

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

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- 6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state :	ROMANIA				
Disease	Transmissible Spongiform Encephalopa	athies			
This program is 1	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

12/12/2022 11:08:40

Submission Number

1670839721908-19267

2. Description of the programme

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

Represents the program for monitoring, control and eradication of BSE/TSE in 2023. The tests for BSE/TSE will continue in Romania under the following program:

BSE

Examination by rapid tests approved by CE, according to annex X, chapter C of Regulation (EC) no. 999/2001 in the edition in force and the subsequent amendments, of:

- all the bovines animals, indifferent of their age, in the BSE suspect cases;
- all healthy slaughtered bovines with the age over 30 months;
- all the bovines with the age over 24 months which are emergency slaughtered, found sick at antemortem inspection and the dead bovines with the age over 24 months are also examined for BSE. Confirmatory testing in case of BSE suspect cases;

In case of BSE confirmation, discriminatory testing of all positive BSE cases.

TSE/scrapie

- examination of all the ovine and caprine animals, indifferent of their age, in the TSE suspect cases;
- examination of a minimum annual sample of 10 000 ovine/caprine animals slaughtered for human consumption;
- examination of a minimum annual sample of 10 000 ovine/caprine animals not slaughtered for human consumption;
- monitoring of infected flocks (slaughtered and killed animals) –in accordance with Annex III and Annex VII to Regulation EC no. 999/2001;
- genotyping of each positive TSE case in sheep and goats;
- genotyping of infected flocks under the requirements of Annex VII to Regulation (EC) no. 999/2001;
- confirmatory testing in case of TSE suspect case;
- discriminatory testing of all positive scrapie cases.

Eradication of TSE: slaughtering or killing and complete destruction of animals in accordance with Annex VII of the Regulation (EC) no. 999/2001.

Genotyping of breeding sheep under the framework of a breeding program as established in Chapter B, Annex VII of Regulation (EC) no. 999/2001.

Objective for BSE: review the BSE monitoring and control program to increase the testing age for cattle slaughtered for human consumption

Objective for scrapie: classification of sheep and/or goat holdings with negligible or controlled risk regarding scrapie by fulfilling the provisions of Regulation (EC) no. 999/2001, with subsequent amendments and additions.

Objective for breeding sheep program: increasing ARR haplotype frequency within the sheep flock of Romanian breeds, while reducing the prevalence of haplotypes that have been shown to determine susceptibility to scrapie.

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)	34	34	0	0
Scrapie case (caprine)	3	3	0	0
Last case of		date (classical case)	date (atypical case)	date (undetermined case)
BSE			23/12/2014	
Scrapie (ovine)		12/05/2022		
Scrapie (caprine)		12/11/2021		

Comments (if any)

RSF

The examination of the bovines for the BSE is carried out in Romania with the application of the provisions of the art. 6, indent 1 and according to Annex III, Chapter A paragraph I no.2 and 3 of Regulation 999/2001 regarding the establishing of the prevention, control, eradication rules of some transmissible spongiform encephalopathies.

Per total, in Romania between 2001-2021 there were examined for BSE a number of 1.634.690 bovines out of which we had two positive atypical cases confirmed in 2014.

Atypical BSE was diagnosed at the National Reference Laboratory (NRL) for the first time in 2014 and confirmed by LCR VLA Weybridge, the disease being nationally and internationally notified. Eradication measures according to Regulation (EC) no. 999/2001 were taken.

The results of the active and passive surveillance activity for BSE, the monitoring of the bovine flocks, the clinical and laboratory investigations undertaken up to the present did show 2 atypical cases of bovine spongiform encephalopathy in Romania in 2014.

TSE

The examination of ovine and caprine to identify the presence of scrapia is carried out in Romania according to the provisions of Article 6, paragraph 1 and according to Annex III Chapter A paragraph II, no. 2, 3, 4 and 5 of Regulation No 999/2001 regarding the establishing of the prevention, control and eradication rules of some transmissible spongiform encephalopathies.

Scrapia was diagnosed at the National Reference Laboratory (NRL) for the first time in 2002 and confirmed by LCR VLA Weybridge, the disease being nationally and internationally notified.

During 2002 – 2021 the disease was notified in 31 counties, being found 252 outbreaks in which 1312 diagnosed and confirmed cases were registered.

