EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis preparedness in food, animals and plants
Animal health

SUBMISSION OF ERADICATION PROGRAMMES FOR CATEGORY B AND C DISEASES OF TERRESTRIAL ANIMALS BASED ON GRANTING DISEASE-FREE STATUS AT ESTABLISHMENT LEVEL

Template in accordance with Article 10 of Commission Implementing Regulation (EU) 2020/2002

BOVINE TUBERCULOSIS

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1. **Date of submission:** 31/5/2021

2. **Member State**: Portugal

3. **Name of the disease[1]:** Infection with *Mycobacterium tuberculosis* complex

4. **Contact details:**

   a. **E-mail:**

   b. **Responsibility within the competent authority:** Head of Epidemiology and Animal Health Unit

   c. **Name:**

5. **Territorial scope with a description and demarcation of the geographical and administrative areas 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.**

The eradication programme will be implemented on the entire territory of mainland Portugal with the exception of the Algarve, which obtained officially tuberculosis-free status in 2012, on S. Miguel Island of Autonomous Region of Açores and on Autonomous Region of Madeira.

[1] This template is to be used for the submission of the following eradication programmes for the following listed diseases:

Category B-diseases

a) Infection with Brucella abortus, B. melitensis and B. suis

b) Infection with Mycobacterium tuberculosis complex

Category C-diseases

a) Enzootic bovine leukosis

c) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

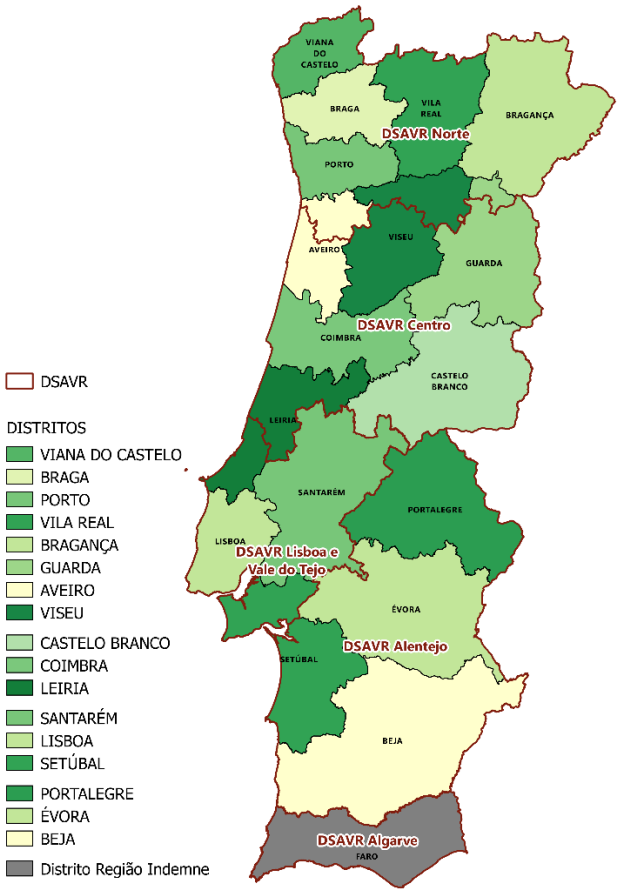
d) Infection with Aujeszky´s disease virus

e) Bovine viral diarrhoea

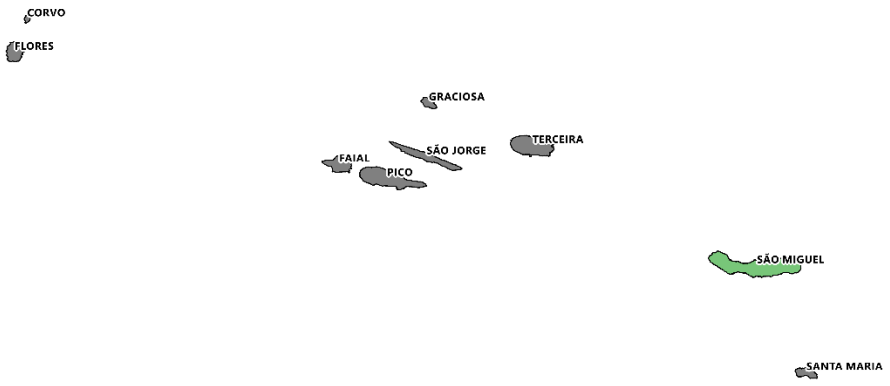
The eradication programme will be implemented at the following geographical and administrative areas:

Administrative areas of the territorial scope	Geographical areas "Distritos /Islands" with eradication programme
Directorate for Food and Veterinary of the Norte Region (DSAVRN)	Part of Aveiro Braga Bragança Part of Guarda Porto Viana do Castelo Vila Real Part of Viseu
Directorate for Food and Veterinary of the Centro Region (DSAVRC)	Part of Aveiro Castelo Branco Coimbra Part of Guarda Part of Leiria Part of Viseu
Directorate for Food and Veterinary of Lisboa and Vale do Tejo (DSAVRLVT)	Part of Leiria Lisboa Santarém Part of Setúbal
Directorate for Food and Veterinary of the Alentejo Region (DSAVRALT)	Beja Évora Portalegre Part of Setúbal
Directorate of Veterinary Services of Autonomous Region of Açores (RAA)	Island of S. Miguel
Directorate for Food and Veterinary Services of the Autonomous Region of Madeira (RAM)	Islands of Madeira and Porto Santo (Not cofinanced by the EU)

Distritos e DSAVR
Tuberculose 2021/22



Região Autónoma dos Açores
Planos de Erradicação 2021/22



6. A description of the epidemiological situation for each zone or region, if more than one region is included in the territorial scope of the programme:

Portugal is implementing the co-financed bovine tuberculosis eradication programme (BTEP) since 1991, based on the application of comparative intradermal tuberculin test (CITT). In 1993 herd prevalence was 0.2%. The programme was progressively consolidated over the years and by 2012 the region of Algarve, in mainland Portugal, was recognized as officially free of tuberculosis (Decision 2012/204/EU of 19 April 2012). In 2020, Decision 2020/2260/EC of 20 April 2020, also recognised eight islands of Autonomous Region of Açores as officially free of tuberculosis – Santa Maria, Terceira, Graciosa, São Jorge, Pico, Faial, Flores and Corvo.

The evolution in the past years is represented in the graphic (d).

Mainland

The bovine tuberculosis eradication programme (BTEP) carried out in 2020 for the non-officially free region of Portugal (4 regions of the mainland area and the S. Miguel Island in the Autonomous Region of Açores) resulted in an overall improvement of the epidemiological indicators. The evolution of the prevalence between 2019 and 2020 corresponds to different situations in the 4 mainland regions under the programme and in the Açores:

Administrative areas of the territorial scope	2019	2020
DSAVRN	0.12%	0.04%
DSAVRC	0.44%	0.38%
DSAVRLVT	0.79%	0.35%
DSAVRALT	1.41%	1.32%
RAA	0.86%	1.54 %

Region Norte (DSAVRN) - the bovine production is characterized by small units, averaging 11.9 bovines controlled per herd. Tuberculosis prevalence has been stable over the last 6 years, from 0.13% to 0.12%. In the end of 2019 there were a total of 10 herds with T2 status from a universe of 15.821 herds. In 2020 the prevalence was 0.04%.

