

UNITROPEAN 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

(OVINE AND CAPRINE ANIMALS)

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1. Date of submission.

31 May 2021

2. Member State.

Portugal

3. Name of the disease1

Infection with *Brucella abortus*, *B. melitensis and B. suis* as regards kept ovine and caprine (ov/cap) animals.

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 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	Viana de Castelo
of the Norte Region (DSAVRN)	Braga
	Bragança
	Porto
	Vila Real
	Part of Aveiro
	Part of Viseu
Directorate for Food and Veterinary	Part of Aveiro
of the Norte Centro (DSAVRC)	Castelo Branco
	Coimbra
	Guarda
	Part of Leiria
	Part of Viseu
Directorate for Food and Veterinary	Part of Leiria
of the Lisboa and Vale do Tejo (DSAVRLVT)	Santarém
	Lisboa
	Part of Setúbal
Directorate for Food and Veterinary	Part of Setúbal

This template is to be used for the submission of the following eradication programmes for the following listed diseases: Category B-diseases

Category C-diseases

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

b) Infection with Mycobacterium tuberculosis complex

a) Enzootic bovine lunitkosis

c) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

d) Infection with Aujeszky's disease virus

e) Bovine viral diarrhoea

of the Alentejo Region (DSAVRALT)	Portalegre Évora Beja
Directorate for Food and Veterinary of the Algarve Region (DSAVRAIg)	Faro
Directorate for Food and Veterinary Services of the Autonomous Region of Madeira (RAM)	Islands of Madeira and Porto Santo (programme not presented for the Commission cofinancing)

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.

Brucellosis is a notifiable disease since 1953.

The Autonomous Region of Açores, listed in Chapter 2 of Part I of Annex I of the Commission Implementing Regulation (EU) 2021/620 of 15 April 2021, has the disease-free status from infection with *Brucella abortus*, *B. melitensis and B. suis* in ovine and caprine animal populations, with a surveillance programme in place.

Along with the policy of eradication through serological survey with Rose Bengal (RBT) and Complement Fixation tests (CFT) and slaughter of positive animals, vaccination of young animals with Rev1 was applied in certain areas of continental territory of Portugal with higher prevalence, namely in Trás-os-Montes in the Directorate for Food and Veterinary of the Norte Region (DSAVRN), and some counties of the other Regions.

The ovine and caprine brucellosis eradication programme carried out in 2020 for the non-officially free Regions of Portugal (5 Regions of the continental area) resulted in a positive evolution of the epidemiological indicators.

Compared to 2019, herd apparent prevalence remained 0,39% and herd incidence had a slight increase from 0.33% to 0.34%. The percentage of seropositive animals decreased from 0.05% to 0.04%. All Regions, except Norte, are below 1% herd prevalence.

The eradication programme was implemented as foreseen, reaching coverage of 97.14% of herds, varying from 96.62% in the Lisboa e Vale do Tejo Region to 99.59% in the Algarve Region.

There were 196 herds with at least one positive animal and 170 were new positive. By the end of 2020, 16 herds were infected.

Most positive animals were subjected to sanitary slaughter and those coming from newly infected herds were subjected to organ collection for bacteriology. A total of 533 animals were slaughtered and the percentage of slaughtered positive animals with isolation of *B. melitensis* was of 10.09% (31/307). From these 31 isolates 83.87% were from the Norte Region. Vaccination was applied in 2.928 herds /34.379 animals.

The eradication programme implemented in 2020 resulted in maintenance of the herd apparent prevalence (0,39%) and a slight increase in the herd incidence, from 0,33% to 0,34%. The percentage of positive animals decreased 24,5%.

The variation of apparent herd prevalence by region, from 2019 to 2020, was the following:

- Norte from 1.18% to 1.27%
- Centro –from 0.01 % to 0.04%
- LVT from 0.44% to 0.10%
- Alentejo from 0.10% to 0.09%
- Algarve from 0.0% to 0.10%

The percentage of free (B3), officially free (B4) and B3S/B4S herds was 99.92%.

By the end of 2020, 16 herds had an infected status in 2 Regions: Norte (14) and Lisboa e Vale do Tejo (2). No counties had more than 2 infected herds.

The eradication programme foresees the investigation of positive and infected herds in order to access the origin of infection. For this evaluation a specific data collection questionnaire is used (epidemiological enquiry). These enquiries are implemented with the objective to establish possible links to other farms (trace-back and trace-forward) and characterize possible risk factors and sources of infection.

