

Department A Health and Food Unit A2 EU4Health/SMP

Food Programmes for eradication, control and surveillance of animal diseases and zoonoses

### submitted for obtaining EU financial contribution

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

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- 5) For simplification purposes you are invited to submit multi-annual programmes.
- 6) You are invited to submit your programmes in English.

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Member state :	ALIA
Wichiber State.	ITALIA

Disease Sheep And Goat Brucellosis

Species : Sheep and goats

This program is multi annual : no

Request of the Union co-financing from beginning of:

2023

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

1. Contact data

Name

Email

Phone

Your job type within the CA :

Submission Date 30/11/2022 10:41:26

Submission Number

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Privacy Statement

## 2. Historical data on the epidemiological evolution of the disease

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

#### (max. 32000 chars) :

Brucella abortus, melitensis and suis has been eradicated from most part Italian territory. Out of 19 Regions and 2 Brucella melitensis has been eradicate from most part of Italian territory. Out of 19 Regions and 2

Autonomous provinces, 15 of them, 1 Province of the Campania, 4 of the Puglia and 2 of Calabria Regions have been declare free from B. melitensis - Free according to EU legislation (ANNEX 1, maps). Furthermore the Province of Lecce in Puglia Region have presented at the Commission the dossier for the declaration of territories free for brucella abortus, melitensis and suis for kept sheep and goats populations, actually under evaluation.

Analysis of the data received from the regions concerning the eradication activities carried out between 2017 and 2021, (ANNEX 1 graphics, ANNEX 4 AND 7) has revealed the situation described below. The sheep and goat national establishments' population subject to the program in the year 2021 is decrease (101262), compared with the data of 2017 (104172) of 2910 units. In addition, the number of controlled establishments is decreased (26.550) with respect to 2017 (37938) of 11388 units. This more marked reduction of establishment under program is due at the new territories that in 2021 have been declare free with the commission Decision 385/2021: Abruzzo Region, Provinces of Catanzaro and Cosenza in Calabria Region, Province of Benevento in Campania Region, Provinces of Bari, Barletta-Andria-Trani, and Taranto in Puglia Region. The number of positive establishments is lower (107), than in 2017 (362). The number of outbreaks stamped-out (9) is lower than in 2017 (10).

The percentage of establishments controlled in 2021 (99,38 %) is lower of the percentage of control performed in 2017 (99,56 %), but it is very close to the figure defined as final objective prescribed in new Ministerial Order of the 28 of May 2015 (100%).

The prevalence and incidence registered in 2021 it reduced (0.40 %, 0.28 %) respect to the results obtained in 2017 (0.99 %, 0,77 %) and is in line with the progresses achieve in the eradication of the disease represents by declaration of the free statu by new italian territories.

The expected results indicated 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, for the ovi-caprine brucellosis program in Italy has been establish as minimum percentage

of reduction compared to 2019 = to 100% Free.

The prevalence recorded for the melitensis in Italy in 2021 calculated on all the establishments under control, has been 0.10% (ANNEX 1 GRAPHICS).

The higher prevalence in Italy is report in Sicily region 1.00 % flocks infected. However is important to underline that in Sicily these data of prevalence are in reduction respect the last five years – 2017 (2.96 %) (ANNEX 4).

The 21 of April 2021 the Animal Health Law has enter in force in Europe. For Italy start a time of transition from the national legislation to European legislation. In any case, the Ministry of health has prolonged the Ministerial Ordinance 28 May 2015, until 26 June 2022 to give to the local veterinary services the instruments to continue the process of eradication in the regions where the disease is still present.

The Ordinance is applied in the not free territories as well as in the free territories at the aim of obtain a uniform control of the disease in Italy.

The Ordinance provide for an obligation for all the Regions to insert in the Italian Veterinary Informatic Sistem (VETINFO), a list of the establishments that are plan to control during the year.

The upload of the planning of controls in VETINFO is the base of calculation of a DASHBOARD, that compare the planning, with the data of the veterinary activities performed during the implementation of the program, producing statistic, refreshed weekly, in form of indicators, useful at local, regional and national level to monitoring of the correct application of the plan.

The Ordinance considered also the frequency and the modalities of the controls on dealers. The local veterinary service must check, at least every three months the dealers on site and every month on the veterinary informatics system, (VETINFO). In case the checks on the informatic system reveal unconformity, the local veterinary service control the dealer on site.

Following the synthesis of the measures contained in the Ordinance (ANNEX 2, Ministerial Order 28 may 2015):

- 1) Responsibility of the Chief of local Veterinary service on the control of 100% of the establishments;
- 2) Registration of pastures;
- 3) Controls of Dealers;
- 4) Control of fattening establishments;
- 5) Controls on animals before and after movement;
- 6) Electronic identifications of animals of the outbreak (rumen bolus);
- 7) Electronic identifications of animals subjected to movement;

8) Capture and control of animals at pasture that have no owner or that have an owner that does not assure capture and the restraint of animals;

9) Guidelines for stamping-out;

10) Elaboration, already at the suspect, of the epidemiological investigations, following the guidelines of the Ministry of health (ANNEX 3);

- 11) Compulsory use of the database, SANAN and SIMAN;
- 12) Sanctions and withdrawal of the status of OTF of the establishments in case of fraud;
- 13) Control of the efficacy and efficiency by local and regional veterinary service.

Regarding this last point, to support the enforcement of the verification of the efficacy and efficiency of the

controls by the local veterinary authority, in the dashboard has been provided a function that permit at the chief of the veterinary service to:

1) verify, one by one, all the indicator of the disease;

2) indicate the corrective actions that decides to implement to recovery the unconformities detected. All the data of the verification of the efficacy and efficiency are then saved in changeless way and made available to the Regional and Central Authority for Audit session and other verification.

### 3. Description of the submitted programme

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

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

#### (max. 32000 chars) :

The programme is annual and covers the following objectives:

- to continue with, and step up, animal health measures and measures to prevent brucellosis in sheep and goats;

- to intensify disease eradication on infected establishments so that they can be designated free without vaccination (or disease-free status whit vaccination);

- to retain disease-free status without vaccination (or disease-free status whit vaccination) for establishments that have already achieved that objective.

The planned and achievable objective for 2023 is for other Italian provinces and regions to meet (or retain) the requirements to qualify disease-free status without vaccination or disease-free status with vaccination as regards brucellosis in sheep and goats.

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

In particular:

a) Rapid serum agglutination test with Rose Bengal antigen (RBT) to be performed on all blood samples collected;

(b) The complement fixation test (CFT) to be carried out on all RBT positive samples and on all animals in the establishment in the case of establishments that are not free or not officially free and controlled for the acquisition of the qualification.

In sheep and goat establishments, CFT is also perform on all animals in the establishment if one or more animals have reacted positively to RBT. The CFT test is consider positive at a titer equal to or greater than 20 UIFC / ml.

Interpretation of test results of the above serological tests:

a) In the event that the serum of an animal test gives negative results to RBT and CFT, the animal it is consider negative;

b) if the serum of an animal tested gives a positive result to the CFT (greater than or equal to 20 UIFC / ml) and negative or positive to the RBT, the animal is considered positive;

c) In the event that the serum of an animal tested gives a positive result for RBT and negative for CFT, the result is consider doubtful and the animal suspected.

In the cases reported at point b) and c) the health qualification of the establishments is suspended, others investigations: clinically of laboratories and post mortem, as well as an epidemiological enquire, are put in place by the local veterinary services to confirm or exclude the presence of the disease (art. 55 of the Reg. 429/2016).

In the event that positive serological result is obtain on sera from animals present in an outbreak, the animals with positive RBT and negative CFT are considered infected in any case.

