

SANCO/10612/2013

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

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

* in accordance with Council Decision 2009/470/EC

version: 2.21

1. Identification of the programme

Member state: HRVATSKA

Disease: Transmissible Spongiform Encephalopathies

Request of co-financing for the year:

2013

1.1 Contact

Name: Žaklin Acinger-Rogić

Phone: +385 1 6443 839

Fax.: +385 1 6443 899

Email: zaklin.acinger@mps.hr

2. Description of the programme

(max. 32000 chars):

TSE programme consists of two parts, BSE annual monitoring programme and Scrapie annual monitoring programme, based on active and passive surveillance in accordance to the Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE Regulation). The objective of the programme is to detect and timely implement all control and eradication measures and at the same time ensures that no BSE cases are being slaughtered for human consumption. In case of suspicion or confirmation of TSE, control and eradication measures must be carried out in accordance with TSE Regulation (described in Articles 12 and 13).

BSE Surveillance form is based on active surveillance (testing without previous suspicion) and passive surveillance (testing of clinical suspects identified by veterinarians/farmers) of bovine animals as follows: Bovine animals older than 24 months:

- fallen stock (bovine animals which have died or have been killed on the farm or in transport, but not slaughtered for human consumption nor killed in the framework of an epidemic);
- emergency slaughtered animals (bovine animals subject to "special emergency slaughtering" as described in relevant Community legislation);
- animals with clinical signs at ante mortem examination (bovine animals sent for normal slaughter but

version: 2.21

the slaughter of which was deferred because they were (a) suspected of suffering from a disease which is communicable to humans and to animals or showing symptoms or being in a general condition such as to indicate that such a disease may occur or (b) showing symptoms of a disease or of a disorder of their general conditions which is likely to make their meat unfit for human consumption). Bovine animals older than 30 months:

- healthy slaughtered animals (bovine animals subject to normal slaughter for human consumption and animals without clinical signs of disease slaughtered in the context of a disease eradication campaign other than BSE).

Bovine animals clinically suspected of being infected by BSE:

- bovine animals reported as suspect of TSE as defined in Article 3 of the TSE Regulation and subject to the measures described in Articles 12 and 13 ("animal suspected of being infected by a TSE" means live, slaughtered or dead animals, which show or have shown neurological or behavioral disorders or a progressive deterioration of the general condition linked to impairment of the central nervous system and for which the information gathered on the basis of a clinical examination, response to treatment, a post-mortem examination or an ante or postmortem laboratory analysis do not allow an alternative diagnosis to be established, also, BSE shall be suspected in bovine animals which have produced a positive result from a rapid test).

Scrapie monitoring programme is based on testing on dead ovine and caprine animals according to the size of ovine and caprine population. All ovine and caprine animals older than 18 months or have more than two permanent incisors erupted through the gum which have died or been killed, but which were not killed in the framework of a disease eradication campaign or slaughtered for human consumption, must be tested. The minimum sample size is 1500 for ovine and 500 for caprine animals.

3. Description of the epidemiological situation of the disease

(max. 32000 chars):

TSE has not been confirmed in Croatia. It has never been diagnosed by post-mortem histopathological examination of the brain or by use of rapid tests (Prionics Check) of any tested animal.

In period 2001-2011, 273106 bovine animals has been tested on BSE with negative results (testing of all slaughter cattle over 30 months and fallen stock and all casualty/emergency slaughter cattle over 24 months of age). Supervision of the TSE/BSE epidemio-surveillance is in place.

Numerous activities followed by legal acts have been carried out in the past regarding TSE. Surveillance of the TSE has been regulated in Croatia since 1996, though diagnostic activities began at the Croatian Veterinary Institute one year earlier. Since 1996, a number of legislative measures, ordinances and instructions regulating this field have been issued. The milestone of this process was establishing of the Laboratory for Rapid TSE Testing, which began diagnostic activities in 2001, and has since conducted more than 277 000 tests.

