

## Annex I.a: Programme for Rabies eradication submitted for obtaining EU cofinancing

Member States seeking a financial contribution from the European Union for national programmes of eradication, control and surveillance shall submit online this application completely filled out.

In case of difficulty, please contact <u>SANTE-VET-PROG@ec.europa.eu</u>, describe the issue and mention the version of this document 2015 1.01

Your current version of Acrobat is: 11.015

### Instructions to complete the form:

- 1) You need to have at least the **Adobe Reader version** 8.1.3 or higher to fill and submit this form.
- 2) To verify your data entry while filling your form, you can use the "verify form" button at the top of each page.
- 3) When you have finished filling the form, verify that your internet connection is active, save a copy on your computer and then and then click on the "submit notification" button below. If the form is properly filled, the notification will be submitted to the EU server and a submission number will appear in the corresponding field. If you don't succeed to submit your programme following this procedure, check with your IT service that the security settings of your computer are compatible with this online submission procedure.
- 4) All programmes submitted online are kept in a central database. However only the information in the last submission is used when processing the data.
- 5) IMPORTANT: Once you have received the submission number, save the form on your computer for your records.
- 6) If the form is not properly filled in, an alert box will appear indicating the number of incorrect fields. Please check your form again, complete it and re-submit it according to steps 3). Should you still have difficulties, please contact <a href="mailto:SANTE-VET-PROG@ec.europa.eu">SANTE-VET-PROG@ec.europa.eu</a>. eu.
- 7) For simplification purposes you are invited to submit multi-annual programmes.
- 8) As mentioned during the Plenary Task Force of 28/2/2014, you are invited to submit your programmes in **English**.

Submission Date

13/11/2015

**Submission Number** 

1447412011735-7041

### 1. Identification of the programme

Member state :	ROMANIA		
Disease	Rabies		
Species :	Fox		
This program is multi annual	: yes		
Type of submission	: Modification of already approve	ed multiannual programr	ne
Request of Union co-financing from beginning of:	2015	To end of	2017
	MODIFICATION OF A		ED
	Modification to be ap	pplied from	2016

### Contact

Name: Siposean Cristian

Phone: 0040721337145

Your job type within the CA: Head of Notification and Monitoring Services

Email: siposean.cristian@ansvsa.ro

### A. Technical information

### 1. Submitted programme

- 1.1 Provide a concise description of
- the programme with its main objective, overall strategy and timeframe. In case of a long time strategy, interim objectives for each year should be specified.
- target population for vaccination, surveillance and monitoring
- main measures: vaccination scheme, surveillance, monitoring and other measures
- areas of implementation of the programme

#### (max. 32000 chars):

For 2014, the Programme of Monitoring, Control and Eradication of rabies will rule on the entire territory of Romania and it will be applied to the entire population of foxes.

Concerning the vaccination strategy adopted to the domestic animals, there shall be vaccinated dogs and cats from backyards and also emergency vaccination will be done only for the domestic animals in the outbreaks.

Its objectives will take into account that:

- rabies develops in Romania both in animal population wildlife, especially in foxes, wild dogs and also in domestic animals population;
- rabies develops endemically in foxes and dogs and occasionally in other animals;
- most cases of rabies in domestic animals have been recorded in dogs and cats. The situation is not casual if we consider that Romania has a very large number of stray dogs and cats;
- The Danube Delta, a unique biotope where wild animals live together with domestic animals can be regionalized.

The objectives of the programme comprise:

- surveillance of rabies in wild animals population in Romania
- control of rabies in fox population in Romania
- monitoring of oral vaccination in fox population in Romania
- efficiency of vaccination
- surveillance of rabies'prevalence in the population of domestic animals, including dogs and cats Actions undertaken for the fulfillment of the objectives:
- oral vaccination of foxes by airplane distribution in order to obtain an territory free of rabies;
- creating vaccination barriers around localities by the manual vaccination in foxes in order to decrease the prevalence of rabies in domestic animals;
- public awareness campaigns regarding oral vaccination of foxes;
- monitoring of evolution of rabies correlated with the plan for application of vaccination and the results obtained;
- control of the application of vaccination plans and evaluation of its effectiveness;

- collection of data, their proper registration, their statistic and informatics procession and their presentation in proper forms in order to be used in the practice of control and eradication of rabies in Romania:
- the contractor for aerial distribution provides to the competent authority the recorded flight routes and the encrypted data of the distributed baits at the end of each distribution day.
- the competent authority will control the correct application of the aerial distribution during its implementation, also by checking the recorded flight routes and bait release data. The contractor will be obliged to perform supplementary distribution flights if insufficient coverage is identified.
- vaccination of domestic animals in outbreak;
- compulsory vaccination of dogs and cats; identification and registration of dogs and cats
- monitoring of animal movements in conformity with CE Reg. no.576/2013 and 577/2013 regarding animal health requirements regulating trade and imports of animals, semen and embryos in Community that are not subject to animal health requirements established by the Community norms provided in Annex A, point I to Directive 90/425/EEC.