1. The status free from infection with Brucella abortus, B. melitensis and B. suis without vaccination may only be granted to an establishment keeping ovine or caprine if:

(a) during the past 12 months there has been no confirmed case of infection with B. Abortus, B. melitensis and B. suis in ovine or caprine kept in the establishment;

(b) during the past 3 years none of the ovine or caprine in the establishment has been vaccinated against infection with Brucella abortus, B. melitensis and B. suis;

(c) the entire ovine or caprine animals over 6 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:

(i) the first 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 in an immunological test;

(ii) the second 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 to in point (i);

(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 sampling referred to in point (c)(i) all ovine or caprine introduced into the establishment originate from establishments free from infection with Brucella abortus, B. melitensis and B. suis without vaccination, or free with vaccination and have not been vaccinated against infection with Brucella abortus, B. melitensis and B. suis during the past 3 years, and

(i) originate from a Member State or a zone free from infection with Brucella abortus, B. melitensis and B. suis for the relevant animal population;

(ii) are entire ovine or caprine over 6 months of age and must have tested negative in a serological test carried out on a sample taken:

- during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction provided they have been kept isolated during this period; or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and

(f) since the beginning of the sampling referred to in point (c)(i), all germinal products of ovine or caprine origin introduced into or used in the establishment originate from:

(i) establishments free from infection with Brucella abortus, B. melitensis and B. suis without vaccination; or

(ii) approved germinal product establishments.

By way of derogation from point 1, the status free from infection with Brucella abortus, B. melitensis and B. suis without vaccination may be granted to an establishment if all ovine or caprine originate from establishments free from infection with Brucella abortus, B. melitensis and B. suis without vaccination, or free with vaccination and have not been vaccinated during the past 3 years, and:

(a) originate from a Member State or a zone free from infection with Brucella abortus, B. melitensis and B. suis for the relevant animal population;

(b) are entire ovine or caprine over 6 months of age and have tested negative in a serological test carried out on a sample taken:

- during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction into the establishment provided they have been kept isolated during this period; or

(c) are post-parturient females kept in isolation since their introduction into the establishment until they tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition.

3) By way of derogation from point 1, the status free from infection with Brucella abortus, B. melitensis and B. suis without vaccination may be granted to an establishment with the status free from infection

with Brucella abortus, B. melitensis and B. suis with vaccination if:

- (a) the requirements set out in points (a), (b), (d), (e) and (f) of point 1 are fulfilled; and
- (b) the requirement set out in point (b)(i) of Section 2 is fulfilled.

To confirm or rule out the disease in the event of a suspected case.

The confirmation of a suspected case of B. abortus, melitensis and suis in establishment with or without vaccination occur when there are the condition listed in annex 4 - Chapter 1/2, section 4 point 1 (a,b,c and d) of the EU Reg. 689/2021.

In case of no confirmation of B. abortus, melitensis and suis in establishment with or without vaccination the status free from infection with B. abortus, melitensis and suis and without vaccination may only be restored if, there are the condition prescribed at Chapter 1/2, section 3, point 2 of the Reg. 689/2020:

(a) the requirements set out in points (b), (d), (e) and (f) of point 1 of Section 1 and in point (b) of Section 2 are fulfilled;

(b) 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.

The disease control measures to be apply in the event of a confirmed case;

If the status free from infection with B. abortus, melitensis and suis without vaccination has been withdrawn in case the infection of B. abortus, melitensis and suis has been confirmed in ovine or caprine animal kept in the establishment;

it may only be regained if all confirmed cases and all animals that have tested non-negative have been removed and the remaining ovine or caprine animals over 6 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows: (i) the first 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 in an immunological test; (ii) the second 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 to in point (i);

The biosecurity and risk mitigating measures to be implement;

For mitigating the risk of geopardization of the brucella abortus, melitensis and suis in the Ministerial Order 28 may of 2015 and his prorogation has provided strenght meausures for the animal moving for pasture (control 30 days before moving, identification with endoruminal bolus and geo- referentation of the pastures) and controls on dealers (monthly on the veterinary informatic sistem VETINFO and in case of not conformity controls in place). Furthermore in 2022 has been approved an accord between all the Italian Regions that may have with different status (free and not free) that provide that the establishments that want move animals from a Region or Province with lower status to a Region or Province with higher status must be listed in the Italian informatics identification veterinary system (VETINFO). The provision that the establishments should have to be listed are: 2 years of free status, correct identification of the animals, pre-moving test negative. Furthermore, the Ministry of Health is preparing a specific Decree on biosecurity.

- 4. Measures of the submitted programme
- 4.1 Summary of measures under the programme

Duration of the programme : 2023 - 2023

X Eradication

X Testing

Slaughter of animals tested positive

Vaccination

Other, please specify

### 4.1.1 Timeline for the eradication

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

The Italian target for the program 2023 is to continue to achieve the status of free for further territories. In 2021, the Region Abruzzo, the province of Benevento in Campania Region, The province of Catanzaro and Cosenza in Calabria region and the Provinces of Bari, Barletta-Andria-Trani and Taranto in Puglia has been declare with decision 385/2021. Furthermore, the province of Lecce in Puglia Region has presented in 2022 the request of free status to the Commission. The demand has been assess positively and soon Lecce will be list in the Chapter II of the Reg. 620/2021 as territory free.

In addiction has already indicated, in 2021 the prevalence of the disease calculated on all the establishments keeping sheep and goats present in Italy has been of 0,10%.

Listed below the regions not free and the result of prevalence achieved in 2021 compared with the results of from 2019 (ANNEX 5, 6 and 7) and the target 2023 proposed:

Basilicata all region: - prevalence on holdings registered in in 2019 – 0.39%; in 2020 – 0.15%, 2021= 0.02% target 2023 = 0.00%. Supposed achievement of the target of free status in 2024. Calabria province of Reggio Calabria, Crotone, Vibo Valentia: - prevalence on establishments registered in 2019 – 0.25 %; in 2020 – 0.15%, 2021= 0.23 % - target 2023= 0.00%. Supposed achievement of the target of free status in 2024.

Campania province of Caserta, Napoli, Avellino, Salerno: - prevalence on establishments registered in 2019 – 0.16%; in 2020 – 0.20%, 2021 = 0.10 % -target 2023 = 0.03%. Supposed achievement of the target of free status in 2025.

Puglia province of Foggia, Lecce: - prevalence on establishments registered in 2019 – 0.38%; in 2020 – 0.14%, - target 2021 = 0.28% - target 2023 = 0.19%. Supposed achievement of the target of free status in

2025. Lecce is in course of be listed as free territory in the Chapter 2 of the Reg. 620/2021. Sicilia: prevalence on establishments registered in 2019 -1.68 %; in 2020 – 1.00%, - 2021= 1.11 % - target 2023 = 0.43% - 2024 = 0.36% - 2025 = 0.30% - 2026=0,25% - 2027= 0,21% - 2028= 0,17% - 2029= 0,14%-2030= 0,11% . Supposed achievement of the target of free status in 2030.

### 4.1.2 Interim targets in relation to the timeline for eradication

Describe the intermediate targets of the eradication programme including at least: (a) the expected annual decrease of the number o infected establishments;

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

(c) the expected vaccination coverage, where relevant.

(max. 32000 chars) :

Relatively the intermediate target of this program of eradication of b. abortus, melitensis and suis for kept sheep and goats it is expected the following annual decrease of the number of infected establishments: in 2021 has been registered 107 outbreaks, for the 2022 the regionals Authority expect 43 outbreaks (reduction of 60% of case).

As consequence of the reduction of outbreaks is expect the following proportional increase of the number of disease-free establishments:

in the 2021 on 26550 establishments keeping sheep and goats under program at the beginning of the year 26483 have resulted free by December 31st (95 flocks with unknown or withdrawal status); in the 2023 is expected that on 22.515 flocks under program at the beginning of the year 22441 should resulted free by December 31st (74 flocks with suspension or withdrawal of the status). Regions with territories not free that will apply the program declare the following target 2023 established in function of the result of prevalence registered in the biennial 2020/2021: 1. BASILICATA Region - Provinces of: Matera: 2020 - 0.00%, 2021 - 0.00 %, 2023 - 0.00%; Potenza: 2020 - 0.18%, 2021 - 0.02%, 2023 - 0,00%; 2. CALABRIA Region - Provinces of: Crotone: 2020 - 0.91%, 2021 - 0,95%, 2023 - 0,00%; Vibo Valentia: 2020 - 0.00%, 2021 - 0,00%, 2023 - 0,00%; Reggio Calabria: 2020 - 0.41%, 2021 - 0,09%, 2023 - 0,00%; 3. CAMPANIA Region - Province of: Avellino: 2020 - 0.07%, 2021 - 0,07%, 2023 - 0,00%; Caserta: 2020 - 0.31%, 2021 - 0,00%, 2023 - 0,00%; Napoli: 2020 - 0.00%, 2021 - 0,00%, 2023 - 0,00%; Salerno: 2020 - 0.31%, 2021 - 0,16%, 2023 - 0,06%. 4. PUGLIA Region Province of: Foggia: 2020 - 0.27%, 2021 - 0,38%, 2023 - 0,25%. 5. SICILY Region Province of: Agrigento: 2020 - 0.55%, 2021 - 0.67%, 2023 - 0,00%; Caltanissetta: 2020 – 1.84%, 2021 - 0,53%, 2023 - 0,00%; Catania: 2020 – 1.08%, 2021 – 1.71%, 2023 - 0,00%; Enna: 2020 - 0.61%, 2021 - 0.61%, 2023 - 0,00%; Messina: 2020 - 2.34%, 2021 - 2.43%, 2023 - 0,00%; Palermo: 2020 – 0.44%, 2021 – 0.42%, 2023 - 0,00%; Ragusa: 2020 - 0.19%, 2021 - 0,54%, 2023 - 0,00%; Siracusa: 2020 - 1.52%, 2021 - 0,89%, 2023 - 0,00%;

