

#### EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

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

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

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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.

Document version number: 2022 1.0

Member state :	BULGARIA			
Disease	Transmissible Spongiform Encephalopath	nies		
This program is I	multi annual : no			
Request of Unic	on co-financing from beginning :	2023	To end of	2023
1. Contact data				
Name		Phone		
Email		Your job type within the CA:		

**Submission Date** 

06/12/2022 17:46:48

**Submission Number** 

1670341609942-19149

## 2. Description of the programme

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

Since 2002, the National Veterinary Service of Bulgaria (now Bulgarian Food Safety Agency, since 25.01.2011) carries out active surveillance of TSE in ruminants under the requirements of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies and its amendments. No BSE case has been detected in Bulgaria.

#### Program objectives:

- Surveillance of transmissible spongiform encephalopathies in ruminants (bovine spongiform encephalopathies – BSE and scrapie in small ruminants) in the Republic of Bulgaria and testing of sheep for resistance to scrapie.
- Rapid detection of transmissible spongiform encephalopathies in ruminants and immediate implementation of safety measures for limiting the spread of products from infected animals and eradication of the infection.
- Ensuring consumer safety in the consumption of meat and products obtained from ruminants.
- To provide evidence that the Republic of Bulgaria carries out control on the diseases belonging to the group of transmissible spongiform encephalopathies in the frame of intra-Community trade and international trade network.

The programme includes measures the following measures:

- Monitoring of 20 000 healthy slaughtered bovine animals above 30 months of age.
- Monitoring of at least 5000 risk bovine animals above 24 months of age (including emergency slaughtered, clinical signs at AM, fallen stock);
- Monitoring of BSE suspects of all ages;
- Monitoring of 10 000 healthy slaughtered ovine animals above 18 months of age;
- Monitoring of 10 000 fallen ovine animals;

NEW: Monitoring of 3500 healthy slaughtered caprine animals above 18 months of age;

- Monitoring of 1500 fallen caprine animals;
- Control measures if TSE case is confirmed.

## 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
BSE case	0	0	0	0
Scrapie case (ovine)	6	6	0	0
Scrapie case (caprine)	4	4	0	0
Last case of		date (classical case)	date (atypical case)	date (undetermined case)
BSE		0	0	0
Scrapie (ovine)		30/10/2021	0	0
Scrapie (caprine)		16/09/2021	0	0

Comments (if any)

No BSE case has been detected till this moment in Bulgaria.

The total number of CS in ovines is 36, 5 AS in sheep (in 2021 the cases are 7 CS and 0 AS)

The total number of CS in caprines is 24. In 2021 they are 4. No one AS in caprines.

## 4. Measures included in the programme

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

(max. 32000 chars):

#### Competent Authorities:

- Bulgarian Food Safety Agency (BFSA) at the Ministry of Agriculture, Food and Forestry;
- 28 Regional Food Safety Departments (RFSDs);
- National Reference Laboratory for TSE at the National Diagnostic Research Veterinary Medical Institute (NDRVMI), Sofia, No 15 A Pencho Slaveikov Blvd.;
- TSE laboratory at the Regional Diagnostic Veterinary Institute (RDVI) Veliko Tarnovo No 5 Slavianska Str., tel.: 062-620275;
- TSE laboratory at the Regional Diagnostic Veterinary Institute (RDVI) Stara Zagora, No 58 Slavianski Blvd., tel.: 042-634104.

No one private laboratory has approvement to test brain samples for TSE in 2021.

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

(max. 32000 chars):

The programme will be implemented on the territory of all 28 administrative regions of the country.

### 4.3 System in place for the registration of holdings

(max. 32000 chars):

Pursuant to Article 51, (2), of the LVA the BFSA is the official competent authority for animal identification which maintains a computerized information system for entering data for the identified animals and registered animal holdings. The terms and rules of animal identification, registration of animal holdings and the possibilities for access to the information is regulated by an ordinance of the Minster of Agriculture and Food. (ORDINANCE № 6/08.10.2013 on official identification of animals and maintance of the integrated information system; ORDINANCE № 61/9.05.2006 on the measures and procedures for identification of animals, registration of animal holdings and the availability to access the data base for identified animals and registered animal holdings (Published in SG 47/09.06.2006) –

REGULATION 2016/432, REGULATION 2019/2035; REGULATION 2021/520)

Pursuant to same article (51, (1)) of the Law on the veterinary activity the animals are subject to official identification and the animal holdings are subject of obligatory registration.