Oral vaccination of foxes will be carried out in two vaccination campaigns, in spring and autumn, mostly by plane distribution, 25 baits/ campaign/km2 with a distance between flight lines of 500 meters and 150 meters altitude, by avoiding the territories of localities, water surfaces, highways, etc. Estimated surface suitable for aerial vaccination is approximated at 213.375 square kilometers.

Manual distribution of the vaccine baits against rabies will be done only in the areas where are dens, as follows:

- priority will be areas around settlements where were confirmed cases of rabies (rabies areas) and in areas with adjacent forests near localities, where aerial vaccination is impossible to be done due to the small distance between forests and localities.
- baits will be distributed manual in areas around other localities, lakes and public roads if are known active foxes den or foxes traffic routes adjacent to those.
- in any other zones where airplanes does not have permission to fly and is known that can be foxes den.

At a 45 days'time following each vaccination campaign, there shall be performed the hunting of foxes in order to assess the efficiency of vaccination, for this purpose, there shall be shot 4 foxes/year/100 km2. For the monitoring of vaccination campaign, there shall be taken samples of thoracic liquids in order to determine post-vaccinal antirabies antibodies and samples of mandible in order to determine vaccinal marker (Tetracycline).

Concerning the surveillance of rabies, there shall be taken samples for doing FAT, from suspect animals following clinical examinations and from those who are hunted from areas where rabies evolved in the last year, found dead or killed by accident by cars.

For next period of 3 years, 2015-2017, specifications of the program will be same like the one from 2014, with the following specifications:

- For 2015 programme wil be applied only in Romania,
- For 2016 and 2017, the Programme of Monitoring, Control and Eradication of rabies will rule on the entire territory of Romania and we intend to include a buffer zone at the border with Romania. This buffer zone contains areas of 50 km radius from the border of Romania in Moldavia and will contain 25 counties which are: Brinceni, Ocnita, Edinet, Donduseni, Rascani, Drochia, Glodeni, Balti, Falesti, Sangerei, Ungheni, Telenesti, Calarasi, Straseni, Hancesti, Ialoveni, Leova, Cimislia, Cantemir, Basarabeanca, Cahul, Gagauzia, Taraclia, Chisinau, Nisporeni.

We will make all the efforts to can start and perform antirables vaccination in the buffer zone from Moldavia basing on the approvement from European Commission and folowing Romanian procedures. The buffer zone of 50 km at the borrder with Romania is the only new provision for this programe for the

period 2016-2017.

In Moldavia, manual vaccination will be done only in areas around localities in which had evolved rabies in 2014 and 2015 (maximum 500 meters from locality) and where active dens are.

In the field at the distribution for manual vaccination, will participate a representative from the local sanitary veterinary directorate and a representative from the hunter association. Every bait will be recorded with GPS and after ending of the distribution will be made maps for demonstrate the distribution.

Attached, you will find a table with details regarding areas for manual vaccination in Moldavia.

### 1.2. Benefits of the programme

#### Describe

- progress expected compared to the situation of the disease in the previous years, in line with the objectives and expected results
- cost efficiency of the programme including management costs

(max. 32000 chars):

#### 1. ROMANIA

Rabies is mortal, acute encephalitis of warm blooded animals and humans, caused by a RNA-virus of Genus Lyssavirus, which spreads mainly by the saliva of diseased animals, as a result of their bites. The disease can also spread by the contamination of wounds of the skin or mucous membranes with the saliva of diseased animals. All warm blooded animals are affected. Rabies has two clinical forms – furious and dumb. Both forms are characterized by signs showing the affection of the central nervous system, behavioral deviation, salivation and the paralysis of the skeletal and pharyngeal muscles. The incubation period for rabies varies between 6 days and 6 months, or more.

Animals infected with rabies can spread the virus 10-14 days before the occurrence of clinical signs. Following the occurrence of clinical signs, animals die in approximately 10 days.

Rabies is spread in the whole world, excepting for certain countries in which, due to geographical particularities, either the virus never entered or the country became free of the disease, consequently to the application of certain serious control measures (UK, the British Isles, Scandinavia, Spain and Portugal, Luxemburg).