There were 70 epidemiological inquiries in newly infected herds in the mainland. The main probable reasons were related to direct contact with other ruminants, introduction of animals and other origins. There were no notified abortions.

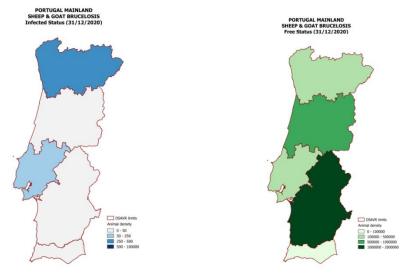
a) the number of establishments keeping animals of the targeted animal population by health status (Disease-free, infected or unknown) excluding establishment falling under the derogation referred to in point (6)(f) at 31 December.

Health status- establishments/units - ovine and caprine - on 31 December 2020					
Regions	Unknown status	Infected status (B2.1)	Disease Free status		
Norte	0	14	14 059		
Centro	0	0	22 220		
Lisboa e Vale do Tejo	0	2	6 504		
Alentejo	0	0	8 280		
Algarve	0	0	968		
Portugal - total	0	16	52 031		

b) the number of animals of the targeted animal population kept in the establishment referred to in point (a) by health status; maps indicating the density of the targeted animal population referred to in point (b) by health status.

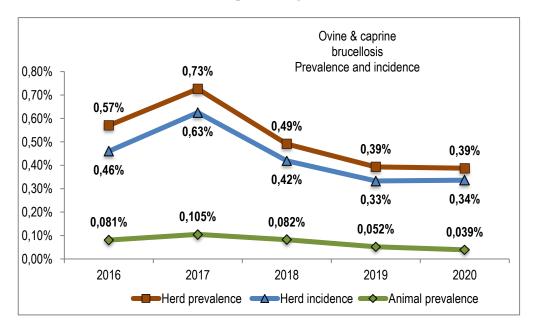
Health status - data on ovine and caprine animals – on 31 December 2020					
Regions	Unknown status	Infected status (B2.1)	Disease free status		
Norte	0	3 360	352 620		
Centro	0	0	518 048		
Lisboa e Vale do Tejo	0	90	215 793		
Alentejo	0	0	1 477 033		
Algarve	0	0	47 972		
Portugal - total	0	3 450	2 611 466		

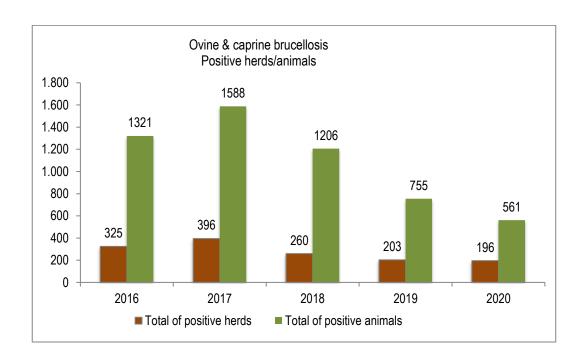
c) maps indicating the density of the targeted animal population referred to in point (b) by health status.

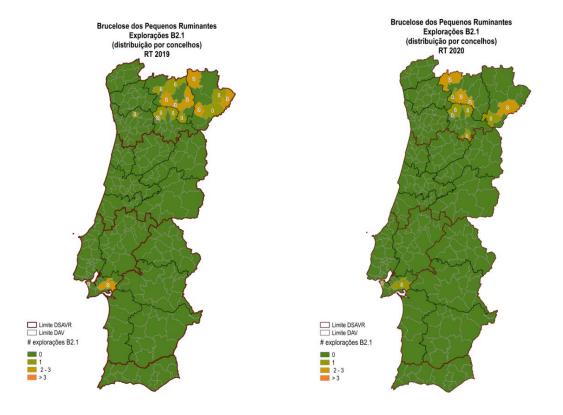


d) timeline with prevalence, incidence data and, where relevant, vaccination history covering at least the past 5 years.

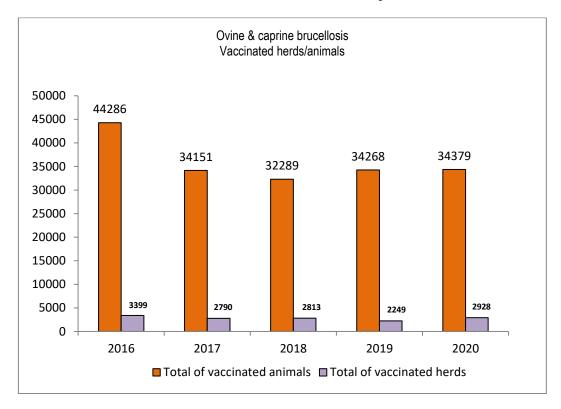
Evolution of epidemiological indicators







Evolution of vaccinated herds and ov/cap animals



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

Not relevant

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.

