EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food sustainability, international relations

Unit D4 - Food safety programmes, Emergency funding

Programmes for eradication, control and surveillance of animal diseases and zoonoses submitted for obtaining EU financial contribution

Annex I.b: Programme for the eradication of bovine tuberculosis, bovine brucellosis or sheep and goat brucellosis (*B. melitensis*)

Member States seeking an EU financial contribution for national programmes of eradication, control and surveillance shall submit online this document completely filled out by the 31 May of the year preceding its implementation(part 2.1 of Annex I to the Single Market Programme Regulation).

Due to the late adoption of the SMP regulation all programmes will be submitted to be approved technically for 2021 and 2022.

Therefore , this document shall also be filled out and submitted after selection of the options:

This programme is multiannual: "YES"

Request for Union cofinancing from beginning 2021 to end of 2022.

If encountering difficulties:

- concerning the information requested, please contact SANTE-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Instructions to complete the form:

1) You can attach documents (.doc, .xls, .pdf, etc) to complete your report using the button "Add attachments" on the last page of the form.

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4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document. Save this completed document on your computer for your record.

5) For simplification purposes you are invited to submit multi-annual programmes.

6) You are invited to submit your programmes in English.

Document version number: 2021 2.1

Member state : ESPANA

Disease	Bovine Tuberculosis
Species :	Bovines

This program is multi annual : yes

Type of submission : New multiannual programme or Modification of already approved multiannual programme

Request of Union co-financing from beginning : 2021 To end of 2022

First year of implementation of the programme described in this document: *2021*

1. Contact data

Name [redacted] Phone [redacted]

Email [redacted] Your job type within the CA : [redacted]

Submission Date

05/11/2021 12:15:25

Submission Number

1636110927147-17997

2. Historical data on the epidemiological evolution of the disease

Describe timeline with prevalence, incidence data and, where relevant, vaccination history covering at least the past 5 years.

(max. 32000 chars) :

The first actions against bovine tuberculosis began in Spain in the early 1950s. In 1965, by means of the Order of May 24, a National Plan for the Fight against bovine tuberculosis and brucellosis was established, focused on the main dairy cattle nuclei in the north and center of Spain. After the entry of our country into the EEC, in 1987 Spain presented an Accelerated Eradication Program, in accordance with Directives 77/391/EEC and 78/52/EEC and Decision 87/58/EEC.

The National Programs for the Eradication of Bovine Tuberculosis 2006-2010 represented a qualitative change in the approach of the objectives, in such a way that they laid the foundations to guarantee continued actions in time under a multiannual approach, established in 5 years. A main objective of these programs was to gradually increase diagnostic sensitivity, both at herd and individual level. Additional measures gradually introduced to manage the identified risk factors have been management measures for possible wild reservoirs or the integration of the surveillance system in slaughterhouses.

For the analysis of the evolution of the control of the disease, a descriptive epidemiological study based on the evaluation of the indicators available historically, and which are based on the Community regulations for the preparation and presentation of reports on the National Disease Eradication Programs, is carried out below. The more detailed analysis is carried out in the 2020 Final Report, attached as Annex I.

Herd prevalence: as can be seen in the evolution of this epidemiological indicator (see Annex II) the trend manifested through the implementation of the national program in the last 15 years has been of a moderate decline in the disease, until 2013, after which this indicator suffered an upturn, especially in 2015 and 2016, leaving it at 2001 levels. The rise in 2016 compared to 2015 was not significant. In 2017 there was a significant decrease of 19% in said indicator with respect to 2016, and of 1.7% (not significant) in 2018 with respect to 2017. Additional declines of around 17% each year occurred in 2019 and 2020.

Incidence in herds and animals: the evolution of these epidemiological indicators shows upward and downward series in the case of new positive herds. In the years 2013- 2015 there was a significant rise, which changed in 2016 and with a very significant decline in 2017 and 2020.

3. Description of the submitted programme

Standard requirements for the submission of programme for eradication, control and monitoring

Describe the disease control strategy of the eradication programme in accordance with Article 16 of Commission Delegated Regulation (EU) 2020/689 including at least:
(a) the sampling schemes and diagnostic methods to be used in accordance with Annex IV to Delegated Regulation (EU) 2020/689:
(i) for the granting of the disease-free status to establishments and the maintenance of that status;
(ii) to confirm or rule out the disease in the event of a suspected case;
(b) the disease control measures to be applied in the event of a confirmed case;
(c) the biosecurity and risk mitigating measures to be implemented;
(e) the measures to be implemented as regards additional animal populations, if relevant;
(f) the derogations to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689, if relevant;
(g) coordinated measures with other Member States or third countries, if relevant.

(max. 32000 chars) :

(a) The diagnostic tests used are those established in Royal Decree 2611/1996 and in Section 2 of Annex III (routine tests) and in Article 9 (investigation of suspected cases by histopathology, immuno-histochemistry, direct PCR, isolation) of Regulation (EU) 2020/689. The use of EURLAB gamma-interferon as an alternative to the skin test will always be decided by the competent authority and following the protocol available on the EURLAB website, in accordance with Article 6 of Regulation (EU) 2020/689. As complementary tests in establishments with the withdrawn qualification shall be used the gamma interferon NRL and any other test that is validated by the National Reference Laboratory and is registered according to Royal Decree 867/2020, of 29 September, which regulates animal health products of diagnostic reagents for veterinary use, control systems of physiological parameters in animals and products intended for the maintenance of animal reproductive material. They will be carried out by laboratories authorized in accordance with the aforementioned Royal Decree 2611/1996, which will periodically participate in inter-laboratorial aptitude tests carried out by the LNR. The tuberculins and kits used will be submitted to the corresponding quality control by the LNR. More details are given in point 4.4.6.

Tests are performed on animals from 6 weeks of age in the case of skin test and from 6 months of age in the case of gamma-interferon when used in parallel with skin test in infected herds from which the qualification has been withdrawn (hereinafter, gamma-interferon NRL). As a routine technique for obtaining and maintaining qualification, SIT and exceptionally, at the discretion of the competent authority, CCIT is used. In the same establishment, the same type of test (SIT or CCIT) will always be used in each sanitary action as a herd test on all the animals to be checked. The gamma-interferon test may be used, always at the discretion of the competent authority, as a routine test, in accordance with Section 2 of Annex III of Regulation (EU) 2020/689 and the protocol published for this purpose on the EURLAB website (hereinafter, EURLAB gamma-interferon), in animals that can be subjected to this test due to their age. In the rest of the animals, the corresponding skin test test will be performed. The frequency of maintenance tests is established according to the prevalence of the different areas. In any case, the maximum period in which the officially free status can be considered as suspended, once the interval to perform them has passed, will be 90 days.

b)At the national level, the measures adopted to deal with positive cases are described in Chapter II of Royal Decree 2611/1996 and in articles 24 to 31 of Regulation (EU) 2020/689. More details are given in point 4.4.9.

(c)Special interest will be placed in those establishments in which a positive animal has appeared in the correct fulfillment of the prophylactic measures established in article 24 of Royal Decree 2611/1996. Specifically, the Official Veterinary Services will certify that the cleaning and disinfection measures have been correctly carried out, that a minimum period of 60 days of sanitary vacuum for the reuse of pastures has been respected, and the correct management of the manure. These certificates may be issued on the basis of others that have been completed by accredited and duly approved companies, mainly with regard to manure management and disinfection of the facilities. More detais are given in

point 4.4.9

(e) (f) see point 4.4.2

(g) not applicable

4. Measures of the submitted programme

4.1 Summary of measures under the programme

Duration of the programme : 2021 - 2022

☒ Eradication

☒ Testing

☒ Slaughter of animals tested positive

☐ Vaccination

Other, please specify

4.1.1 Timeline for the eradication

Describe the timeline with prevalence, incidence data and, where relevant, vaccination history covering at least the past 5 years and the estimated duration of the eradication programme

2022-2030. The goal of achieving eradication is set for the year 2030, considering as such the achievement of an incidence rate of establishments confirmed as infected by the M. tuberculosis complex of no more than 0.1% in that year throughout the country.