Lately, it has been noticed a recrudescence of rabies in different regions of the world, due to maintenance of the virus in the population of wild animals.

Romania is one of the countries with the highest number of rabies cases from Europe.

Romania has a surface of more than 237500 km2 of which 62346 km2 is covered by forests.

The livestock of foxes estimated in 2012 is 61360. The fox population is distributed in 2103 hunting funds administered by the National Administration of Forests, Associations of Hunters and Fishermen and by private administrators, in which these are officially registered.

From numerical point of view, in the last years the fox population in Romania was maintained in steady

limits, which determine that their density is under 1 animal per km2.

The stock-taking of foxes is done annually in spring, when is also established the quota for fox hunting. Rabies in foxes has evolved since many years ago in forests.

The prevalence of rabies, especially in sylvatic reservoir, is a high risk for the most important zoonosis in Romania.

It must be added, that the Danube Delta is a particular area, protected under the Administration of Biosphera's Reservation, where beside the fox population and other wild animals, there are also living domestic animals in a semi wild environment. The veterinarian central service aims to draw up a special program for Danube Delta after study of the existing situation.

In comparison with the situation presented, it can be appreciated that rabies evolves sporadically also in the population of wild animals, other than foxes, disease occurrence not being dependent by the existence of infected foxes in the respective area.

Most cases of rabies were recorded in dogs and a high number was also recorded in the population of cats and bovines. Most positive cases in dogs were registered in rural area. The spread of disease was from wild animals to domestic ones (wild animals-dogs).

In 2011 it was carried out the oral vaccination of foxes in 16 counties (Arad, Alba, Bihor, Mureş, Maramureş, Bistriţa Năsăud, Braşov, Cluj, Covasna, Caraş-Severin, Harghita, Hunedoara, Sălaj, Sibiu, Satu Mare, Timiş) in the west and center of Romania, which is the entire territory bounded by the Carpathian Mountains. The bait distribution included Hungarian, Serbian and part of Ukrainian border. The vaccination of foxes was carried out by air distribution of baits (~ 20 baits/km2) and also by manual distribution around localities and areas difficult to reach by plane (approximately 25 baits/km2). At a minimum 45 days'time since the end of the vaccination campaign, there have been achieved hunting session of foxes for the control of efficiency of vaccination. In order to motivate hunters to get involved in the actions within the National program for the eradication of rabies in foxes, for each fox that was shot and sent to Local Sanitary Veterinary and Food Safety Laboratory there was paid 50 lei in conformity with GD 55/2008.

The oral vaccination of foxes was carried out with vaccinal baits intended exclusively for this species. Baits are made up of two components: live vaccine represented by SAD Bern, closed in an aluminium-plastic blister and the cover of bait is made up of a palatable paste of meat with a strong fish smell. In one bait there is one vaccination virus dose (1.8 ml), closed in an aluminium-plastic blister. The bait is round, dark brown and is made of a feed mixture which is strongly attractive for foxes.

The vaccine is used in several Member States with appropriate results.

In 2011, following the spring vaccination campaign, 982 mandibles of foxes were tested for the presence of tetracycline, of which there were found 269 tetracycline positive results. Chest cavity fluid was available for 770 foxes and 102 were positive for rabies antibodies. The shooting foxes campaign to determine the effectiveness of vaccination continued in 2012, following the autumn vaccination campaign in 2011. The mandibles of 1808 foxes were tested for the presence of tetracycline, 681 samples with positive results for tetracycline. Chest cavity fluid was available for 1363 foxes and 278 were positive for post-vaccinal antibodies against rabies.

In 2011 the hunting funds were privatized. This has led to an increased number of hunting territory managers involved in the shooting of foxes to assess the efficacy of the vaccination campaign. For this reason the number of foxes tested to determine the effectiveness of vaccination has been reduced.

In 2012, due to political and legislative changes that took place in Romania, the legal basis for approving the oral vaccination of foxes in the whole territory was not approved until the 1st of June, 2012.

Therefore, in Romania the spring vaccination campaign of foxes against rabies was not performed. In August 2012 the legal basis has been approved in order to implement the oral vaccination of foxes in the whole territory. We are currently in conflict with the company of aerial distribution of vaccinal baits. The NSVFSA makes all efforts to implement (perform) the oral vaccination campaign of foxes.

The NSVFSA addressed to The Ministry of National Defence, by requesting the support for the carrying out of autumn campaign in 2012, by air distribution of antirabies vaccines, as vaccinal baits for foxes, but from legal and economic reasons, this could not be carried out.