Trapani: 2020 - 0.54%, 2021 – 1.34%, 2023 - 0,00%;

The process of the eradication of brucella abortus, melitensis and suis in the sheep and goats populations is going forward in Italy and also in territories of some regions considered "hot spot", as the Province of Reggio Calabria (prevalence 0.09% in 2021, 0.41% in 2020, 0.55% in 2019, 1.48% - 2018, 1.66% - 2017, 2.42% - 2016) and the Province of Salerno (prevalence 0.16% in 2021, 0,31% in 2020, 0,19% - 2019, 0,49% - 2018, 0,41% - 2017, 0.29% - 2016).

At the opposite in the area of Gargano in Puglia (prevalence 0,38% in 2021, 0,27% in 2020, 0,60 in 2019, 0,75% - 2018, 1,05% 2017, 1.50 %- 2016) and in Sicily in the Provinces of Messina (2.43% in 2021, 2,34% in 2020, 3,60 % -2019, 5,52% - 2018, 4,64% 2017, 7,68% - 2016) and Trapani (1.34% in 2021, 0,54% in 2020, 3,47 % - 2019, 4,75% - 2018, 4,75% - 2017 e 7,69% -2016) is registered a decreasing of the prevalence.

No program of vaccination is preview now for sheep and goat population.

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

Describe the organisation, supervision and roles of the parties involved in the eradication programme including at least:

(a) the authorities in charge of coordinating and supervising the implementation of the programme;

(b) responsibilities of all stakeholders involved.

#### (max. 32000 chars) :

1) Ministry of Health: this is the central body of the National Health Service. It is responsible for health policy and planning, setting targets for improving the health of the population, and determining the uniform levels of care to be provide to all citizens throughout the country. The Directorate-General for Animal Health and Veterinary Medicine has responsibility for the Animal Health sector.

2) Regional Health Departments (Assessorati Regionali alla Sanità): these are the bodies responsible for health protection services and activities within their region. They are also responsible for planning the measures to be implement by coordinating the activities of the Local Veterinary Unit (LOCAL VETERINARY UNITs) and monitoring their work.

3) Local Veterinary Unit (Aziende Sanitarie Locali – LOCAL VETERINARY UNITs, Aziende Sanitarie Provinciali - ASP) are the unit's operating on the terrain. They ensure the levels of assistance in their geographical areas by means of their own services. They are under the administrative and financial control of the Regions but enjoy wide operational autonomy.

4) Laboratories of analysis (Istituti Zooprofilattici Sperimentali – IZSs): these are public-law health bodies with operational and administrative autonomy and are the technical and operational arm of the National Health Service, particularly as regards animal health, monitoring the quality and fitness for consumption of foodstuffs of animal origin, establishment hygiene and the proper relationship between human settlements, animals and the environment.

By means of ring trials involving the main laboratory and the provincial diagnostic centers, each IZS ensures that brucellosis is diagnose in a uniform manner in its geographical area. The National Reference Centre for Brucellosis organizes annual ring trials involving Italy's ten IZSs.

By means of the Ministerial Decree of 4 October 1999, Abruzzo and Molise IZS, which has its headquarters in Teramo, was designated the National Reference Centre for Brucellosis. Further information on the Ministry of Health and, in particular, on the Directorate-General for Animal

Health and Veterinary Medicine is available at http://www.salute.gov.it/

Brucellosis in sheep and goats is a disease of the List B of the Reg. 429/2016 therefore eradication plan

are compulsory. Local veterinary authorities operating in the area carry out the information and programming from the operators.

In some Region the official vet involve liberal vets to collect the blood samples in the field with conventions and different contracts depending on the Regions concerned. Establishmenters collaborating to the program, creating favorable conditions for the work of veterinary (animal capture, restraint, etc.). The competent local veterinary unit monitors the supervision of traceability by Italian veterinary system VETINFO. The certificate for movement is electronic and validate by the competent veterinary local service.

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

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

#### (max. 32000 chars) :

The programs will be apply to the whole of Italy, taking account of the epidemiological differences found in the various areas of the country. Regions and provinces that have obtained the disease-free status will adopt specific regional surveillance and control programmes. Although these specific surveillance programmes are part of this national plan for the eradication of brucellosis in sheep & goats no EU cofinancing has been requeste for them. The five regions that are still performing the eradication program to obtain the status free are indicate in the maps.21 (SEE ANNEX 1 MAP).

### 4.4 Description of the measures of the programme

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

### 4.4.1 Notification of the disease

(max. 32000 chars):

From 21 April 2021, required notification is provided for in Article 18(1) of Regulation (EU) 2016/429; and by Reg. 689/2020 as indicated in PART II SURVEILLANCE, ERADICATION PROGRAMMES, DISEASE-FREE STATUS, CHAPTER 1, Surveillance, Section 1, Design of surveillance, Targeted animal population and diagnostic methods, Article 3, point 1 (i).

The Ministry of Health has put in place a veterinary general surveillance system (VETINFO) for the notification and investigations of outbreaks in targeted animal population for the brucella abortus, melitensis and suis program.

In particular regarding the notification of the b. abortus, melitensis and suis the extension of 6 June 2017, of the Ministerial Ordinance of 28 May 2015, has provided that in the event of suspicion or confirmation of the presence of brucella abortus, melitensis and suis in an establishment with "status free without vaccination" or "status free with vaccination", the veterinary service, excluding the application of what provided for in the European veterinary health measures currently in force, provides for that:

a) within two days of the suspension of officially free herd status without or with vaccination following suspicion of positivity for ovine-caprine brucellosis in establishment, starts the epidemiological investigation, inserts in the national information system for the notification of animal diseases (SIMAN),

the reason for the suspicion of positivity and any other data available;

b) after starting the epidemiological investigation, acquires the first findings relating to clinical and/or pathological examinations and/or serological checks and/or microbiological tests and/or

epidemiological links, inserts them in SIMAN, confirms or not the outbreak and, if confirmed, continues the investigations using the collaboration of the regional epidemiological observatory, where present, or the competent Laboratory (IZS) for territory to identify strategies for the rapid extinction of outbreak and containment of the infection and to determine the causes of its origin;

c) within two days from the confirmation of positivity, withdrawn of the status of establishment free without vaccination or free with vaccination or, in case of confirmation not preceded by suspicion, starts the epidemiological investigation in the SIMAN and, in any case, continues the epidemiological investigation of the regional epidemiological observatory, where present, or the Laboratory competent for the territory;

d) Simultaneously with the withdrawal of the status, orders the notification of the withdrawal to the breeder and the compulsory slaughter of the animals declared infected within 15 days;

e) the territorially competent local health authority inform the "human public health office" of the zoonosis outbreak and the measures adopted;

f) within two days from the exclusion of the suspicious or from the extinction of the outbreak, inserts the cancellation in the SIMAN of the unconfirmed suspicion or the extinction of the outbreak and give the status of establishment free without vaccination or with vaccination in accordance with current European legislation.