Region Centro (DSAVRC) - also presents a majority of small herds, averaging 18.3 bovines controlled per herd. In certain areas, *M. bovis* circulates in wild animals (deer and wild boars) constituting a serious risk to extensive production herds. The percentage of positive herds has been stable over the last 6 years, from 0.37% to 0.44%, but in the end of 2019 this region had 21 herds with T2 status from a universe of 6.271 herds. In 2020 the prevalence was 0.38%

Region Lisboa e Vale do Tejo (DSAVRLVT) - has an average size of controlled bovine per holding of 65.3 animals. Some stability was observed in the programme results over the last 6 years, varying from 0.39% to 0.44% positive herds. In the end of 2019 this region had only 5 herds with T2 status from a universe of 1.719 herds. In 2020 the prevalence was 0.35%.

Region Alentejo (DSAVRALT) - has a different production system, with larger herds with 133.6 bovines controlled per herd on average, most reared in extensive systems, where farms have their own land without much contact between herds. However, there is a recognized risk of contact with infected wild boars and deer in certain areas. Stability was also observed in Tuberculosis programme results over the last 6 years, with herd prevalence varying from 1.30% to 1.41%. In the end of 2019 a total of 59 herds with T2 status from a universe of 4661 herds were present. In 2020 the prevalence was 1.32%.

Madeira Autonomous Region (MAA)

Madeira has never diagnosed tuberculosis in animals born in the island, both in CITT survey or in meat inspection at the abattoir. This Region has started the testing of tuberculosis but has not made relevant progress so far.

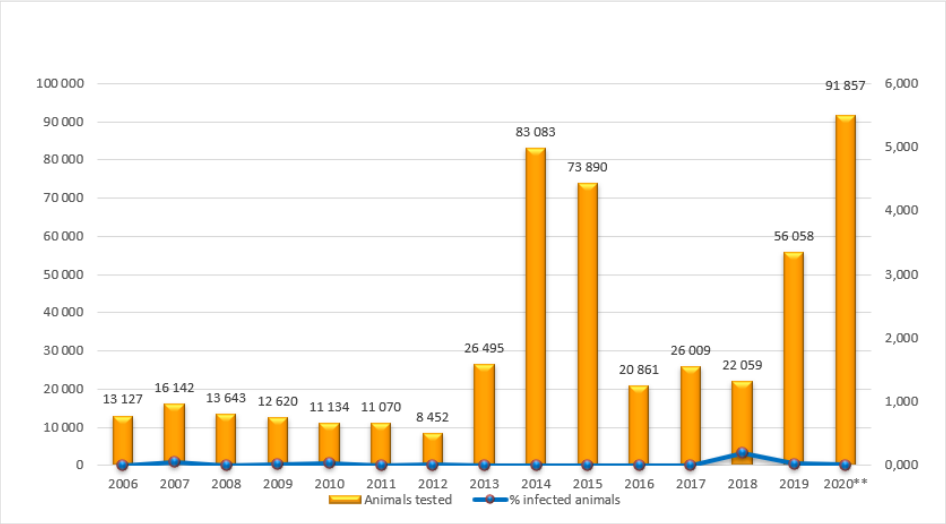
Autonomous Region of Açores (RAA)

The herd apparent prevalence of BTEP implemented in 2020 is of 1.54%. It is important to register that this is the first year that prevalence, only takes in account one island, so it seems to be much higher, but considering only S. Miguel, it decreased from 1.89% in 2019 to 1.54% in 2020.

The BTEP in the Autonomous Region of the Açores (RAA) was launched in January 2004. In 2007, for the first time over the preceding 20 years, 2 animals tested positive in the island of S. Miguel and required the implementation of the officially stipulated measures to eliminate this outbreak. In the last 18 years, a total of 902.712 intradermal tuberculin tests were carried out in the RAA.

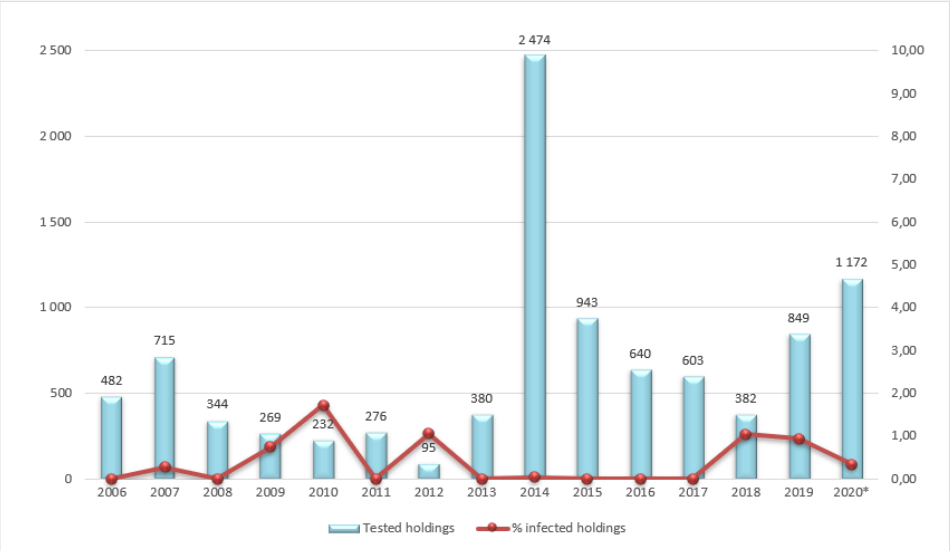
Two other infected animals were diagnosed in October 2012 and May 2014. The epidemiological data between 2006 and 2020 is presented in the following graphics. In 2017 one positive but non-confirmed animal was identified in the island of Faial.

Açores
Evolution of bovine tuberculosis tested and infected animals



**In 2020, only S. Miguel Island remained in the programme

Açores
Evolution of bovine tuberculosis tested and infected herds S. Miguel



**In 2020, only S. Miguel Island remained in the programme

Following a bovine tuberculosis outbreak on the Island of S. Miguel in the Açores, some adjustments in the programme of TB for 2019 were made, in order to adapt the strategy to this occurrence in the Autonomous Region.

Summary

In 2019, at national level, a total of 137 positive herds were identified, with 780 positive animals. From the 77 investigated herds with collection of organs from positive slaughtered animals, 57 were confirmed with isolation of Mycobacterium bovis. The 720 histopathological examinations and 396 bacteriologic tests resulted in 225 animals with positive isolation of *M. bovis*.

Post-mortem inspection at slaughterhouses and investigation of lesions (histopathology and bacteriology) is a routine procedure. The decline in the prevalence also lead to a decline in the number of suspect lesions detected at slaughter with confirmation of the disease, which decreased from 48 in 2012 to 38 in 2018.