From these reasons, in the autumn of 2012, Romania failed to carry out the vaccination of foxes by manual distribution to dens of 80475 vaccinal baits (58.680 national vaccination +21.795 emergency vaccination in counties AG, DB, PH, VN) in 41 counties (aprox. 3350 km2). In the autumn of 2012, there has been purchased a number of 80.520 baits, of which 40 baits were sampled for testing for establishing the stability of vaccinal titer and 5 baits being kept as counter samples. Of 40 baits samples, 16 baits were tested for virus titer and stability of virus titer.

For 2013 the program for surveillance, control and eradication of rabies in Romania approved by Commission Decision 2012/761/CE, submitted by Romania, provides application in 41 counties. On 20.05.2013, the subsequent contract for the services of storage, the air distribution of antirabies vaccine for foxes as vaccine baits and the distribution of informative materials and the campaign of people's warning was signed between the service provider and N.S.V.F.SA., for both 2013 vaccination campaigns applying on whole territory of Romania.

The first campaign of antirabies oral vaccination started on June 07, 2013 and was completed in July 13, 2013. The bait distribution includes border with Serbia, Hungary, Ukraine, Moldova and Bulgaria. The vaccination of foxes was carried out by air distribution of baits (number of 3.846.098 baits with an approx. 20 baits/km2), see the map, and also by manual distribution (number of 58735 baits) around localities and areas difficult to reach by plane (approximately 25 baits/km2).

At a 45 days'time following first vaccination campaign, there shall be performed the hunting of foxes in order to assess the efficiency of vaccination, for this purpose, there shall be shot 4 foxes/year/100 km2. Shooting campaign of foxes for vaccination efficacy determination started in august 6.

The second antirabies vaccination campaign started on 01 October 2013 and was completed in 28 November 2013. The bait distribution includes border with Serbia, Hungary, Ukraine, Moldova and Bulgaria.

The vaccination of foxes was carried out by air distribution of baits (number of 3.928.810 baits with an approx. 20 baits/km2), see the map, and also by manual distribution (number of 58.715 baits) around localities and areas difficult to reach by plane (approximately 25 baits/km2).

At a 45 days'time following first vaccination campaign, there shall be performed the hunting of foxes in order to assess the efficiency of vaccination, for this purpose, there shall be shot 4 foxes/year/100 km2. Shooting campaign of foxes for vaccination efficacy determination started in December 7. In 2013, at the end of the year, we had, 982 mandibles of foxes were tested for the presence of tetracycline, of which there were found 269 tetracycline positive results. Chest cavity fluid was available for 770 foxes and 102 were positive for rabies antibodies. The shooting foxes campaign to determine the effectiveness of vaccination continued in 2012, following the autumn vaccination campaign in 2011. The mandibles of 1808 foxes were tested for the presence of tetracycline, 681 samples with positive results for tetracycline. Chest cavity fluid was available for 1363 foxes and 278 were positive for post-vaccinal antibodies against rabie.

For the year 2014, ANSVSA done a new tender for starting a new vaccination programme for the period 2014-2017. Because the tender was finalized in june we started the first campaign in autumn. Campaign was performed in the period 6 octomber 2014 – 27 november 2014.

Autumn campaign took more then 30 days because in that period were registered many days without activity for airplanes due to the bad wheather conditions for flying.

Short sumarise of autumn campaign:

- were used 25 airplanes from 3 different flyng companies from Cehia, Bulgaria and serbia,
- Was distributed a number of 5.334.375 vaccine baits for aerial distribution and 75.400 vaccine baits for manual distribution,
- Airplanes droped baits over 475322,6 linear km,
- It were recorded 3120 flight hours,
- Media of density of the droped baits was of 25 baits/square km, avoiding localities and water surfaces. At a 45 days'time following first vaccination campaign, there shall be performed the hunting of foxes in order to assess the efficiency of vaccination, for this purpose, there shall be shot 4 foxes/year/100 km2.

For the 2014 year, 5385 mandibles of foxes were tested for the presence of tetracycline, of which there were found 2978 tetracycline positive results. Chest cavity fluid was available for 5048 foxes and 1574 were positive for rabies antibodies.

Our conclusion is that we have improvements about the effectiveness of the antirabies vaccination of foxes in Romania, basing on the percent of 56% of positive results for tetracycline detection and 32% positive results of ELISA test for rabies antybody detection.

#### 2. MOLDOVA

Republic of Moldova is one of the countries with the highest number of rabies cases in Europe (animal and humans).