Disease-specific requirements for the granting, maintenance, suspension and withdrawal of the disease-free status at the level of establishments/epidemiological units were in accordance with Council Directive 91/68/EEC of 28th January and national legislation and will be adapted in accordance with the Animal Health Law (AHL) and the requirements of Annex IV to Delegated Regulation (EU) 2020/689 of 17th December 2019.

Health status is assigned or amended by the Regional official veterinary services (DSAVR).

The DSAVR shall grant, suspend or withdraw disease-free status at establishment level when the conditions for these measures have been met and shall specify the maximum period of time during which disease-free status may be suspended (365 days).

The DSAVR may attribute distinct health status to different epidemiological units of the same establishment provided that there is information from its operator about:

- the different unit established within the establishment to be granted distinct health status prior to any suspicion or confirmation of the disease;
- accessible tracing of the movements of animals and germinal bovine origin products to, from and between the units;

- the unit has separated by physical, and management means and complies with any risk mitigating measures requested by the DSAVR for that purpose.

The existing health status for establishment/unit, adapted to AHL are as follows:

- B4 establishment/unit with the disease-free status from infection with *Brucella abortus*, *B. melitensis and B. suis* without vaccination.
- B3 establishment/unit with the disease-free status from infection with *Brucella abortus*, *B. melitensis and B. suis* with vaccination.
- B2 establishment/unit the disease-status not free status from infection with *Brucella* abortus, B. melitensis and B. suis.

In complement:

- B2.1 establishments/unit infected with *Brucella abortus*, *B. melitensis and B. suis* (withdraw the disease-free status, when isolation of *Brucella abortus*, *B. melitensis and B. suis* is officially confirmed, post-mortem or other).
- B4S establishment/unit with the suspended disease-free status from infection with *Brucella* abortus, B. melitensis and B. suis without vaccination.
- B3S establishment/unit with the suspended disease-free status from infection with *Brucella* abortus, B. melitensis and B. suis with vaccination.

The eradication programme related to ov/cap is based on the health status of the establishment/unit through a test and slaughter policy, with compensation of slaughtered animals to operators. Before compensation for compulsory slaughter is paid out, the respective DSAVR must confirm that the operator of the slaughter animals has complied with the legal provisions related to the eradication programme, with the animal movement and the specific animal health measures imposed in the notification assigned by the DSAVR. These procedures include a declaration issued by the DSAVR. If the aforementioned check reveals evidence of non-compliance by the operator, the DSAVR must immediately initiate the relevant penalty process, and payment of compensation will depend on the final decision in the case.

In some areas vaccination with rev1 is under the programme in some Regions/areas.

The operators of establishment/unit where ov/cap animals are kept, shall comply with the general and disease specific requirements ordered by DGAV/DSAVR, in order to obtain and maintain the disease-free status of their establishments/unit.

Brucellosis is a notifiable disease and treatment is strictly prohibited. Notification of abortions is compulsory and must give rise to an epidemiological investigation and the collection of material for bacteriological diagnosis. There are procedural rules for collecting and sending material from abortions to the laboratory, drawn up jointly by DGAV and the INIAV IP, published on the website of both Institutions.

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

In accordance with section 1 of annex III of Reg. (EU) 2020/689, the following serological diagnostic tests (tests for blood samples) will be used for the granting and maintenance of disease-free status:

- buffered Brucella antigen tests, i.e, Rose Bengal Test (RBT);
- complement fixation test (CFT)

Serological Rose Bengal test (RBT) will be used as screening test, and the Complement Fixation Test (CFT), as confirmatory test, when serial diagnostic is applied.

An ov/cap animal is considered "positive" to brucellosis, if for the serological tests for blood samples it has a positive result to Rose Bengal test and has a CFT >=20 IU/ml. In B2 (infected with last test negative) and B2.1 (infected) establishment/unit, a ov/cap positive to RBT and/or CFT is considered positive to brucellosis.

A brucellosis "infected animal" is the one with bacteriological isolation.

An infected establishment/unit is the one where *Brucella* was isolated, either through bacteriological confirmation and detection of brucellosis after confirmed abortion, through epidemiological evidence or when the repetition of tests with positive results does not allow discarding the presence of brucellosis.