Compulsory pre-movement testing has been applied to avoid the entrance of infected bovine in T3 herds, including from non-OTF islands to OTF ones.

In the mainland, the following data regarding 2020 was:

- 39 098 holdings / 313 834 animals.

In the Autonomous Region of Açores:

In 2020, two epidemiological inquiries were done (considering only the new infected herds): one concluded that the reason of the infection was reoccurrence of the disease and the other was inconclusive.

There were no slaughter of suspicious animals.

Lesions found in abattoir (surveillance data): a total of 60 animals were slaughtered (49 testing positive in tuberculin and 11 cohabitants). From those 49 bovines, only 3 had compatible lesions with tuberculosis in post-mortem inspection and 7 were positive on microbiological test.

In Madeira, the programme has been progressing with difficulties regarding human resources, but strategic testing of larger holdings has been adopted. This Region is not included in the co-financed programme.

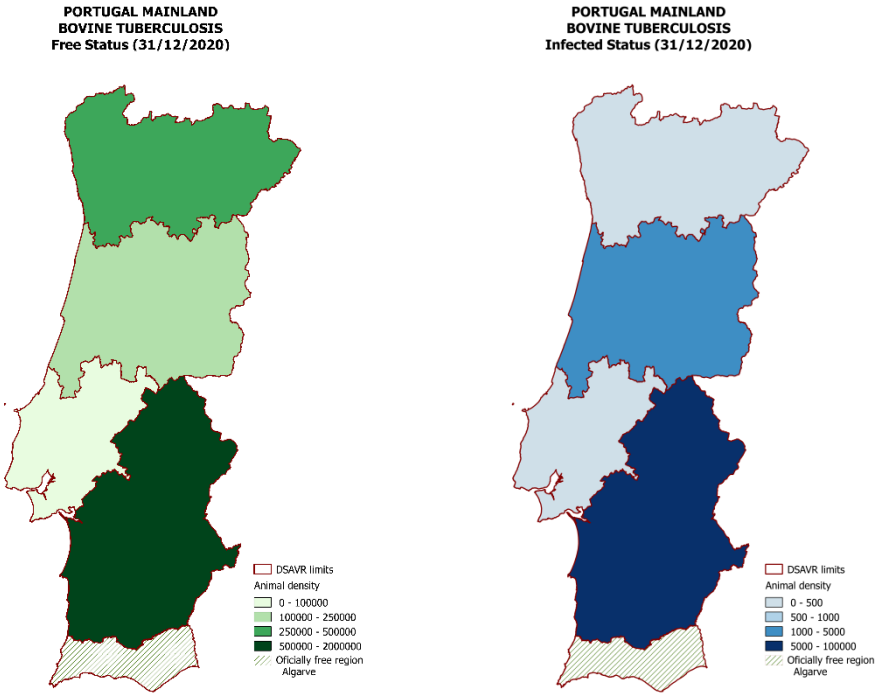
(a) the number of establishments keeping animals of the targeted animal population by health status (Disease-free, infected or unknown) excluding establishments falling under the derogation referred to in point (6)(f) at 31 December;

Health status- establishments/units - bovine - 2020				
Regions	Unknown status	Non-Free status		Disease Free-status
		Infected status (T2.1)	Non-infected status (T2)	
Norte	0	4	4	15.813
Centro	0	14	13	6.244
Lisboa e Vale do Tejo	0	2	4	1.713
Alentejo	0	39	18	4.620
RAA (Açores)	0	4	4	2.133
Portugal - total	**0**	**63**	**43**	**30.523**

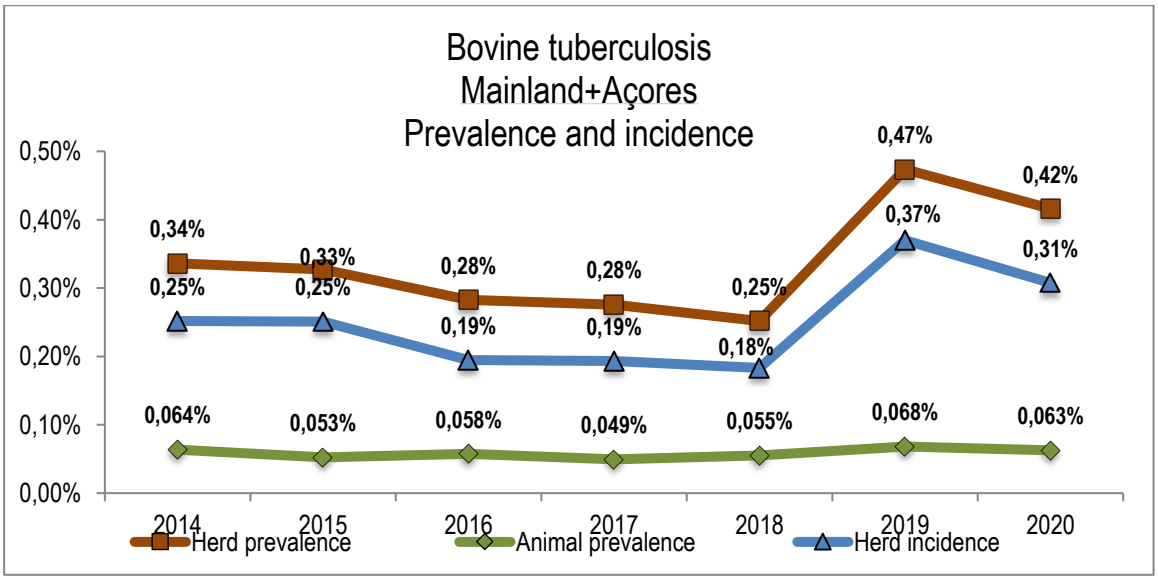
(b) the number of animals of the targeted animal population kept in the establishments referred to in point (a) by health status;

Health status - data on bovine animals – 2020				
Regions	Unknown status	Non-Free status		Disease Free-status
		Infected status (T2.1)	Non-infected status (T2)	
Norte	0	106	83	299.032
Centro	0	2.626	2.257	145.847
Lisboa e Vale do Tejo	0	155	302	179.400
Alentejo	0	6.854	4.424	673.507
RAA (Açores)	0	1.100	411	127.640
Portugal - total	**0**	**10.841**	**7.477**	**1.425.426**

(c) maps indicating the density of the targeted animal population referred to in point (b) by health status;



(d) timeline with prevalence, incidence data and, where relevant, vaccination history covering at least the past 5 years; and



(e) information as regards the epidemiological situation in additional animal populations, where relevant.

A tuberculosis surveillance plan for large game animals is in place in the risk area of the country (interior of Centro and Alentejo regions). This plan includes the following measures:

- In all big game hunting activities, a veterinarian or some expertise in collecting samples is present.

- All hunted animals are submitted to an initial examination, made by the veterinarian or some expertise in collecting samples, to ensure food security and the protection of hunters and personnel involved in these activities.