At the official internet page of the BFSA there are registers of animal holdings for large and small ruminants containing the registration number and location of the holdings and the number of animals in the holdings.

### 4.4 System in place for the identification of animals

(max. 32000 chars):

The BFSA maintains computerized information system (VetIS) for entry of data on the identified animals, their owners and registered animal holdings. The modules are elaborated for registration and notifications of movements of animals, health status and veterinary activities and for additional data.

Large ruminants shall be identified until the 20th day of their birth but in any cases identification is performed before the animals leave the animal holding of origin. (Art. 13 of Commission Implementing Regulation (EU) 2021/520 of 24 March 2021)

Small ruminants shall be indentified until the 9th month of their birth but in any cases identification is performed before the animals leave the animal holding of origin. (Art. 14 of Commission Implementing Regulation (EU) 2021/520 of 24 March 2021)

The ear tags shall be put by the owner or the registered veterinarian. (Art. 13 and 14 of Commission Implementing Regulation (EU) 2021/520 of 24 March 202 and National legislation)

Ear tags contain the following information:

For regular ear tags for large ruminants – the BFSA abriviation, followed by the code of the Republic of Bulgaria "BG", 2 digit code and 6-digit individual serial number.

For electronic ear tags for large ruminants - the BFSA abriviation, followed by the code of the Republic of Bulgaria "100", 3 digit code and 9-digit individual serial number. This set for identification contains 1 regular ear tag and 1 electronic ear tag or the combination of 2 regular ear tags and a bollus. (Art. 12, Annex I and Annex II of Commission Implementing Regulation (EU) 2021/520 of 24 March 2021 and National legislation)

For regular ear tags for small ruminants - the BFSA abriviation, followed by the code of the Republic of Bulgaria "BG", 3 digit code and 9-digit individual serial number. For the electronic set the options are 1 regular and 1 electronic ear tag or 1 regular ear tags and a bollus. For small ruminants (to 12 months of age) that are for slaughter there is an individual green colored ear tag with the BFSA abriviation, followed by the code of the Republic of Bulgaria "BG", 3 digit code and 9-digit serial number. (Art. 12, Annex I and Annex II of Commission Implementing Regulation (EU) 2021/520 of 24 March 2021 and National legislation)

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

(max. 32000 chars):

The contagious diseases are subject to notification pursuant to Art.50 of LVA. TSEs are notified according the requirements of ORDINANCE  $N^2$  23/ 14.12.2005 laying down the terms and procedure for notification and registration of contagious animal diseases (Published in SG 6/20.01.2006) transposing COUNCIL DIRECTIVE 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community

The Bulgarian Food Safety Agency ensures that it is notified immediately of any animal suspected of being infected by a BSE.

The Executive Director of the BFSA informs the European Commission and the Member States of the occurrence of BSE as well as of any other cases of TSE different from BSE.

### 4.6 Testing

#### 4.6.1 Rapid tests in bovine animals

### Targets for year 2023

	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			
Risk animals born in MS listed in Annex to CD 2009/719/EC			
Healthy slaughtered bovine animals NOT born in MS liisted in Annex to CD 2009/719/EC	30	25 000	27 000
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	5 000	5 500
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)		50	100

### 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.	1 000 000
Targets for year 2023	
	Estimated number of animals to be tested
Healthy slaughtered ovine animals (a)	10 000
Healthy slaughtered ovine animals (a)  Dead ovine animals (b)	10 000
	10 000
Dead ovine animals (b)	10 000
Dead ovine animals (b)  In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III an	10 000  d VII of the TSE regulation
Dead ovine animals (b)  In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III an  Ovine animals from holdings affected by classical scrapie	10 000 d VII of the TSE regulation
Dead ovine animals (b)  In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III an Ovine animals from holdings affected by classical scrapie  Ovine animals from holdins affected by atypical scrapie	10 000 d VII of the TSE regulation 15 10
Dead ovine animals (b)  In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III an Ovine animals from holdings affected by classical scrapie  Ovine animals from holdings affected by atypical scrapie  Ovine animals from holdings affected by BSE	10 000 d VII of the TSE regulation  15  10
Dead ovine animals (b)  In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III an Ovine animals from holdings affected by classical scrapie  Ovine animals from holdins affected by atypical scrapie  Ovine animals from holdings affected by BSE  Suspect animals (c)	10 000 d VII of the TSE regulation  15  10  0  10
Dead ovine animals (b)  In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III an Ovine animals from holdings affected by classical scrapie  Ovine animals from holdings affected by atypical scrapie  Ovine animals from holdings affected by BSE  Suspect animals (c)  Total number of tests  (a) Annex III, A, II, 2 of the TSE regulation (b) Annex III, A, II, 3 of the TSE regulation	10 000 d VII of the TSE regulation  15  10  0  10
Dead ovine animals (b)  In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III an Ovine animals from holdings affected by classical scrapie  Ovine animals from holdings affected by atypical scrapie  Ovine animals from holdings affected by BSE  Suspect animals (c)  Total number of tests  (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	10 000 d VII of the TSE regulation  15  10  0  10

