



submitted for obtaining EU financial contribution

Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies

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Document version number: 2022 1.0

Member state : MALTA

Disease Transmissible Spongiform Encephalopathies

This program is multi annual :

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

1. Contact data

Name	Phone
Email	Your job type within the CA :

Submission Date

23/05/2022 13:25:00

Submission Number

1653305102410-18269



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2. Description of the programme

Please give a short description of the programme (max. 32000 chars) :

In accordance to EU Directives 999/2001/EC and 1041/2006 screening for TSE's has been carried out since March 2001, using the Enfer® test. In October 2002, the Division changed to Bio-Rad TeSeE® detection kit. A contract has been signed with the VLA – Weybridge (UK) for the performing of histopathological and immunocyto-chemistry examination of positive samples. Testing is carried out on Bovine, Ovine and Caprine species. Community financial participation is not being requested for the implementation of the breeding programme for the resistance to TSE in Sheep (decision 2003/100/EC).

The objective of the programme includes:

- Achieving harmonization with other EU countries in veterinary control and surveillance programmes;
- The strengthening of veterinary epidemiological surveillance measures in accordance with EU legislation;
- Ensuring the early recognition of TSEs within the local animal population;
- The rapid implementation of investigation protocols with all relevant restrictions on the movement of animals and animal products coming into force until confirmatory results are received.

Monitoring in bovine animals:

The aim of the programme in bovine animals is the implementation of the surveillance programme for BSE as detailed in ANNEX III, Chapter A, (I) of Regulation 999/2001 as amended.

Brain samples for BSE testing will be taken from all bovines of the following groups:

- bovines exhibiting clinical signs of neurological disease
- dead animals over the 48 months of age (central carcass disposal centre)
- emergency slaughtered animals over 48 months of age
- animals over 48 months of age with clinical signs at ante-mortem

The objectives of the programme in small ruminants are:

- a. To implement a TSE monitoring and surveillance programme as laid down in Reg. (EC) 999/2001
- b. To identify the presence scrapie infected animals in the national flocks

100 dead ovines and 100 dead caprines will be sampled. These animals will be sampled at the central carcass disposal centre. Older animals will be targeted among this population.

3. Description of the epidemiological situation of the disease

Last year's No of cases	Total No	No of classical cases	No of atypical cases	No of undetermined cases
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BSE case	0	0	0	0
Scrapie case (ovine)	0	0	0	0
Scrapie case (caprine)	0	0	0	0
Last case of		date (classical case)	date (atypical case)	date (undetermined case)
BSE				
Scrapie (ovine)				
Scrapie (caprine)				

Comments (if any)

4. Measures included in the programme

4.1 Designation of the central authority in charge of supervising and coordinating the departments responsible for implementing the programme

(max. 32000 chars) :

Designation of the central authority charged with supervising and coordinating the departments responsible for implementing the programme

- The Veterinary Regulation Directorate is the Competent Authority based in Malta responsible for Veterinary regulation, administration, laboratory testing, sampling and collecting of data in Malta.
- Ministry of Gozo (Veterinary Division): responsible for sampling in Gozo.

The National Veterinary Laboratory functions both as a National Reference Laboratory and as a Testing Laboratory. All testing for TSE's in Malta and Gozo is carried out by the NVL.

4.2 Description and delimitation of the geographical and administrative areas in which the programme is to be applied

(max. 32000 chars) :

- The surveillance programmes shall apply to the Islands of Malta and Gozo (one region);
- There is a lack of extensive grazing land available;
- Average farm size is 0.5 hectares;
- Livestock is reared on farms having a higher stocking density than would apply to an extensive system.

4.3 System in place for the registration of holdings

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(max. 32000 chars) :

Veterinary Services Act, section 7
Swine Keeping Regulations S.L. 36.28 section 3
Milking Animals Regulation S.L. 36.32 section 3
Poultry Breeding Stock Regulation S.L. 36.40 section 3

All livestock holdings are registered with the Veterinary Regulation Directorate. Milk producing herds are allotted a unique herd number (churn number), while non milk producing herds are allotted a unique premises number. All the information pertinent to each farm is also kept on the National Herd database, Intertrace. This system covers all bovine, ovine and caprine holdings in Malta and Gozo.