- Reinforcement of correct destination of the by-products of hunting.

- Collection of samples for laboratory diagnosis (histopathological and bacteriological examination) of any suspected lesions of tuberculosis is carried out.

Results obtained in the last years indicate that in 39% of the hunting acts, suspected lesions were found and in 28% of the hunting acts, tuberculosis confirmation is achieved. This represents 4,6% of positives in hunter deer and 4,8% of positive hunter wild boars.

7. A description of the disease control strategy of the eradication programme in accordance with Article 16 of Commission Delegated Regulation (EU) 2020/689 including at least:

Objectives: The purpose of the Portuguese Bovine Tuberculosis Eradication Program, both in the mainland and in S. Miguel island of the Autonomous Region of Açores is to reduce the herd incidence and prevalence creating officially free areas and achieving the eradication of the disease. Early diagnosis and good containment of the infection is therefore necessary, while implementing also the protection of free herds through the control of animal movements or other risk contacts.

In the mainland and in S. Miguel island of Açores the programme covers all bovines over six weeks of age in accordance with Delegated Regulation (EU) 2020/689.

Frequency of CITT or Single Intradermal Tuberculin Test (SITT) depends on the herd's health status and on the epidemiological indicators of the region.

(a) the sampling schemes and diagnostic methods to be used in accordance with Annex IV to Delegated Regulation (EU) 2020/689:

Diagnosis: The official diagnostic test is the CITT, which considers positive, negative and doubtful results. Following a doubtful result, a new CITT test is carried out 42 days later, to clarify the result. In these cases the positivity of the animal is determined by a non-negative result (positive or doubtful) in this second test. In infected herds the decision on positivity takes into account the Single Intradermal Tuberculin Test (SITT).

The gamma-interferon test is a complementary diagnostic test which is used (in parallel with SITT or CITT), upon decision of the official veterinary services, in the following situations:

a) When there is a significant number of doubtful results in the CITT.

b) In infected herds where animals successively test positive in the intradermal tuberculin test (chronic positivity).

Case definition: Under this program a positive case is an animal with positive (or doubtful at retesting) result in the CITT or SITT tests applied in accordance to the protocol of the EU TB Reference Centre; an infected animal is the one with isolation of a Mycobacteria of the *M. tuberculosis* complex or with histopathological characteristic lesion(s).

General testing scheme: All bovines over 6 weeks of age are subject to CITT or SITT.

Circumstances for the application of CITT:

1 - Officially tuberculosis-free herds (T3 and EB4T3L4):
- As a routine test for maintenance of health status, the animals to be tested being determined by the rules described in the programme.
- As a pre-movement test.

2 - Suspended officially tuberculosis-free herds (T3S and ES):
- Following slaughter of a positive animal.
- Following a suspect tuberculosis lesion in routine examination in a slaughterhouse.
- As a risk assessment test (TAR) as described at point (i).

3- Non-disease free herds (T2):
- Following slaughter of a positive animal.
- As a test to recover higher status.
- As a risk assessment test (TAR) as described at point (i).

4- Non-disease free herds, infected (T2.1 and E2.1):
- As a risk assessment test (TAR) as described at point (i).

Circumstances for the application of SITT:

Non-disease free herds (T2.1 and E2.1).
- Following slaughter of a positive animal.
- As a test to recover higher status (T2 or ES).

The 2022 Tuberculosis eradication programme will apply the derogation from point 1(c) of the testing regime in accordance with Section 2 of Chapter 1, Part II of Annex 4 of Delegated Regulation (EU) 2020/689, based on the indicators of previous years calculated on the 31st of December of each year, as follows:

- In districts with % of establishments infected with MTBC is not more than 1% during the last 24 months, the interval between tests may be extended to 24 months;
- In districts with % of establishments infected with MTBC is not more than 0,2% during the last 36 months, the interval between tests may be extended to 36 months;
- In districts with % of establishments infected with MTBC is not more than 0,1% during the last 72 months, the interval between tests may be extended to 48 months.

If any risk of tuberculosis infection is detected, the frequency of testing will not apply the derogation.

(i) for the granting of the disease-free status to establishments and the maintenance of that status;

All the herds covered by the programme have a health status in accordance with Delegated Regulation (EU) 2020/689 and Decree-Law No 272/2000 of 8 November 2000; Directive 2008/73/CE and Decree-Law No 79/2011 of 20 June.

Reproductive herds: officially disease free (T3) and non-disease free, including herds which are undergoing health measures (T2) and infected (T2.1 – with isolation of Mycobacteria of the M. tuberculosis complex).

Fattening herds: classified as free (EB4T3L4), suspended (ES) or infected (E2.1).

The dynamic assignment, maintenance and change of health status defined in the program is the following:

Reproductive herds:

- T3 officially tuberculosis free herds are those that fulfil the program and in which the bovines over six weeks of age introduced, were submitted to a CITT in the previous 30 days with negative result (pre-movement test), according with the criteria set out in the legislation and specific guidelines on the subject "Manual of procedures for health qualification".

- The officially free herd status (T3) is suspended (T3S) in the following situations:

a) If any CITT reveals positive animal(s).

b) As a result of the detection of suspicious lesions on routine examination at slaughterhouse.

c) If an Epidemiological Inquire (EI) reveals the possibility of infection.

d) When the conditions to be considered officially free are not fulfilled by all animals in the herd.

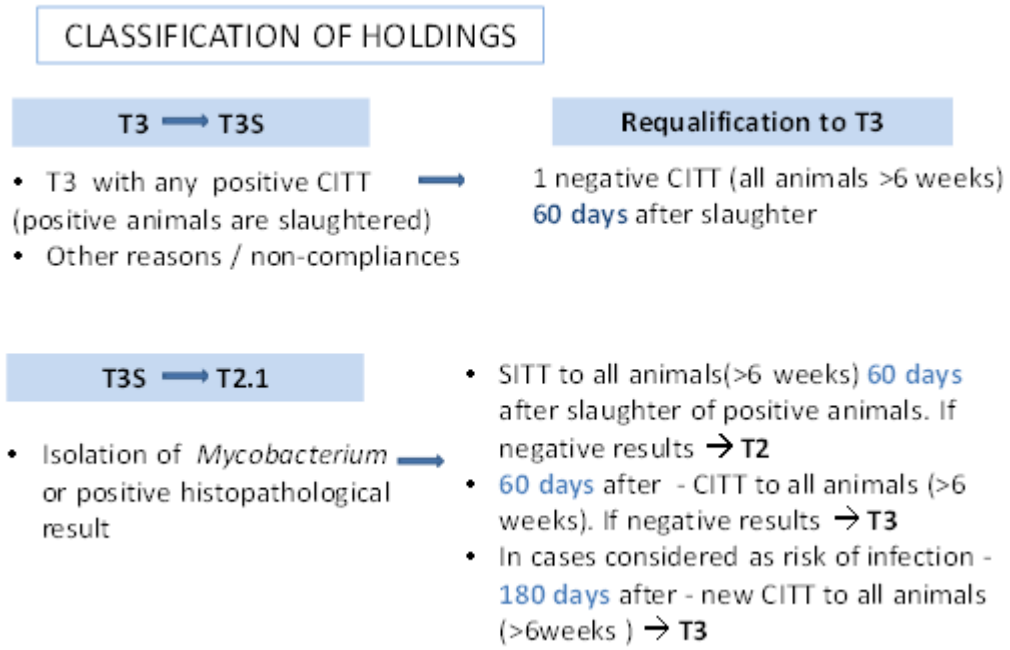
e) For any other reason considered relevant to the strategy against tuberculosis by the official veterinary services.

