



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Unit G5 - Veterinary Programmes

**SANCO/10750/2012**

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

## **Survey programme for Transmissible Spongiform Encephalopathies (TSEs)**

**Approved\* for 2012 by Commission Decision 2011/807/EU**

**Romania**

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



**AUTORITATEA NAȚIONALĂ SANITARĂ VETERINARĂ  
ȘI PENTRU SIGURANȚA ALIMENTELOR**

**DIRECȚIA GENERALĂ SANITARĂ VETERINARĂ ȘI PENTRU SIGURANȚA  
LANȚULUI ALIMENTAR**



VETERINARY PROGRAMMES -UNIT G5

Mr. Panayiotis Demetriou

Regarding your *e-mail on Romania's TSE monitoring and eradication program for the year 2012*, we communicate the following:

1. Regarding the testing target on group *sheep not slaughtered for human consumption*, we would like to clarify the following aspects:

- the proposed number of tests to be done in 2012 on target group ovine not slaughtered for human consumption, was set taking in account the actual tests made by Romania in previous years on this category.
- Romania has realized a realist estimate, as much as possible, of tests number that will be done in 2012 at this category, so we'll not ask for large amounts of money, which will remain unused and will not be used in other purposes by blocking them, given the fact that we've often received observations on this issue.
- it was taken into account that in case of testing of a larger number of animals then it was foreseen in the program, supplementary funds will be asked in September when usually programs' budget adjustment takes place.
- also, we mention that Romania has done and does efforts to increase tests number on ovine from target group not-slaughtered for human consumption. For 2012 were set testing targets for each county from Romania according to ovine population over 18 months and taking in

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account mortality rate. NSVFSA oversees, by monthly checks, the achievement grade of these targets, so by the end of the year, Romania should accomplish the requirements of 999/2001 Regulations by realizing a minimum sample of 10.000 tests.

- the same procedure of setting the targets for each county will be used also in 2012, Romania overseeing the substantial increase of tests number by finding solutions in collecting dead bodies of ovine.

*Like you suggest, we entered in the program project, the execution of 10.000 tests on target group ovine not slaughtered for human consumption.*

Regarding the tests proposed by Romania for ovine slaughtered for human consumption, the Regulation (EC) no. 999/2001 provides in Annex III, point II, 2, (a) that "Member States in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals shall test in accordance with the sampling rules set out in point 4 a minimum annual sample of 10 000 ovine animals slaughtered for human consumption", **not telling precisely the maximum limit of the sample.**

We mention that Romania, taking in account the growing number of animals positive diagnosed in 2010, has took the decision of implementing in 2011 the **testing** of all ovine **over 18 months**, both for target group ovine slaughtered for human consumption, as well as for target group ovine notslaughtered for human consumption, as supplementary measure in order not to miss animals that could be diagnosed with scrapie.

Taking in account that Regulation (EC) no. 999/2001 **doesn't provide a maximum sample of tests that should be tested**, we kindly ask you to communicate why the tests done over the minimum sample of 10.000 tests, wouldn't be eligible for co-financing.

2. We mention that the PHARE program, of which Romania has benefit, closed in 2010, all the tests that will be done in 2011, will be done only from budgetary funds, as Romania won't be benefitting from other financed program from other EU funds.

The Romanian authorities estimation is realistic as much as possible, based on the bovines, ovines and caprines population, as well as on tests number done during the previous years on



## Romania plan for the prevention and monitoring of Transmissible Spongiform Encephalopathy (EST)

2012

### Preamble

The objective of the plan is that of establishing additional measures for the prevention of bovine spongiform encephalopathy (BSE), scrapia and chronic wasting disease (CWD) in cervids appearance, as well as for monitoring the epidemiological situation in Romania in order to detect in time and eradicate these diseases at bovine, ovine and caprine animals.

The plan has at the basis :

- decision 2009/470/CE ( background decision ) from the date of 29.05.2009 and
- decision 425/2008/CE (standard requirements of Communities) from the date of 25.04.2008

### **The Surveillance, control, and monitoring of the domestic bovines, ovines, and caprines and of the ruminants from the silvan environment and in captivity**

The Surveillance, control, and monitoring of ruminant flocks for TSE makes the objective "The programme for the actions of surveillance, prevention and control of animal diseases, of those transmissible from animals to man, for protection of animals and environment" which is carried out yearly by the National Sanitary Veterinary and for Food Safety Authority; this programme is supplemented, everytime it is necessary, with epidemiological and risk analysis.

