

# Royal Decree on Tuberculosis vs. new Animal Health Law (AHL): state of play

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## Legal basis

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- ✓ Regulation (EU) 2016/429 on transmissible animal diseases 'AHL'=Animal Health Law (*very general provisions*)
- ✓ Commission implementing regulation (EU) 2018/1882 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases
  - *Tuberculosis = category B disease (compulsory eradication programme throughout the EU)*

|  |       |   |
|--|-------|---|
| Infection with <i>Mycobacterium tuberculosis</i> complex ( <i>M. bovis</i> , <i>M. caprae</i> , <i>M. tuberculosis</i> ) | B+D+E | <i>Bison</i> ssp., <i>Bos</i> ssp., <i>Bubalus</i> ssp.                                 |
|  | D+E   | <i>Artiodactyla</i> others than <i>Bison</i> ssp., <i>Bos</i> ssp., <i>Bubalus</i> ssp. |
|  | E     | <i>Mammalia</i> (terrestrial)   |

- ✓ 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 rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (*annex IV part II*)



## Annex IV - part II Commission Delegated Regulation (EU) 2020/689

DISEASE-SPECIFIC REQUIREMENTS FOR THE GRANTING, MAINTENANCE, SUSPENSION AND WITHDRAWAL OF THE DISEASE-FREE STATUS AT THE LEVEL OF ESTABLISHMENTS AND DISEASE-SPECIFIC REQUIREMENTS FOR THE GRANTING AND MAINTENANCE OF THE DISEASE-FREE STATUS AT THE LEVEL OF MEMBER STATES OR ZONES



## ANNEX III Commission Delegated Regulation (EU) 2020/689

### DIAGNOSTIC METHODS FOR THE GRANTING AND MAINTENANCE OF DISEASE-FREE STATUS FOR CERTAIN DISEASES OF TERRESTRIAL ANIMALS

#### Section 2

#### Infection with mycobacterium tuberculosis complex

##### 1. Tuberculin skin tests

- (a) the single intradermal tuberculin test (SITT)
- (b) the comparative intradermal tuberculin test (CITT)

##### 2. Gamma-interferon assay



## Maintenance of the status (establishment)

- during the past 12 months there has been no confirmed case of infection with MTBC in bovine animals kept in the establishment;
- all bovine animals introduced into the establishment originate from establishments free from infection with MTBC and:
  - (i) originate from a Member State or a zone free from infection with MTBC;
  - (ii) are bovine animals over 6 weeks of age and have tested negative in an immunological test:
    - during the 30 days prior to their introduction into the establishment; or
    - during the 30 days after their introduction provided they have been kept isolated during this period; and
- all germinal products of bovine origin introduced into or used in the establishment originate from:
  - (i) establishments free from infection with MTBC; or
  - (ii) approved germinal product establishments.
- any suspected case of infection with MTBC in a bovine animal kept on that establishment or introduced from that establishment into a slaughterhouse is notified to the competent authority and investigated; and
- an immunological test has been carried out, with negative results, on all bovine animals over 6 weeks of age, at intervals of not more than 48 months (>< surveillance wild animals → the interval between tests may be based on the type of production and the risk factors identified),



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## Conclusion- Maintenance of the status (establishment)

In order to maintain the status of the establishments (farms), **all** bovine animals **over 6 weeks of age** must be tested every four years using a INTg test (>< surveillance wild animals?)

### Difference with the new RD:

Surveillance = 1 ELISA test in one out of five farms (+ 1 INTg test in case of positive ELISA test results) on a random number of bovine animals over 12 months of age.



## Maintenance of the status (Belgium)

- General surveillance requirement: the systematic research of lesions of infection with MTBC in all bovine animals slaughtered through ante- and post-mortem surveillance + investigations of lesions;
- random annual surveillance to demonstrate at least with a confidence level of 95 %, that the incidence rate of establishments confirmed infected during the year does not exceed 0,1 %.