- After a positive CITT result, animals are subjected to sanitary slaughter and sampled for bacteriological or histopathological confirmation. If all the animals over 6 weeks of age test negative in a CITT carried out 60 days after the slaughter of positive animals and the bacteriological and histopathological tests are negative, the suspension is withdrawn.

- The officially free suspended status (T3S) becomes infected status T2.1 when the presence of Mycobacterium is confirmed by isolation of the agent or positive histopathological result.

- Infected herds (T2.1) can became non disease-free (T2) after one SITT test with negative results on all bovines more than 6 weeks of age, carried out 60 days after the slaughter of the last animal reacting positive.

Herds with non-free status (T2), undergoing health measures, reacquire officially free status (T3) after one negative test carried out 60 days after the previous one. However, in cases considered as risk of infection, a second test will be performed 180 days after the previous before granting the T3 status.



Fattening herds:

EB4T3L4 is the disease free status assigned to fattening herds that receive animals from free reproduction herds and other free fattening herds with negative pre-movement tests. These herds can send animals to slaughter and to other fattening herds.

Maintenance of the classification regime includes:

- movements of animals to this establishments are carried out in compliance with the requirements of premovement tests set out in Delegated Regulation (EU) 2020/689 and holdings of origin are MTBC free.

- the animals kept in the units for more than 12 months will be tested.

Whenever there is a positivity at CITT the EB4T3L4 status is withdrawn (ES) and whenever there is infection (presence of Mycobacterium is confirmed by isolation of the agent or positive histopathological result) the status becomes infected E2.1.

E2 is the status assigned to special non-free fattening herds that are controlled by DSAVR. Biosecurity measures are evaluated in order to ensure that there are no contacts with other holdings and that only receive negative animals from free or non-free herds (with pre-movement negative test - risk assessment test TAR). These herds can exclusively send animals to slaughter.

Measures regarding animal movement:

Decree-Law No 142/2006 of 27 July 2006 and its amendments, regulates the National Animal Information and Registration System (Sistema Nacional de Informação e Registo

Animal - SNIRA) and lays down measures for the identification, registration and movement of bovine animals, with specific regard to the accompanying documentation required. SNIRA for bovine includes the following essential elements:

- Means of identification to identify animals individually.

- Individual passport mandatory only for animals intended for intra-Community trade.

- Updated registration of movements per holding extracted from the database.

- National computerised database (SNIRA) with holding registration and each animal and its movement, which is the base of updated farms registration.

All bovine holdings are identified with a unique holding code (ME), attributed by DGAV and are recorded in SNIRA database. This thus contains all cattle producer and their premises and animals.

The bovine passport is issued only for bovine animals intended for intra-Community trade. The PB has the registration of the identity of the animal, the current holding, the holdings where the cattle went by and the health status of the herd.

Currently, the official identification of bovine animals consists of two conventional ear tags, applied in each ear. Infrastructure is in place providing that, on an optional basis, one of the ear tags may be replaced by an electronic identifier (electronic ear tag or a ruminal bolus).

The means of identification are attributed to the holdings, officially authorized, and the respective keeper is responsible for this identification and as well to communicate to SNIRA database the birth of any animal within 7 days from the date of identification.

Identification is mandatory and the means of identification should be applied up to 20 days after the birth of the animal. For reasons related to the physiological development of the animals, that period may, for the second mean of identification, be extended up to 60 days following the birth of the animal. No animal may leave the holding of birth before the two means of identification have been applied.

When cattle are transferred from one holding to another, or when they are sent for slaughter they must be accompanied of the respective movement document (Declaration of Movements) currently issued from the SNIRA database according to health status of herds involved.

There is a web service between SNIRA and sanitary data base PISA.Net used to validate the movement. The kind of movement authorized, the document that is necessary, who can obtain it and the predictor conditions for each movement, were previously fixed and are part of the informatics system validation. The system is prepared to issue alerts that will help veterinary official services to perform control activities and to confirm the ownership of the animal.

The Declaration of Movement documents can therefore be obtained directly from the online system by the animal owner or at the information collection points located at the SVO or at Agricultural Confederations reception desks.

Despite the emission of the Declaration of Movement ensures the movement's registration on the SNIRA database, the owner of the holding of destination must notify the database of the entrance of the animal within the period of 7 days, and this procedure is mandatory to update the information in the system.

Irregularities to animal movement rules are detected either during visits to the farms or through reports of SNIRA database and all infractions are subjected to administrative offense.

Animals from officially disease-free herds may be moved without restrictions with premovement test (TPM). This control is based on the updated information concerning herds' status and date of last TPM recorded in PISA.Net which interacts with SNIRA database.

Herds with suspended (T3S or ES) or non-free disease status (T2, T2.1 or E2.1) are only allowed to move animals to slaughter or to non-free fattening herds E2, under official control, and regular checks on movements are scheduled in SNIRA.

(ii**) to confirm or rule out the disease in the event of a suspected case;**

When animals in an officially tuberculosis-free holding test positive, DSAVR are informed and trigger a set of actions including the suspension of the holding health status, the issuing of a quarantine order ("sequestro"), the marking and preparation for slaughter and compensation of the positive animal(s) (within 15 days) and the execution of an epidemiological survey.

The follow up of positive herds starts 60 days following sanitary slaughter - all cattle in the herd over 6 weeks of age undergo CITT. The result of this check and the result of the bacteriological examinations of the samples collected during the slaughter on health grounds determines the implementation and frequency of subsequent checks, as well as whether the status is maintained or altered.

The main measures are the following:

a) Prohibition on moving susceptible animals to and from holdings by imposing quarantine wherever animals with a positive reaction are identified in officially disease-free (T3 or EB4T3L4) herds. This restriction ("sequestro") remains in place until the herd has regained its status. It applies to all T3S, T2, T2.1, ES and E2.1 herds.

b) Compulsory slaughter (sanitary slaughter) of all positive animals under the supervision of the official services, within 30 days after official notification of the owner. The objective of having 75% of animals slaughtered no later than 15 days after their owners are officially notified will be maintained.

The destination of the carcass is determined by the sanitary inspector of the slaughterhouse, depending on the lesions observed.