4.1.2 Interim targets in relation to the timeline for eradication

Describe the intermediate targets of the eradication programme including at least:
(a) the expected annual decrease of the number o infected establishments;
(b) the expected annual increase of the number of disease-free establishments;
(c) the expected vaccination coverage, where relevant. *(max. 32000 chars) :*

Intermediate targets at the national level are set in accordance with the Commission's Implementation Decision (EU) 2021/3046, which provides for the Multiannual Work Program 2021-2024 for the co-funded programs of the European Commission and its guidelines. The objective is to achieve an annual reduction from 2022 to 2030 of the herd prevalence of at least 20% and of the herd incidence of at least 20% compared to those obtained two years earlier.

(a)Herd prevalence 2020: 1.61; 2021: 1.52; 2022: 1.22; 2023: 0.97; 2024: 0.78; 2025: 0.62; 2026: 0.50; 2027: 0.40; 2028: 0.32; 2029: 0.26; 2030: 0.20.

Herd incidence 2020: 0.75; 2021: 0.74; 2022: 0.59; 2023: 0.47; 2024: 0.38; 2025: 0.30: 2026: 0.24; 2027: 0.19; 2028: 0.15; 2029: 0.12; 2030: 0.10.

(b)20%, in line with the annual decrease in the number of infected herds.

4.2 Organisation, supervision and role of all stakeholders involved in the programme

Describe the organisation, supervision and roles of the parties involved in the eradication programme including at least:
(a) the authorities in charge of coordinating and supervising the implementation of the programme;
(b) responsibilities of all stakeholders involved.

(max. 32000 chars) :

(a) The Subdirectorate General for Animal Health, Hygiene and Traceability is in charge of coordinating the Eradication Program and reporting to the Commission on the evolution of this disease. The competent Services of the Autonomous Communities are responsible for the execution of this Program. Royal Decree 1440/2001, of December 21, 2001, which establishes the veterinary health alert system, created the "National Committee of the Veterinary Health Alert System", which is responsible for studying and proposing measures for the eradication of diseases and monitoring the evolution of the epidemiological situation for diseases subject to eradication programs, as well as for the approval of exceptional measures within the framework of such programs.

The aforementioned Committee is attached to the Ministry of Agriculture, Fisheries and Food and all the Autonomous Communities and, in the case of zoonotic diseases, the Ministry of Health are represented on it. It is the Authority in charge of supervising and coordinating within the framework of the functions assigned by Royal Decree 1440/2001.

The organization of the development of the Livestock Sanitation Campaigns in each Autonomous Community includes the following levels:

1.-Regional Level: the Regional Director of Campaigns harmonizes and controls the Campaigns in all the provinces of the region.
2.-Provincial Level: through a provincial coordinator who harmonizes and controls the actions of the different counties of the province.
3.-County Level: through the coordinators specialized in Sanitation Campaigns and responsible for:

- Supervision of field veterinary personnel, collaborating veterinarians, ...
- Meetings with farmers to prepare the campaigns.
- Coordination with regional offices of the Regional Ministries.
- Repetition of tests and action in doubtful cases, if necessary.

4.-Field level: there are veterinary personnel in charge of carrying out diagnostic tests or whole blood extractions, under the direct dependence of the coordinators.
These personnel, who depend on the Autonomous Communities, are in charge of the control, execution and development of the program.

(b)The owners of the livestock establishments will make available to the field veterinary personnel and the OVS, if applicable, the necessary means and facilities for the correct performance of the tests and other measures contemplated in the program, adequate in quantity and quality for each establishment, and adapted in such a way as to minimize the risks of accidents both for the persons involved and for the animals. The suitability of these facilities will be verified by the competent authority.

The execution of skin tests can be contrasted by the owners of the livestock establishments. To this effect, the owners who wish to make use of this practice, must present an application before the competent authority of their Autonomous Community, stating this fact and designating the veterinarian who will act as a party expert.

Said veterinarian must have passed and have in force the training courses contemplated in this program, which will be accredited with documents before the competent authority prior to the beginning of the official test. The competent authority will appoint an official veterinarian who will intervene in the contrasting of the test.

The contrastation of the official test will be carried out in a single act during the performance of the official test, which will be carried out by the veterinarian designated by the competent authority of the Autonomous Community within the framework of the tuberculosis eradication program. Both the expert designated by the owner of the establishment and the official veterinarian designated by the competent authority for the contrast of the test will be present. In those autonomous communities in which the authorized veterinarian is an official veterinarian, a different one will be designated to intervene in contrasting the test.

In case of discrepancy between the veterinarian performing the test within the framework of the program and the expert, the official veterinarian appointed by the competent authority will make the final decision.

The expert of part will have to justify previously to the beginning of the contrast of the official test, before the competent authority of the autonomous community in which the test is carried out, the condition of having passed, and in its case, to have updated the training course for the application of the IDTB. Likewise, he/she must be present during the performance of the official diagnostic tests of all the animals sanitized in the performance, both at the moment of the inoculation of the tuberculins, and at the moment of their reading; otherwise it will be considered as a waiver of the right of contrast.

The additional costs, as well as in its case the taxes that supposes the accomplishment of the contrast of the official tests will be in charge of the holder of the establishment. In no case, the request for contrasting the official tests after the official results have been obtained will be accepted.

Likewise, both the M.A.P.A. and the competent bodies of the Autonomous Regions will hold informative

meetings with the representatives of the sector annually prior to the presentation of the national program to the European Commission for co-financing, during which the results of the previous year's programs will be discussed and the concerns of both parties regarding the evolution and application of the future program will be analyzed.

4.3 Description and demarcation of the geographical and administrative areas in which the programme is to be implemented

Describe territorial scope with a description and demarcation of the geographical and administrative area covered by the eradication programme and the names of the zones and regions, if more than one region is included in the territorial scope of the programme.

(max. 32000 chars) :

The eradication program is applicable throughout the national territory, except in the Autonomous Cities of Ceuta and Melilla and in the Autonomous Communities or provinces declared officially free of CMT infection, where a surveillance and action program will be applied to maintain this status. To date, only the Autonomous Community of the Canary Islands and the province of Pontevedra have been declared as such.

4.4 Description of the measures of the programme

A comprehensive description needs to be provided of all measures and detailed reference must be made to Union legislation. The national legislation in which the measures are laid down is mentioned.

4.4.1 Notification of the disease

(max. 32000 chars) :

The official declaration of the disease will be made in accordance with the provisions of Law 8/2003, on animal health, and with Royal Decree 526/2014, which establishes the list of notifiable animal diseases and the regulations for their communication. Tuberculosis is a notifiable disease in Spain.

4.4.2 Target animals and animal population

Describe the epidemiological situation for each zone or region, if more than one region is included in the territorial scope of the programme:
(a) the number of establishments keeping animals of the targeted animal population by health status (Disease-free, infected or unknown) excluding establishments falling under the derogation to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December;
(b) the number of animals of the targeted animal population kept in the establishments referred to in point (a) by health status;
(c) maps indicating the density of the targeted animal population referred to in point (b) by health status
and
(d) information as regards the epidemiological situation in additional animal populations, where relevant. *(max. 32000 chars) :*

The program to gain and maintain T3 statusshall apply to all establishments keeping bovine animals (including bison and buffalo) for breeding, meat, milk or other production, or for work, contests or exhibitions, including all fattening units T3 or in the process of obtain T3 status. The remaining non-qualified fattening units will be progressively be included in the

programme of qualificaction as T3 in order that by 2030 at least 99,8% of all establishments in the country have rached the T3 status. Non-qualified and T1 fattening establishments may be excluded from the program of testing to gain T3 status, understanding as such those located in provinces, counties or UVLs (or municipalities, as the case may be) whose prevalence is not zero, provided that they are pure fattening units, kept in closed conditions through facilities that ensure the maintenance of biosecurity for themselves and their environment, so that they do not pose any risk of spreading the disease, and that are supervised by the competent authority. These establishments, not included in the program, can only source from breeding establishments negative to diagnostic tests (or negative animals from positive establishments in accordance with the "Protocol for the authorization of calf movements from positive establishments to feedlots authorized by the competent authority 2021") and can only move animals with direct and exclusive destination to slaughter.