In line with the objective, serological diagnosis is part of:

- the surveillance activities for maintenance of the health status;
- the eradication measures and validation of absence of infection when applied following detection of a positive animal;
- to clarify risk situations, when applied in contact establishment/unit following an epidemiological investigation;
- vaccinated animals are serologically tested at the day of vaccination. Vaccination is carried out on animals, between 3 and 6 months of age, after blood collection for serology and specific identification of vaccinated animal. Vaccinated animals will be included in the screening of the establishment/unit 18 months after vaccination. The establishment/unit to be vaccinated must be defined annually by the DSAVR with the OPPs, and any changes must be previously approved by the DSAVR.
- in the certification of intra Union movement of animals and repopulation of holdings.

RBT and CFT are used, with the following methodology:

- <u>RBT</u> is carried out on all tested animals, over 6 months of age (or 3 months when vaccinated with rev1).
 - CFT is carried out to all the animals, in the following cases:
 - On RBT-positive animals, in establishment/unit that are B3 and B4;
 - On all animals vaccinated with Rev1 that are RBT-positive, irrespective of the establishment/unit health status;
 - On all samples from B3 and B4 establishment/unit if, after performance of the RBT, more than 5% of the samples were RB positive;
 - On all samples from B3 and B4 establishment/unit, if at least one sample was RBT and CFT positive;
 - On RBT-negative animals B3 and B4 establishment/unit if, after performance of the CFT, at least one animal shows a positive reaction to this test;
 - On RBT-negative animals in establishment/unit infected with Brucellosis (B2.1), irrespective of the existence or otherwise of RBT-positive animals;
 - To lift the suspension of B4S or B3S herds (RBT and CFT are conducted in parallel) and to apply retesting the protocol under suspition of false ositive results;
 - For classification of a B2 establishment/unit as B3 or B4.

Bacteriology is an important tool to confirm infection. Bacteriological diagnosis is applied in serological positive animals detected in establishment/unit where brucellosis was not yet confirmed (all non B.2.1 establishment/unit). Samples are collected from animals subjected to sanitary slaughter by official veterinarians and tests are performed only in the National Reference Laboratory (NRL). Isolation of Brucella is also followed by typing.

(i) for the granting of the disease-free status to establishment and the maintenance of that status.

Establishment/unit with B4 status

The disease-free status from infection with *Brucella abortus*, *B. melitensis and B. suis* without vaccination (B4) may only be granted to an establishment/unit keeping ov/cap animals if:

- a) during the past 12 months there has been no confirmed case of infection with *Brucella abortus*, *B. melitensis and B. suis* in ov/cap kept in the establishment/unit;
- b) during the past 3 years none of the ov/cap animals in the establishment/unit has zbeen vaccinated against infection with *Brucella abortus*, *B. melitensis and B. suis*;
- c) the entire ov/cap animals over 6 months of age present in the establishment/unit at the time of sampling have tested negative to serological tests on following occasions:
 - First negative test must be carried out on blood samples taken 30 days after slaughter of all positive /confirmed bovine animals, all undergo to RBT and FCT.
 - Second test must be carried out on samples taken not earlier than 3 months after the removal of the last confirmed case and of the last animal that tested positive;
 - Third test must be carried out on samples taken not earlier than 6 months and not later than 12 months, following the date of sampling referred above.
- d) Animals showing clinical signs consistent with infection with *Brucella abortus*, *B. melitensis and B. suis*, such as abortions, have been subjected to investigations with negative results;
- e) Since the beginning of the first sampling referred above, all ov/cap animals (and all germinal products of ov/cap origin) introduced into the establishment/unit must have been originated from B3 or B4 establishment/unit, animal must have not been vaccinated during the past 3 years and come from a free MS or free Region and, in the case of repopulation, entire ov/cap animals over 6 months of age must have been tested negative in a PreMT or PosMT.

The B4 status may be granted to an B3 establishment/unit if requirements for granting the status are fulfilled and if all entire ov/cap animals over 6 months of age are serologically tested with negative results at appropriate intervals of not more than 12 months determined by the official regional services (DSAVR), taking into account the type of production, the situation of the disease and the identified risk factor.

The status (B4) may only be maintained if:

- the requirements set for granting continue to be fulfilled and serological testing is carried out with negative results on samples taken from all entire ov/cap animals over 6 months of age at appropriate intervals of not more than 12 months, considering the type of production, the situation of the disease and the identified risk factor or
 - are entire ov/cap animals over 6 months of age kept in establishment/unit located in a MS or a Region free from infection, in accordance with a testing regime set up by DGAV, taking into account the type of production and the identified risk factors.