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	Estimated number of animals to be tested
Healthy slaughtered caprine animals (a)	0
Dead caprine animals (b)	500
In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III and	d VII of the TSE regulation
Caprine animals from holdings affected by classical scrapie	15
Caprine animals from holdins affected by atypical scrapie	10
Caprine animals from holdings affected by BSE	0
Suspect animals (c)	10
Total number of tests	535

<sup>(</sup>a) Annex III, A, II, 2 of the TSE regulation

## 4.6.3 Confirmatory tests <u>other than rapid tests</u> 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	5
Confirmatory tests in Ovine an Caprine animals	100

#### 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	5
Primary molecular testing on ovine and caprine animals	20
Total	25

## 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

<sup>(</sup>b) Annex III, A, II, 3 of the TSE regulation

<sup>(</sup>c) Art 12 of the TSE regulation

Genotyping of TSE cases	10
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):

Measures in case of confirmation of BSE

When the presence of BSE has been officially confirmed, the following measures are immediately applied:

- The animal, which was found positive, shall be completely destroyed by rendering.
- An inquiry shall be carried out to identify all animals at risk.
- All animals and products of animal origin that have been identified as being at risk by the inquiry shall be culled and completely destroyed by rendering.

However, BFSA may decide:

- not to cull and destroy animals of the cohort if evidence has been provided that such animals did not have access to the same feed as the affected animal,
- to postpone the culling and destruction of animals in the cohort until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death.

The holding on which the animal was present when the presence of BSE was confirmed shall be placed under official control and all movements of animals susceptible to BSE and products of animal origin derived from or from the holding shall be subject to authorisation by the CA, with a view to ensure immediate tracing and identification of the animals and products of animal origin concerned.

Owners shall be compensated for the loss of the animals and for the destroyed products of animal origin. Epidemiological inquiry

The epidemiological inquiry must identify:

- All other ruminants on the holding where the BSE case was confirmed.
- If the disease was confirmed in a female animal, its progeny born within two years prior to, or after, clinical onset of the disease.
- All animals of the cohort of the positive animal.

"Cohort" means a group of bovine animals which includes both: (i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal and (ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life.

- The possible origin of the disease.
- Other animals on the holding where the positive animal was found or on other holdings, which may have become infected by the TSE agent or have been exposed to the same feed or contamination source.
- The movement of potentially contaminated feeding stuffs, or other material or any other means of transmission, which may have transmitted the BSE to or from the holding in question.

Detailed information on the control measures are described in the relevant contingency plan, published on the BFSA web-side.

#### 4.7.1.2 Summary table

Targets for year

2023

	Estimated number
Bovine animals culled and destroyed	100

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

#### 4.7.2.1 Description

(max. 32000 chars):

Measures in case of confirmation of scrapie

After confirmation of diagnosis, the following measures are put in place in the infected flock:

- Regular inspections of positive flocks. A detail register of each flock is kept at the RFSD and at the Animal Health and Welfare, Feed Control Directorate at BFSA.
- Movement of animals from infected flocks for breeding or fattening purposes is prohibited. In case of movement of animal for slaughtering the slaughter declaration document is stamped in red ink with the following: "HOLDING INFECTED WITH SCRAPIE".
- If there is evidence that the holding where the affected animal was present when scrapie was confirmed is not likely to be the holding where the animal was exposed to scrapie, the competent authority may decide that either holdings or only the holding of exposure shall be placed under official control.
- Owners shall be compensated without delay for the loss of the animals that have been killed.