4.4 System in place for the identification of animals

(max. 32000 chars) :

European Union Act, Chapter 460 of the laws of Malta, section 3-4
Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council regulation (EC) No 820/97
Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals (amended by OJ L 005 09.01.2004 p.8)
Control of marking of animals regulation S.L. 36.17 sections 2-3
Undulant fever (prevention) regulation S.L. 36.04 section 4

All bovine, caprine and ovine animals are individually tagged with two ear-tags and all the information is digitally stored in Intertrace. The transfer or movement of animals from one holding to another can only be done with the authorisation of the Competent Authority. A farm census is carried out between once and twice a year in conjunction with Brucella and TB testing.

4.5 Measures in place as regards the notification of the disease

(max. 32000 chars) :

The Veterinary Service Act (ACT XXIII of 2001, as amended by Act XVIII of 2002; Legal Notice 426 of 2007; and Act XXIII of 2009) states:

Art. 6. Notification of diseases- (1) The Department shall, within twenty-four hours of each such occurrence, notify trading partners about -

(a) the primary outbreak, confirmed in Malta, of any of the diseases listed in the Second Schedule; and
(b) the removal, after the eradication of the last case in an outbreak, of restrictions imposed in relation to the outbreak of the disease.

(2) Without prejudice to the provisions of subarticle (1), the Department shall notify directly to the trading partners, at least on the first working day of each week, the secondary outbreaks of any of the diseases listed in the Second Schedule which are confirmed in Malta. The aforesaid notification shall cover the week ending at midnight between the Sunday and Monday prior thereto.

(3) The notifications referred to in subarticles (1) and (2) shall be communicated in such a manner as may be determined by the Director.

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Diseases which are the subject of the notification referred to in article 6

Foot-and-mouth disease

Rinderpest (cattle plague)

Contagious bovine pleuropneumonia

Bluetongue

Swine vesicular disease

Classical swine fever

African swine fever

Porcine enterovirus encephalomyelitis (was Teschen disease)

Avian influenza (was fowl plague)

Newcastle disease

African horse sickness

Vesicular stomatitis

Peste des petits ruminants

Rift Valley Fever

Lumpy skin disease

Sheep and goat pox (Capripox)

Infectious hematopoietic necrosis

Bovine spongiform encephalopathy

The subsidiary legislation 437.42 'Prevention, control and eradication of certain transmissible spongiform encephalopathies regulations' (LEGAL NOTICE 58 of 6th February, 2004) states:

Art. 3. Definitions (1) For the purposes of these regulations the following definitions shall apply -

(a) "animal suspected of being infected by a TSE" means live, slaughtered or dead animals, which show or have shown neurological or behavioural disorders or a progressive deterioration of the general condition linked to impairment of the central nervous system and for which the information gathered on the basis of a clinical examination, response to treatment, a post-mortem examination or an ante or post-mortem laboratory analysis do not allow an alternative diagnosis to be established. Bovine spongiform encephalopathies (BSE) shall be suspected in bovine animals which have produced a positive result from a rapid test specifically for BSE;

Art.11. Notification -Without prejudice to European Union Council Directive 82/894/EEC, the territory of Malta shall ensure that any animal suspected of being infected by a TSE is notified immediately to the Veterinary Services. The Veterinary Services shall without delay take the measures laid down in regulation 12, together with any other necessary measures.

Since March 2015 the VRD has put in place an emergency service designed to ensure the presence of a Veterinarian during on farm slaughter. This service enables the Competent Authority to examine and identify animals which fall within the higher risk category and thus alert the Competent Authority in the case of animals showing symptoms of the disease.

4.6 Testing

4.6.1 Rapid tests in bovine animals

Targets for year

2023

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	Age (in months) above which animals are tested	Estimated number of animals to be tested	Estimated number of rapid tests, including rapid tests used for confirmation
Healthy slaughtered bovine animals born in Ms listed in Annex to CD2009/719/EC	72	0	0
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	240	250
Healthy slaughtered bovine animals NOT born in MS listed in Annex to CD 2009/719/EC	30	0	0
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	0	0
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)		0	0

4.6.2 Rapid tests on small ruminants

The sampling rules applicable for the monitoring of ovine and caprine animals slaughtered or not for human consumption (described below as healthy slaughtered/dead animals) are in compliance with provisions of Annex III, II, 4 of Regulation (EC) No 999/2001, in particular:

- Animals are over 18 months of age or have more than two permanent incisors,
- No over-representation of any group (origin, age, breed, production type, etc),
- Sampling representative of each region and season,
- Multiple sampling in the same flock avoided whenever possible,
- A system is in place to ensure that in successive sampling years, all officially registered holdings with more than 100 animals where TSE cases have never been detected are subject to TSE testing,
- A system is in place to check that animals are not being diverted from sampling (except derogation communicated to the Commission):

yes

no

If no please explain.

