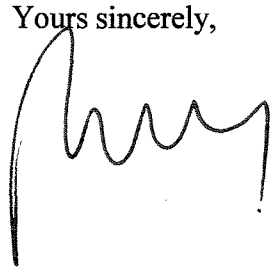
---

[1] DIVA: Differentiating Infected from Vaccinated Animals

Finally, I would like again to bring to your attention the crucial importance of the application of the strict measures at farm level, as foreseen in the bTB approved 2013 programme and also committed by your authority.

Given the importance of this issue may I assure you that my services remain at your disposal for any information or possible assistance that you might require on these issues.

Yours sincerely,



ANNEX

A TENTATIVE TIME LINE FOR POSSIBLE USE OF

A VACCINE AGAINST BOVINE TUBERCULOSIS IN THE EU

A series of steps would needed to be undertaken as follows:

1. In order to provide answers to the still open scientific questions on bTB vaccination, substantial experimental research and large scale long lasting (possibly 2-5 years) trials, also under EU field conditions, are needed [start 2013, end 2015-2016].

2. Scientific consensus should be reached on the conditions for use of the candidate vaccine and the DIVA test in order to ensure better bTB control. Scientific opinion from EFSA will be needed (could take 12-18 months once science is available). The vaccine should also undergo marketing authorization procedure, as appropriate [2016-2017].

3. Debate on the veterinary conditions to allow the use of vaccine, that would possibly end with new EU rules (possibly encompassed within delegated and implementing acts that would follow the new Animal Health Law) authorizing vaccination as an additional tool for bTB control. It looks realistic that these rules would not allow vaccinated animals to enter intra-Union trade (like ewes vaccinated against brucellosis in Greece) [2017-2018].

4. Practical experience on the use of the vaccine and DIVA test under the new rules above. This phase will be important to decide on a wider use of vaccine in the EU regions not bTB-free (currently less than 20% of the EU territory) and on the possible conditions for intra-Union and international trade of vaccinated animals and herds [2018-2023].

5. Possible EU rules on vaccinated animals and herds to enter intra-Union trade in parallel with amendments of international standards (OIE Terrestrial Code and Diagnostic Manual) [2023].