The program is also developed for all goat establishments that coexist or maintain an epidemiological relationship with cattle herds, with the competent authorities of the autonomous communities being able to include all goat establishments in their territorial area, as an additional target population, if they affect the health status of the target cattle population. Official diagnostic tests will be carried out in those goat herds that coexist or use common pastures or maintain epidemiological relationship with cattle herds and those herds that, although not complying with the coexistence requirement, are detected by the epidemiological survey and/or the Spoligotype Base (strains shared between cattle and goats) as sources of the disease for the cattle herds in the area of the establishment. For these purposes, the cases of goat herds located in municipalities where the disease has been confirmed in cattle in those municipalities can be considered as epidemiological relationship.

In the rest of the goat herds included in programs of the Autonomous Communities, each Autonomous Community will determine the frequency and testing regime to be carried out, in accordance with the Manual for the control of CMT infection in goat establishments included in this national program.

Establishments containing animals whose only purpose is the mere exhibition or participation in cultural or sporting events, such as zoos with such purposes and circuses, are not included in the program. These establishments will have the active and/or passive surveillance and control programs determined by the competent authority in application of point 1.a) of Article 18 of Regulation (EU) 2020/689.

Figures requested in (a), (b), (c) and (d) are provided in annex II.

4.4.3 Identification of animals and registration of holdings including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

(max. 32000 chars) :

Law 8/2003, of April 24, 2003, on Animal Health establishes (article 38.1) that all animal establishments must be registered in the autonomous community in which they are located, and that their basic data must be included in a national registry.

Based on this, Royal Decree 479/2004, of March 26, 2004, was approved, establishing and regulating the General Register of Livestock Farms (REGA). It is a multi-species registry that contains data on all the establishments located in Spain and which are provided by each of the Autonomous Communities.

REGA is part of the Integral Animal Traceability System (SITRAN) together with the Register of Movements (REMO) and the Register of Individually Identified Animals (RIIA) whose legal basis is Royal Decree 728/2007, of June 13, which establishes and regulates the General Register of Livestock Movements and the General Register of Individual Animal Identification.

SITRAN consists of a heterogeneous database that communicates the existing registries in the different autonomous communities with a centralized registry, by means of specifically developed information exchange mechanisms.

The traceability system for bovine animals is regulated at Community level by Commission Delegated

Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules on establishments keeping terrestrial animals and hatcheries, and traceability of certain terrestrial animals in captivity and hatching eggs; and by Commission Implementing Regulation (EU) 2021/520 of 24 March 2021 laying down detailed rules for the implementation of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the traceability of certain terrestrial animals in captivity.

The elements that constitute the identification system are the following:

Ear tags: these are made up of two plastic ear tags that are placed in each ear and carry the same and unique identification code that allows the individual identification of each animal and the establishment in which it was born.

Computerized database: in Spain it is called SITRAN and integrates the Registro General de Explotaciones Ganaderas (REGA), the Registro de Identificación Individual de Animales (RIIA) and the Registro de Movimientos (REMO).

Bovine Identification Document (DIB) that will accompany the animal in all its movements.

Establishment's record book: which can be kept manually or computerized and must be accessible to the competent authority for a minimum period of three years.

4.4.4 Qualifications of animals and herds including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

(max. 32000 chars) :

The qualifications of animals and herds are set out in Royal Decree 2611/1996 and in Chapter I of Part II of Annex IV of Regulation (EU) 2020/689, for obtaining, maintaining, suspending, reestablishing, withdrawing and recovering T3 status.Additionally, a T3H herd or establishment is defined as one that has maintained T3 status without being withdrawn uninterruptedly for at least the last 3 years.

4.4.5 Rules of the movement of animals including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

Please detail also the rules existing for transhumance and common grazing areas, if any.

(max. 32000 chars) :

Animal movements are carried out under veterinary control, as established in Royal Decree 2611/96 and its subsequent amendments. For the movement of cattle in Spain, the Official Veterinary Services must issue the "Guía de Origen y Sanidad Pecuaria", a document that covers this movement. Likewise, through the SITRAN system (Royal Decree 728/2008), an integral traceability system, the movements of animals between different establishments are controlled through the REMO module.

When the animals come from a feedlot and transit through a commercial operator, assembly center, fair

or market, it will be specified that they are feedlot animals in the Sanitary Certificate of Origin and in the individual identification document in a clearly visible way, so that in no case can the final destination be other than a feedlot or slaughterhouse.

From positive establishments or establishments with suspended qualification, the movement of calves to approved feedlots not included in the program (T1) and to other feedlots may exceptionally be authorized following the provisions of the "Protocol for the authorization of calf movements from positive establishments to feedlots approved by the competent authority 2022".

Pre movement tests:

Not required if the province of origin is officially free of CMT.

Pre- or post-testing will be performed on animal movements (all animals over 6 weeks of age subject to the movement), with the following exceptions:

- any movement originating in a province free of CMT infection;

- in movements destined for qualified fattening establishments if the establishment of origin and the animals subject to the movement have been checked in the previous 6 months, or in the previous 12 months if the province of origin is of prevalence < 2% the last 4 years. This exception does not apply if the province of destination is declared free of CMT infection and the province of origin is not.

- in movements destined to other establishments (except exhibitions, non-permanent livestock shows or common use pastures) if the establishment of origin and the animals subject to the movement have been checked in the previous 6 months and if the province of origin is of prevalence < 0.1%; This exception will not be applicable if the province of destination is declared free of CMT infection and the province of origin is not.

- in movements without change of ownership (except for exhibitions, non-permanent livestock shows or common use pastures, already covered in the previous script) when the establishment of origin is T3H and: either it has been checked in the previous 6 months, or the county or LVU of origin has a prevalence < 1%. This exception does not apply if the province of destination is declared free of CMT infection and the province of origin is not.

- within CCAA of prevalence <1%, in internal movements from T3H establishments decided by the competent authority (including to exhibitions, contests or common use pastures where only animals from that autonomous community are present), as long as these establishments and the animals object of the movement have been checked in the previous 12 months. Internal movements can be considered as those of common pastures in neighboring autonomous communities, as long as only animals from the same autonomous community of origin of prevalence < 1% are present in said pasture. These exceptions will not be applicable if the province of destination is declared free of CMT infection and the province of origin is not.

Pre movement tests, if required, are performed within 30 days prior to movement. However, when for justified cause the movement of the animal or group of animals has not been carried out within the 30 days of validity of the test, such validity may be extended up to a maximum of 45 days, as in the case of a new change of establishment.

During the pre-movement tests, the presence of a veterinarian as an expert appointed by the buyer or by the SVO of destination will be allowed.

Also the check can be carried out after the movement, previous agreement of the competent authorities of origin and destination of the animals, for which it will be necessary to maintain the isolation of the animals until obtaining the negative result to the test. Under these conditions, the tests may be carried out within 45 days.

No animal may be moved if it has not tested negative to bovine ppd in the last test carried out on that animal.

Likewise, post-movement tests (within 90 days after the entry of the animals) will be carried out randomly and according to the risk. For each CCAA, all those movements that the competent authority considers appropriate according to their sanitary situation and at least 10% (or alternatively, of a minimum of 500 annual controls planned according to a risk analysis) of movements of animals destined to a breeding or production establishment (not feedlots) whose origin is preferably CCAA of prevalence >1%, will be controlled by means of post-movement tests. The animals will be kept isolated in the establishment until the tests are carried out. In the case that the previous movement tests are carried out by the OVS, these controls will be carried out on at least 10% of the movements coming from other Autonomous Communities.

EURLAB gamma-interferon may be used as a pre movement test.

4.4.6 Tests used and sampling and testing schemes including detailed reference to relevant Union legislation and its implementation in the Member State for this disease (including herd frequency per region, animal coverage in each herd, interpretation rules of the test,...)

For bovine tuberculosis, please detail how the quality/reliability of the skin-testing is ensured/verified (training and supervision of field veterinarians, recheck of some officially-free herds by the official veterinarians, quality insurance system in force if any, etc. ...)
Please detail also how the surveillance of bovine tuberculosis is monitored in slaughter houses (Training of vets, monitoring of the lesions submission rates and positivity rates, link with the field vets in case of positive results, etc. ...)