Establishment/unit with B3 status

The disease-free status from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination (B3) may only be granted to an establishment/unit keeping ov/cap animals if:

- a) during the past 12 months there has been no confirmed case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in ov/cap kept in the establishment/unit;
- b) the entire ov/cap animals over 6 months of age present in the establishment/unit at the time of sampling have tested negative to serological tests on the following occasions:

- First negative test must be carried out on blood samples taken 30 days after slaughter of all positive /confirmed bovine animals, all undergo to RBT and FCT.
- Second test must be carried out on samples taken not earlier than 3 months after the removal of the last confirmed case;
- Third test must be carried out on samples taken not earlier than 6 months and not later than 12 months, following the date of sampling referred above.
- c) animals showing clinical signs consistent with infection with *Brucella abortus*, *B. melitensis* and *B. suis*, such as abortions, have been subjected to investigations with negative results;
- d) Since the beginning of the first sampling referred above, all ov/cap animals (and all germinal products of ov/cap origin) introduced into the establishment/unit must have been originated from B3 or B4 establishment/unit and come from a free MS or free Region and, in the case of repopulation, entire ov/cap animals over 6 months of age must have been tested negative in a PreMT or PosMT.

The B3 status may be granted to an establishment/unit (as derogation to the above requirements) if all ov/cap animals come from B3 or B4 establishment/unit and are originate from a MS or a Region free from infection, are entire ov/cap animals over 6 months of age and must have been tested negative in a PREMT or PostMT.

The status (B3) may only be maintained if the requirements set for granting the status continue to be fulfilled and serological testing is carried out with negative results on samples taken from all entire ov/cap animals over 6 months of age at appropriate intervals of not more than 12 months, taking into account the type of production, the situation of the disease and the identified risk factor.

In B3 and B4 establishment/unit, all sera submitted undergo to RBT and all ov/cap animals with RBT positive undergo to CFT. If at least 1 of the RBT positive samples is also positive to CFT, all other RBT negative samples are also tested for FCT and, accordingly to the results, the DSAVR can consider animals positive with only one of the positive tests.

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

Section 3 and 4 of Chapter 1 for the establishment free from infection with *Brucella bortus*, *B. melitensis and B. suis* without vaccination and Section 3 and 4 of Chapter 2 for the establishment free from infection with *Brucella abortus*, *B. melitensis and B. suis* with vaccination to confirm or rule out the disease in the event of a suspected case will be followed.

Whenever there is a suspected case of the disease and until it's confirmation or rule out, the DSAVR shall conduct investigations, shall initiate an epidemiological enquiry (EI), shall suspend the disease-free status of the establishment/unit (B3S/B4S) where it occurred until the investigations and the EI are concluded and shall prohibit movement of germinal products of ov/cap and and ov/cap animals from and out of the establishment/unit, unless the animals are for immediate slaughter in a designated slaughterhouse. Besides the animal movement restrictions, operators are also notified to isolate the suspected cases, where technically possible.

The DSAVR may decide not to suspend the disease-free status of the whole establishment when there are different epidemiological units.

The suspicion is carried out on the following occasions:

- If <u>one</u> ov/cap animal from a B3 or B4 establishment/unit is positive to a serological test (positive to RBT and has CFT >=20 IU/ml).
- As a result of the detection of brucellosis following an abortion investigation;
- If the EI reveals the possibility of infection;
- When there are no conditions for the establishment/unit to be classified as B3 or B4 (whenever the plan is not being fulfilled);

- For any other reason considered relevant to the strategy against brucellosis by the veterinary services.

The above measures shall be maintained until the presence of the disease has been ruled out or confirmed and, if necessary, can be extended to additional susceptible species kept in the establishment/unit and to any establishment/unit with epidemiological link with the establishment/unit where the suspected case occurred.

Whenever the pattern of positive results in B3 and B4 establishment/unit are not compatible with infection (single reactors, low CFT titres, etc.), DSAVR decide for a specific investigation of a possible false positive serological reaction.

The B3 or B4 status may only be restored if the requirements set out for the granting and maintenance for this status are fulfilled and the results of further investigations substantiate absence of infection with *Brucella abortus*, *B. melitensis and B. suis* and the status of all suspected cases has been determined.