In 1996 Ordinance on measures for detection, control and eradication of BSE, came into force (Official Gazette No. 44/96). This included the legal obligation of notification of the suspicion or confirmed case of BSE. In 1996 the Programme for monitoring and diagnostics of BSE was adopted by the Government of Croatia. In 1997 specified risk material (SRM) was designated and removal of specified SRM from the food chain was introduced (Decree banning the use of tissues/organs (brain, eyes, spinal cord, thymus,

version: 2.21

spleen, intestines and mesentery lymph nodes and nerve tissue) as well as mechanically deboned meat of ruminants which might contain the causative agent of BSE, in the production of meat products (Official Gazette No. 129/97). In 1997 prohibition of feeding of ruminants with proteins of ruminants origin (except milk and milk products) was introduced (Decree, Official Gazette No 28/97). Since 2001 a total ban on use of animal proteins in feed for production animals has been in force (Total feed ban Decree – Official Gazette No. 8/01). In 2001 Decree on compulsory testing of bovine animals for the presence of the causative agent of BSE was adopted (Official Gazette No. 45/01). In 2001 BSE Contingency Plan was drafted and published on www.mps.hr. In 2001 the Program for collecting and disposal of dead animals and animal by-products was drafted. During the 2001 and 2002, all existing quantities of meat and bone meal had been withdrawn from warehouses and safely destroyed at the cost of the state budget. In 2003 Ordinance on the manner of handling animal carcasses and waste of animal origin and their destruction was adopted (Official Gazette No 24/03). In 2006 Croatian legislation regulating TSE adopted the provisions of Regulation (EC) No 999/2001 and the Regulation (EC) 1774/2002. In 2007 Prionics [®] Check Priostrip test is introduced (as the second rapid test). In 2007 new Veterinary Act (Official Gazette No 41/2007, Article 120) stipulates that the costs of disposal of dead bovine, ungulates, pigs, goats and sheep are settled from state budget funds. From 2009 funds for disposal according to the Article 120 of the Veterinary Act, are assured in the state budget. In 2009 Croatian legislation on TSE is fully aligned with Regulation (EC) No 999/2001 as well as Regulation (EC) 1774/2002. In terms of import of live bovine animals and relevant products of thereof, import of such commodities to Croatia was allowed only from countries implementing at least equivalent BSE control measures.

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 is Veterinary Directorate (VD) of the Ministry of Agriculture. Animal Health Sector within VD is responsible for drafting legislation and preparing the annual TSE programme while supervision of the implementation of the programme is carried out by the Veterinary Inspection Sector within VD.

The Croatian Veterinary Institute (CVI) is the reference laboratory for TSE tests.

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

(max. 32000 chars):

For the purposes of this Programme, Croatia will be treated as a single geographical and administrative

version: 2.21

region.			

4.3 System in place for the registration of holdings

(max. 32000 chars):

Each holding containing bovine, ovine and caprine animals is registered and identified with an unique farm number within Farm Register. A uniform farm register is fully operational for cattle, sheep and goats. It contains all relevant farm information (name, owner, location, type of production, No of animals, etc.) as well as information on the animal identification number(s) and animal movements. The Veterinary Directorate has entered into contract with the Croatian Agricultural Agency (CAA) delegating to it the keeping and maintenance of the database (Central Register of Domestic Animals, which includes the Farm Register, Register of Bovine, Ovine and Caprine Animals).

The alignment of the system for the identification and registration of bovine animals commenced late in 2003 and from that was subsequently enhanced. Bovine database is being fully operational and allows the tracing of the dam and cohort in case of any possible BSE positive case as well as origin of a cattle (including the first keeper, ID Code, date of birth, sex, ID code of the mother, ID number of calves, all the movements of an animal, information about the keeper, all the bovine animals that had ever kept on the farm, all movements from and to a specified farm in a specified time interval).

4.4 System in place for the identification of animals

(max. 32000 chars):

Animal identification is obligatory for all bovine, ovine and caprine animals. The animal numbers and ear tags are allocated by the CAA. Each number is unique for cattle, sheep and goats. Ear tagging is carried out by animal keepers, CAA or authorised veterinarians (AVs), all of whom may enter data on animal identification in the register. AVs enter the data on animal movements. It is the responsibility of the holder of animals to ensure that the animals are properly identified and registered, to keep the required records and to ensure the traceability of animals in case of their movement.