The measures in infected holdings shall comprise at least:

- Gradual elimination of all ARQ/ARQ and ARR/ARQ ovine animals and their replacement with animals of the ARR/ARR genotype.
- Movement of ARR/ARR sheep from the holding shall not be subject to any restriction and ewes carrying one ARR allele and no VRQ allele may be moved to other holdings which are also restricted.
- Sheep carrying at least one ARR may go directly for slaughter for human consumption.
- Animals under the age of 3 months, both ovine and caprine animals of unknown genotype may go directly for slaughter for human consumption, under the following conditions:
- (i) the animals are examined by an official veterinarian on the holding of origin who shall confirm the absence of any clinical symptoms of scrapie, prior to dispatch to the slaughterhouse;
- (ii) the entire head and organs of the thoracic and abdominal cavities of such animals shall be disposed.
- Sheep of other genotypes may only be moved from the holding for the purposes of destruction.

In case of confirmation of TSE in an ovine or caprine animal, the following measures will be applied in the infected holding:

Culling and destruction of all animals, embryos and ova identified by the epidemiological inquiry:

breeding rams of the ARR/ARR genotype,

- breeding ewes carrying at least 1 ARR allele and no VRQ allele, and
- sheep carrying at least one ARR allele which are intended solely for slaughter,
- sheep and goats less than two months old which are intended only for slaughter.

If the infected animal has been introduced from another holding, based on the history of the case, eradication measures can be applied in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed.

The restrictions measures shall continue to apply to the holding for a period of three years from:

- a) the date of attainment of ARR/ARR status by all ovine animals on the holding or
- b) the last date when any ovine or caprine animal was kept on the premises or
- c) the date when all breeding rams on the holding are of ARR/ARR genotype and all breeding ewes carry at least one ARR allele and no VRQ allele, provided that during the three-year period, negative results are obtained from TSE testing of the following animals over the age of 18 months:
- —an annual sample of ovine animals slaughtered for human consumption at the end of their productive lives and
- all ovine animals which have died or been killed on the holding, but which were not killed in the framework of a disease eradication campaign, or slaughtered for human consumption.

Procedure followed in infected holdings

Infected farms are inspected on regular basis (every 10-14 days). However, the owner is responsible for informing the CA if any suspect cases are identified. An official veterinarian responsible for the holding registers the ear tags of the suspected animals and provides a copy of the protocol to owner who have been informed to bring the animals identified for culling. The ear tags of the suspected animals are confirmed by the copy that the official veterinarian has with him/her at the culling.

All the culled animals suspected of being scrapie infected are transported to the rendering processing plant and disposed by incineration.

Epidemiological inquiry

The inquiry must identify:

- All ruminants other than ovine and caprine animals on the holding where the infected animal was confirmed.
- If identifiable, the parents, all embryos, ova and the last progeny of the animal in which the disease was confirmed.
- All other ovine and caprine animals on the holding where the infected animal was found in addition to those mentioned in the second indent.
- The possible origin of the disease and the identification of other holdings where animals, embryos or ova which may have become infected with Scrapie or been exposed to the same feed or contamination source.
- The movement of potentially contaminated feeding stuffs, other material or any other means of transmission, which may have transmitted scrapie to or from the holding in question.
- Biosecurity practices are reinforced especially in the intensive systems. Measures such as cleaning and disinfection, disinsection, safe disposal of expelled placenta, stillborn lambs or kids, thorough investigation of production losses are put in place.

### 4.7.2.2 Summary table

Targets for year

2023

	Estimated number
Ovine and caprine animals culled and destroyed (due to classical scrapie)	100
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	100
Genotyping tests - monitoring and eradication measures	100

### 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):	

### 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

#### 5.3. 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 sampling is performed by the private veterinarians with signed contract with the Regional food safety directorate. The sampling is paid by RFSD.

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 20221 and 2022 only BFSA laboratories perform official control. The private laboratory performed official contral only in 2019 and 2020. Related laboratory work is paid by 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):
the compensations are paid by local RFSD.
d) Implementing entities - <b>vaccination (if applicable)</b> : 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) :
n/a
e) Implementing entities - <b>other essential measures</b> : who implements this measure? Who provides the equipment
service? Who pays?
(max. 32000 chars):
n/a

# Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies 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. $\boxtimes$ yes $\square$ 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:

#### **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 <u>SEVERAL MINUTES TO UPLOAD</u> 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.

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