Regarding the serological positive animals, DSAVR sets the following standard procedures:

- serological positive animals are marked (and in certain occasions, also other animals in the same unit) and are destined for compulsory slaughter; the remaining animals are submitted to serological test following the removal of the last positive animal for slaughter;
- collection and transport of the animals destined for compulsory slaughter shall be under official supervision within 30 days following the date of official notification of the operator; animals subject to compulsory slaughter are sent to processing industry (not for human consumption);
- collection of material for laboratory diagnosis, except from animals of infected unit;
- preparation of a dossier for the payment of compensation.

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

An establishment/unit is considered to be infected, if the presence of *Brucella abortus*, *Brucella melitensis and Brucella suis* is confirmed, by its isolation in a bacteriological examination of samples taken from sanitary slaughter. In this cases, the B3 and B4 health status of the establishment/unit must be withdrawn and it shall be classified as infected (B2.1). The withdrawal may be limited to the epidemiological unit where the case was confirmed.

The B3/B4 status may only be regained if all confirmed cases and all animals that have tested non-negative have been removed and the remaining animals fulfil the requirements set out for the granting status.

DSAVR shall applied measures to the infected establishment/unit, namely conduct investigations and the epidemiological enquiry (EI), as mentioned to the suspicious case; shall prohibit movement of germinal products of ov/cap and ov/cap animals from and out of the establishment/unit, unless the animals are for immediate slaughter in a designated slaughterhouse.

The EI requires the characterization of the establishment/unit, the investigation of possible sources of infection including introduction of animals and contacts at pasture. It also investigates all units that have contacts with the one in question. Non-compliances identified are subjected to penalties and contact establishment/unit must be controlled.

Besides the animal movement restrictions, operators are also notified to isolate the suspected and confirmed cases, where technically possible. This restriction remains in place until the establishment/unit has regained its status. Consequently, all B4S, B3S, B2 and B2.1 establishment/unit are under restrictions (sanitary sequestration).

Following measures shall also be in taken by the DSAVR, such as:

- notifying the operator on the results obtained and the imposition of animal movement restrictions, prohibiting on moving susceptible animals to and from the establishments/unit;

- compulsory slaughter of all confirmed cases and all animals that have tested non-negative, under the official supervision in a designated slaughterhouse and with appropriate compensation for their operators (owners). Animals will be slaughtered no later than 30 days following the official notification of the operator;
- collection and transport of the animals destined for compulsory slaughter shall be under official supervision within 30 days following the date of official notification of the operator; animals subject to compulsory slaughter are sent to processing industry (not for human consumption);
- data on slaughtered animals shall enter in the animal health data base (PISA.NET) and the veterinarians of the Livestock Producers Organisations (OPP- most field activities of the programme are implemented by private veterinarians) shall be informed so that these may assist with the subsequent checks;
- the use of depopulation (total slaughter) of outbreaks, when necessary;
- the remaining entire ov/cap animals over 6 months of age (18 months if vaccinated) present in the establishment/unit at the time of sampling have to be tested negative to the following serological tests of infected establishment/unit (B2.1), until they achieve the B3 or B4 status and will be carried out as following (additional test in order to accelerate the eradication of the infection):
 - a) First test carried out on all animals 30 days after slaughter of the positive animal(s); all sera undergo to RBT and CFT;
 - b) Second test of all the animals on all the animals not earlier then 60 days later (=3 months after the removal of last confirmed case);

If all the results of the serological test referred above are negative, the establishment/unit will cease to be regarded as infected (B2.1) and will from then on be regarded as non brucellosisfree (B2) undergoing rehabilitation;

c) A third test will be carried out on all the animals not earlier than 6 months and not later than 12 months, following the date of above sampling (=180 days after the previous negative result).

If the infection with *Brucella suis biovar 2* was confirmed in a single ov/cap animal, the B3/B4 status may be regained after negative testing obtained on the sampling carried out not earlier then 60 days later after the removal of the animal.

Operators are also notified of the following requirements:

- milk from confirmed cases shall either be fed only to animals in the same establishment/unit after it has been processed to ensure the inactivation of the disease agent or it shall be disposed of;
- manure, straw, feed or any other matter and substance that have been into contact with a confirmed case or with contaminated material shall be either collected and disposed of as soon as possible, after treatment with officially approved disinfectant solution;
- foetuses, still-born animals, animals which have died from the disease after birth and placenta shall be collected and disposed of;
- The grazing areas where infected animals were kept may not be used within 120 days in winter or 60 days in summer, though it is recommended that the depopulation period should not be less than 120 days;
- Cleaning and disinfection with officially approved disinfectants and other measures to prevent the spread of infection, of all parts of the establishments that may have been contaminated after the removal of the confirmed and suspected cases and before repopulation as well as cleaning and disinfection of all means of transport, containers and equipment after the transport of animals or products from infected establishments/unit.

