



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director General

SANCO/10618/2013

*Programmes for the eradication, control and monitoring of certain  
animal diseases and zoonoses*

**The programme for the monitoring of  
transmissible spongiform encephalopathies (TSE) and for  
the eradication of bovine spongiform encephalopathy  
(BSE) and of scrapie**

**Malta**

**Approved\* for 2013 by Commission Decision 2012/761/EU**

\* in accordance with Council Decision 2009/470/EC

# Standard requirements for the submission of programmes of eradication and monitoring of TSE

version : 2.2

## 1. Identification of the programme

Member state : MALTA

Disease : Transmissible Spongiform Encephalopathies

Request of co-financing for the year :

2013

### 1.1 Contact

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## 2. 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.

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## 3. Description of the epidemiological situation of the disease

(max. 32000 chars) :

TSE in bovine animals using one of the EU approved rapid tests commenced in March 2001. Ovines and caprines were included in the testing regime as from the year 2002. In that same year the National Veterinary Laboratory shifted from using the Enfer® kit to the BioRad TeSeE® kits since the former was not giving repeatable results. This shift explains a slight decrease in the tests performed during that year. During the successive years, there has been a gradual increase in the number of emergency slaughtered and fallen animals tested.

To date, since the TSE monitoring programme has been running, no positive samples were detected in bovine, ovine or caprine species.

The VAFD laboratory has participated in four ring tests as follows:

- November 2002 organised by IRMM, Belgium; BSE
- November 2004, organised by VLA, Weybridge; BSE
- October 2005, organised by VLA – Weybridge; BSE
- November 2005, organised by VLA, Weybridge. Scrapie
- October 2006, organised by VLA – Weybridge; BSE
- November 2006, organised by VLA, Weybridge. Scrapie
- October 2007, organised by VLA – Weybridge; BSE
- December 2007, organised by VLA, Weybridge. Scrapie
- October 2008, organised by VLA – Weybridge; BSE
- November 2008, organised by VLA, Weybridge. Scrapie
- January 2009, organised by VLA – Weybridge; BSE
- July 2009, organised by VLA – Weybridge; BSE
- November, 2009, organised by VLA, Weybridge. Scrapie
- July, 2010, organised by VLA, Weybridge. BSE
- November, 2010, organised by VLA, Weybridge. Scrapie
- July, 2011, organised by VLA, Weybridge. BSE
- November, 2011, organised by VLA, Weybridge. Scrapie

In all the trials the National Veterinary Laboratory achieved very satisfactory results.

## 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

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- The Agriculture and Fisheries Regulation Division 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.

## 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 will 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

(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 Agriculture and Fisheries regulation Department. 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. This system covers bovine, ovine and caprine holdings.

## 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

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All bovine, caprine and ovine animals are tagged and all the information is stored in the National Herd database. The transfer or movement of animals from one holding to another can only be done with the authorisation of the competent authority.

## 4.5 Measures in place as regards the notification of the disease

(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.

## 4.6 Testing

### 4.6.1 Rapid tests in bovine animals

|  | 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 |          |
|--|--|--|--|----------|
| Animals referred to in Annex III, Chapter A, Part I, point 2.1, 3 and 4 of Regulation (EC) No 999/2001 of the European Parliament and of the Council | 48   | 1 000                                    | 1 050  |          |
| Animals referred to in Annex III, Chapter A, Part I, point 2.2 of Regulation (EC) No 999/2001  | 72   | 2 000                                    | 2 050  |          |
| Other please specify here  |  |  |  | <b>X</b> |
|  |  | <b>Add a new row</b>                     |  |          |

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## 4.6.2 Rapid tests in ovine animals

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

8 913

|  | Estimated number of animals to be tested |   |
|--|--|---|
| Ovine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001   | 100                                      |   |
| Ovine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001   | 100                                      |   |
| Ovine animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) No 999/2001   | 0  |   |
| Ovine animals referred to in Annex VII, Chapter A, point 2.3(d) of Regulation (EC) No 999/2001       | 0  |   |
| Ovine animals referred to in Annex VII, Chapter A, point 3.4(d) of Regulation (EC) No 999/2001       | 0  |   |
| Ovine animals referred to in Annex VII, Chapter A, point 4(b) and (e) of Regulation (EC) No 999/2001 | 0  |   |
| Ovine animals referred to in Annex VII, Chapter A, point 5(b)(ii) of Regulation (EC) No 999/2001     | 0  |   |
| Other please specify here  |  | X |
|  | <b>Add a new row</b>                     |   |

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## 4.6.3 Monitoring in caprine animals

Estimated population of female goats and female kids mated .

