Opinion 14-2022 of the Scientific Committee established at the FASFC on the draft royal decree on the control of bovine tuberculosis

Background & Terms of reference

Belgium has been officially free of bovine tuberculosis (bTB) since 2003. To maintain its status, Belgium organises a surveillance programme coordinated by the FASFC in collaboration with recognised animal health associations. Since January 2021, a new surveillance programme against bTB has started in Belgium. The Scientific Committee has already issued two opinions on the bTB surveillance programme (12-2016 and 08-2019).

Since 21 April 2021, Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on communicable animal diseases and amending and repealing certain acts in the field of animal health (the new Animal Health Act - AHL) has been in force.
Commission delegated regulation (EU) 2020/689 of 17 December 2019 supplementing regulation (EU) 2016/429 of the European Parliament and of the Council as regards to rules on surveillance, eradication programmes and "disease-free" status for certain listed diseases and emerging diseases contains specific dispositions for the control of bTB.
These regulations are directly applicable to the Belgian law.

Moreover, the Royal Decree of 17 January 2021 on the control of bovine tuberculosis has now been in force for more than a year, which has revealed a number of gaps or inaccuracies. Consequently, Belgian legislation on the control of bTB needs to be updated.

The draft royal decree takes into account both the adjustments concerning the dispositions of the AHL and its delegated acts and the experience gained in the field since more than a year following the introduction of the new programme on the surveillance of bTB.

The Scientific Committee is requested, on the one hand, to review the draft RD and assess the continued relevance of the various measures contained in this draft RD and, and on the other hand, to examine a number of specific questions that arose as a result of experience in the field or the application of the AHL.

Method

This risk assessment was carried out on the basis of expert opinion and available and relevant data in the scientific literature.

Conclusions and recommendations

The Scientific Committee has formulated a response to the specific questions:

1. *The draft RD does not provide for blood sampling in fattening farms nor in veal calf farms, as the animals are destined for the slaughterhouse directly.*
   Can the Scientific Committee express an opinion on the relevance of that measure? When should the measures in a fattening farm be lifted? What should be done with manure from contaminated holdings?
   Given the young age of veal calves and the risk of nonspecific reactions with the IFNγ test, the Scientific Committee can agree to no longer carry out surveillance in veal calves before the animals go to slaughter.
   With regard to fattening farms, the Scientific Committee proposes to limit surveillance using serology (detection of antibodies) and the IFNγ test to the animal category with the highest risk: female cattle older than 24 months.
   However, animals present on a veal calf holding or a fattening holding that have been in contact with an outbreak holding and/or a suspicious animal should always be tested to determine their infection status, regardless of their age.
   Regarding manure from positive farms, according with the opinion 06-2019, it is recommended that both slurry and solid manure be stored for at least 6 months.

Considering that *M. bovis* survives longer in slurry than in solid composted manure, it is from the responsibility of the competent authorities to decide whether solid manure can be released earlier. It is important to consider the climatic conditions during storage. Chemical and thermal treatment can also achieve sufficient inactivation of mycobacteria in manure under certain conditions and thus lead to faster lifting of the measures.