A system is established for the verification of cleaning and disinfection by the OPP or the DSAVR, after the slaughter of positive/infected animals or after total slaughter (depopulation), prior to reintroduction

of animals. The cleaning and disinfection shall be supervised and the disease-free status shall not be restore or grant again until it considers that this measures has been completed. There is an approved protocol.

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

During the EI, operators are faced with a range of questions related to biosecurity measures and management which have also informative and educational purposes. Subjects as management of pregnant animals, use of pastures, risk on sharing equipment, and the scope for direct or indirect contact with other epidemiological units are referred.

The notification to the operator related to sanitary "sequestro" contains instructions related to cleaning and disinfection of the stables and outbuildings areas and loading points, of the materials or substances from animals or been in contact with them, as well as containers, utensils and other objects used by animals.

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

The importance of the vaccination as a strategy for controlling the disease under the ovine and caprine brucellosis eradication programme is emphatized in certain areas, given that it allows the animals to be protected from infection, reduces shedding of *Brucella* into the environment and, at the same time, reduces the number of abortions and the number of animals slaughtered on health grounds.

Vaccination will be used with *Brucella melitensis*, live attenuated, strain Rev-1 vaccine, with one drop (approx. 35µl) by ocular route in sheep and goat (conjunctival administration) in certain areas, namely in Trás-os-Montes (Norte Region -DSAVRN) and some units of the Centro Region (DSAVRC) and Lisboa e Vale do Tejo Region (Setúbal - DSAVRLVT).

From 2022 eradication programme, vaccination will continue only in the Norte Region.

Subcutaneous vaccination is prohibited.

The decision to proceed with or cease vaccination will always be subject to authorisation from the DSAVR/DGAV.

As a rule, vaccination is carried out in young animals, between 3 and 6 months of age (up to 5 months of age when possible), from infected or non-infected establishments/unit, that are well developed, shown no evident signs of a debilitating condition (parasitic infestation, excessively thin etc.) or sexual activity, and are serologically negative for brucellosis (blood samples are collected at the same time of vaccination and positive animals are removed). Vaccination of adult animals is allowed under conditions defined by DGAV.

All vaccinated animals shall be subject to electronic identification, which, as an alternative to the classic method (a ruminal bolus and a green eartag) may use a conventional ear tag and an electronic one. This electronic identification may optionally be supplemented by a tattoo in the ear or in the left inguinal fold.

In vaccination areas DGAV may give permission for certain establishments/unit not to be vaccinated on request of the operator and if the epidemiological assessment of the "unit" and it the biosafety does not support vaccination.

- (e) measures to be implemented as regards additional animal populations, if relevant. Not relevant.
 - 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. Not relevant
 - (h) targeted animal populations and when applicable, additional animal populations.

The eradication programme covers all ov/cap animals.

- 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 infection with *Brucella abortus*, *B. melitensis and B. suis* as regards kept ov/cap animals and its central service, the Directorate for Animal Protection (DSPA) is responsible for coordinating and monitoring the programme.

Five Regional Directorates for Food and Veterinary (DSAVR), decentralized services of DGAV (Norte, Centro, Lisboa e Vale do Tejo, Alentejo and Algarve), are responsible for overseeing the implementation of the various activities under the eradication programme in their area, for the attribution of the health status for the establishments/unit and the implementation of restrictions in positive establishments/unit. DGAV/DSAVR is also responsible for monitoring compliance with the legal requirements arising from the agreements signed with the OPP.

(b) responsibilities of all stakeholders involved.

Most field activities of this programme are implemented by private veterinarians from Livestock Producers Organisations (OPPs) which annually submit sanitary programmes to be approved by the official services. There is one veterinary co-ordinator per OPP. Each OPP is assisted by several veterinarians. OPP is responsible for the animal identification, vaccination, blood sampling, computerization of the data in the Animal health database (PISA.Net) and communication to the Regional veterinary services of all irregularities.

The entity that collects the samples is also responsible for submitting them to the laboratory. Sampling during sanitary slaughter is carried out by the official veterinary inspector of the DSAVR.

All laboratories involved in Brucellosis Eradication Programmes are accredited by Portuguese Accreditation Body, named IPAC.