### 4.4.2 Target animals and animal population

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

(a) the number of establishments keeping animals of the targeted animal population by health status (Disease-free, infected or unknown) excluding establishments falling under the derogation to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December;

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

(d) information as regards the epidemiological situation in additional animal populations, where relevant. (max. 32000 chars):

The b. abortus, melitensis and suis is still present in five regions located in the South of Italy (ANNEX 1 graphic and maps). The Regions where the program 2023 will be applied are:

BASILICATA: the whole region:

CALABRIA: Provinces of Reggio Di Calabria, Crotone, Vibo Valentia;

CAMPANIA: Provinces of Caserta, Napoli, Avellino, Salerno;

PUGLIA: Provinces of Foggia, Lecce;

SICILIA: the whole region.

a) The number of establishment keeping S&G by health status are the following:

BASILICATA: total number of establishments where the program will be applied – 5,389, percentage of free establishment-100%, infected 0, Unknown 0;

CALABRIA: total number of establishments where the program will be apply – 2,659, percentage of free establishment- 91.95 %, infected 0, Unknown 12;

CAMPANIA: total number of establishments where the program will be apply – 4,782, percentage of free establishment- 98.75 %, infected 0, Unknown 0;

PUGLIA: total number of establishments where the program will be apply – 1480, percentage of free establishment- 99.86 %, infected 2, Unknown 0;

SICILIA: total number of establishments where the program will be apply – 8,205, percentage of free establishment- 99.00 %, infected 60, Unknown 0;

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

BASILICATA: total number of sheep & goats animal population kept in the establishments – 190,786, percentage of free animals-100%, infected 0, Unknown 0;

CALABRIA: total number of sheep & goats animal population kept in the establishments – 150,723, percentage of free animals- 96.41 %, infected 0, Unknown 45;

CAMPANIA: total number of sheep & goats animal population kept in the establishments – 168,438, percentage of free animals- 99.41%, infected 0, Unknown 0;

PUGLIA: total number of sheep & goats animal population kept in the establishments – 134,400 , percentage of free animals-99,93 %, infected 100, Unknown 0;

SICILIA: total number of sheep & goats animal population kept in the establishments – 787,246, percentage of free animals-98.97 %, infected 5,353, Unknown 0;

c) see annex (MAPS)

d) no relevant.

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

#### (max. 32000 chars) :

Until the publication of the implementing Italian legislative decree and the operating manual, and therefore until the reorganization of the entire Identification & Registration system, continue to be apply the following indications:

i) the provisions currently in force for the identification of cattle, sheep, goats and pigs approved before 21 April 2021, as permitted by Article 20 of the Implementing Regulation (EU) 2021/520 which, until 21 April 2023, provides for the possibility of maintaining identification means provided before the application of the Regulation;

ii) as regards the maximum recording time in the computer database set up for cattle, sheep and goats of the information referred to in Article 112, letter d) and 113, paragraph 1, letter c) of the Regulation, the provisions of referred to in Article 3, paragraph 1, of the aforementioned Regulation referred to in document SANCO / 11123 2018 CIS published in the Official Journal of the EU;

iii. the provisions currently in force for registries other than those referred to in the previous point; iv. the sanctions provided for by the current provisions on the zootechnical registry of the various species as well as, as applicable, the measures provided for by articles 137 and 138 of Regulation (EU) 2017/625 and the provisions of the legislative decree of February 2, 2021 n. 27.

#### ANIMALS

Decree No 317/96, transposing Directive 92/102/EEC, lays down the rules for the compulsory registration of all sheep and goat holdings. Regulation (EC) No 21/2004 defines the procedures for identifying sheep & goats.

The LOCAL VETERINARY UNITs' veterinary services assign an identification code to holdings and take care of their registration. Animals are identified individually, except those intended to be slaughtered before the age of 12 months, which are identified by the holding's code only.

When animals are moving, electronic Form 4 must be completed (Ministerial Decree 28 June 2016). This form contains information on the origin and destination of the consignment, the necessary health information and, where relevant, any health restrictions that apply to the animals or to their holding of origin.

In implementing the eradication programme, the official veterinarians check on the correct registration of holdings and identification of animals.

HOLDINGS

Decree No 317/96, transposing Directive 92/102/EEC, lays down the rules for the compulsory registration of all sheep & goat holdings with more than three animals of these species. However, it should be note that Ministerial Decree No 453/92 requires disease prevention operations to be carried out on all holdings, even those not subject to compulsory registration.

The LOCAL VETERINARY UNIT veterinary service allocates the establishments an identification number and takes care of the relevant registration. +++"Each animal is identified by an individual number made up of the identification number of the holding, on an ear tag or by electronic disposal (ear tag/ endoruminal bolus)".

In implementing the eradication programme, the official veterinarians check on the correct registration of holdings and identification of animals.

Reg. 1505/2006 provides a minimum level of annual inspections of at least 3% of establishments and at least 5% of the sheep and goats in the area of competence, to verify the correct application of the system of identification and registration of sheep and goats. Local Veterinary Unit carries out the control registers during operations prophylaxis.

With a note of DGVA.VIII / 22577 / PI.5.i / 8 of 13 June 2006 the Ministry of Health has confirmed the minimum level of checks required by the said Regulation and issued a specific check list in order to standardize the methods for carrying out establishment controls as sheep and goats.

The selection of companies that are inspect annually shall be based on risk analysis and is based on the following risk criteria:

- Number of animals

- Implications for human and animal health, in particular the existence of previous outbreaks

- Amount of annual premiums required and / or paid to the holding, compared with the amount paid the previous year;

- Significant changes in comparison with situations in previous years.

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

#### (max. 32000 chars) :

In accordance with the Reg. (UE) 429/2016 and with the Reg. (UE) 689/2020 all establishment must achieve disease-free status without vaccination or disease-free status with vaccination (in provinces in which vaccination will be eventually plans or if vaccinated animals are present).

In particular the Annex IV of the Reg. (UE) 689/2020 at the part 1, chapter 1, section 1 specifie the rule for the granting of the status of Establishment free from infection with B. abortus, melitensis and suis without or with vaccination:

1. The status free from infection with B. abortus, melitensis and suis without or with vaccination may only be granted to an establishment keeping bovine, ovine or caprine animals if:

(a) during the past 12 months there has been no confirmed case of infection with B. abortus, melitensis and suis in ovine or caprine animals kept in the establishment;

(b) the entire ovine or caprine animals over 6 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:

(i) the first 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 in an immunological test;

(ii) the second 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 to in point (i);

(c) animals showing clinical signs consistent with infection with B. abortus, melitensis and suis such as abortions, have been subjected to investigations with negative results;

(d) since the beginning of the sampling referred to in point (b)(i) all ovine or caprine introduced into the establishment originate from establishments free from infection with B. abortus, melitensis and suis without vaccination, or free with vaccination and have not been vaccinated against infection with B. abortus, melitensis and suis during the past 3 years, and

(i) originate from a Member State or a zone free from infection with B. abortus, melitensis and suis for the relevant animal population;

(ii) are entire ovine or caprine animals over 6 months of age and must have tested negative in a serological test carried out on a sample taken:

- during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction provided they have been kept isolated during this period; or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and

(e) since the beginning of the sampling referred to in point (c)(i), all germinal products of ovine or caprine origin introduced into or used in the establishment originate from:

(i) establishments free from infection with B. abortus, melitensis and suis without vaccination; or (ii) approved germinal product establishments.

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

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

#### (max. 32000 chars) :

The animal movement are in accordance with the Reg. (UE) 429/2016 and with the Reg. (UE) 688/2020 about the rules for the prevention and control of animal diseases transmissible to animals or to humans as regards movements within the Union of kept terrestrial animals.

In respect of what prescribed in the art. 15, chapter 2, section 2 point 1 (a,b,c) of the Reg. (UE) 688/2020, operators shall only move kept ovine and caprine animals to another Member State when the following requirements are fulfilled:

(a) the animals have been continuously resident in the establishment for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with kept ovine or caprine animals of a lower health status or subject to movement restrictions for animal health reasons, or with kept animals coming from an establishment which did not fulfil the requirements set out in point (b);

(b) any animals entering in Italy from a third country or territory during the last 30 days prior to the departure of the animals referred to in point (a), and introduced into the establishment where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment;

(c) except when they are moved in accordance with Article 16 of Reg. 688/2020, they come from an establishment free from infection with B. abortus, melitensis and suis and without vaccination regarding ovine and caprine animals, and either

(i) the establishment is situated in a Member State or zone thereof with the status free from infection with B. abortus, melitensis and suis regarding the ovine and caprine population;

or (ii) the animals have been subjected to a test for infection with B. abortus, melitensis and suis with one of the diagnostic methods provided for in Part 1 of Annex I, carried out, with negative results, on a sample taken during the last 30 days prior to departure, and in the case of post-parturient females, taken at least 30 days after parturition;

or

(iii) the animals are less than 6 months old;

or

(iv) the animals are castrated.