(max. 32000 chars) :

Active surveillance: sampling frequencies and protocols:

At least all comarcas or UVLs and, when considered by the competent authority, municipalities, which obtain or maintain prevalence 0 (no positive herd) in the previous year, will include and maintain within the program to gain and maintain the T3 status the existing fattening units within their territorial scope (100% of the herds). In these cases, fattening animals (males and females) may be submitted to a special protocol of testing if they all come from T3 herds and the competent authority guarantees that they will not be used for breeding and are sent for slaughter or exported to third countries. After obtaining T3 status in accordance with Chapter I, Part II of Annex IV to Regulation 689/2020, and given that fattening units periodically introduce animals (many of which have already been checked at their holding of origin) for the sole purpose of finishing their fattening for a few months before being sent for slaughter, the health status will be maintained in the same way as it was obtained, if the animals introduced into the fattening unit continue to meet the necessary conditions of pre-movement tests, do not remain in the feedlot more than 12 months and with the addition of the post-mortem surveillance system in the slaughterhouse.

The competent authorities may maintain within the program all feedlots, even if the prevalence is not zero in the previous year, in the case that it had been zero in previous years and they already had all the feedlots included in the National Program.

1. Autonomous Communities and provinces declared as Officially Free of tuberculosis or with 0 prevalence:

In these Autonomous Communities or provinces the competent authority may extend the interval between routine testing to two years in accordance with Annex IV Part II Chapter I section 2 Point 2 a) of Regulation (EU) 2020/689. The Autonomous Community of the Canary Islands and the province of Pontevedra, as well as others that will be declared free of CMT infection (officially CMT-free) will apply the surveillance program for the maintenance of that status as contained in point 4.3.11 of this program. These Autonomous Communities or provinces are not included in the cost analysis in point 8, but are included in the rest of the points of the program, including the objectives (targets) in point 7. In addition, the rest of the measures contemplated in the Autonomous Communities with low prevalence will be applicable to these Autonomous Communities or provinces.

2. Autonomous Communities with a herd prevalence range below 1% or "low prevalence":

In provinces that have maintained herd prevalence below 1% for two consecutive years, the competent authority may, following a risk analysis, extend the interval between maintenance testing to two years (24 months) to T3H establishments, provided that in those provinces 100% of the target herds are included in the national program, in accordance with Annex IV Part II Chapter I Section I Point 2 Point a) of Regulation (EU) 2020/689.

This interval cannot be extended in the case of bullfighting establishments, or of rearing heifers in common, or of commercial operators of animals destined for reproduction, or of reproduction establishments that have a commercial operator as owner, or that have a history of infection without having carried out sanitary emptying, or that incorporate animals from zones of prevalence higher than 1%, or that use pastures of common use (including common use mountains), or that carry out transhumance, or that participate in livestock exhibitions or contests, or that have a percentage of entry of animals > 10% of their census in the previous year, with a minimum of 10 animals, or any other establishment that the competent authority considers to be at risk.

T3 and T3H bovine establishments: at least an annual maintenance test must be carried out on all animals that, due to their age, are susceptible to be investigated, except in those Autonomous Communities or provinces that decide to apply maintenance intervals every two years.

In T3H establishments (except in bull fighting herds), SIT or CCIT may be used as routine test, at the discretion of the competent authority based on a risk assessment. In the event that positive animals are found if the CCIT is used, the results will be re-evaluated on the basis of SIT. The EURLAB gamma-interferon test can also be used in them as a routine test with the same consideration of use as the SIT. Likewise, in case the competent authority decides to apply CCIT in an establishment, initially or after the use of SIT or EURLAB gamma-interferon, the animals negative to this test but positive in the simple interpretation (increase of the skin fold greater or equal to 4mm to the bovine ppd, without clinical signs) will be marked as "Follow-up cattle" so that, when they are destined for slaughter or die in the establishment, they can be sampled in the slaughterhouse or in the by-product processing plant to carry out a microbiological investigation for tuberculosis. For these animals, the only permitted destinations are slaughterhouses in the same autonomous community or closed feedlots whose subsequent

destination is a slaughterhouse in the same autonomous community of origin of these animals.

However, the competent authority of the autonomous community, only within its territory, may decide to allow the movement for the rest of destinations, after testing with negative results for bovine PPD. The marking of "follow-up cattle" will be carried out in the DIB and preferably in a computerized form, so that this circumstance is reflected in the animal's health history and in the successive DIBs (Bovine ID Document) or duplicates of DIBs that are issued in the future, among other accompanying documentation.

This procedure will also be followed whenever the comparative test is used in any of the situations contemplated in the high prevalence Autonomous Communities.

In the rest of T3 establishments, SIT or EURLAB gamma interferon should be used as a routine test. The competent authority may also mark as "follow-up animals" those animals that are negative to the test but that it considers that epidemiologically they should be subjected to follow-up, among which could be those that had been located at the time when an establishment was positive to tuberculosis, without a depopulation having been carried out.

If, after the appearance of suspect animals, the etiological diagnosis of the disease is not achieved or the herd cannot be considered, in principle, as infected in accordance with point 2 of Article 9 of Regulation (EU) 2020/689, SIT or CCIT or EURLAB gamma interferon, as well as any other complementary and differential diagnostic test considered necessary, shall be carried out on the entire herd of the establishment. In cases where it is decided to use CCIT, the provisions of the previous paragraphs shall be applicable.

The skint tests and gamma-interferon tests will be performed following the "Procedural Manual for the performance of the skin test and gamma-interferon test 2019-2020" and the protocols published on the EURLAB website.

T2 and Tr bovine establishments: at least 2 check-ups per year.

Criteria for the application of depopulation in the Autonomous Communities with prevalence < 1%, including the Autonomous Communities and provinces declared free of infection by CMT: to ensure the general interest, avoiding the persistence of the infection and the risk of contagion to healthy herds, the convenience of performing depopulation is especially valued in these areas, mainly in the case of repeated positive results. When a herd or an epidemiological unit considered infected appears in any veterinary district of 0 prevalence, depopulation will always be carried out (except in justified situations, such as the protection of genetic resources).

3. Autonomous Communities with a herd prevalence range greater than 1% or "high prevalence":

T3 and T3H bovine establishments:

In those counties or veterinary units where herd prevalence is below 1%, SIT with the standard interpretation of the test or EURLAB interferon gamma will be used as a routine test, except in specific cases duly justified by the epidemiological survey (intermittent herds in which the etiological diagnosis of the disease is not achieved and positive results have been obtained in the differential diagnosis). However, in the Autonomous Communities that the previous year were in the <1% prevalence range, they will be able to continue applying on the T3H herds of these districts or veterinary units what is

established for these establishments in the low prevalence Autonomous Communities.

Additionally, breeding establishments located in counties or LVUs whose herd prevalence in 2020 has been higher than 3%, must increase their frequency of routine maintenance tests to 2 tests per year, with an interval between them of minimum 4 and maximum 6 months. On the basis of a risk analysis carried out by the competent authority, only T3H herds may be exempted from the second annual test. The competent authority may decide to increase the frequency of checks in adjacent areas epidemiologically related to these districts or LVUs.

CCAA of herd prevalence between 1 and 2%: in those counties or veterinary units with prevalence >1%, SIT with severe interpretation or EURLAB interferon gamma will be used as maintenance tests, so that any animal with doubtful SIT will be considered positive if there is also at least one positive reactor in the herd, except in specific cases duly justified by the epidemiological survey (intermittent herds in which the etiological diagnosis of the disease is not achieved and positive results have been obtained in the differential diagnosis). Only T3H herds may be exempted from severe interpretation when the competent authority deems it appropriate on the basis of a risk analysis of each establishment.
When the competent authorities deem it appropriate, following epidemiological criteria for each case, what is established with respect to criteria for the application of depopulation of low prevalence ACs for districts with 0 prevalence may be applied.

Autonomous Communities with herd prevalence > 2%: in those counties or veterinary units with prevalence >1%, SIT with severe interpretation or EURLAB interferon gamma will be used as maintenance tests, so that any animal with doubtful SIT will be considered positive if there is also at least one positive reactor in the herd, except in specific cases duly justified by the epidemiological survey (intermittent herds in which the etiological diagnosis of the disease is not achieved and positive results have been obtained in the differential diagnosis).