3 705

|   | Estimated number of animals to be tested |   |
|---|--|---|
| Caprine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001            | 100                                      |   |
| Caprine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001            | 100                                      |   |
| Caprine animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) No 999/2001            | 0  |   |
| Caprine animals referred to in Annex VII, Chapter A, Part II, point 2.3(d) of Regulation (EC) No 999/2001       | 0  |   |
| Caprine animals referred to in Annex VII, Chapter A, Part II, point 3.3(c) of Regulation (EC) No 999/2001       | 0  |   |
| Caprine animals referred to in Annex VII, Chapter A, Part II, point 4(b) and (e) of Regulation (EC) No 999/2001 | 0  |   |
| Caprine animals referred to in Annex VII, Chapter A, Part II, point 5(b)(ii) of Regulation (EC) No 999/2001     | 0  |   |
| Other please specify here   |  | X |
|   | <b>ADD A NEW ROW</b>                     |   |

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

|   | Estimated number of tests |
|---|---------------------------|
| Confirmatory tests in Bovine animals            | 5                         |
| Confirmatory tests in Ovine and Caprine animals | 5                         |

## 4.6.5 Discriminatory tests

|   | Estimated number of tests |  |
|---|---------------------------|--|
| Primary molecular testing referred to in Annex X, Chapter C, point 3.2(c)(i) of Regulation (EC) No 999/2001 | 0                         |  |

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## 4.6.6 Genotyping of positive and randomly selected animals

|  | Estimated number |  |
|--|------------------|--|
| Animals referred to in Annex III, Chapter A, Part II, point 8.1 of Regulation (EC) No 999/2001 | 0                |  |
| Animals referred to in Annex III, Chapter A, Part II, point 8.2 of Regulation (EC) No 999/2001 | 0                |  |

## 4.7 Eradication



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## 4.7.1 Measures following confirmation of a BSE case

### 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

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 where 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

|   | Estimated number |  |
|---|------------------|--|
| Animals to be killed under the requirements of Annex VII, Chapter A, point 2.1 of Regulation (EC) No 999/2001 | 0                |  |

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## 4.7.2 Measures following confirmation of a scrapie case

### 4.7.2.1 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 scrapie in the Maltese Islands

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 where 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.

### 4.7.2.2 Summary table

|   | Estimated number |  |
|---|------------------|--|
| Animals to be culled and destroyed under the requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001                       | 0                |  |
| Animals to be sent for compulsory slaughter in application of the provisions of Annex VII, Chapter A, point 2.3(d) of Regulation (EC) No 999/2001 | 0                |  |

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## 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

|   | Estimated number |
|---|------------------|
| Ewes to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) | 0                |
| Rams to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) | 0                |

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## 5. Costs

### 5.1 Detailed analysis of the costs

(max. 32000 chars):

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

The test used will be the Bio Rad TESE 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 3000 samples will be tested from bovine animals, while it is estimated that 200 samples of ovine and 200 samples from caprines will be tested.

The estimated cost of each ELISA test is estimated at Euro 7.80

Bovine

Animals referred to in Annex III, Chapter A, Part I, point 2.1, 3 and 4 of Regulation (EC) No 999/2001 = 1000 samples@ Euro 7.80 = Euro 7,800

Animals referred to in Annex III, Chapter A, Part I, point 2.2 of Regulation (EC) No 999/2001= 2000 samples@ Euro 7.80 = Euro 15,600

Ovine and Caprines

Ovine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001=100 samples@ Euro 7.80 = Euro 780

Ovine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001= 100 samples@ Euro 7.80 = Euro 780

Caprine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001 =100 samples@ Euro 7.80 = Euro 780

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Caprine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001 = 100 samples @ Euro 7.80 = Euro 780

Western Blot

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 43.16 per test, 200 bovine, 100 ovine and 100 caprine are planned to be tested. The total amount of this testing is estimated at Euro 17,264.