At integration of the above mentioned legislation for the animals movement Italy has provided for specific rules.

All the animal's movimentation are authorized only by the electronic Form 4, available in the national database.

Apart from being sent for slaughter, animals may be moved only if they come from establishment brucellosis-free without vaccination and brucellosis-free establishment with vaccination accompanied by Form 4. In all cases where the animals are not being sent to the slaughterhouse, the official veterinarian will fill the Form 4, indicating the date of the last inspection of the animals and the holding of origin, in addition to the health status of the holding of origin.

Penalties are applied in the event of irregularities.

Each movement in the summer fields and communal grazing field is authorized by the Veterinary Services and all the authorization procedure is managed through the Information System.

The prorogation of the Ministerial Order 28 May 2015 states that only animals, originating from establishment brucellosis-free without vaccination or with vaccination, negative at the SAR and Fdc test for brucellosis, electronically identified and registered in the National Database, can be moved and in the not brucellosis-free territories, the animals are submitted to a diagnostic test for brucellosis during the previous 30 days.

In all the national territory and on a risk-based evaluation, the animals can be tested for brucellosis during the 30 days before the re-entry from grazing too.

The Veterinary Services upon authorization verifies that territories destined to grazing are identifies, georeferenced and registered in the National Database.

In 2022, an accord between Regions has been approve for the regulation of movements of sheep and goats from territories not free to territories free. A special list is in preparation in National Data Base to insert all the data of the establishments that have the characteristics and the permission to move animals from territories not free to territories free.

The provision to be satisfied to be list are:

1. Favorable animal identification and registration situation (correct identification of all animals on the farm) at the last annual official control;

2. Uninterrupted possession of the free status of the establishment concerned in the last 2 calendar years;

3. Correct identification with endoruminal bolus of all sheep and goats on the establishment and their individual registration in National Data Base;

4. Checks on establishments: screening tests (RBT and CFT) negative for brucellosis carried out on all animals of the establishment (if these coincide with the scheduled date for a prophylaxis check, the test is valid for both purposes), in addition to the annual tests provided for in the eradication plan.

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

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

#### (max. 32000 chars):

The official tests used in Italy (the rapid agglutination test (RBT) with Rose Bengal antigen and the complement fixation test (CFT) are listed in the ANNEX III Section 1 of the Reg. (UE) 689 /2020. The antigen used for the Rose Bengal test is the same throughout Italy and is produced by Abruzzo and Molise IZS. The antigen used for the complement fixation test is the same throughout Italy, and is produced by Lombardy and Emilia-Romagna IZS. The quality of antigens is checked by the National Reference Centre for Brucellosis. The standardisation of the antigens is carried out in accordance with the relevant Community provisions.

The veterinary medicine laboratory are accredited according to ISO 17025 by the independent organization "Accredia" responsible for verifying the quality of the tests performed in Italy. All official tests are performed at the IZSs responsible for each geographical area.

The procedure of test for ovine and caprine brucellosis are also summarised in ANNEX 1 of the prorogation of 25 June 2022 of the Ministerial Order 28 may 2015.

The Rose Bengal test is used for screening ovine or caprine holdings in order to establish the status of holding as officially brucellosis-free. The CFT is used as individual animal test in order to establish the status of holdings in case of positivity to RBT.

In other terms the diagnostic procedure provides for performing of Rose Bengal test on all the animals . Following the application of the prorogation of the Order of the Ministry of health the 25 June 2022 in the annex 1 is provided-for that all the ovine-caprine in the flock > 6 months of age are test with RBT and positive ones tested with CFT. In accord with the art. 9 of the UE Reg. 689/2020 in case of animal positive at CFT if present one or more of these elements: clinical sign, epidemiological link the outbreak is confirm.

As provided in the art. 9 of the UE Reg. 689/2020 to confirm infected a flock with animal positive at CFT is necessary that are present one or more of these elements: clinical sign, epidemiological link. The isolation of brucella spp. is sufficient by itself to confirm the outbreak.

The bacteriology is used for the differential diagnosis in case of abortion or with the aim of isolating the circulating B. abortus, melitensis and suis strain.

In addition the animal positive slaughtered are sampled for a bacteriological examination.

The results of all the above examination are considered in an epidemiological investigation that, has provided for in the art. 5 of the M.O. 28 may 2015, the local veterinary service started already at the suspect of the outbreak following apposite guide line.

The epidemiological investigation consider:

a) the results of the laboratory analysis;

b) the analysis of the data, present in the informatic veterinary system (VetINFO) related to status of the establishment, identification of the animals, movement of the animals, persons, tools, epidemiological link with other establishment, link with the dealers, food and water supply.

In case the test is overdue, the status is signalize by the Italian informatics system by apposite functionality (VETINFO) and the local veterinary service than is alerted to perform the control. After six

months, the status is withdrawn.

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

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

#### (max. 32000 chars) :

At the moment the vaccination with the Brucella abortus, abortus, melitensis and suis and suis REV1 vaccine is not planned. However, this option could be consider in some provinces in relation to the epidemiological situation registered of the territory and to the analysis of the persistence factors of the infection.

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

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

#### (max. 32000 chars) :

The EU Reg. 689/2020 at the article 81 specify the criteria on surveillance and biosecurity measures for the maintenance of disease-free status.

In: Section 2 of Chapter 4 of Part I of Annex IV for status free from infection with Brucella abortus, melitensis and suis as regards kept ovine and caprine animals are provided the specific requirements as regards surveillance and biosecurity measures that are implemented to achieve a good level of biosecurity and lower the risk of dissemination of the infection.

2. The status of a Member State or a zone free from infection with B. abortus, melitensis and suis as regards kept ovine and caprine animals is not affected by the confirmation of infection of B. abortus, melitensis and suis in an animal population other than kept ovine and caprine animals provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with B. abortus, melitensis and suis to kept ovine and caprine animals.

The EU Reg. 689/2020 at the article 81 specify the criteria on surveillance and biosecurity measures for the maintenance of disease-free status.

In: Section 2 of Chapter 4 of Part I of Annex IV for status free from infection with Brucella abortus, melitensis and suis as regards kept ovine and caprine animals are provided the specific requirements as regards surveillance and biosecurity measures that are implemented to achieve a good level of biosecurity and lower the risk of dissemination of the infection.

2. The status of a Member State or a zone free from infection with B. abortus, melitensis and suis as regards kept ovine and caprine animals is not affected by the confirmation of infection of B. abortus, melitensis and suis in an animal population other than kept ovine and caprine animals provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with B. abortus, melitensis and suis to kept ovine and caprine animals.

The local competent veterinary service elaborate specific risk assessment/management in other species depending on the type of production, type of breeding, prevalence registered in the area, movement, status, distance from cluster of infection, presence of other species susceptible, presence of wild animal.

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

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

#### (max. 32000 chars) :

Following the measures in case of positive animals and detailed reference to the union legislation provisions.

slaughter

As provided for in the prorogation of the Ministerial Order 28 May 2015, the animals testing positive will be identified, within two days of notification of a positive result, by means of a rumen bolus and then be slaughtered within 15 days of the official notification of a positive result.

destination of carcasses

The carcasses after veterinary inspection are intended to the human consumption.

use or treatment of animal products,

As provided for in the art. 28 of the (EU) REG. 689/2021 the milk from confirmed cases shall either be fed only to animals in the same establishment after it has been processed to ensure the inactivation of the disease agent, or it shall be disposed of;

the destruction of all products which could transmit the disease

In according to the art. 28 of the (EU) REG. 689/2021 point 1 (b), manure, straw, feed or any other matter and substance which has come into contact with a confirmed case or with contaminated material is collected and disposed of as soon as possible or, following an appropriate risk assessment, stored and processed to reduce to an acceptable level the risk of spreading of the disease.