The Surveillance of animal flocks for TSE by laboratory examinations has at the basis the provisions of Regulation 999/2001 regarding the establishing of the prevention, control, eradication rules of the transmissible spongiform encephalopathies.

During carrying out the programmes, the competent authority has in its view the representation of the samples for each district and season, as well as the selection of the samples regarding the species, age, race, productive type.

Yearly there is programmed a minimum number of samples which are analyzed for TSE according to the estimated number of animals which is provided to be slaughtered in that year and taking into account the total number of sampled tested for TSE from previous years.

## **The Epidemiological Situation**

### **1. Bovine Spongiform Encephalopathy (BSE)**

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 according to Annex III, Chapter A paragraph 1 no.2 and 3 of Regulation 999/2001 regarding the establishing of the prevention, control, eradication rules of some transmissible spongiform encephalopathies.

All the healthy bovines slaughtered for human consumption with the age over 30 months are examined, by rapid tests approved by CE, according to annex X, chapter C of Regulation 999/2001 in the edition in force and the subsequent amendments.

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.

The epidemiological situation regarding BSE, the statistic information regarding the animal flocks in 2005, 2006, 2007, 2008, 2009 and 2010 the number of animals which were slaughtered normally, the number of the dead animals, the number of animals which were emergency slaughtered and found sick at antemortem inspection, the number of samples taken and the results in 2005, 2006, 2007, 2008, 2009 and 2010 are presented in the annex no 1.

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 not show the presence of bovine spongiform encephalopathy in Romania.

In the year 2005 there were examined for BSE a number of 55.414 bovines covering all eligible categories for testing from a total population of 2.421.685 of bovines.

In the year 2006 there were examined for BSE a number of 73.444 bovines covering all eligible categories for testing from a total population of 3.185.443 of bovines.

In the year 2007 there were examined for BSE a number of 132.682 bovines covering all eligible categories for testing from a total population of 3.762.708 of bovines.

In the year 2008 there were examined for BSE a number of 131.482 bovines covering all eligible categories for testing from a total population of 2.326.832 of bovines.

In the year 2009 there were examined for BSE a number of 73.381 bovines covering all eligible categories for testing from a total population of 2.254.190 of bovines.

In the year 2009 there were examined for BSE a number of 79.190 bovines covering all eligible categories for testing from a total population of 4.007.482 of bovines.

Per total, in Romania between 2001- 2010 there were examined for BSE a number of 734.632 bovines which had a negative result at the BSE test.

## **2. Transmissible Spongiform Encephalopathies (TSE) at the small ruminants**

The Surveillance, control, and monitoring of small ruminant flocks for scrapia are accomplished according to the provisions of "The programme for the actions of surveillance, prevention and control of animal diseases, of those transmissible from animals to man, for protection of animals and environment" carried out yearly by the National Sanitary Veterinary and for Food Safety Authority under the provisions of Regulation 999/2001 and the national legislation Community adapted. The epidemiological situation regarding scrapia, the statistic information regarding animal flocks, the number of slaughtered and dead animals, and the number of the samples taken, scrapia outbreaks and the number of diagnosed and confirmed animals are presented in the *annex no.1* and *annex no.2*.

The examination of ovines and caprines to identify the presence of scrapia is carried out in Romania according to the provisions of Article 6, paragraph 1 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 according to the provisions of MAFF Order 156/1999.

During 2002 – 2010 the disease was notified in 16 counties, being found 58 outbreaks in which 154 diagnosed and confirmed cases were registered.

Information regarding the system in place for the identification of animals and system in place for registration of holdings are presented in *annex no.3*

*Regarding the necessary of tests for BSE for bovines, scrapia for sheep and goats for 2012, we inform you that this necessary is determined in annex III, according of Decision Commission no. 425/2008.*

Number of tests requested for genotyping, the discriminatory molecular tests and the estimation of number of animals which will be killed/slaughtered following of application of eradication measure for scrapie in 2012 is presented in annex III.