## 5.2 Summary of costs

| 1. Testing in bovine animals (as referred to in point 4.6.1)                      |                   |                 |                     |                      |                             |   |
|---|-------------------|-----------------|---------------------|----------------------|-----------------------------|---|
| Costs related to  | Specification     | Number of units | Unitary cost in EUR | Total amount in EUR  | Community funding requested |   |
| 1.1. Rapid tests  | Bio-Rad TeSeE SAP | 3 100           | 7.8                 | 24180                | yes                         | X |
|   |                   |                 |                     | <b>Add a new row</b> |                             |   |
| 2. Testing in ovine and caprine animals (as referred to in point 4.6.2 and 4.6.3) |                   |                 |                     |                      |                             |   |
| Costs related to  | Specification     | Number of units | Unitary cost in EUR | Total amount in EUR  | Community funding requested |   |
| 2.1. Rapid tests  | Bio-Rad TeSeE SAP | 400             | 7.8                 | 3120                 | yes                         | X |
|   |                   |                 |                     | <b>Add a new row</b> |                             |   |
| 3. Confirmatory testing (as referred to in point 4.6.4)                           |                   |                 |                     |                      |                             |   |
| Costs related to  | Specification     | Number of units | Unitary cost in EUR | Total amount in EUR  | Community funding requested |   |
| 3.1. Confirmatory tests in Bovines  | Immunoblotting    | 5               | 43.16               | 215.8                | yes                         | X |

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| Costs related to  | Specification  | Number of units | Unitary cost in EUR | Total amount in EUR | Community funding requested |
|---|----------------|-----------------|---------------------|---------------------|-----------------------------|
| 3.2. Confirmatory tests in Ovines and Caprines  | Immunoblotting | 5               | 43.16               | 215.8               | yes                         |
| <b>Add a new row</b>  |                |                 |                     |                     |                             |
| <b>Add a new row</b>  |                |                 |                     |                     |                             |
| <b>4. Discriminatory testing (as referred to in point 4.6.5)</b>  |                |                 |                     |                     |                             |
| Costs related to  | Specification  | Number of units | Unitary cost in EUR | Total amount in EUR | Community funding requested |
| 4.1. Primary molecular tests  | na             | 0               | 0                   | 0                   | no                          |
| <b>Add a new row</b>  |                |                 |                     |                     |                             |
| <b>5. Genotyping</b>  |                |                 |                     |                     |                             |
| Costs related to  | Specification  | Number of units | Unitary cost in EUR | Total amount in EUR | Community funding requested |
| 5.1 Determination of genotype of animals in the framework of the monitoring and eradication measures laid down by Regulation (EC) No 999/2001 (as referred to in point 4.6.6 and 4.7.2.2) | na             | 0               | 0                   | 0                   | no                          |
| <b>Add a new row</b>  |                |                 |                     |                     |                             |
| Costs related to  | Specification  | Number of units | Unitary cost in EUR | Total amount in EUR | Community funding requested |
| 5.2 Determination of genotype of animals in the framework of a breeding programme (as referred to in point 4.7.3.2)   | na             | 0               | 0                   | 0                   | no                          |
| <b>Add a new row</b>  |                |                 |                     |                     |                             |

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| 6. Compulsory culling/slaughter  |               |                 |                     |                      |                             |   |
|--|---------------|-----------------|---------------------|----------------------|-----------------------------|---|
| Costs related to   | Specification | Number of units | Unitary cost in EUR | Total amount in EUR  | Community funding requested |   |
| 6.1 Compensation for bovine animals to be culled and destroyed under the requirements of Annex VII, Chapter A, point 2.1 of Regulation (EC) No 999/2001 (as referred to in point 4712)                                   | na            | 0               | 0                   | 0                    | no                          | X |
|  |               |                 |                     | <b>Add a new row</b> |                             |   |
| 6.2 Compensation for ovine and caprine animals to be culled and destroyed under the requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001 (as referred to in point 4722)                        | na            | 0               | 0                   | 0                    | no                          | X |
|  |               |                 |                     | <b>Add a new row</b> |                             |   |
| 6.3 Compensation for ovine and caprine animals to be sent for compulsory slaughter in application of the provisions of Annex VII, Chapter A, point 2.3 (d) of Regulation (EC) No 999/2001 (as referred to in point 4722) | na            | 0               | 0                   | 0                    | no                          | X |
|  |               |                 |                     | <b>Add a new row</b> |                             |   |
| <b>Total</b>   |               |                 |                     | 27 731,60 €          |                             |   |

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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 : .zip, .jpg, .jpeg, .tiff, .tif, .xls, .doc, .bmp, .pna.
- 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.
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