T2 and Tr cattle establishments:

At least three checkups per year shall be performed as long as the herd remains positive.

4. Measures for all regions:

The "System of control of field veterinarians responsible for carrying out diagnostic tests within the National Program for the Eradication of Bovine Tuberculosis 2022" will be applied to the veterinary personnel executing the program at field level, whether they are private or public entities (free practice professionals, companies, cooperatives, A.D.S.). For each of these controls, the corresponding report is made and the implications in the case of detecting irregularities are also included in accordance with the "Non-compliance and Repercussions Guide 2022".

All veterinary professionals involved in the execution of field tests must have passed regulated training courses in the theoretical, practical and legal aspects of bovine tuberculosis diagnosis, which will include a validation test of the IDTB technique on animals infected and/or sensitized by M. tuberculosis complex and non-infected/sensitized animals. For the professionals who start performing the test for the first time, they must pass them within the first year in which they exercise this activity, being able to perform them for diagnostic purposes as trainee professionals, together with professionals in possession of the authorization issued by the competent body of the Autonomous Communities for the performance of the tests in their territorial area.

Likewise, in 2016 the update courses (first edition) were started for those veterinarians who had passed the regulated training and validation courses, required with a periodicity of 3 years, and that will continue during the year 2022. The deadline for authorized veterinarians to take this update course is 6 months after the 3-year period from the date of obtaining the certificate of the regulated theoretical-practical training course or, as the case may be, of the previous refresher course. Once this 6-month period has passed, the authorization given by the ACs to participate in the National Program will be suspended until the update course is completed.

The update courses (second edition) started in 2019 and will continue in 2022. The programs and systematics of organization and participation in the different courses are published on the MAPA website. After this second edition of the periodic update course, which must also be held 3 years after the first edition, the third and following editions will be held by veterinarians with a periodicity of 5 years.

In the event that theoretical-practical courses designed and intended specifically for OVSs performing official controls on field veterinary personnel included in this program, already started in 2014, continue to be carried out, the Official Veterinary Services of Public Health-Food Safety will be invited to participate in them, in accordance with Recommendation No. 2 of the bovine tuberculosis subgroup of the Task Force 2012.

Monitoring of passive surveillance at slaughterhouses:

Surveillance and control systems at farm level must necessarily be complemented by a slaughterhouse surveillance system for animals routinely slaughtered for human consumption, regardless of the health status of the herd of origin of the animals. The provisions of the “Performance Protocol for the slaughterhouse surveillance component of bovine tuberculosis in the framework of the National Eradication Program, Coordination between the competent authorities for animal health and food safety (public health)” will be applicable.

The competent animal health authorities will communicate, if the animals do not belong to their territorial area, to the competent animal health authorities of the Autonomous Community of origin of the animals, the suspected cases of tuberculosis identified by the Oficcial Veterinary Services of public health during the post-mortem inspection of the routine slaughtered animals and the corresponding sampling. This communication will be made within a maximum of 2 working days. The LVU of origin of the animals must have received the information and proceeded to suspend the T3 status in the herd of origin within a maximum of 7 working days. In the establishment of origin of the animals, suspicion actions will be applied in accordance with Article 23 of Royal Decree 2611/1996, with a detailed study of each case to evaluate the possible existence of lack of sensitivity in the field tests, in accordance with Recommendation No. 1 of the bovine tuberculosis subgroup of the Task Force 2012. Such study will be carried out on the basis of the indicator "Number of herds detected in post-mortem inspection with subsequent reactors" included in point 3.8 of Document SANCO/10067/2013.

Moreover, each year an evaluation is performed on lesions submission rates by slaughterhouse and region, and published in the MAPA Webpage. An advance of the data for 2020 is provided in annex II.

4.4.7 Vaccines used and vaccination schemes including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

Describe the vaccine(s) to be used and the vaccination scheme, if relevant;

(max. 32000 chars) :

Not applicable

4.4.8 Information and assessment on bio-security measures management and infrastructure in place in the holdings involved.

Please detail also the situation as regard to this disease in the wildlife, and explain the surveillance and control measures in wildlife if any, and the coordination between the stakeholders involved (hunters, farmers, official service labs, vets, etc ...)

(max. 32000 chars) :

Actions in domestic animals are complemented by a surveillance and control program in wildlife through the Action Plan on Tuberculosis in Wildlife Species (PATUBES), which was published in 2017, and which includes proposals for specific measures to be applied depending on the classification of the different regions according to their epidemiological risk situation (removal of hunting by-products, limitation of densities by different methods, advice on biosecurity in livestock establishments, training...). The regulations developed for its application focus on the management of by-products not intended for human consumption in hunting activities and on sanitary actions in hunting species that act as a reservoir of CMT.

Monitoring data for 2020 is provided in annex II.

The correct application of pasture qualification measures will be controlled and ensured by the establishment by the Autonomous Communities of a written protocol for rigorous control of access to pastures, so as to ensure that pastures where positive reacting animals appear are not reused for a minimum period of 60 days, except for the exceptions provided for in the regulations. Since the pasture is considered as an epidemiological unit, the exception referred to consists of the application of the provisions of Royal Decree 2611/1996, according to which, upon confirmation of the disease, the only movement allowed is to slaughterhouse (or according to the "Protocol for the authorization of movements of calves from positive establishments to feedlots authorized by the competent authority 2022") until, after carrying out the necessary battery of tests, all the animals that remain isolated in these pastures pastures obtain negative results. This protocol will include at least 2 inspection visits, which will be recorded by means of standardized minutes.

Access to sanitary qualified pastures is granted only to animals from sanitary qualified establishments. Each pasture is considered a single epizootiological unit and has a single sanitary qualification that affects all the establishments with animals in that pasture. If new livestock are introduced, the pasture automatically acquires the lowest health status of the livestock on the pasture. The tests for the recovery of the qualification are carried out in accordance with Community regulations. In areas devoid of physical or natural barriers, prevention will be reinforced by proceeding to the artificial division of pastures. In order to comply with the provisions, the town councils with pasture ordinance, will keep

updated the register of the pastures of common use, as well as the occupation of the same.
All these prevention, control and eradication measures must necessarily be complemented, in order to be effective, by adequate management practices applicable to the prevention and control of other infectious-contagious diseases. For this reason, the competent authorities will provide, during the different activities of execution of the program, the delivery of the Guides of Correct Hygiene Practices, elaborated by the MAPA and the different productive sectors.

4.4.9 Measures in case of a positive result including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

A description is provided of the measures as regards positive animals and detailed reference to the Union legislation provisions (slaughter, destination of carcasses, use or treatment of animal products, the destruction of all products which could transmit the disease or the treatment of such products to avoid any possible contamination, a procedure for the disinfection of infected holdings, a procedure for the restocking with healthy animals of holdings which have been depopulated by slaughter. A definition of a suspicion and of a confirmation should be provided, with detailed measures implemented in both situation and how the herd is requalified as free after a positive result. Detailed information should also be provided as regard the epidemiological investigations done, and the additional laboratory tests foreseen (culture, PCR, IFGamma, etc ...). Please mention if national guidelines are available.

(max. 32000 chars) :

An establishment is considered a case, according to RD 2611/1996 and amendments, if at least one animal susceptible to be examined for its age has not passed any of the official tests (both routine and complementary) with a favorable result or has not been submitted to any of the diagnostic tests foreseen in Annex III of Regulation (EU) 2020/689.

In addition to what is described previous pragraphs, if post-mortem examinations and sampling of positive reactors or animals that appear with suspicious lesions during post-mortem inspection during routine slaughter are not carried out or are not completed according to the established protocol ("Procedural Manual for the collection and submission of samples for microbiological diagnosis of tuberculosis") for any reason, the T3 or T3H status will be, in any case, withdrawn. Similarly, even if sampling has been completed as established and infection has not been confirmed in any suspect animal by laboratory testing, the competent authority may decide to withdraw the T3 or T3H status if infection cannot be ruled out due to the high number of reactors, epidemiological reasons, herd history or for any other reason considered necessary for the control of infection by the CMT.