4.6.2.1 Rapid tests on ovine animals

Estimated population of adult ewes and ewe lambs put to the ram.

10 500

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Targets for year **2023**

	Estimated number of animals to be tested
Healthy slaughtered ovine animals (a)	0
Dead ovine animals (b)	100
In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III and VII of the TSE regulation	
Ovine animals from holdings affected by classical scrapie	0
Ovine animals from holdings affected by atypical scrapie	0
Ovine animals from holdings affected by BSE	0
Suspect animals (c)	0
Total number of tests	100

(a) Annex III, A, II, 2 of the TSE regulation

(b) Annex III, A, II, 3 of the TSE regulation

(c) Art 12 of the TSE regulation

4.6.2.2 Rapid tests on caprine animals

Estimated population of female goats and female kids mated .

4 500

Targets for year **2023**

	Estimated number of animals to be tested
Healthy slaughtered caprine animals (a)	0
Dead caprine animals (b)	100
In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III and VII of the TSE regulation	
Caprine animals from holdings affected by classical scrapie	0
Caprine animals from holdings affected by atypical scrapie	0
Caprine animals from holdings affected by BSE	0
Suspect animals (c)	0
Total number of tests	100

(a) Annex III, A, II, 2 of the TSE regulation

(b) Annex III, A, II, 3 of the TSE regulation

(c) Art 12 of the TSE regulation

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4.6.3 Confirmatory tests **other than rapid tests** as referred to in Annex X Chapter C of Regulation (EC) No 999/2001

Targets for year **2023**

	Estimated number of tests
Confirmatory tests in Bovine animals	0
Confirmatory tests in Ovine and Caprine animals	0

4.6.4 Discriminatory tests (Annex X.C point 3.1 (c) and 3.2 (c)(i) of Regulation (EC) No 999(2001)

Targets for year **2023**

	Estimated number of tests
Primary molecular testing on bovine animals	0
Primary molecular testing on ovine and caprine animals	0
Total	0

4.6.5 Genotyping of positive and randomly selected animals

Adult sheep population

More than 750,000 animals

Less than or equal to 750,000 animals

Targets for year **2023**

	Estimated number
Genotyping of TSE cases	0
Random genotyping	0

4.7 Eradication

4.7.1 Measures following confirmation of a TSE case in bovine animals

4.7.1.1 Description

(max. 32000 chars) :

Veterinary Services Act, Chapter 437 of the laws of Malta, sections 5 and 6
Prevention Control and Eradication of Certain TSE's, L.N. 58/2004, regulation 11
Prevention of Disease Ordinance, Chapter 36 of the laws of Malta, section 68.
There have not been any cases of BSE in the Maltese Islands.

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1. When the presence of a BSE has been officially confirmed, the following measures shall be applied immediately in accordance with requirements set up in Regulation European Parliament and of the Council (EC) No 999/2001:

(a) all parts of the body of the animal shall be completely destroyed in accordance with Annex V apart from material retained for records in accordance with Annex III, Chapter B, III, 2 ;

(b) an investigation shall be carried out to identify all animals at risk in accordance with Annex VII, point 1;

(c) all animals and products of animal origin referred to in Annex VII, point 2, that have been identified as being at risk by the investigation referred to in (b), shall be slaughtered and completely destroyed in accordance with Annex V, points 3 and 4.

2. Pending the implementation of the measures referred to in paragraph 1(b) and (c), the holding on which the animal was present when the presence of a TSE was confirmed shall be placed under official control and all movement of animals susceptible to TSEs and products of animal origin derived from them from or to the holding shall be subject to authorisation by the competent authority, with a view to ensuring immediate tracing and identification of the animals and products of animal origin concerned. If there is evidence that the holding where the affected animal was present when the TSE was confirmed is not likely to be the holding where the animal was exposed to the TSE, the competent authority may decide that both holdings or only the holding of where the first case was detected shall be placed under official control.

3. Following the investigation, owners may be compensated for the loss of the animals that have been killed or products of animal origin destroyed in accordance with Article 12(2) and paragraph 1(a) and (c).

4. The confirmed presence of any TSE shall be immediately notified to the Commission and to the OIE.

4.7.1.2 Summary table

Targets for year

2023

	Estimated number
Bovine animals culled and destroyed	0

4.7.2 Measures following confirmation of a TSE case in ovine and caprine animals

4.7.2.1 Description

(max. 32000 chars) :

being at risk by the investigation referred to in (b), shall be slaughtered and completely destroyed in accordance with Annex V, points 3 and 4.