Bovine animals must be tagged (both ears) and registered following birth, and ovine and caprine animals no later than 6 months after birth or earlier in case of movement from the holding. Ovine and caprine animals identification consists of right ear tag and bolus electronic transponder. Animals could not be moved from the holding of origin without proper identification, valid passport with all relevant data (ID number, birth date, movements records etc.) and with health certificates issued by the AVs. The certificates are required when animals are to be sent to an animal market or when there are movement of animals e.g. from the holding to another holding, slaughterhouse, sport events, fair, common pasture. The certificate contains information on: identity of the owner; identity and place of origin of the animal; and health status and eligibility to be placed on the market or to be moved

version: 2.21

according to the relevant legal requirements.

At slaughterhouses strict procedures are in place to verify both the origin and the health status of the animal came for slaughter. This include checks of identification marks, documentation and ante mortem inspections. All carcass and all parts of the body of an animal tested for BSE including the hide shall be retained under official control until a negative result to the rapid test has been obtained. Traceability of meat and meat products is strictly regulated. Accordingly, any single meat or meat product must be accompanied by the information which ensure the full control of traceability. That means that meat or meat product can be in every moment, by the batch number and other information, traced back to the mincing/processing/cutting batch and finally linked with the carcass of origin, consequently to the farm of origin. In addition, procedure for recall of the products from the market is obliged part of HACCP documentation for approved food business operators, and the subject of official controls performed by the official veterinarians and state veterinary inspectors.

4.5 Measures in place as regards the notification of the disease

(max. 32000 chars):

Obligations of the owner of the animals, authorised veterinarian and state veterinary inspector/official veterinarian in terms of notification of suspicion and confirmed case of an animal disease are stipulated in Articles 13 to 16 of the Veterinary Act.

Notification on TSE suspicion and confirmed case(s) must be carried out according to the TSE Regulation. Disease notification forms and procedure is prescribed by the Ordinance on the notification of animal diseases (OG 62/11, 114/11).

4.6 Testing

4.6.1 Rapid tests in bovine animals

	Ada (in months) abova	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	24	12 000	13 500	
Animals referred to in Annex III, Chapter A, Part I, point 2.2 of Regulation (EC) No 999/2001	30	36 000	36 500	
Other please specify here				X
	Add a new row			

version: 2.21

4.6.2 Rapid tests in ovine animals

Estimated population of adult ewes and ewe lambs put to the ram . 650 000

	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	0	
Ovine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001	1 500	
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
	Add a new row	

version: 2.21

4.6.3 Monitoring in caprine animals

Estimated population of female goats and female kids mated . 60 000

	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	0	
Caprine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001	500	
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 999/2	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
	ADD A NEW ROW	

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

	Estimated number of tests	
Confirmatory tests in Bovine animals	50	
Confirmatory tests in Ovine an Caprine animals	30	

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	

version: 2.21

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	10	
Animals referred to in Annex III, Chapter A, Part II, point 8.2 of Regulation (EC) No 999/2001	100	

4.7 Eradication

4.7.1 Measures following confirmation of a BSE case

4.7.1.1 Description

(max. 32000 chars):

Following confirmation of the presence of a BSE measures as defined by TSE Regulation (Article 13) must be carried out. This include: disposal of all parts of the body of the infected animal, tracing of cohorts and progeny, all at risk animals shall be killed and disposed, an epidemiological inquiry shall be carried out, the holding on which the animal was present when the presence of a TSE was confirmed shall be placed under official control and all movement of animals susceptible to TSE 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. Owners shall be compensated without delay for the loss of the animals that have been killed or products of animal origin destroyed.

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	100	

4.7.2 Measures following confirmation of a scrapie case

4.7.2.1 Description

(max. 32000 chars):

Following confirmation of the Scrapie, measures as defined by TSE Regulation (Article 13) must be carried out. This include: disposal of all parts of the body of the infected animal, tracing of cohorts and progeny, all at risk animals shall be killed and disposed, an epidemiological inquiry shall be carried out, the holding on which the animal was present when the presence of a scrapie was confirmed shall be placed under official control and all movement of animals susceptible to TSE 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

version: 2.21

animal origin concerned. Additional measures following confirmation of the presence of a Scrapie will be carried out according to the Annex VII, Chapter A, regarding testing of infected flock, restriction, genotyping and depopulation of susceptible animals. Owners shall be compensated without delay for the loss of the animals that have been killed or products of animal origin destroyed.