In T3H herds located in low prevalence provinces (<1%), upon the appearance of reacting animals, the competent authority may apply any of the possibilities for action provided for in Sections 3 and 4 of Chapter I of Part II of Annex IV of Regulation (EU) 2020/689) in accordance with the provisions of the "Procedure for actions and livestock movements upon the appearance of reacting animals in T3H herds without suspected disease in low prevalence areas of tuberculosis 2022".

In low prevalence ACs, in T3 or T3H establishments in which this classification is withdrawn and microbiological isolation has been obtained, an epidemiological survey will be carried out following the "Manual for conducting reduced epidemiological surveys 2020" for recording in BRUTUB database. In the rest of the Autonomous Communities, these surveys of establishments in which the qualification has been withdrawn will be carried out and recorded in BRUTUB. The degree of compliance with the general biosecurity measures contained in the Good Hygiene Practice Guidelines will also be checked.

In T3 or T3H establishments in which this qualification is suspended or withdrawn, after the slaughter of the positive reactors, samples will be taken in order to try to isolate Mycobacterium tuberculosis complex, according to the "Manual of procedure for the collection and shipment of samples for

microbiological culture of tuberculosis 2021". In the event that the number of positive reactors is high and it is not possible to take samples from all of them for logistical reasons, samples will be taken from a representative proportion of animals, prioritizing those that show compatible lesions. In the event that no animal shows lesions, samples shall be taken from all positive animals. It will not be necessary to take samples from animals that are subject to a sanitary depopulation for bovine tuberculosis.

In cases where the establishment has been considered infected, in addition to the entry of animals from the previous control, the exit of animals for breeding purposes that have occurred from the establishment since the last control prior to the appearance of the positive animals will be checked, so that tests can be carried out in these establishments of destination to verify if these animals may have acted as sources of infection in these establishments. The National Spoligotype Database will also be used in the investigation of the possible origin of the disease.

Likewise, establishments adjacent to the one considered infected and those epidemiologically related, will be subjected to at least one additional test at the same time as the first repetition of the confirmed establishment, unless their biosecurity conditions rule out that they could have been infected.

In the case of the appearance of animals reacting positive to this disease, they will be identified by means of ruminal bolus or genetic marking systems. This identification system will not be necessary if the animals are marked and transported to the slaughterhouse or slaughtered in the establishment on the same day of marking, and in addition, in the first case, they are transported in vehicles sealed by the competent authority. These marking systems may be replaced by equivalent systems when the competent authority considers that they show similar effectiveness in risk management. In the case of fighting cattle, the traditional method contemplated in Royal Decree 2129/2008, of December 26, 2008, establishing the National Program for the conservation, improvement and promotion of livestock breeds, will also be considered valid for this identification.

These animals shall be isolated within the establishment. In each Autonomous Community, a written protocol for on-site inspections of establishments subject to movement restrictions will be drawn up to supervise its application. This protocol will include at least 25% of the establishments in which more than 5 days have passed since the marking of the animals without their transfer for slaughter, and always in the case of establishments where irregularities have been detected previously in the fulfillment of the measures. A standardized record of all these inspections will be drawn up and recorded in a register of inspections.

The farmer will be informed in writing that milk from his herd cannot be destined for human consumption under any circumstances if it comes from positive animals, and without having undergone an authorized heat treatment in the case of the other animals in the herd, in accordance with Regulation 853/2004. The purpose of this information provided to the farmer is to enable him to pass it on to the next stage of the food chain. The farmer will also be informed in writing that his establishment is subject to movement restrictions, specifying the legal basis and the penalties that non-compliance with these restrictions entails.

Positive animals will be slaughtered under official control as soon as possible and no later than fifteen days after official notification to the owner or keeper of the test results (although certain exceptions are contemplated in very specific situations and always due to force majeure) and the farmer will be compensated according to the officially established scales, except in the case of animals belonging to a feedlot and animals located in a commercial operator type establishment that exceed 30 days of stay in the same.

Positive reacting animals are sent to slaughterhouses authorized for this purpose. For this purpose, at the time of marking, the farmer is given the necessary documentation (“conduce” or “conduce” and Health Certificate of Origin) so that they can be transferred to the slaughterhouse.

The slaughter will be carried out in an authorized slaughterhouse of the Autonomous Community where the establishment of the positive animals is located, and within the Autonomous Community, preferably in an authorized slaughterhouse of the province where the establishment is located. In exceptional cases, justified by the Services with competence in health of the Autonomous Community of origin, if there are no authorized slaughterhouses or due to capacity problems in the slaughterhouses of said Autonomous Community that make it impossible to slaughter the positive reactors within 15 days, this Service may exceptionally request slaughter in the nearest slaughterhouse of another neighboring Autonomous Community, with prior authorization from the same (by the Services with competence in public health and animal health) and with prior notification to the SGSHAT. The slaughter of positive reactors can also be carried out in the establishment itself or in places expressly authorized for this purpose, and after slaughter, they must be transferred to centers for the elimination and transformation of dead animals and animal by-products, regulated by Regulation 1069/2009.

After the slaughter of positive animals, the cleaning and disinfection of establishments and utensils shall be carried out under the supervision of an Official Veterinarian.

Likewise, slaughterhouses and means of transport will be subjected to disinfection and control. Manure management will be carried out in accordance with the "Protocol for Manure Management in tuberculosis and brucellosis positive farms".

The restocking of animals in positive establishments can only be carried out after the bovines over six weeks old remaining in the establishment have presented a favorable result in at least one tuberculosis investigation test. However, the competent authority may exceptionally authorize, on a case-by-case basis, the entry of animals into these establishments, provided that it considers that the activity of these establishments could be seriously compromised without such entry of animals, and that the competent authority considers that the epidemiological conditions of the establishments are safe to authorize such restocking, in the following cases:

- Large capacity fattening establishments in accordance with the “Feedlot Qualification Manual 2022”.
- Stallions in a zootechnically adequate number in function of the size of the establishment, including halters when they are necessary in bullfighting establishments.
- Dairy cattle establishments when they are own heifers that are in a heifer rearing establishment.
- Other exceptional situations, as long as the competent authority of the autonomous community evaluates such exceptional situation as necessary, and it is authorized by the MAPA.

In all these cases, if the introduced animals must be compulsorily slaughtered because they are positive before the establishment returns to officially free status, they will not be entitled to compensation, to which the owner of the establishment will commit himself in writing, together with the acceptance of the biosecurity and biosafety measures determined by the OVS, prior to the authorization of these exceptions.

In the case of establishments with the qualification withdrawn by laboratory tests, recovery tests with SIT and extra-severe interpretation and, in the case of parallel use, with gamma-interferon NRL, will be performed with an interval of at least 60 days, but not more than 120 days, until T3 qualification is recovered after obtaining two consecutive negative tests with an interval of at least 60 days. These

recovery intervals can only be applied if, after the corresponding epidemiological investigation, the withdrawal of the T3 status has occurred as a consequence of the introduction of infected animals in the 12 months prior to the detection of the infection; or in T3H establishments if there has been only one animal positive to routine tests or with etiological diagnosis; or when the establishment has carried out the maintenance test within the 12 months prior to the detection of the infection. In other cases, the deadlines will be the same as for obtaining the qualification.

At least in all herds in which microbiological isolation has been obtained, the use of the SIT and gamma-interferon NRL tests shall be carried out in parallel, at least in the first repetition after the positive detection test, and shall be maintained at least as long as microbiological isolation continues to be obtained in the slaughtered animals or, in the event that samples have not been taken from them, as long as SIT reactors continue to appear or the competent authority considers that the epidemiological risk continues. The specific identification of gamma-interferon positive animals will be communicated to the owner of the establishment at the time of marking.

Establishments with withdrawn status in which infection has been confirmed by laboratory testing may not send breeding animals to other breeding establishments, after negative recovery tests, until they obtain negative results in a test performed at least 12 months after the slaughter of the last positive animals, regardless of whether they have regained health status through two negative tests performed in less than 12 months.

The Autonomous Communities may declare as ZEI (Special Incidence Zone) those counties or LVUs with herd prevalence > 3%. In them, an increase in the routine checks on T3 and/or T3H herds will be applied by means of two annual tests. Likewise, within them, the competent authority may decide to apply, after an epidemiological study of the area, additional measures in municipalities with more than 5% of positive herds, which will include, among others:
- the restriction of movements of any herd to areas of common use
- movements of any type of T3/T3H establishments within the municipality, even if belonging to the same establishment code, must be authorized by the SVOs
- any other additional measures that the SVOs consider necessary for disease control.