In case of increase of number of bovines, sheeps and goats slaughtered will be over our expectations and if the epidemiologic situation will be changed or if the additional amendments of Regulation CE no.999/2001 will impose the performing of additional tests in comparison with our estimation, we will require supplementary funds for testing bovines, sheep and goats.



Annex III

Standard requirements for the submission of national programmes of eradication and monitoring of TSEs<sup>1</sup> as referred to in Article 1(c)

1. Identification of the programme

Member State: Romania

Disease(s)<sup>2</sup>: Transmissible spongiform encephalopathy (TSE)

Year of implementation: 2011

Reference of this document:

Contact (name, phone, fax, e-mail): Niculae Lazar, DVM phone: +40213157875, fax: +40213124967, lazar.niculae@ansvsa.ro

Date sent to the Commission:

2. Description of the programme

Eradication and monitoring TSE.

3. Description of the epidemiological situation of the disease

TSE epidemiologic monitoring (see annexes 1 and 2)

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<sup>1</sup> Bovine Spongiform Encephalopathy (BSE), Scrapie and Chronic Waste Disease (CWD)  
<sup>2</sup> One document per disease is used unless all measures of the programme on the target population are used for the control and eradication of different diseases.

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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:

The National Sanitary Veterinary and Food Safety Authority

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

Counties' borders.

4.3. System in place for the registration of holdings:

Bovines: Art. 5 and 7 of Regulation CE no. 1760/2000 regarding identification and registration system of bovines correlated with labeling of bovine meat and of products from meat bovine.

Sheeps/goats: Art. 7 of Regulation CE no. 21/2004 regarding identification and registration system of sheeps and goats.

Description of system in place for holding registration of bovines, ovines and goats and also the legislation in force are presented in annex no.3

4.4. System in place for the identification of animals:

Bovines: Art. 4 of Regulation CE no. 1760/2000 regarding identification and registration system of bovines correlated with labeling of bovine meat and of products from meat bovine.

Sheeps/goats: Art.4 of Regulation CE no. 21/2004 regarding identification and registration system of sheeps and goats.

Description of system in place for identification and registration of bovines, ovines and goats and also the legislation in force are presented in annex no.3.

4.5. Measures in place as regards the notification of the disease:

NSVISA Order No.77/2005, with subsequent modifications and completions, concerning international notification of diseases which transpose the Directive Council 1982/894/CE regarding notification of animal disease, with subsequent modifications and completions, published in Official Journal of European Communities (JOCE) no. L 378 from 31 december 1982, p. 58.

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#### 4.6. Monitoring

##### 4.6.1. Monitoring in Bovine Animals

		Estimated Number of tests
Animals referred to in Annex III, Chapter A, Part I, points 2.1. 3 and 4 of Regulation (EC) No 999/2001 of the European Parliament and of the Council <sup>3</sup>		5000
Animals referred to in Annex III, Chapter A, Part I, point 2.2 of Regulation (EC) No 999/2001		100000
Others (specify):	Healthy shot cervids	
Chronic wasting disease in cervids <sup>4</sup>	Healthy slaughtered cervids	
	Clinical/sick cervids	
	Road-injured or killed cervids	
	Fallen/culled cervids	

<sup>3</sup> OJ L 147, 31.5.2001, p. 1.

<sup>4</sup> Accounting of provisions of Commission Decision (8.2.2007) on a survey for chronic wasting disease in cervids published in Official Journal L no.84/ 24.03.2007

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4.6.2. *Monitoring in Ovine animals*

	Estimated Number of tests
Ovine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001	12000
Ovine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001	10000
Ovine animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) No 999/2001	100
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 5(b)(ii) of Regulation (EC) No 999/2001	0
Others (specify)	0

4.6.3. *Monitoring in Caprine animals*

	Estimated Number of tests
Caprine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001	2000
Caprine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001	1500
Caprine animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) No 999/2001	100

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Caprine animals referred to in Annex VII, Chapter A, point 3.3(c) of Regulation (EC) No 999/2001	0
Caprine animals referred to in Annex VII, Chapter A, point 5(b)(ii) of Regulation (EC) No 999/2001	0