In Romania, the prevalence of TSE in sheep is higher than in goats.

The measures foreseen for 2023 are similar with the ones from last years, we will continue with given rewards for sampling dead animals, involving the mayors to support the collection of fallen stock, strict monitoring of the achievements of each county in testing for BSE/TSE, performing trainings with personnel involved, and we will insist on assessing the work of each empowered free practice veterinarian which is responsible for taking the sample by the county directorates and for complying with the Eco conditionality measures by the owners.

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):

The central competent authority (National Sanitary Veterinary and Food Safety Authority) through the County Sanitary Veterinary and Food Safety Directorates which are regional competent authorities for each relevant area.

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

(max. 32000 chars):

The program will be implemented in the entire territory of Romania, which is divided into 42 administrative areas-counties.

4.3 System in place for the registration of holdings

(max. 32000 chars):

- article102 (1) of Regulation(UE) no. 2016/429;
- Part II title III chapter 1 of Delegated Regulation (UE) no. 2035/2019.

4.4 System in place for the identification of animals

(max. 32000 chars):

- Bovine: part III, title I, chapter 1 of Delegated Regulation (UE) no.2035/2019
- Ovine/caprine: part III, title II, chapter 1 of Delegated Regulation (UE) no. 2035/2019

4.5 Measures in place as regards the notification of the disease

(max. 32000 chars):

Art. 11 of Regulation 999/2001/EC and national legislation in force regarding notification.

4.6	Testing
4.6.1	Rapid tests in bovine animals

Targets for year

2023

	Ade (in months) above	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	30	5000	5000
Risk animals born in MS listed in Annex to CD 2009/719/EC	24	1 000	1 000
Healthy slaughtered bovine animals NOT born in MS liisted in Annex to CD 2009/719/EC	30	145 000	145 000
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	12 000	12 000
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)		50	50

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.			

Rapid tests on ovine animals 4.6.2.1

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

8 976 503

Targets for year

2023

	Estimated number of animals to be tested		
Healthy slaughtered ovine animals (a)	10 000		
Dead ovine animals (b)	10 000		
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	5 000		
Ovine animals from holdins affected by atypical scrapie	50		
Ovine animals from holdings affected by BSE	0		
Suspect animals (c)	50		
Total number of tests	25 100		

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

Rapid tests on caprine animals 4.6.2.2

Estimated population of female goats and female kids mated

1 202 490

Targets for year

2023

	Estimated number of animals to be tested	
Healthy slaughtered caprine animals (a)	10 000	
Dead caprine animals (b)	10 000	
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	500	
Caprine animals from holdins affected by atypical scrapie	5	

⁽b) Annex III, A, II, 3 of the TSE regulation (c) Art 12 of the TSE regulation

Caprine animals from holdings affected by BSE	0
Suspect animals (c)	50
Total number of tests	20 555

⁽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	60
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	35
Total	40

4.6.5 Genotyping of positive and randomly selected animals

Adult sheep population

Less than or equal to 750,000 animals

Targets for year 2023

	Estimated number
Genotyping of TSE cases	80
Random genotyping	0

4.7 Eradication

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

⁽c) Art 12 of the TSE regulation

4.7.1 Measures following confirmation of a TSE case in bovine animals

4.7.1.1 Description

(max. 32000 chars):

According to Art.13 and Annex VII, Chapter B, point 1(a) and point 2.1 of the Regulation (CE) no. 999/2001

4.7.1.2 Summary table

Targets for year

2023

	Estimated number
Bovine animals culled and destroyed	5

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

4.7.2.1 Description

(max. 32000 chars):

According to Art. 13 and Annex VII, Chapter B, point 1 (b) and point 2, 2.2.1 and 2.2.2, letter b) and c) of the Regulation (CE) no. 999/2001

4.7.2.2 Summary table

Targets for year 2023

	Estimated number	
Ovine and caprine animals culled and destroyed (due to classical scrapie)	50	
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	6 000	
Genotyping tests - monitoring and eradication measures	3 500	

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):

The program for 2023 aims to continue setting an initial population of Karakul, Merinos, Turcana and Tigaie sheep breeds, with known genotype resistant to scrapie, to increase ARR haplotype frequency within the sheep flock of these breeds, reducing in the meanwhile, the prevalence of haplotypes that

have been shown to determine susceptibility to scrapie.