Further more according the art. 28 of the (EU) REG. 689/2021 point 2 in the event of infection with B. abortus, melitensis and suis the competent authority order that in all infected establishments foetuses, still-born animals, animals which have died from the disease after birth and placentae must be collected and disposed of.

a procedure for the disinfection of infected holdings,

In according with the the art. 30 of the (EU) REG. 689/2021, the local veterinary authority order the operators of all infected establishments and those receiving animals from infected establishments the cleaning and disinfection or, where relevant, the safe disposal of:

(a) all parts of the establishments that may have been contaminated after the removal of the confirmed and suspected cases and before repopulation;

(b) any feed, materials, substances, husbandry related equipment, medicinal equipment and production related equipment that may have been contaminated;

(c) any protective clothing or safety equipment used by operators and visitors;

(d) all means of transport, containers and equipment after the transport of animals or products from infected establishments;

(e) loading areas for animals after each use.

2. The local veterinary authority approve the protocol for the cleaning and disinfection.

3. The local veterinary authority supervise the cleaning and disinfection, or where relevant, the safe disposal and do not restore or grant again disease-free status to the establishment until it considers that the cleaning and disinfection, or where relevant, the safe disposal, has been completed.

4. The local veterinary authority may, based on a risk assessment, regard a pasture as contaminated and prohibit its use for kept animals of higher health status than that of the targeted animal population or, if epidemiologically relevant, additional animal populations, for a period of time sufficient to consider the risk of persistence of the disease agent to be negligible.

A procedure for the restocking with healthy animals of holdings, which have been depopulate by slaughter.

The prorogation of Ministerial Order at the annex 2 has provided for specific indications, to the region, for apply the stamping out. These indications should take in account the clinical signs (abortion), the prevalence of serological positivity, the isolation of brucella, the species and the recrudescence of the positivity in the animals kept in the establishment.

"Guidelines stamping-out".

In case of an outbreak of S&G brucellosis the stamping out, can be apply considered the following items: h. a positivity rate of animals more than 5% at the time of the check;

i. positivity in two consecutive controls, after the opening of the outbreak;

j. the livestock health situation in the last two years, paying attention in particular to the causes of the persistence of the infection and the origin of the infection;

k. the isolation of Brucella spp.;

I. the risk of spreading to other farms, also in relation to the type of handling of animals or in relation to the type of farming (pasture stray and / or tethering);

m. failure to comply with current regulations related to: the frequency of tests; the movimentation to mountain grazing / pasture / grazing/ wandering animals; the animals identification, the controls, the lack of cooperation in the activities of prophylaxis prescribed by this decree; as well as the killing of Positive animals within the prescribed period.

n. the health status of the adjacent territory.

After slaughtering of all the infected animals and before the farm is restock, the pens and other buildings used to house the animals, as well as the containers, equipment and tools used for the animals, must be cleaned and disinfected under official supervision; the veterinarian will issue the certificate of disinfection. The pasture previously used by those animals cannot be reused for 60 days after they have been removed. All means of transport, containers and equipment must be cleaned and disinfected, under official supervision.

The ovine or caprine for the repopulation of the establishment should originate from establishments free from infection with B. abortus, melitensis and suis without vaccination, or free with vaccination and have not been vaccinated against infection with B. abortus, melitensis and suis during the past 3 years, and

(i) originate from a Member State or a zone free from infection with B. abortus, melitensis and suis for the relevant animal population;

(ii) are entire ovine or caprine animals over 6 months of age and must have tested negative in a serological test carried out on a sample taken:

— during the 30 days prior to their introduction into the establishment; or

- during the 30 days following their introduction provided they have been kept isolated during this

period;

or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested

negative in a serological test carried out on a sample taken not earlier than 30 days after parturition.

A definition of a suspicion and of a confirmation should be provide, with detailed measures implemented in both situation and how the herd is requalified as free after a positive result. An establishment keeping ovine or caprine is suspected of infection with with B. abortus, melitensis and suis without vaccination or with vaccination if:

a) serological testing are not carried out with negative results on samples taken from:

(i) all entire ovine or caprine animals over 6 months of age at appropriate intervals of not more than 12 months determined by the competent authority, taking into account the type of production, the situation of the disease and the identified risk factors; or

(ii) entire entire ovine or caprine animals over 6 months of age kept in establishments located in a Member State or in a zone free from infection B. abortus, melitensis and suis in accordance with a testing regime set up taking into account the type of production and the identified risk factors. or

a case of infection with B. abortus, melitensis and suis is suspected in a ovine or caprine animal kept in the establishment.

or when the following requirement are not fullfilled:

(a) during the past 12 months there has been no confirmed case of infection with B. abortus, melitensis and suis

in ovine or caprine animals kept in the establishment;

(d) animals showing clinical signs consistent with infection with B. abortus, melitensis and suis such as abortions,

have been subjected to investigations with negative results;

(e) since the beginning of the sampling referred caprine animals introduced into the establishment originate from establishments free from infection with B. abortus, melitensis and suis without vaccination, or free with vaccination and

(i) originate from a Member State or a zone free from infection with, B. abortus, melitensis and suis for the relevant animal population;

(ii) are entire ovine or caprine animals over 6 months of age and must have tested negative in a serological test carried out on a sample taken:

- during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction provided they have been kept isolated during this period;

or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and

(f) all germinal products of bovine, ovine or caprine origin introduced into or used in the establishment originate from:

(i) establishments free from infection with B. abortus, melitensis and suis without vaccination; or (ii) approved germinal product establishments.

g) there are no epidemiological link with an outbreak of brucella abortus, melitensis and suis;

Furthermore, in accordance with the Ministerial Order 28 may 2015, the local veterinary authority in cases of suspected replacement of animals, suspected identification alteration, suspected unauthorized

movement, suspected malicious spread of infectious disease or suspected unauthorized vaccination or suspected use of pharmacologically active substances designed to mask the results of diagnostic tests, suspends the status of "establishment free without vaccination or with vaccination" of the holding concerned and any compensation procedures in progress and carries out all the checks deemed necessary.

An animal is suspected of brucella abortus, melitensis and suis when: show clinical sign (abortion), give doubt result at the RBT test; is positive at RBT test and negative at CFT test. An animal is confirmed infected with brucella meiltensis when: from his abortion or from his carcass (if slaughtered) has been isolated the b. abortus, melitensis and suis; when result positive at RBT test and at CFT test in presence of clinical signs or epidemiological link or positive results at brucellin test. Furtermore the ovi-caprine kept in an outbreak are infected when result positive only at the RBT test.

In a confirmed outbreak all the positive ovi-caprine are slaughtered and on their carcasses are done microbiological analisys to try to isolate the b. abortus, melitensis and suis for genotipization for epidemiological enquire porpose. In the outbreak every 21 days the local veterinary authority perform controls on the rest of animal kept in the establishment with the porpose to remove all the animal positive till when, the results of the serological tests on the entire flock results negative.

The status of free without or with vaccination is regained if the entire ovine or caprine animals over 6 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:

(i) the first 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 in an immunological test;

(ii) the second 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 to in point (i);

Detailed information should also be provide as regard the epidemiological investigations done, and the additional laboratory tests foreseen

Already at the suspicious the prorogation of a Ministerial Order 28 May 2015, provide for that within 2 days from the suspicious or positivity confirmation, the local Veterinary Service in collaboration with the regional Veterinary Service or the local competent Laboratorie (Istituto Zooprofilattico Sperimentale) have to carry out an epidemiological investigation with the aim of confirm, manage and close the outbreak as soon as possible, investigating the origin of the infection and verifying the possibility of any contact with other farms

In the establishment epidemiologically linked with the outbreak all the susceptible animals are tested. The epidemiological investigation is register in the appropriate Information Systems (SIMAN) and according to the prorogation, of the Ministerial Order 28 May 2015 the person in charge of the Animal Health Veterinary Service verifies, at least every 4 months, the compliance of epidemiological investigations execution timing with the regulations in force. The National Reference Centre for Animal Brucellosis carries out periodically an extraction from SIMAN of a significant number of epidemiological investigations aimed to verify their quality and completeness. Twice a year is programmed the monitoring of the E.E. by the National Centre of Reference for Brucellosis. A special dashboard is in available on VETINFO to perform automatically the extraction of the data from the SIMAN System.