2. Pending the implementation of the measures referred to in paragraph 1(b) and (c), the holding on which the animal was present when the presence of a TSE was confirmed shall be placed under official control and all movement of animals susceptible to TSEs and products of animal origin derived from

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them from or to the holding shall be subject to authorisation by the competent authority, with a view to ensuring immediate tracing and identification of the animals and products of animal origin concerned. If there is evidence that the holding where the affected animal was present when the TSE was confirmed is not likely to be the holding where the animal was exposed to the TSE, the competent authority may decide that both holdings or only the holding of where the first case was detected shall be placed under official control.

3. Following the investigation, owners may be compensated for the loss of the animals that have been killed or products of animal origin destroyed in accordance with Article 12(2) and paragraph 1(a) and (c).

4. The confirmed presence of any TSE shall be immediately notified to the Commission and to the OIE.

4.7.2.2 Summary table

Targets for year

2023

	Estimated number
Ovine and caprine animals culled and destroyed (due to classical scrapie)	0
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	0
Genotyping tests - monitoring and eradication measures	0

4.7.3 Breeding programme for resistance to TSEs in sheep

4.7.3.1 General description

Description of the programme according to the minimum requirements set out in Annex VII, Chapter B of Regulation (EC) No 999/2001

(max. 32000 chars) :

Malta does not have a breeding programme for the Resistance of TSE in sheep

4.7.3.2 Summary table

Targets for year

2023

	Estimated number
Ewes to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	0
Rams to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	0
Total	0

5. Costs

5.1 Detailed analysis of the costs

(max. 32000 chars):

Tse testing will be carried out by the National Veterinary Laboratory.

The test used will be the IDEXX herd check ELISA kit which will be used for both bovine, ovine and caprine animals.

Sampling is carried out by Veterinary auxiliaries who are supervised by an official Veterinarian on the slaughter line. There is no cost involved in sampling and transporting of samples to the National Veterinary Laboratory due to its close proximity to the slaughter house.

It is estimated that a total of 240 samples will be tested from bovine animals, while it is estimated that 100 samples of ovine and 100 samples from caprines will be tested.

The average cost of each ELISA test is estimated at 30 Euro for a bovine test and 10 Euro for an ovine/caprine test. This depends on the number of tests being carried out at one particular time or other.

Bovine

Animals referred to in Annex III, Chapter A, Part I, point 2.1, 3 and 4 of Regulation (EC) No 999/2001 = 240 samples@

Ovine and Caprines

Ovine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001= 100 samples@

Caprine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001 =100 samples@

Western Blot

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A number of samples (ovine, caprine and bovine) will be tested using the western blot technique. These samples will consist mainly of negative samples previously tested using the ELISA kit.

The cost of this testing will amount to Euro per test, 10 bovine, 10 ovine and caprine are planned to be tested. The total amount of this testing is estimated at Euro

5.3. Financial information

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):

The program will be under the supervision of the Veterinary Regulation Directorate as the Competent Authority. The National Veterinary Laboratory will have the role of testing and coordinating the sampling program. Sampling is carried out by the Official Veterinarians and their Auxiliaries. As described earlier samples from "higher risk animals" such as on farm slaughter animals are sampled by the veterinarian on duty, who is employed by the Competent Authority, and delivered to the NVL. All fallen animals are collected at a central incineration plant where the OV and his Auxiliaries sample all eligible

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animals prior to incineration. All officers involved in sampling or employed by the Competent Authority and are paid through public funds i.e. from State Budget. All sampling equipment and sampling disposable are purchased and supplied by the NVL and thus paid for from public funds/NVL budget.

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 the Maltese island there is only one Veterinary Laboratory, this laboratory falls under the responsibility of the VRD. The NVL fulfills the role of both National Reference Laboratory and that of testing laboratory.
All samples for TSE testing regardless of their origin are tested by the NVL.
All funds for purchase of kits, equipment and personnel are derived from the VRD budget thus are entirely taken from the State budget.

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

(max. 32000 chars):

N/A

d) Implementing entities - **vaccination (if applicable)** : 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)

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(max. 32000 chars):

N/A

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

(max. 32000 chars):

N/A

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.

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

N/A

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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.
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- 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

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	ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
		Total size of attachments :	576 kb