The National Institute for Agrarian and Veterinary Research (Instituto Nacional de Investigação Agrária e Veterinária, I.P., hereinafter - INIAV, I.P.) is the national reference laboratory (NRL) for food safety, animal and plant health.

INIAV, I.P., is the NRL for brucellosis and is responsible for the coordination and technical supervision of the official laboratories and the harmonization of the testing methods used, following guidelines supplied by ÉURL and OIE Manual. There are two delegations of INIAV performing official samples for brucellosis diagnosis. One is located in the Norte (Vila do Conde - Vairão) and the other in Alentejo (Évora). These delegations perform Rose Bengal Test (RBT) and Complement Fixation Test (CFT). *Brucella* bacteriological examination and typing of *Brucella* are only performed at NRL at central level and the results are electronically communicated to DGAV.

In the continental territory, there are 6 private official laboratories located at the following districts:

- SEGALAB (Laboratório de Sanidade Animal e Segurança Alimentar, S.A) Póvoa do Varzim - Porto;
- PROLEITE (Cooperativa Agrícola de Produtores de leite, C.R.L) Oliveira de Azeméis Aveiro:
- LMV (Laboratório de Medicina Veterinária, Lda) Santarém;
- SOCLAB (Polo Litoral Alentejano) Santiago do Cacém Setúbal;

- COPRAPEC (Cooperativa Agrícola de Compra e Venda de Montemor-o-Novo, C.R.L) Montemor-o-Novo Évora;
- ACOS (Associação de Agricultores do Sul) Beja.

These laboratories carry out RBT and CFT and record the results in PISA.Net.

NRL provides technical training for staff either for initial qualification or for requalification on RBT and CFT techniques. NRL provides official Labs with Positive Control Serum for RBT and CFT techniques.

Operators and traders have the responsibility to provide access and the necessary means to carry out the interventions on the animals, to comply with the rules on identification and animal movement, to allow loading and transport for slaughter of positive animals and to comply with the movement restrictions and depopulation periods imposed, following total slaughter.

Operators have the right to be compensated for the value of their animal's compulsory slaughtered or culled provided that they fulfil their responsibilities under the applicable legislation.

9. The estimated duration of the eradication programme.

According to the Working Document SANTE/2020/10502, "guidelines for the Union co-funded programmes of eradication, control and surveillance of animal diseases and zoonoses for the years 2021-2022", when compared to 2019, the expected results (targets) considering minimum % reduction of 30%, will be as follows:

- herd prevalence: with 0.273% in 2021 and 0.191% in 2022;
- herd incidence: with 0.231% in 2020 and 0.162% in 2022.

However, good results have been achieved in the Norte Region in the vaccinated areas, allowing for a less conservative estimation as follow (please see also the table in point 10.a), regarding infected animals):

Years	2021	2022	2023	2024
Continent	0.07	0.03	0.008	0

Considering our vaccination program that Vila Real and Bragança will be caried out, for at least 3 more years, full indemnity will be achieved in 2028, however we intend to submit the 8 districts for indemnity recognition in 2022.

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

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

The following table separates the infected establishments from those that are no longer infected but are not yet disease-free

Region	District	2021	2022	2023	2024
Norte	Viana do Castelo	0			
	Braga	0			
	Porto	0			
	Vila Real	10	5	1	0
	Bragança	20	10	3	0

N /C					
Norte/Centro	Aveiro	0			
	Viseu	1	0		
	Guarda	0			
Centro	Coimbra	0			
	Castelo Branco	0			
Centro/LVT	Leiria	0			
LVT	Santarém	2	0		
	Lisboa	0			
LVT/Alentejo	Setúbal	4	2	0	
Alentejo	Portalegre	0			
	Évora	0			
	Beja	0			
Algarve	Faro	0			

(b) the expected annual increase of the number of disease-free establishment.

The expected number of disease-free establishments are the entire ovine and caprine population, except the cases in the table in point 10.a)

(c) the expected vaccination coverage, where relevant.

The expected vaccination coverage will be as follows:

Regarding North Region:

Distrito of Braga: will stop vaccination in 2022.

Districts of Vila Real and Bragança: will continue vaccination up to, at least, 2024.

Districts of Viseu and Guarda (partially): will stop vaccination in 2022.

Regarding Centro Region:

Districts of Viseu and Guarda (partially): will stop vaccination in 2022.

District of Castelo Branco: will stop vaccination in 2022.

Regarding LVT Region:

District of Setúbal: will stop vaccination in 2022.