#### Identification of genetic clusters

Some research conducted at the National Center of Reference for Brucellosis has allowed the identification of genetic clusters with specific geographic spreads. For example, it is important to note that some genetic clusters are exclusively present in some geographic areas as in some Sicilian and Calabrian provinces. In conclusion, the molecular epidemiology methodologies implemented by the

National Reference Center allow to analyze the Brucella strains by determining their genetic variants and to report them to the global and local epidemiological context. This helps to support epidemiological investigations in order to determine the dynamics of outbreaks by monitoring their temporal evolution.

### 4.4.10 Compensation scheme for owners of slaughtered and killed animals

#### (max. 32000 chars) :

The value of the compensation is set, and updated annually, by the Ministry of Health, in agreement with the Ministry of Agricultural Policy and the Financial Ministry, after market values have been determined (Article 6 of Law No 296/81).

To respond at the outcome of the visit of the follow-up of the implementation of the sheep and goat eradication programme of the DGSANTE held in Sicily from the 18 to 21 March 2013 where was reported in one point that "the compensation to be paid to owners for the value of their animals slaughtered under the programme fixed at national level is significantly higher than the market value in Sicily for sheep and goats and this as agreed with the veterinary services met on the spot, has a negative impact on the performances of the programme"; the Ministry of Health and the Ministry of Agriculture have done a Decree for compensation in 2015 that reduce at 35% of the market value (which is equivalent to 90 euros more or less.) the price of reimbursement of the sheep and goats over 6 years old . Since then, this measure is extended every year with the release of the Decree of Compensation.

Proceeds from the sale of slaughtered animals are paid to the farmer by the trader who purchased them. Furthermore, Law No 218/88 provides for increases (up to a maximum of 40% of the compensation due) if a high percentage of the stock has to be slaughter.

The regions and the ASLs must take all the necessary measures to ensure compliance with the deadlines laid down in the art.8 of the Ministerial Order 28 may 2015, for paying compensation to farmers.

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

Please indicate also when the last FVO audit has taken place and provide a table listing the recommendations and the actions taken by the national authorities to this regard.

Please mention if a Task Force subgroup visit has taken place and the state of play as regards the implementation of the recommendations suggested if any.

#### (max. 32000 chars) :

Commission Implementing Regulation (EU) 2002/2020 provides for the deadlines for Member States to submit eradication programmes and Union surveillance programmes.

At national level the implementation of the eradication programme is monitored by the Central Authority, the Regional Authority and the Local Authority.

The Ministerial Order 28 may 2015 provided all the measures for a correct monitoring of the plan: programming, inserting of data, verification of the controls performed, using the veterinary informatic system (VETINFO). This system is compose from sub-systems that have different functionality: -BDN, is the system where the veterinary services charge all the data for the identification of the establishments and for the identification of the animals. The animals are identify individually and electronically.

-SANAN, is the management system of the local veterinary Authority. In this system is inserted the scheduled of the activities at the beginning of the year and all the controls performed day by day during

#### the year.

-SIMAN, is the system where the local veterinary Authority charge all the information regarding outbreaks and elaborate electronally the epidemiological enquire;

- SISTEMA CONTROLLI, is the system where the local veterinary authority charge the data of the check list of the controls performed on dealers.

All the data inside these above mentioned system are elaborated every week by a statistic program that give, to the locale veterinary authority, the regional authority, laboratories (Istituti Zooprofilattici Sperimentali) and the Central Autority by a DASHBOARD, an analysis of the controls performed showing by specific indicators (prevalence, incidence, controls performed, dealers, movement cheks, outbreaks, epidemiological enquires done, etc).

The Ministerial Order 28 may 2015 provided for at the art, 12 that the local veterinary Authority perform every 4 months a check on the DASHBOARD, for the verification of the efficacy of the controls related at the application of the program of eradication for brucella abortus, melitensis and suis.

Furthermore for the monitoring of the application of the program are performed Audits and inspections of the Ministry of Health on the Regional Authorities and by these, on the Local veterinary Authorities.

AUDIT FVO and actions taken to respond at the recommendations.

During the GENERAL FOLLOW-UP AUDIT held in Italy in March 2021 - ref 2021-7155 all the Recommendations regarding the Audit FVO on brucellosis program and TB program (2013-6979) have been close.

### 5. Benefits of the programme

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

progress expected compared to the situation of the disease in the previous years, in line with the objectives and expected results

cost efficiency of the programme including management costs

#### (max. 32000 chars) :

The eradication programme makes provision for specific costs of the services of self-employed veterinarians, reimbursement of the IZSs that carry out the serological tests, the disinfection of premises on infected holdings and compensation to farmers for animals slaughtered during the eradication operations.

There has been progress in the eradication process in the last years. More territories have been declare free and. The declaration of status free of new Italian territories will bring a large numbers of benefit at the Country in terms of trade of the animal products that will increase; movements of animals and animal products that will be facilitated; veterinary resource that may be addressed to eradicate the disease in the hot spot. All this benefits will anyway bring at the principal target of the eradication of the disease that means the availability of higher quality, safer foodstuffs, which will eliminate the negative impact of this zoonosis on human health.

Targets 7.

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

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

### 7.1.1 Targets on diagnostic tests for year: **2023**

Region	Type of the test	Target population	Type of sample	Objective	Number of planned tests	
BASILICATA	Rose Bengal test	Sheep and goat	blood	seroconversion	200 786	Х
CALABRIA	Rose Bengal test	Sheep and goat	blood	seroconversion	155 000	Х
CAMPANIA:	Rose Bengal test	Sheep and goat	blood	seroconversion	168 747	Х
PUGLIA	Rose Bengal test	Sheep and goat	blood	seroconversion	137 000	Х
SICILIA	Rose Bengal test	Sheep and goat	blood	seroconversion	762 683	Х
BASILICATA	complement fixation test	Sheep and goat	blood	seroconversion	10 500	Х
CALABRIA	complement fixation test	Sheep and goat	blood	seroconversion	3 200	Х
CAMPANIA	complement fixation test	Sheep and goat	blood	seroconversion	7 548	Х
PUGLIA	complement fixation test	Sheep and goat	blood	seroconversion	5 250	Х
SICILIA	complement fixation test	Sheep and goat	blood	seroconversion	118 757	Х
CAMPANIA	bacteriological test	Sheep and goat	milk, foetus, organs	confirmation of suspected cases	34	Х
SICILIA	bacteriological test	Sheep and goat	milk, foetus, organs	confirmation of suspected cases	340	X

SICILY	PCR	Sheep and goat	milk, foetus, organs	confirmation of suspected cases	170	
				Total	1 570 015	
				Add a new row		
					Total number of tests	
				Total number of tests	1 570 015	
				Rose Bengal test	1 424 216	
				complement fixation test	145 255	
				bacteriological test	374	
				PCR	170	

7.1.2 Targets on testing herds and animals

7.1.2.1 Targets on the testing of herds for year: **2023** 



Region	Animal species	Total number of herds	Total number of herds under the programme	Number of herds expected to be checked	Number of expected positive herds	Number of expected new positive herds	Number of herds expected to be depopulated	% positive herds expected to be depopulated	Expected % herd coverage	% positive herds Expected period herd prevalence	% new positive herds Expected herd incidence		
BASILICATA	Sheep and goats	5 389	5 389	5 389	0	0	0	0,000	100,000	0,000	0,000	Х	
CALABRIA	Sheep and goats	3 654	2 492	2 492	0	0	0	0,000	100,000	0,000	0,000	Х	
CAMPANIA	Sheep and goats	6 092	4 782	4 782	2	2	0	0,000	100,000	0,042	0,042	Х	
PUGLIA	Sheep and goats	1 589	1 480	1 480	3	3	2	66,667	100,000	0,203	0,203	Х	
SICILIA	Sheep and goats	8 929	8 190	8 190	38	38	8	21,053	100,000	0,464	0,464	х	
Total		25 653	22 333	22 333	43	43	10	23,256	100,000	0,193	0,193		
									Add a new row				

### 7.1.2.2 Targets on the testing of animals for year : **2023**

							Slaug	ntering	Target ir		
Region	Species	Total number of animals	Number of animals under the programme	Number of animals expected to be tested	Number of animals to be tested individually	Number of expected positive animals	Number of animals with positive result expected to be slaughtered or culled	Total number of animals expected to be slaughtered	Expected % coverage at animal level	% positive animals (Expected animal prevalence)	
BASILICATA	Sheep and goats	219 831	190 786	190 786	190 786	0	0	0	100,000	0,000	Х
CALABRIA	Sheep and goats	153 346	150 164	150 164	150 164	0	0	0	100,000	0,000	Х