2. *Interpretation of IFNγ test results leads to confusion in the field. The IFNγ MixEC test is not fulfilling its role as a confirmatory test.*
   Can the Scientific Committee suggest a grid for interpreting the results or confirm the grid used (Annex 2)?
   In a context of bTB control, he IFNγ test has only been used in Belgium since February 2021. The IFNγ test can be actually assessed in the context of the contact tracing performed during 2 recent outbreaks, in which no secondary outbreaks were detected.
   Analysis of the IFNγ MixEC results for all cattle sampled during these two outbreaks is revealing a high positivity rate (5.93% for hearth 1 and 3.37% for hearth 2). Based on the IFNγ MixEC results on cattle samples that tested positive to the IFNγ PPDA-PPDB test, the number of cattle that were considered positive and thus had to be culled could be reduced: When contact farms were followed up by the IFNγ PPDA-PPDB test, 30 out of 6232 animals were found to be positive. Ten of these animals also tested positive with the IFNγ MixEC test. None of these 10 animals showed any suspicious lesion at slaughter. Consequently, the testing strategy is giving excellent specificity (> 99.5%).
   In conclusion, the use of IFNγ PPDA-PPDB has been successfully applied in the Belgian context; the IFNγ MixEC allows an improvement in the specificity of the test. Thus, the IFNγ MixEC test has mainly an added value as a confirmatory test in cattle that test positive with the IFNγ PPDA-PPDB. However, additional data are recommended to be collected and examined longer the course of the implementation of the new control programme.
   The Scientific Committee suggests in this opinion some further changes to the grid aiming at interpretation of the results.
3. *Imported cattle from a non-tuberculosis-free area are surveyed for 3 years. The administration wondered why cattle are not surveyed for 5 years as it is currently done for the follow-up of cattle in old outbreaks, or can a one-year follow-up be considered?*
   Considering the worst-case scenario (= cattle originating from a herd where measures were lifted after a long outbreak period), data in the scientific literature suggest that a five-year monitoring period is appropriate. On this basis, a 5-year period is recommended for cattle imported from a non-tuberculosis-free area, instead of 3 years.
4. *In case of an outbreak, the herd is currently being completely culled. Delegated Regulation (EU) 2020/689 provides for the removal of cattle with confirmed infection and cattle that have tested positive with an IFNγ test. The remaining cattle must undergo 2 IFNγ tests after 2 and 4 months respectively following the removal of infected cattle or cattle with a positive IFNγ test.*
   The cost of reimbursement in case of complete culling is very high for the Fund. In its 08-2019 opinion, the Scientific Committee recommends complete culling. Does this recommendation still apply or could partial culling be considered, and if so, under what conditions?
   If complete culling continues to apply, the draft decision stipulates not to perform blood tests on animals with unconfirmed infection.
   Monte-Carlo simulations were carried out to estimate the impact of partial culling on the risk of re-emergence of bTB on the same holding. Practically speaking, it can be said that partial culling will increase the risk of re-emergence of bTB on the same holding. Indeed, partial culling will lead to a reduction in the number of infected animals but, due to the possible presence of false negatives, there is a chance that infected animals will be detected at subsequent controls of the farm (depending on the sensitivity of the test, the number of animals present, the number of false negatives left behind, etc.). To avoid this, it is recommended to apply partial culling only twice on an outbreak holding.

In case of a third, consecutive, outbreak in a herd, complete culling of the herd is recommended.

In case all animals on a confirmed herd are culled, no samples are currently taken from the animals for bTB diagnosis . However, it is recommended to do so in any case as this can provide important insights regarding the infection rate in an outbreak herd.

5. *What are the risks posed by other susceptible animal species present on an infected holding for maintaining infection cycles and what measures can be recommended for those species?*

   Given the limited time frame for issuing this opinion, the Scientific Committee, in consultation with the opinion requesters, limited the answer to this question to the following animal species/animal categories: companion animals (dogs and cats), small ruminants (sheep and goats) and horses. These animal species also pose the highest risk for maintaining infection cycles of bTB on cattle holdings under Belgian epidemiological conditions.

   A review of the data in the scientific literature concerning potential diagnostic tests in the specified animal species is presented. A number of diagnostic tests prove to be interesting for bTB diagnosis . However, although some progress has been made in the performance of diagnostic tests, few diagnostic tests have been yet validated for bTB diagnosis in the specified animal species. Passive surveillance (based on clinical signs) is therefore recommended.

   If animals have been in contact with cattle infected with bTB, a combination of tests is recommended on a case-by-case basis, eventually combined with euthanasia. Treatment of companion animals infected with tuberculosis is not recommended because of the potential zoonotic transmission, especially in cases of obvious respiratory clinical signs. Moreover, prognosis is often unfavourable. Measures to consider regarding the treatment of tuberculosis infections are listed in the opinion.

The Scientific Committee examined the draft RD and made a number of comments. The main comments on the RD and the control programme are as follows:

- In the context of putative reduced surveillance in fattening holdings (see specific question 1), grazing ban already in force on these holdings is highlighted because it can be considered as an important risk-reducing measure regarding the spread of bTB. Livestock farmers should be sensitised to this and given clear recommendations.
- All suspected bTB infections in both cattle and other species should be registered in a central database that should be consultable by all actors participating to the control programme.
- Belgium's approach for the surveillance of all cattle holdings using serological tests is highly innovative. This approach aims to actively look for any farms positive for bTB infection and does not aim to prove that the Belgian cattle population is free of bTB. However, the use of serological tests in this context has never been carried out aiming at bTB control. It is therefore appropriate to remain cautious and assess again this approach after 1 year. One of the possible concerns that could arise is the detection of many (false) positive animals and holdings. This could potentially lead to high costs and decreased motivation among actors in the field. If this trend is confirmed, there are a number of options to tackle this:
  - establish a risk profile of cattle holdings (see Table 3 for risk factors) and test only those that have a high risk profile. Of course, legal requirements on surveillance for bTB should be met and follow-up of previous outbreaks and follow-up of imported animals should not be compromised.
  - consider a holding as positive only if more than 1 animal tests positive during the testing strategy.

The full text is available on this website in dutch and in french.