Data on the slaughtered animals is registered in PISA.Net, by DSAVR and livestock producers' associations (OPP) are informed so that these may follow with the subsequent checks.

c) After animals from an infected holding have been unloaded, the vehicles are cleaned and disinfected with officially approved disinfectants in line with the defined codes of good practices

d) In order to clarify positive results, samples are always taken from animals subject to sanitary slaughter for laboratory (histopathological and bacteriological) analysis, except when they come from infected herds (T2.1).

e) Compensation for sanitary slaughter of animals.

f) Formal notification and instructions on cleaning and disinfection.

Diagnosis of tuberculosis at meat inspection:

Meat inspection of bovine animals is performed in approved slaughterhouses by official veterinarians who may be assisted by official auxiliaries.

The official veterinarians and official auxiliaries receive regular training on meat inspection procedures and are supported by written procedures on post-mortem inspection of animals.

The official veterinarians and official auxiliaries are supervised regularly according to PAIS (Meat Inspection Supervision Plan) to assess compliance with the established procedures.

In slaughterhouses the official veterinarian is always present during the ante mortem and *post-mortem* inspection.

During the reception of live animals, the official veterinarians check the identification papers and movement documents of cattle. The animals from TB non free herds are identified and inspected taking that information into consideration and samples are collected accordingly.

After a sanitary slaughter of positive TB animals, the official veterinarian fills out a form which describes the lesions found in the animals slaughtered and samples taken for analysis.

The experience of years dealing with tuberculosis lesions gives Portuguese meat inspector veterinarians enough expertise in identifying suspected tuberculosis lesion, which contributes to the high rate of TB positivity in the suspected lesions collected for diagnosis. Furthermore, some of the parasitic and other diseases included in the differential diagnosis of tuberculosis have been decreasing over time with the general sanitary and biosecurity improvement of herds.

Measures following sanitary inspection suspicion notification:

The detection of suspected tuberculosis lesions in *post-mortem* routine examination at slaughterhouse leads to the collection of samples which are sent to NRL for histopathological and bacteriological diagnosis.

The official veterinarian makes a notification of suspected Notifiable Disease (DDO), which is sent to the central and regional services. Data is introduced in SIPACE (the national database for the results of official controls on establishments).

Trace back investigation is carried out to identify herds where that animal may have been. Consequently, in those other contact herds, all cattle over 6 weeks of age are submitted to CITT test, and any positive reaction conducts to the previously described procedures.

(b) disease control measures to be applied in the event of a confirmed case;

Measures in positive herds:

In the non-free herds the following testing methodology is applied:

a) In the herds confirmed as infected with tuberculosis by means of isolation of a Mycobacteria of the M. tuberculosis complex (T2.1), all animals over 6 weeks of age are tested with SITT, 60 days after removal of the last animal with positive reaction.

If no more positive reactions are found, the herd reaches the T2 status, still a non-free status.

b) In the T2 status, all bovine animals over 6 weeks of age are tested (CITT) 60 days after the previous one. If no positive reactions are found, the herd reaches the T3 status. However, in cases considered as risk of infection, a second test will be performed 180 days after the previous before granting the T3 status.

In herds confirmed as infected, the owners are instructed to:

- ensure that milk from positive animals may only be used by animals from the same holding after undergoing suitable heat treatment, in accordance with Regulation (EC) No 853/2004 of 29 April 2004.

- ensure that milk from negative animals is prevented from leaving the holding, except where it has undergone suitable heat treatment, in accordance with Regulation (EC) No 853/2004 of 29 April 2004.

- destroy by incineration or burial, after treatment with officially approved disinfectant solution, the straw, bedding and any other materials or substances that have been in contact with infected animals.

- prevent the use, without appropriate treatment, of manure from infected sheds or any other quarters used by the animals.

- provide evidence of cleaning and disinfection, which is validated by OPP or the official veterinarian, after the slaughter of positive animals or after total slaughter, prior to reintroduction of animals.

An epidemiological investigation following a specific procedure (mod 758/DGAV) is carried out by the local veterinary services, if it has not been yet performed, whenever the presence of CMTB is confirmed through positive bacteriological result and also when old lesions are detected. The programme's objective is that the survey is carried out within 15 days after the positive result. This Enquiry (IE) includes the characterization of the holding, herds in contact and the investigation of possible sources of infection including introduction of animals, contacts at pasture and possible contacts with wildlife. Non-compliances identified are subjected to penalties and contact herds have to be controlled. In the retesting of the herd it takes place an official control of SITT performing.

In addition to these measures, following the epidemiological investigation, related herds are investigated and recommendations made on the maintenance and stepping up of biosafety measures and, if necessary, CITT testing.

Reinforcement of measures in herds where the bovine-wildlife interface poses a risk, by development of intervention plans targeted at reducing the probability of contact and transmission of tuberculosis.

Adoption of reinforced measures in risk areas, where CMTB was confirmed in wildlife by increasing the surveillance of bovine herds to twice a year.

Total slaughter/depopulation of outbreaks, when this is identified as the more adequate measure to deal with the outbreak, as laid down in Decree-Law No 79/2011 of 20 June. DGAV may determine this measure based on the risk assessment of specific situations, according to the following criteria:

- When there is no improvement in the health qualification of an infected herd or an epidemiological unit, in the last 12 months.

- When CMTB has been isolated.

- When, in certain epidemiological conditions of a geographical area, it is the most appropriate measure to improve the situation.

- When it is not possible to implement any other animal health measure.

The decision for depopulation, is taken by the official veterinary regional services (DSAVR), or by the General Director, and is always based in two documents:

- The epidemiological inquiry and the supporting technical evaluation.

- An expressed commitment of the owner regarding its compliance with the expressed conditions for restocking, namely the waiting period before restocking.

In the event of slaughter of the entire herd and the corresponding depopulation, holders are obliged to undertake the disinfection of the holding (initial and final) and the equipment, under a specific protocol. The procedures are supervised by the OPPs and validated by the DSAVR's. The costs of the total slaughter includes slaughter, transportation from the holding to the slaughterhouse(s), considering the distance (value per Km), cost of the disposal of carcasses and the cleaning and disinfection of vehicles.

(c) biosecurity and risk mitigating measures to be implemented;

During quarantine notice ("sequestro") and epidemiological investigation, farmers are faced with a range of questions related to biosecurity measures and management which have also informative and educational purposes. Items as the use of pastures, the risk of sharing equipment and the direct or indirect contact with other herds are referred.

The notification to the owner related to quarantine notice contains detailed instructions related to cleaning and disinfection based on the "Codes on good practices on farms" describing biosecurity measures and management, produced by agricultural associations in cooperation with the DGAV, available in DGAV website.

The over-population of large game animals (deer and wild boar) in some areas of the mainland acting as reservoirs for domestic cattle is identified as one of the critical points in the control of TB. Measures are being taken in articulation with the Forestry Authority in order to deal with the over population of large game animals (deer and wild boar), also following the recommendations on the reduction on wild board populations considering the risk of progression of African Swine Fever.