CAMPANIA	Sheep and goats	172 305	168 438	168 438	168 438	3	3	3		100,000	0,002	Х
PUGLIA	Sheep and goats	135 100	134 400	134 400	134 400	20	20	150		100,000	0,015	Х
SICILIA	Sheep and goats	800 488	784 267	784 267	784 267	2 026	2 026	2 426		100,000	0,258	Х
Total		1 481 070	1 428 055	1 428 055	1 428 055	2 049	2 049	2 579		100,000	0,143	
								Ac	dd a n	new ro	w	
			Total number of	f animals expected	to be slaughtered a			2 579				
Total number of animals expected to be slaughtered or culled : SHEEP AND GOAT Total number of animals expected to be tested												

### 7.2 Targets on qualification of herds and animals

### 7.2 Targets on qualification of herds and animals for year: **2023**

Targets on the status of herds and animals under the programme Expected not free or not free from disease Total number of herds Expected free or officialy and animals under the free from disease status Expected free from Expected officially free Last check positive from disease Expected unknown Last check negative suspended disease programme Herds Animals Region Animal species

												Add a new row				
Total		22 515	1 431 593	12	45	62	5 453	284	9 120	119	7 116	////1	15	22 157	1 416 975	
SICILIA	Sheep&goats	8 205	787 246	0	0	60	5 353	22	2 753	59	5 071	1	15	8 123	779 140	Х
PUGLIA	Sheep&goats	1 480	134 400	0	0	2	100	0	0	6	50	0	0	1 478	134 300	Х
CAMPANIA	Sheep&goats	4 782	168 438	0	0	0	0	60	1 000	27	650	0	0	4 722	167 438	Х
CALABRIA	Sheep&goats	2 659	150 723	12	45	0	0	202	5 367	27	1 345	0	0	2 445	145 311	Х
BASILICATA	Sheep & goats	5 389	190 786	0	0	0	0	0	0	0	0	0	0	5 389	190 786	X

### 7.3 Targets on vaccination or treatment

### 7.3.1 Targets on vaccination or treatment for year : **2023**

					Targets on vaccination or treatment programme						
Region	Animal species	Total number of herds in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Number of herds in vaccination or treatment programme	Number of herds expected to be vaccinated or treated	Number of animals expected to be vaccinated or treated	Number of doses of vaccine or treatmentexpected to be administered		Number of young animals expected to be vaccinated		
										X	
Total							0				
						A	dd a new ro	w			

### 8.2. Financial informaton

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

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursement/payment claim to the EU. Describe the financial flows/circuits followed.

Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who performs the official sampling? Who pays?

(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

(max. 32000 chars) :

In Italy the sampling is performed from state veterinarians that work in a local veterinarian unit called ASL or ASP. In some Regions, private veterinarians

are called to support the state veterinarians in their work. These veterinarians have private contracts calculated in hours per week of work. They are paid, as well as the state veterinarians, from the Regions using their sanitary fund.

For state prevention operations relating to brucellosis in cattle and buffaloes, ovine and caprine brucellosis and tuberculosis, the regions use the resources allocated by the Treasury to the National Health Fund.

Under the legal and economic framework governing the National Health Service, all such expenses incurred are paid out of the National Health Fund's appropriations.

The share of that fund due to the individual regions is credited to them from year to year as a lump sum; that is to say, the total amount is used to run the entire regional health service (the region in turn distributes the amount to the individual ASLs), of which the veterinary service constitutes only a very small part.

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

#### (max. 32000 chars) :

In Italy the testing are performed from public Laboratories called IZS (Istituti Zooprofilattici Sperimentali). Also these Institutes are financiated from the Regions using their sanitary fund.

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

(max. 32000 chars) :

The compensation of the animals positive a the tests for brucellosis, are paid from the Local veterinary Public Servise Called ASL or ASP. They use regionals fund that are resources allocated by the Treasury to the National Health Fund.

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

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

(max. 32000 chars):

AT THE MOMENT, IN ITALY HAS NOT BEEN PLANNED ANY VACCINATION FOR SHEEP AND GOATS BUT IS NOT EXCLUDED THAT IN SOME "HOT SPOT", (AREAS WITH HIGH PREVALENCE) MAY BE USE AS STRATEGIES TO CONTAIN THE INFECTION. WE WILL INFORM ON THAT CASE.

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

(max. 32000 chars) :

For all the operations related to state prevention relating to ovine and caprine brucellosis the regions use the resources allocated by the Treasury to the National Health Fund.

#### 2. Source of funding of eligible measures

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

⊠yes □no

#### 3. Additional measures in exceptional and justified cases

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

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

Cofinancing proposal, for a plan for disposal of endoruminal boluses.

Italy has used the electronic identification for bovine / buffalo and sheep & goat, since 2006, year of enactment of the Ordinance of the Ministry of Health "Extraordinary Measures veterinary police regarding tuberculosis, brucellosis and bovine buffalo, sheep and goat brucellosis, enzootic in Calabria, Campania, Puglia and Sicily ", by adopting specifically the rumen bolus ceramic as containing an electronic device able to guarantee the certainty of the identification of animals especially in herds at pasture.

That position was later confirmed in the ordinances issued August 9, 2012 and May 28, 2015.

The massive use of this device, that after death / killing / slaughter of the animals must be recovered and kept by the competent veterinary service, resulted in an accumulation of about 165,000 ceramic bolus (approximately 10 tons) at the slaughterhouse and the veterinary services waiting for directives about the correct way of disposal of them.

Till now the disposal of such endoruminal boluses has taken in some regions an emergency character, primarily from the point of view of safety of their custody (possible theft and re-use for the identification of animals not declared), thus making it urgent to find a solution for the disposal of the same.

In Italy the Ordinance of the Ministry of Health have introduced the mandate of using endoruminal boluses on the basis of the recommendations of the European Commission, in order to improve animals identification and therefore enhance the plans for the eradication of Brucellosis. In this respect it would therefore helpful if the European Commission may consider: the disposal endoruminal boluses, their recover, kept and distruction; an indispensable voice of cost of the program, and consider the possibility to co-financy the use of it, in the next the Guidelines for co-financed programs for the eradication, control and monitoring of animal diseases and zoonoses. ++++"Furthermore, we would like to underline that Italy has invested a big amount of resource to develop informatics veterinary systems with the aim of

+++"Furthermore, we would like to underline that Italy has invested a big amount of resource to develop informatics veterinary systems with the aim of better monitor the program. This investment has been at central, Regional and local levels and has asked a lot of energy in terms of economic as well as of human resource. The veterinary informatics systems are implemented by the veterinarians of the local veterinary unit that are not only in duty for sampling the animals but are also responsible of the implementation, quality control and analysis of the data charged in the systems. To do this work they utilize a large amount of time that is not calculate at the aim of co-financing. Also at regional and central level the implementation and the analysis of the data charged in the systems request a big amount of time for their correct use. The veterinarian work, to implement an eradication program is changed and is not only done of samplings and analysis of the flocks but is composed from these elements more the informatics needs for the constant control of the program. We wish that the Commission will take in consideration the evolution of the veterinarian work in relation of the development of the informatics need and start to consider a way to co-financing these measures."

### **Attachments**

#### IMPORTANT :

1) The more files you attach, the longer it takes to upload them .

2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.

3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.

4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!

5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

### List of all attachments

Attachment name	File will be saved as (only a-z and 0-9 and) :	File size
18883_14519.pdf	18883_14519.pdf	690 kb
18883_14520.pdf	18883_14520.pdf	412 kb
18883_14521.pdf	18883_14521.pdf	203 kb
18883_14522.pdf	18883_14522.pdf	184 kb
18883_14523.pdf	18883_14523.pdf	142 kb
18883_14524.pdf	18883_14524.pdf	186 kb
18883_14525.pdf	18883_14525.pdf	29 kb

	18883_14526.pdf	18883_14526.pdf	184 kb
	18883_14527.pdf	18883_14527.pdf	185 kb
	ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
		Total size of attachments :	2502 kb

The total size of the attachments is more than 5 MB. You should delete some attachments, otherwise submission won't work.