Also, due to low prevalance of ARR haplotype in national breeds we intend to extend the testing in other holdings where high genetic animals from breeds like Awassi, Suffolk, Charollais, Texel, Hampshire, Vendeen, Merinofleisch, Blance du Massif Central, etc. are reared.

Long-term goal of the program is to identify all sheep with at least one ARR allele, the application of selective breeding for increased resistance to TSEs herds and increased ARR allele in sheep population in Romania.

Genotyping and molecular epidemiology studies will be carried out in the National Reference Laboratory for Molecular Biology of the Institute for Diagnosis and Animal Health and 2 Regional state laboratory. Having regarding that it will take time to improve the genetic resistance of the national flock, we will concentrate on testing rams from new holdings with at least 5 rams to exclude the VRQ gene (the most susceptible) and allow the continued use of sheep with the AHQ, ARH and ARQ genes.

We will continue testing new rams in the holdings were genotyping test were performed, and also after excluding the rams with VRQ gene, we intend to test the females from the holdings where genotyping was performed, to eliminate also the VRQ gene, in order to improve prevalence of ARR allele.

TECHNICAL PROVISIONS

- 1. The program focuses on the examination of a sufficient number of samples collected from the reproduction rams from breeds such as Merinos, Ţigaie, Ţurcana, Karakul, Awassi, Suffolk, Charollais, Texel, Hampshire, Vendeen, Merinofleisch, Blance du Massif Central, reared in holdings located on the territory of Romania for the determination of their genotype related to TSE resistance;
- 2. The CSVFSA carries out an initial checking of the sanitary veterinary status of the holdings which participate in the program based on the history of previous diseases and on clinical inspections and specific laboratory tests, if necessary.
- 3. The reproduction rams from breeds such as Merinos, Ţigaie, Ţurcana, Karakul, Awassi, Suffolk, Charollais, Texel, Hampshire, Vendeen, Merinofleisch, Blance du Massif Central, etc. which participate in the program, after complying with general requirements of Part 1, Chapter C of Annex VII to Regulation (EC) No 999/2001, shall be subject to a genotyping test for the identification of the genotype, complying with the specific requirements provided at Part 2,Chapter C of the annex VII to the Regulation (CE) no. 999/2001, with further amendments and completions.
- 4. The NSVFSA, following a request written by the CSVFSA, can grant derogations from the requests established at the Chapter C, Part 2, point 2, letter (c) and (d) of the annex VII to the Regulation (EC) no. 999/2001, with further amendments and completions, in order to protect the breeds and their production characteristics.
- 5. The recognition of the scrapie resistance status of the ovine livestock from breeds such as Karakul, Ţigaie, Ţurcana, Merinos, Awassi, Suffolk, Charollais, Texel, Hampshire, Vendeen, Merinofleisch, Blance du Massif Central wiil be granted only to livestock which participates in the program and complies with its requests and it is granted for the level represented by the livestock, out of which, progeny come exclusively from rams with the ARR/ARR genotype, in conformity with the provisions mentioned in the Chapter C, Part 4, point 1, letter (b) from the annex VII to the Regulation (CE) no. 999/2001, with further amendments.
- 6. The CSVFSA carries out the certification of the rams participating in the program, which were subject to a genotyping test, by allocating an individual identification number, in conformity with the guidelines submitted by the NSVFSA.
- 7. The selection of reproduction rams from the breeds such as Karakul, Ţigaie, Ţurcana, Merinos, Awassi, Suffolk, Charollais, Texel, Hampshire, Vendeen, Merinofleisch, Blance du Massif Central for the genotyping tests, shall be carried out based on the guidelines submitted by the NSVFSA by the service note.
- 8. The collection of whole blood samples is carried out under special conditions, by a vacutainer system containing EDTA as anticoagulant substance. The tube and the sampling needle are used individually, for each animal.