There is also a specific control plan in large game animals considering the transmission of TB agent. The Notice ("Edital"), in force since April 2011, defines the area of epidemiological risk for tuberculosis for the largest game animals, according to the

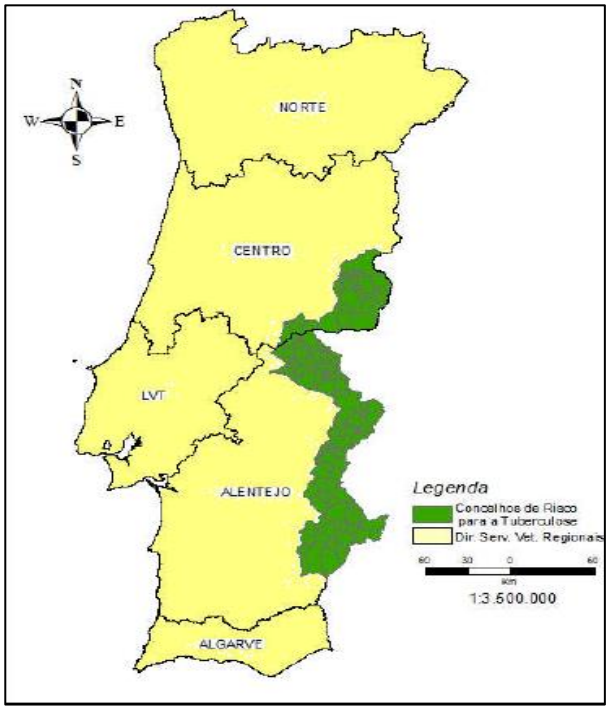
distribution of these animals in the country. This area includes several counties of DSAVR Centro and DSAVR Alentejo.

All game initiatives should be previously reported to regional veterinary services, indicating the veterinary in charge of all the procedures. Specific training courses were carried out in order to prepare veterinarians for the inspection tasks.

Furthermore, in the defined risk area cattle owners are advised to reinforce biosecurity measures in order to keep their cattle separated from game animals, developing several strategies in order to ensure that feeding and watering places are not used by both cattle and game animals. Some municipalities and hunters' associations took an important role in promoting information and debate on the implementation of the safeguard measures and improvement of field structures.

Results obtained in 1932 hunting acts, between 2011-2018, indicate that in 39% of the hunting acts, animals with suspected lesions were found and 28% were confirmed as positive. This represents 4.6% of positive results in hunted deer and 4.8% of positive results in hunted wild boars, with differences between regions. With the exception of tuberculosis in deer in the region of Alentejo, which revealed a slight increase over the 5 years, trends are stable.

A new sample-base sanitary surveillance programme in hunted wild boars and deer started in 2017-2018 in non-risk areas. From 300 hunted wild boars 3 had suspected lesions with negative results to histology and bacteriology.



(d) type of vaccine(s) to be used and the vaccination scheme, if relevant;

All desensitizing, immunoprophylactic and therapeutic treatment is expressly prohibited.

(e) measures to be implemented as regards additional animal populations, if relevant;

As mentioned in point (c), a general surveillance plan for large game animals (which include tuberculosis) is carried out in all country and a specific tuberculosis surveillance plan is in place in the risk area of the country (interior of Centro and Alentejo regions).

In additional, in infected herds if there are goats cohabiting, all goats over 6 months are subjected to SITT.

(f) derogations to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689, if relevant;

Not relevant.

(g) coordinated measures with other Member States or third countries, if relevant.

The decisions related to the control plan in large game animals are often discussed with the Spanish authorities in contiguous territories.

(h) targeted animal populations and when applicable, additional animal populations

The programme covers all bovine females and males over 6 weeks of age in accordance with Delegated Regulation 689/2020, both in the mainland (with the exception of the Algarve), in S. Miguel Island of RAA and in RAM.

In 2021, on officially free herds the age of testing was determined depending on the epidemiological indicators of the region and the respective risk assessment.

The programme covered all females and males over 6 weeks of age in accordance with Annex A, I, 2(C) of Directive 64/432/EEC, both in the Mainland, S. Miguel Island of Açores, with the exception of males in isolated officially free herds intended for slaughter in areas with 1% or less herd prevalence. On herds that were not disease-free all bovines over 6 weeks old were checked.

In 2022, the age of testing will be 6 weeks of age for all animals. However, the derogations regarding the frequency of testing in accordance with Delegated Regulation 689/2020 will be applied by district.

Caprine animals co-habitants with bovine in infected holdings shall also be tested.

8. A description of 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;

The Directorate-General for Food and Veterinary (DGAV) is the authority responsible for the control and eradication of bovine tuberculosis and its central service (DSPA) is responsible for coordinating and monitoring the programme.

In the mainland, the 5 Directorates for Regional Food and Veterinary Services (DSAVR), decentralized services of DGAV (Norte, Centro, Lisboa e Vale do Tejo (LVT), Alentejo and Algarve), are responsible not only for overseeing the implementation of the various activities under the Programme in their area, but also for the attribution of herd status and the official control of measures carried out. DSAVR monitors the execution of CITT and SITT and the compliance with the legal requirements arising from the agreements signed with OPPs. Routine surveillance in the slaughterhouse is performed by veterinary inspectors of DSAVRs.

In the Autonomous Region of Açores, the authority responsible for coordinating and monitoring the Tuberculosis Eradication Programme is the Regional Directorate of Agriculture, via the Directorate for Veterinary Services.

The implementation of measures is coordinated in S. Miguel Island by a Veterinarian who is Head of Division of the Veterinary Service Sector of the Agricultural Development Service of the island, in collaboration with other technicians. The measures under the plan are implemented by Veterinarians from the Agricultural Association of São Miguel and Young Farmers Agricultural Association of S. Miguel, through an agreement signed between those entities and the regional veterinary authority.

Globally the activities of the programme are controlled as following:

- Regular controls: data on field work is entered by OPP on the national data base (PISA.Net) – DSAVR control the compliance with annual checking and suspend free status of herds and advise OPP when necessary. The access profile and circuits of information are well defined allowing regular monitory and standardization of information.

- Positive/Infected herd's controls: repeated checking of positive/infected herds is monitored in what concerns the compliance of intervals between CITT/SITT after slaughter of positive animals. This is carried out in a continuous way, along the programme, whenever a status is suspended. Furthermore, movements control is carried out through SNIRA and observation of animals during the re-checks.

- Slaughter of positive animals: sanitary slaughter is directly organized by the official vet services which personally marks the animals and organize the schedule of transport to slaughterhouse.

- General movement control: the movement database issues movement permits in accordance with the information obtained through the webservice with sanitary data base (PISA.Net) based on the updated sanitary status of herds and the presence of valid pre-movement tests.

- Compliance with movement restrictions are assured through the blocking of permissions for issuing of movement permits in the electronic data base. In situ ID checks are regularly performed in 3% of herds comparing existing animals with SNIRA registries.

- The quality of the execution of CITT and SITT is considered one of the critical points of the programme: There is a specific official control, at regional level, on the execution of CITT and SITT by private veterinarians (10%) using a risk-based approach. This control is done by official vets on the field, follows a specific checklist, and evaluates whether procedures are correctly followed. A specific report is issued with recommendations if necessary. This evaluation is also applied to the herds of origin of animals that were detected with suspected lesions in slaughterhouses and in any other risk situations.