## Suspension and restoring of the status (establishment)

### When?

- one or more of the requirements laid down in slide about 'maintenance of the status establishment' are not fulfilled (no confirmed case of infection, bovine animals introduced into the establishment originate from establishments free from infection +test, germinal products of bovine origin originate from establishments free from infection with MTBC/ approved germinal product establishments, any suspected case of infection is notified, immunological test on all bovine animals over 6 weeks of age, at intervals of not more than 48 months).

or

- a case of infection with MTBC is suspected in a bovine animal kept in the establishment.

### Restoring?

- bovine animals introduced into the establishment originate from establishments free from infection + test; germinal products of bovine origin originate from establishments free from infection with MTBC/ approved germinal product establishments ; any suspected case of infection is notified, immunological test on all bovine animals over 6 weeks of age, at intervals of not more than 48 months;
- the results of further investigations substantiate absence of infection with MTBC and the status of all suspected cases has been determined. In case, suspected bovine animals are slaughtered in that context, investigations must include examination of samples with direct diagnostic methods.





## Withdrawal and regaining of the status (establishment)

### When?

- One of more of the requirements for maintenance of the status are not fulfilled after a maximum period of time (30 days) since the status was suspended;
- the infection with MTBC cannot be ruled out;
- a case of infection with MTBC has been confirmed in a bovine animal kept in the establishment;
- it is justified by other needs to control infection with MTBC;

### Regaining?

- If the status free from infection with MTBC has been withdrawn in accordance with les conditions relatives aux maintien du statut, it may only be regained if the requirements are fulfilled;

- **Other cases:**

- all confirmed cases and all animals that have tested non negative in a immunological test have been removed;
- the remaining bovine animals over 6 weeks of age fulfil the following requirements:
  - 2 immunological tests (the first 6 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test and the second test minimum 6 months and not later of 12 months following the date of the first testing)
  - 2 immunological tests (the first 2 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test and the second test minimum 2 months and not later of 12 months following the date of the first testing) if
    - the conclusion of the epidemiological enquiry indicates that the infection is due to the introduction of one or more infected animals into the establishment during the past 12 months prior to the detection of the infection with MTBC; or
    - only a single case was confirmed or only a single bovine animal tested positive in an immunological test for MTBC since the detection of the infection with MTBC, and the status of the establishment has not been withdrawn during the past 3 years; or
    - bovine animals in the establishment have tested negative in an immunological test carried out less than 12 months prior to the detection of the infection with MTBC



## Confirmed case

### Confirmed bovine infection with MTBC: a bovine animal

- a) from which the disease agent has been isolated in a sample;
- b) from which an antigen or nucleic acid specific to the disease agent has been identified in a sample and showing clinical signs consistent with the disease or an epidemiological link with a suspected or confirmed case;
- c) from which a positive result from an indirect diagnostic method has been obtained in a sample and showing clinical signs consistent with the disease or an epidemiological link with a suspected or confirmed case.

New RD - bovine animal with tuberculosis: bovine animal which has been shown to be infected with bovine tuberculosis after being tested positive in a bacteriological examination;



## Differences between the new legislation and the post AHL legislation - Summary

1. Definition of a confirmed case
2. Status suspended pending ELISA and INTg results or awaiting the results of the bacteriological examination
3. Standard surveillance programme (maintenance of disease-free status of establishments) INTg test on all bovine animals over 6 weeks of age every four years
4. Possibility of not suspending the whole establishment in case of several epidemiologic entities
5. In case of transport of calves under 6 weeks of age from an establishment with suspected cases to a calves fattening farm: the status of the destination establishment is suspended until all calves are slaughtered
6. Testing in a outbreak area: all bovine animals (not only animals over 6 months of age)
7. Testing for clearance: 2 INTg tests on all remaining bovine animals over 6 weeks of age



**Thank you  
for your attention !**