- 9. The packing of blood samples is carried out in designed support systems vacutainer tube supports, complying with the order from the sampling table;
- 10. The identification of blood samples is carried out by means of the ear tag number of the animal, which, the sample is collected from and the number can be found also in the nominal table attached to the sample accompanying note. In order to facilitate the procedure, the number of the sampling tube can be the one attributed to the number from the nominal table attached to the sample accompanying note.
- 11. On the accompanying note, there are inscribed the date, and the hour of sampling, as well as the identification code, the breed, sex and the age of the animal, in order to elaborate statistics based on the results (classified on breed, sex etc.).
- 12. The transport of whole blood samples is carried out within the shortest time, in order to facilitate the extraction of genomic DNA under optimal conditions, at refrigerated temperatures;
- 13. After sampling, the samples are preserved under refrigerated temperatures, at a temperature covered between 2-8°C, for maximum 12 hours until their processing. This interval includes the necessary time for the transport of samples to the laboratory;
- 14. If the time interval exceeds 12 hours, samples shall be kept at freezing temperatures until their processing, including the time interval that is necessary for the transport of samples to laboratory.
- 15. CSVFSA sent to NSVFSA a report on the requirements provided under chapter C, part 1, point 2, letter a) and b) from Annex VII to EC Reg. no. 999/2001, with further amendments. LNR-EST, IS and PH county LSVSA sends to NSVFSA a report on the requirements provided under chapter C, part 1, point 2, letter c) of Annex VII to EC Reg. no.999/2001.
- 15. CSVFSA carried out periodical or spontaneous inspections in the holdings that participate at the program and sanctions the nonconformities in implementing the program on the territory of the county. 16. CSVFSA organizes informative campaigns for the veterinarians, breeder associations and other institutions with attributions in implementing the program on the objectives, content and the measures provided by it.
- 17. CSVFSA provides upon the request relevant information to ovine breeders interested in the purchase of ovines with a genotype resistant to scrapie.
- 18. CSVFSA monitors the appropriate implementing of the measures established in the program after the finding out of the result of the genotyping test within the holdings that take part in the program by carrying out regular checks (every 4 months), as well as spontaneous inspections.

The program was not extended to other holdings which are not high genetic merit flocks, so we won't make any test for random genotyping in 2023.

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	500
Rams to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	2 500
Total	3 000

5. Costs

5.1 Detailed analysis of the costs

(max. 32000 chars):

In the frame of "The programme for monitoring, control and eradication of BSE/TSE in 2023" in Romania we envisage 208.705, respectively 163.050 TSE rapid tests in bovine animals, 25 100 TSE rapid tests in ovine animals and 20 555 TSE rapid tests in caprine animals.

In 2023, we will continue with the eradication program in small ruminants and with the breeding programme for resistance to TSE's in sheep. In 2023, we will genotype 20.000 animals in the framework of the breeding program, and 5.250 animals in the framework of Scrapie eradication. Compensations will be paid to the owners for all ovine and caprine animals slaughter or culled and destroyed.

5.2 Detailed analysis of the cost of the programme

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):

empowered free practice veterinarian performs the sampling based on a contract with County sanitary veterinary and food safety Directorate, which pays the empowered veterinarian.

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):

state laboratories performs the testing for TSE surveillance, the cost are paid 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):

The compensation file is made by the County sanitary veterinary and food safety Directorate where a scrapie outbreak was confirmed and the payment is also done by County sanitary veterinary and food safety Directorate, after requesting the sum to be paid to the owner to the central sanitary veterinary authorithy (NSVFSA)

- 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)

(max. 32000 chars):

not applicable

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

(max. 32000 chars):

NSVFSA is responsible for the implementation of the program which is performed by the 42 County sanitary veterinary and food safety Directorates. All equipments and services are assured from state budget.

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

 \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:

Having regarding that Romania implements a breeding program in order to increase TSE resistance in sheep, we would like to request additional costs for the costs appeared due to the replacement of the animals eliminated after performing the genotyping tests, of those susceptible ones that have to be castrated or slaughtered.

We kindly ask this because the TSE resistance of sheep in Romania is very low (less than 10%) and with this measure we will improve the reluctance of the owners in participating to the breeding program for improving TSE resistance.

By involving a higher number of breeders, we will performed more tests and also by supporting the cost for the replacement value of the animals eliminated, we will increase TSE resistance in sheep, we will decrease th number of scrapie cases, and by this we will spend less for compensations to owners, and all this measures will bring added value to this breeding program.

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.

List of all attachments

	Attachment name	File will be saved as (only a-z and 0-9 and) :	File size
	ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
	importFile.txt	importFile.txt	896 kb
		Total size of attachments :	1184 kb