



**EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL**

**Directorate G - Veterinary and International Affairs
Unit G2 – Animal Health**

Brussels,

SANCO/7059/2013

Working Document
on
causal agents of bovine tuberculosis

This document does not necessarily represent the views of the Commission Services

1.1. Introduction

The purpose of this document is:

- to exchange views on the possible interpretation of the term "bovine tuberculosis" in the light of the modifications made at beginning of the 2000 years to the nomenclature of *Mycobacteria* and considering recent expert advice;
- to provide assistance to the veterinary services of the Member States as regards the application of the control measures for bovine tuberculosis described in Part I of Annex A to Council Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine.

1.2. Definition of bovine tuberculosis (bTB)

1.2.1. Legislative context

The rules on bovine tuberculosis laid down in Council Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine¹, and in particular in Annex A thereto, were last amended by Council Directive 98/46/EC and Article 1(6) of Council Directive 2000/20/EC.

Unlike Annex B to that Directive relating to the diagnosis of tuberculosis, which was last amended by Commission Regulation (EC) No 1226/2002 of 8 July 2002, Annex A describing the procedures for classifying herds and assigning official status to herds can only be amended by the Council in accordance with the procedures referred to in Article 16 of that Directive.

1.2.2. Scientific context

During the period between 1999 and 2003, the taxonomy of this group of bacteria has been modified twice. At a first instance, Aranaz et al. (1999) named this organism *Mycobacterium tuberculosis subsp. caprae*. Not without controversy, Niemann et al. (2002) transferred *M. tuberculosis subsp. caprae* to the *M. bovis* group as *M. bovis subsp. caprae*. Later, scientific studies reinforced the idea that the caprine mycobacterial strains are a taxon of the *M. tuberculosis* complex, independent of *M. bovis* and it was proposed by Aranaz et al. (2003) that *M. tuberculosis subsp. caprae* be elevated to species status, as *Mycobacterium caprae comb. nov., sp. nov.*

M. tuberculosis, *M. bovis*, *M. africanum* and *M. microti* are the classical members of the *M. tuberculosis* complex to which the newer species *M. caprae* should be added. These closely related pathogens cause tuberculosis in both humans and animals.

Moreover, the scientific debate is on-going on the convenience of the reorganisation of the *Mycobacterium tuberculosis* complex as a single species while other experts claim that some bacteriological phenotypic differences, some epidemiological factors, some pathology characteristics, and the inertia to keep the classical names would support keeping the traditional nomenclature. In this line the Commission has always considered that *M. caprae* is

¹ OJ 121, 29.7.1964, p. 1977.

a causal agent of bovine tuberculosis and tuberculosis in animals of other domestic species (goats) and in wildlife (deer, wild boar).

1.2.3. The Task Force on monitoring disease eradication

Experts on tuberculosis and members of the tuberculosis subgroup of the Task Force on monitoring disease eradication ("the Task Force") clearly support the view that species other than *M. bovis* belonging to the genus Mycobacteria can cause tuberculosis in animals and therefore proposed the following definition "For the purpose of this document, the definition of bovine tuberculosis (TB) is: "Infection in cattle with any of the disease-causing mycobacterial species within the *M. tuberculosis* complex"². This approach has been maintained in the last revision of Working Document on Eradication of Bovine Tuberculosis in the EU, which was accepted by the Bovine tuberculosis subgroup of the Task Force (Document SANCO/10067/2013).

1.2.4. The World Organisation for Animal Health (OIE)

The OIE Terrestrial Manual provides guidance on *M. caprae* and other Mycobacteria infection in cattle: "It should be noted that other members of the *M. tuberculosis* complex, previously considered to be *M. bovis*, have been accepted as new species despite identical 16s RNA sequences and over 99.9% identity of their genome sequences. These include *M. caprae* (in some countries considered to be a primary pathogen of goats) and *M. pinnipedii*, a pathogen of fur seals and sea lions. These two new species are known to be zoonotic. In central Europe, *M. caprae* has been identified as a common cause of bovine tuberculosis. Disease caused by *M. caprae* is not considered to be substantially different from that caused by *M. bovis* and the same tests can be used for its diagnosis."³

1.2.5. The *Mycobacterium tuberculosis* complex and bovine tuberculosis

The relevance of each Mycobacterium species for bovine animal species should be considered to clarify which members of the complex should be included in the definition of bovine tuberculosis. *M. bovis*, *M. caprae*, *M. tuberculosis*, *M. africanum*, *M. microti* and *M. pinnipedii* all have zoonotic potential.

Infections with *M. pinnipedii*, *M. microti* and *M. africanum* have so far been sporadic and opportunistic in bovines. Therefore there is insufficient evidence to consider them as agents of bovine tuberculosis.

However, *M. caprae* infects and is maintained in cattle and there is also an increasing number of reports of *M. tuberculosis* infection in cattle and therefore both species together with *M. bovis* should be included as members of the *M. tuberculosis* complex causing bovine tuberculosis, not least due to its zoonotic potential.

For the time being as vaccination against tuberculosis is forbidden in accordance with Article 13(b)(ii) of Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and

² http://ec.europa.eu/food/animal/diseases/eradication/tb_workingdoc2006_en.pdf

³ http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.04.07_BOVINE_TB.pdf

enzootic leukosis in cattle⁴, vaccine strains are not excluded from the definition of bovine tuberculosis as BCG vaccine strain belongs to *M. bovis* species.

1.3. The *Mycobacterium tuberculosis* complex as causal agent of bovine tuberculosis in the EU legislative context

The status of a herd as regards bovine tuberculosis is determined in accordance with the criteria set up in Annex A to Directive 64/432/EEC by the absence of reactor animals to an intradermal tuberculin test. In the case of positive reactions to the test, the status of the herd is suspended and depending on the outcome of further investigations, the competent authority may withdraw the status. However, Point 3B of that Annex clarifies that following the isolation of the pathogen, the officially tuberculosis-free status of the herd is to be withdrawn in all cases, with consequences for the reinstatement of the previous officially free status.

Consequently, as *M. caprae* was considered part of *M. bovis* at the time Directive 97/12/EC was adopted and there is substantial scientific evidence indicating that *M. caprae* causes bovine tuberculosis, all surveillance and laboratory findings related to *M. caprae* (skin test reactions, agent isolation, PCR, spoligotyping) should be considered indication or confirmation of bovine tuberculosis.

Already the aforementioned Annex B to Directive 64/432/EEC clarifies that isolates may be characterised by their cultural and biochemical properties, and in particular that the genetic fingerprinting allows distinguishing between different strains of *M. bovis* and describing of patterns of origin, transmission and spread of *M. bovis*.

Commission Implementing Decision 2012/737/EU⁵ included tuberculosis in the Annex to Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community⁶ to provide for the possibility to specify (in case it is known) the bacterial species causing the notified tuberculosis outbreak.

The consequence of that is that all provisions explicitly referring to *M. bovis* in Directive 64/432/EEC should be understood as applicable to *M. caprae* and therefore should also be reported to ADNS.

The above considerations support the Commission's view that the recent discussion and evolution of the taxonomy of the Mycobacterium species should not lead to neglecting the fact that *M. caprae* is a causative agent of bovine tuberculosis. Therefore, in order to ensure that the objectives of Directive 64/432/EEC are achieved, the references to *M. bovis* in that Directive should be interpreted in the correct historical and scientific context.

⁴ OJ L 15, 19.1.1978, p. 34.

⁵ OJ L 329, 29.11.2012, p. 19.

⁶ OJ L 378, 31.12.1982, p. 58.