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#### 4.6.4. 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	50

#### 4.6.5. Genotyping of positive and randomly selected animals

	Estimated number of tests
Animals referred to in Annex III, Chapter A, Part II, point 8.1 of Regulation (EC) No 999/2001	50
Animals referred to in Annex III, Chapter A, Part II, point 8.2 of Regulation (EC) No 999/2001	1450

#### 4.7. Eradication

##### 4.7.1. Measures following confirmation of a BSE case:

4.7.1.1. Description; according of Art.13 and Annex VII, Chapter A, point 1(a) and point 2.1 of the Regulation (CE) no. 999/2001

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: according of Art. 13 and Annex VII, Chapter A, part 1)(b) and point 2.3 of the Regulation (CE) no. 999/2001

4.7.2.2. Summary table

	Estimated number
Animals to be killed under the requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001:	5000
Animals to be genotyped under the requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001:	5000

4.7.3. Breeding programme for resistance to TSEs in sheep

4.7.3.1. General description<sup>5</sup>: see breeding programme for resistance to TSEs 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) 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

<sup>5</sup> Description of the programme according to the minimum requirements set out in Annex VII, Chapter B of Regulation (EC) No 999/2001.

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5. Costs

5.1. Detailed analysis of the costs:

5.2. Summary of the costs

<i>Costs related to</i>	<i>Specification</i>	<i>Number of units</i>	<i>Unitary cost in EUR</i>	<i>Total amount in EUR</i>	<i>Community funding requested (yes)</i>
<b>1. BSE testing<sup>6</sup></b>					
1.1. Rapid tests for bovines	Test: No. 2.1, 3 and 4	5000	16 euro/test	80000	
Bio-Rad TeSeE, Prionics Check Western, Prionics Check PrioSTRIP, IDEXX	Test: No. 2.2	100000	16 euro/test	1600000	
1.2. Rapid tests for cervids	Test: Others (cervids)	0	0	0	
Bio-Rad TeSeE, IDEXX					
<b>2. Scrapie testing<sup>7</sup></b>					
2.1. Rapid tests	Test: No.2 (ovines)	12000	16 euro/test	192000	
	Test: No.3 (ovines)	10000	16 euro/test	160000	
	Test: No.5 (ovines)	100	16 euro/test	1600	
	Test: No 3.4(ovines)	0			
	Test: No 2 (caprines)	2000	16 euro/test	32000	

<sup>6</sup> As referred to in point 4.6.1. Here is included also the number of tests for cervids

<sup>7</sup> As referred to in points 4.6.2 and 4.6.3.



	Test: No 3 (caprines)	1500	16 euro/test	24000
	Test: No 5 (caprines)	100	16 euro/test	1600
<b>3.</b>	Discriminatory testing <sup>8</sup>			
<b>3.1.</b>	Primary molecular tests	Test: TeSeE Western Blotting Biorad (CEA)	15	250 euro/test
				3750

<sup>8</sup> As referred to in point 4.6.4.

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4. Genotyping					
4.1.	Determination of genotype of animals in the framework of the monitoring and eradication measures laid down by Regulation (EC) No 999/2001 <sup>9</sup>	Method: 1. Light Typing Sheep PrP Gene Mutation Detection Kit 2. PrP Gene Sequency	5000 (Annex VII eradication)  15000(Annex III 8.1 si 8.2)	30 euro/animal  30 euro/animal	150000  45000
4.2.	Determination of genotype of animals in the framework of a breeding programme <sup>10</sup>	Method 1. Light Typing Sheep PrP Gene Mutation Detection Kit 2. PrP Gene Sequency	See breeding program		
5. Compulsory Slaughter					
5.1.	Compensation for bovine animals to be killed/slaughtered under the requirements of Annex VII,		0		0

<sup>9</sup> As referred to in points 4.6.5 and 4.7.2.2.

<sup>10</sup> As referred to in point 4.7.3.2.

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Chapter A, point 2.1 of Regulation (EC) No 999/2001					
5.2. Compensation for ovine and caprine animals to be killed/slaughtered under the requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001	4000	100 euro/animal	4000000		
<i>TOTAL</i>					2.644.950 EURO

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