Specific training sessions for the veterinarians of OPP are being done since 2009 in order to ensure that their performance on CITT was properly updated. In 2016, 2017 and 2018 210 veterinarians had practical training in CITT. This practical training were carried in 2019 and foreseen to continue in 2021 and 2022.

The frequency of a training session in the last 8 years is mandatory for a veterinarian to be accepted as an executor of CITT under the programme submitted for each OPP.

- Controls of cleaning and disinfection: these controls are routinely applied before restocking in case of total slaughter and following partial slaughter in infected farms. Specific recommendations are issued by the official veterinarians and OPP veterinarians make the verification of compliance with these requests. Lifting of restrictions is conditioned to this control of cleaning and disinfection. In Açores, instructions in this issue have been given by the Region Competent Authority to the veterinary services involved in the programme.

Non-compliances are subject to penalties.

In Açores the direction of Veterinary Services prepares quarterly technical reports of activities, which contains data on the Program Health of the Region, informing the various islands.

Half-yearly meetings are held with all Agrarian Development Services Island and submission of the report to the National Veterinary Authority simultaneously with the semi-annual and annual technical report.

(b) responsibilities of all stakeholders involved.

In the mainland, the national reference laboratory INIAV, I.P. is responsible for the post-mortem diagnosis (histopathology and bacteriological tests on suspicious tuberculosis lesions samples). The Gamma interferon test is made in a private official laboratory COPRAPEC.

In the Autonomous Region of Açores the Regional Veterinary Laboratory of the Açores carries out gamma-interferon testing for laboratory diagnosis. The Regional Laboratory also carries out histopathological examination of every single sample. Bacteriological examination alone is carried out in the National Agrarian and Veterinarian Research Institute (INIAV).

In the mainland, the diagnostic tests are carried out by veterinarians of the OPP, who register the results of the test in the national animal health programme (PISA.Net).

In brief, the organization of activities of the programme is the following:

OPP submits an annual health programme to DSAVR. The programme is evaluated and approved, regarding the compliance with the established rules. Field activities are carried out by OPP, namely animal identification and execution and recording of results of CITT and SITT in PISA.Net.

DSAVR are in this way informed whenever positive results are detected. DSAVR validates or changes the health status of the herd in light of the results of CITT (or SITT), considering also the results of histopathological and bacteriological tests obtained latter from INIAV in the samples collected from positive or suspected animals.

In face of positive results, DSAVR sets the procedures described in point 7 (a) (i) and (ii), including:

- In T3 or EB4T3L4 herds the health status is suspended and the owners are directly notified of the results obtained together with the imposition of restrictions on animal movement. The positive animals are officially identified for slaughter and transported to the slaughterhouse under official control.

- In T3S, T2, T2.1, ES and E2.1 herds the holders are informed of the results obtained; the animals intended for sanitary slaughter are marked and transported to slaughterhouse under official control.

- DSAVR supervises sanitary slaughter and the collection of samples, organizes the compensation process, registers data on PISA.Net and organizes the following CITT or SITT to be carried out in the positive/infected holding.

DSAVR also carries out epidemiological investigation involving the farmers and the OPP veterinarians in the identification of risk factors and measures to limit transmission.

Farmers have the responsibility to provide access and the means to implement measures on animals, to comply with the rules on identification and movement of animals (including pre-movement tests), to allow the loading and transport for slaughter on health grounds and to comply with the movement restrictions and the depopulation periods imposed following total slaughter. They have the right to compensation for slaughter on health grounds provided they assume their responsibilities pursuant to the laws that apply. Their active involvement is provided by OPP veterinarians who have an important role in education and information on good practices and legal obligations.

Signed compromise with farmers is assumed following partial or total slaughter for the compliance of movement restrictions and depopulation imposed periods.

Whenever infection is diagnosed, the implementation of restrictions requires direct involvement of farmers in the programme.

9. The estimated duration of the eradication programme.

Taking into consideration the expected results (targets) referred to in the working document SANTE/2021/10502 - guidelines for the union co-funded programmes of eradication, control and surveillance of animal diseases and zoonoses for the years 2021-2022, the interim targets, considering a minimum reduction of 20% (in relation to 2019 – 0.47 prevalence and 0.37 incidence), are:

- herd prevalence: 0.38% in 2021, 0.30% in 2022
- herd incidence: 0.30% in 2021, 0.24% in 2022.

Using a linear trend line the estimate duration of the programme will be at least 6 more years.

The timeline estimated by DSAVR is:

Region %Prev	2021	2022	2023	2024	2025	2026	2027
DSAVRN	0,090	0,050	0,020	0,010	0,005	0,00	0
DSAVRC	0,310	0,250	0,170	0,080	0,040	0,020	0
DSAVRLVT	0,070	0,060	0,050	0,040	0,030	0,010	0
DSAVRALT	1,380	1,111	0,770	0,360	0,180	0,080	0,04
Açores	0,330	0,280	0,200	0,100	0,050	0,020	0
Total	0,38	0,30	0,19	0,09	0,04	0,02	0

In Alentejo and Centro regions, where the main problems are identified, there is a persistent risk of *M. bovis* transmission from infected deer and wild boars to bovines maintained in extensive beef production systems. Efforts are being made to work with hunters regarding the correct disposal of by-products and with farmers to apply measures to avoid contacts. However, it will be difficult to completely avoid in these regions' sporadic introduction of tuberculosis in the herds.

Madeira has not completed the classification of all establishments, but there was never a diagnostic of tuberculosis in animals born in the island both in CITT survey or in meat inspection at the slaughter (zero prevalence).

10. The intermediate targets of the eradication programme including at least:

(a) the expected annual decrease of the number of infected establishments;

The programme is progressing in most areas but in risk areas, those with stablished infection in wildlife, progress is slower. We foresee the eradication of tuberculosis in 5 years in all non-risk districts.

Table bellow presents the expected reduction in percentage of positive holdings.

% prevalence reduction	2021	2022	2023	2024	2025	2026	2027
Herd prev	-21%	-37%	-53%	-56%	-50%	-100%	0
Herd incid	-21%	-27%	-50%	-50%	-50%	-100%	0

(b) the expected annual increase of the number of disease-free establishments;

%T3 establishments	2021	2022	2023	2024	2025	2026	2027
DSAVRN	99,91	99,95	99,98	99,99	99,995	100	100
DSAVRC	99,69	99,75	99,83	99,92	99,96	99,98	100
DSAVRLVT	99,93	99,94	99,95	99,96	99,97	99,99	100
DSAVRALT	98,62	98,89	99,23	99,64	99,82	99,92	99,96
Açores	99,67	99,72	99,8	99,9	99,95	99,98	100
Total	99,62	99,70	99,81	99,91	99,96	99,98	100

(c) the expected vaccination coverage, where relevant

Not relevant.