4.4.10 Compensation scheme for owners of slaughtered and killed animals

(max. 32000 chars) :

Royal Decree 389/2011, as amended by Royal Decree 904/2017 and APA Order 513/2020, establishes the compensation scales for compulsory slaughter of animals subject to National Disease Eradication Programs.

4.4.11 Control on the implementation of the programme and reporting including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

Please indicate also when the last FVO audit has taken place and provide a table listing the recommendations and the actions taken by the national authorities to this regard.
Please mention if a Task Force subgroup visit has taken place and the state of play as regards the implementation of the recommendations suggested if any.

(max. 32000 chars) :

The necessary communications between the MAPA and the Autonomous Communities for the control of

the execution of the program, and the communication of data to the European Commission, will be carried out following the "Manual for sending data and reports in the national programs for the eradication of tuberculosis, bovine brucellosis and ovine-caprine brucellosis and in the surveillance programs of other diseases" through the IT Rasve program.

The competent authorities in Animal Health will communicate, as soon as possible and at least on a monthly basis, to the competent authority responsible for the sanitary control of the milk processing establishments, the list of dairy cattle establishments not sanitarily qualified within their territorial scope, so that they can proceed to the communication of the same, if necessary, to the owners of the dairy establishments. In the case of new positive establishments, such communication will be made within a period not exceeding 7 days.

5. Benefits of the programme

A description is provided of the benefits of the programme on the economical and animal and public health points of view. Describe

- progress expected compared to the situation of the disease in the previous years, in line with the objectives and expected results
- cost efficiency of the programme including management costs

(max. 32000 chars) :

The difficulties involved in the eradication of bovine tuberculosis are well known, which leads to conflicting opinions regarding the economic evaluation of eradication programs, especially in endemic areas with particular geographic and ecological characteristics. However, the zoonotic nature of the disease alone justifies the maintenance of eradication strategies. Therefore, any cost/benefit assessment must be considered within the scope of food safety and public health.
At the beginning of the program, compensation costs for slaughtering animals were very high due to the high incidence. These values decreased progressively due to the favorable evolution of the program, on the contrary, the implementation costs have increased, being necessary to maintain the degree of financing to reach the final objective. Likewise, there has been an increase in laboratory costs, due to the use of a greater diversity of diagnostic tests in order to try to make an etiological diagnosis or, if necessary, to make a differential diagnosis of the disease.
The number of human tuberculosis cases due to M. bovis/caprae according to The European Union One Health 2019 Zoonoses Report was 32.
The main benefits for farmers derive from the increase in income as they are freed from the limitations on animal movement imposed on the basis of health status. This fact allows them to expand the number of commercial operators with whom they can trade and strengthen their negotiating position, as well as the valorization of their products. And most importantly, the eradication of the disease offers unquestionable benefits to society as a whole by fighting and eliminating this serious zoonosis.

7. Targets

The blocks 7.1.1, 7.1.2.1, 7.1.2.2, 7.2, 7.3.1 and 7.3.2 are repeated multiple times in case of first year submission of multiple program.

7.1 Targets related to testing (one table for each year of implementation)

7.1.1 Targets on diagnostic tests for year : **2021**

Region	Type of the test	Target population	Type of sample	Objective	Number of planned tests	
SPAIN	tuberculin test	Bovines	skin test	qualification	5 416 302	X
SPAIN	tuberculin test	Goats	skin test	surveillance	764 320	X
SPAIN	gamma-interferon test	Bovines	blood	qualification	271 259	X
SPAIN	gamma-interferon test	Goats	blood	surveillance	1 323	X
SPAIN	PCR	Bovines		confirmation of suspected cases	19 119	X
SPAIN	PCR	Goats	Organs/tissues	confirmation of suspected cases	1 491	X
SPAIN	bacteriological test	Bovines	Organs/tissues	confirmation of suspected cases	25 532	X
SPAIN	bacteriological test	Goats	Organs/tissues	confirmation of suspected cases	2 003	X
				Total	6 501 349	
				Add a new row		

	Total number of tests
Total number of tests	6 501 349
tuberculin test	6 180 622
tuberculin test (only purchase of tuberculin)	0
gamma-interferon test	272 582
bacteriological test	27 535
PCR	20 610

7.1.1 Targets on diagnostic tests for year : **2022**

Region	Type of the test	Target population	Type of sample	Objective	Number of planned tests	
SPAIN	tuberculin test	Bovines	skin test	qualification	5 584 000	X
SPAIN	tuberculin test	Goats	skin test	surveillance	1 487 300	X
SPAIN	gamma-interferon test	Bovines	blood	qualification	468 140	X
SPAIN	gamma-interferon test	Goats	blood	surveillance	1 240	X
SPAIN	bacteriological test	Bovines	organs/tissues	confirmation of suspected cases	24 280	X
SPAIN	bacteriological test	Goats	organs/tissues	confirmation of suspected cases	2 772	X
SPAIN	PCR	Bovines	organs/tissues	confirmation of suspected cases	12 251	X
SPAIN	PCR	Goats	organs/tissues	confirmation of suspected cases	1 569	X
				Total	7 581 552	
				Add a new row		

	Total number of tests
Total number of tests	7 581 552
tuberculin test	7 071 300
tuberculin test (only purchase of tuberculin)	0
gamma-interferon test	469 380
bacteriological test	27 052
PCR	13 820

7.1.2 Targets on testing herds and animals

7.1.2.1 Targets on the testing of herds for year : **2021**

									Target indicators			
Region	Animal species	Total number of herds	Total number of herds under the programme	Number of herds expected to be checked	Number of expected positive herds	Number of expected new positive herds	Number of herds expected to be depopulated	% positive herds expected to be depopulated	Expected % herd coverage	% positive herds Expected period herd prevalence	% new positive herds Expected herd incidence	
SPAIN	Bovines	109 793	109 793	103 500	1 445	711	81	5,606	94,268	1,396	0,687	X

SPAIN	Goats	25 985	8 553	8 224	319	210	28	8,777	96,153	3,879	2,554	X
Total		135 778	118 346	111 724	1 764	921	109	6,179	94,405	1,579	0,824	
									Add a new row			

7.1.2.1 Targets on the testing of herds for year : **2022**

									Target indicators			
Region	Animal species	Total number of herds	Total number of herds under the programme	Number of herds expected to be checked	Number of expected positive herds	Number of expected new positive herds	Number of herds expected to be depopulated	% positive herds expected to be depopulated	Expected % herd coverage	% positive herds Expected period herd prevalence	% new positive herds Expected herd incidence	
SPAIN	Bovines	107 866	107 866	103 700	1 149	675	87	7,572	96,138	1,108	0,651	X
SPAIN	Goats	32 499	16 689	16 688	430	306	82	19,070	99,994	2,577	1,834	X
Total		140 365	124 555	120 388	1 579	981	169	10,703	96,654	1,312	0,815	
									Add a new row			

7.1.2.2 Targets on the testing of animals for year : **2021**

							Slaughtering	Target indicators	

Region	Species	Total number of animals	Number of animals under the programme	Number of animals expected to be tested	Number of animals to be tested individually	Number of expected positive animals	Number of animals with positive result expected to be slaughtered or culled	Total number of animals expected to be slaughtered	Expected % coverage at animal level	% positive animals (Expected animal prevalence)	
SPAIN	Bovine	6 619 678	6 619 678	5 535 692	5 535 692	12 379	12 379	21 742	83,625	0,224	X
SPAIN	Goat	1 997 826	674 017	610 600	610 600	11 284	11 284	13 599	90,591	1,848	X
Total		8 617 504	7 293 695	6 146 292	6 146 292	23 663	23 663	35 341	84,269	0,385	
								Add a new row			
							Total number of animals expected to be slaughtered or culled : BOVINES	21 742			
							Total number of animals expected to be slaughtered or culled : BUFFALO	0			