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 No 999/2001	100	
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	200	
Animals to be genotyped under the requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001	110	

4.7.3 Breeding programme for resistance to TSEs in sheep

4.7.3.1 General description

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

(max. 32000 chars):	
N/A	

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

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

5

Detailed analysis of the costs

(max. 32000 chars):

(depopulation of herds, killing and disposal of all animals identified as cohort and progeny and other at risk animals). In case of confirmation of Scrapie, The cost of TSE programme will include costs of samples collection, laboratory testing and compensation to farmers in case of confirmation of TSE genotyping and rapid testing in infected flock is included as well.
Estimated Costs in 2013 may be broken down roughly as shown in Attached Table 1. "ESTIMATED COSTS of TSE programme year 2013".

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

5.2 Summary of costs

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

	(V	
١	(vi	
,			
		240	
	٠	250	

			×				×			×			
Add a new row		Community funding requested	0 yes	Add a new row		Community funding requested	yes	Add a new row	Community funding requested	0 yes	Add a new row		Community funding requested
Add a		Total amount in EUR		Add		Total amount in EUR	880 yes	Add a	Total amount in EUR		Ppq 9		Total amount in EUR
		Unitary cost in EUR	120			Unitary cost in EUR	4		Unitary cost in EUR	4			Unitary cost in EUR
		Number of units	0			Number of units	220		Number of units	0			Number of units
	(as referred to in point 4.6.5)	Specification	Shall be carried out in a Community reference laboratory			Specification	Shall be carried out in case of Scrapie confirmation		Specification	N/A			Specification
	4. Discriminatory testing (as re	Costs related to	4.1. Primary molecular tests		5. Genotyping	Costs related to	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)		Costs related to	5.2 Determination of genotype of animals in the framework of a breeding programme (as referred to in point 4.7.3.2)		6. Compulsory culling/slaughter	Costs related to

Page 14 sur 15

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

×			×		×		
yes	Add a new row	Community funding requested	yes	Add a new row	yes	Add a new row	
50000 yes	Add a	Total amount in EUR	7000 yes	Ppy S	14000 yes	Add a	515 880,00 €
200		Unitary cost in EUR	70		70		
100		Number of units	100		200		
Measures following BSE confirmation		Specification	Measures following Scrapie confirmation		Measures following Scrapie confirmation		Total
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)		Costs related to	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)		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)		

Page 15 sur 15

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

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: <u>zip, jpg, jpeg, tiff, tif, xls, doc, bmp, pna.</u>
- 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 SEVERAL MINUTES TO UPLOAD ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a
 - Submission Number!
- 5) Zip files cannot be opened (by clicking on the Open button). All other file formats can be opened

Table 1. ESTIMATED COSTS of TSE programme year 2013								
Disease	Animal species	Tests	No. Of samples to be tested	Price per unit (€)	Total sum			
BSE bovine		Healthy slaughtered bovine older than 30 months	36.000	22,50	810.000,00			
	bovine	Fallen stock, casualty/emergency slaughtered older than 24 months	12.000	32,50	390.000,00			
		Confirmatory testing suspicion, at risk animals	50	65,50	3.275,00			
		Depopulation compensation	100	870,00	87.000,00			
	ahaan	Dead or killed sheep older than 18 months	1.500	32,50	48.750,00			
	sheep	Confirmatory testing	20	65,50	1.310,00			
SCRAPIE	goats	Dead or killed goats older than 18 months	500	32,50	16.250,00			
		Confirmatory testing	10	65,50	655,00			
	ahaan and maata	Depopulation compensation	300	200,00	60.000,00			
	sheep and goats	Genotyping	220	16,00	3.520,00			
Additional costs in addition to testing (protective clothing, transport, sample collection, equipment) 47.000,00 13,50								
Total Net /VAT excluding/								
VAT 25%								
Total /including VAT/								