7.1.2.2 Targets on the testing of animals for year : **2022**

							Slaughtering		Target indicators		
Region	Species	Total number of animals	Number of animals under the programme	Number of animals expected to be tested	Number of animals to be tested individually	Number of expected positive animals	Number of animals with positive result expected to be slaughtered or culled	Total number of animals expected to be slaughtered	Expected % coverage at animal level	% positive animals (Expected animal prevalence)	
SPAIN	Bovine	6 714 209	6 714 209	5 322 255	5 322 255	10 280	10 280	19 668	79,269	0,193	X
SPAIN	Goat	2 146 355	841 184	803 684	803 684	16 590	16 590	21 592	95,542	2,064	X
Total		8 860 564	7 555 393	6 125 939	6 125 939	26 870	26 870	41 260	81,080	0,439	
								Add a new row			

Total number of animals expected to be slaughtered or culled : BOVINES	19 668
Total number of animals expected to be slaughtered or culled : BUFFALO	0

7.2 Targets on qualification of herds and animals

7.2 Targets on qualification of herds and animals for year : 2021

				Targets on the status of herds and animals under the programme												
						Expected not free or not free from disease										
		Total number of herds and animals under the programme		Expected unknown		Last check positive		Last check negative		Expected free or officialy free from disease status suspended		Expected free from disease		Expected officially free from disease		
Region	Animal species	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	
SPAIN	Bovines	108 042	6 320 012	32	2 500	502	67 433	648	62 344	386	35 546	0	0	106 474	6 154 179	X
Total		108 042	6 320 012	32	2 500	502	67 433	648	62 344	386	35 546	0	0	106 474	6 154 179	
												Add a new row				

7.2 Targets on qualification of herds and animals for year : 2022

			Targets on the status of herds and animals under the programme					
				Expected not free or not free from disease				

		Total number of herds and animals under the programme		Expected unknown		Last check positive		Last check negative		Expected free or officialy free from disease status suspended		Expected free from disease		Expected officially free from disease		
Region	Animal species	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	
SPAIN	Bovines	106 222	6 385 649	30	2 208	380	51 277	434	48 876	523	35 602	0	0	104 855	6 247 736	X
Total		106 222	6 385 649	30	2 208	380	51 277	434	48 876	523	35 602	0	0	104 855	6 247 736	
												Add a new row				

7 .3 Targets on vaccination or treatment

7.3.2 Targets on vaccination or treatment of wildlife for year : **2021**

		Targets on vaccination or treatment programme			
Region	Square km	Number of doses of vaccine or treatments expected to be administered in the campaign	Expected number of campaigns	Total number of doses of vaccine or treatment expected to be administered	
SPAIN	504 923	0	0	0	X
Total				0	
			Add a new row		

7.3.2 Targets on vaccination or treatment of wildlife for year : **2022**

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		Targets on vaccination or treatment programme			
Region	Square km	Number of doses of vaccine or treatments expected to be administered in the campaign	Expected number of campaigns	Total number of doses of vaccine or treatment expected to be administered	
SPAIN	504 923	0	0	0	X
Total				0	
			Add a new row		

8. Detailed analysis of the cost of the programme

The blocks are repeated multiple times in case of first year submission of multiple program.

To facilitate the handling of your cost data, you are kindly requested to:

1. *Fill-in the text fields IN ENGLISH*
2. *Limit as much as possible the entries to the pre-loaded options where available.*
3. *If you need to further specify a pre-loaded option, please keep the pre-loaded text and add your clarification to it in the same box.*

Costs of the planned activities for year : 2021

1. Sampling

Cost related to	Specification	Number of samples	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	

2. Testing

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Tuberculin test	6 180 622	6.19	38,258,050.18	yes	16	6 121 288,03	
		0		0			0	
Testing	Gamma-Interferon test	272 582	4.38	1,193,909.16	yes	16	191 025,47	
Testing	Bacteriological test	27 535	26.47	728,851.45	yes	16	116 616,23	
Testing	PCR	20 610	12.27	252,884.7	yes	16	40 461,55	

3. Vaccines

Cost related to	Specification	Number of vaccine dosis	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
4. Compensation paid to owners								
Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Compensation	Slaughtered/culled with salvage value excluded | Bovines	21 742	544	11,827,648	yes	16	1 892 423,68	
Compensation	Slaughtering/culling with salvage value | Buffalo	0		0		16	0	
Compensation	Value of destroyed milk			0		16	0	
5.Cleaning and disinfection								
Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Cleaning and disinfection	Cleaning and disinfection in case of full holding depopulation			0		16	0	
6. Slaughtering/culling costs								
Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Slaughtering/culling	Slaughtering/culling costs - full holding depopulation			0		16	0	
7.Other costs								
Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	

				0			0	X
Duly justified measures	Vaccine doses used for wild animals	0		0		16	0	X

Add a new row

Total with Union funding request (€):	52,261,343.49	including	8,361,814.96
Total without Union funding request (€):	0		= requested EU contribution in €

Costs of the planned activities for year : **2022**

1. Sampling

Cost related to	Specification	Number of samples	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	

2. Testing

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Tuberculin test	7 071 300	6.19	43,771,347	yes	16	7 003 415,52	
		0		0			0	
Testing	Gamma-Interferon test	469 380	4.38	2,055,884.4	yes	16	328 941,5	
Testing	Bacteriological test	27 052	26.47	716,066.44	yes	16	114 570,63	
Testing	PCR	13 820	12.27	169,571.4	yes	16	27 131,42	

3. Vaccines

Cost related to	Specification	Number of vaccine dosis	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
4. Compensation paid to owners								
Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Compensation	Slaughtered/culled with salvage value excluded | Bovines	19 668	582	11,446,776	yes	16	1 831 484,16	
Compensation	Slaughtering/culling with salvage value | Buffalo	0		0		16	0	
Compensation	Value of destroyed milk			0		16	0	
5.Cleaning and disinfection								
Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Cleaning and disinfection	Cleaning and disinfection in case of full holding depopulation			0		16	0	
6. Slaughtering/culling costs								
Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Slaughtering/culling	Slaughtering/culling costs - full holding depopulation			0		16	0	
7.Other costs								
Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	

				0			0	X
Duly justified measures	Vaccine doses used for wild animals	0		0		16	0	X
				Add a new row				
			Total with Union funding request (€):	58,159,645.24	including		9,305,543.23	
			Total without Union funding request (€):	0			= requested EU contribution in €	

8.2. Financial informaton

1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursement/payment claim to the EU. Describe the financial flows/circuits followed.
Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who performs the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

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(max. 32000 chars) :

N/A

b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

(max. 32000 chars) :

Veterinarians that perform the tuberculin tests can be authorised private vets or can belong to public or private companies, depending of the region and are paid by the regional veterinary authorities for this service (state budget). Laboratory tests : national or regional public laboratories perform the testing of official samples (interferon gamma, culture, PCR) and costs related to this testing are entirely paid by the state budget

c) Implementing entities - **compensation**: who performs the compensation? Who pays?
(e.g. compensation is paid by the central level of the state veterinary services,
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

(max. 32000 chars) :

compensation is paid 50% by MAPA (central level) and 50% by regional competent authorities

d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?

(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

(max. 32000 chars) :

N/A

e) Implementing entities - **other essential measures**: who implements this measure? Who provide the equipment/ service? Who pays?

(max. 32000 chars) :

N/A

2 Co-financing rate (see provisions of applicable Work Programme)

The maximum co-financing rate is in general fixed at 50%. However based on provisions of Article 5.2 and 5.3 of the Regulation (EU) No 652/2014, we request that the co-financing rate for the reimbursement of the eligible costs would be increased:

☐ Up to 75% for the measures detailed below

☐ Up to 100% for the measures detailed below

3. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursement will be claimed are financed by public funds.

☒ *yes*

☐ *no*

4. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

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If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

N/A

Standard requirements for the submission of programme for eradication, control and monitoring

Attachments

IMPORTANT :

1) The more files you attach, the longer it takes to upload them .
2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.
3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
4) IT CAN TAKE ***SEVERAL MINUTES TO UPLOAD*** *ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!*
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

		Attachment name	File will be saved as (only a-z and 0-9 and -_) :	File size
		17997_13410.pdf	17997_13410.pdf	1781 kb
		17997_13411.docx	17997_13411.doc	453 kb
			Total size of attachments :	2235 kb