In year 2014, 140 animals had positive results for rabies (from them 32 were foxes),

in 2013 - 109 animals were positive (from them 22 were foxes),

in 2012 - 184 animals were positive (from them 26 were foxes),

in 2011 - 58 animals were positive(from them 16 foxes ) and

in 2010 - 111 animals were positive (from them 28 foxes i).

Rabies in Humans

The last death Rabies case in human was registered in 2003 (Drochia district - the bite caused by a marten). In year 2011 was registered next dates:

no. of animal biten humans - 4598,

no. of vaccinated humans- 1752,

no. of vaccin dosses used for humans - 12321 doses;

2012 was registered next dates:

no. of animal biten humans - 5244,

no. of vaccinated humans - 2056,

no. of vaccin used for humans - 14254 doses;

2013 was registered next dates:

no. of bites people - 4572,

no. of vaccinated people - 1950,

no. of vaccin used for humans - 12281 doses;

2014 was registered next dates:

no. of bites people - 4476,

no. of vaccinated people - 1677,

no. of vaccin used for humans - 11307 doses.

Republic of Moldova has a surface of approximatively 33803,5 km2 of which 4431 km2 is covered by

forests. The Selfdeclarere Region of Transnistria which is not under the coordination of the government authorities of Republic of Republic of Moldova has a surface of 3363 Km2.

The livestock of foxes estimated in 2014 is approximate at 30.000 animals.

From numerical point of view, in the last years the fox population in Republic of Moldova was maintained in steady limits, which determine that their density is under 1 animal per km2.

The stock-taking of foxes is done annually without limit.

The prevalence of rabies, especially in sylvatic reservoir, is a high risk for the most important zoonosis in Republic of Moldova.

In comparison with the situation presented, it can be appreciated that rabies evolves sporadically also in the population of wild animals, other than foxes, disease occurrence not being dependent by the existence of infected foxes in the respective area.

Most cases of rabies were recorded in dogs and a high number was also recorded in the population of cats and bovines. Most positive cases in dogs were registered in rural area. The spread of disease was from wild animals to domestic ones (wild animals-dogs).

In 2014 it was carried out the oral vaccination of foxes in 35 districts and 2 municipalitis by the manual distribution of the baits about 6.7 of baits for 1 burrows of foxes.

The oral vaccination of foxes was carried out with vaccinal baits intended exclusively for this species. Baits are made up of two components: live vaccine represented by SAD Berne, closed in an aluminium-plastic blister and the cover of bait is made up of a palatable paste of meat with a strong fish smell. In one bait there is one vaccination virus dose (1.8 ml), closed in an aluminium-plastic blister. The bait is round, dark brown and is made of a feed mixture which is strongly attractive for foxes.

The vaccine is used in several Member States with appropriate results.

In 2014 was carried out 2 antirabies vaccination campaigns in March and November by the manual distribution of 70000 doses of vaccine in first vaccination campaign and 70000 doses of vaccine in second vaccination compaign in total 140000 doses of vaccine.

In MOLDOVA, the bait distribution will be done at a distance of 50 km from the border with ROMANIA, in the 25 counties mentioned.

An efficient achievement of the Programme will decrease the risk of spreading rabies at susceptibile animals, domestic and wild, removing the danger of transmiting rabies to human and allow to Moldavia to obtained status of "free of rabies". In the same time, for Romania, benefits of the extended programme in Moldavia, is eradication of rabies on the entire surfaces of the country and reducing the risk of reintroducing rabies virus from Moldavia.

2. Description and demarcation of the geographical and administrative areas in which the programme is to be implemented

Provide the name and surface of the areas where the following activities are implemented (if administravive areas are not used, describe the natural or artificial boundaries used to determine the geographical areas)

- vaccination and monitoring
- surveillance

Attach maps as necessary

#### (max. 32000 chars):

In Romania, oral vaccination of foxes will be carried out early, in two vaccination campaigns, in spring and autumn, in all 42 counties, mostly by plane distribution, 25 baits/ campaign/km2 with a distance between flight lines of 500 meters and 150 meters altitude, by avoiding the territories of localities, water surfaces, highways, etc. In these areas and around localities where rabies has evolved, distribution of vaccinal baits shall be done manually, at den.

Estimated surface suitable for aerial vaccination is approximated at 213.375 square kilometers.

At a 45 days'time following each vaccination campaign, there shall be performed the hunting of foxes in order to assess the efficiency of vaccination, for this purpose, there shall be shot 4 foxes/year/100 km2. Manual vaccination will be carried out also in all 42 counties from Romania.

In Moldavia, we intend to perform vaccination campaign into a 50 km buffer zone from the border with Romania, in the same technical conditions, like it is performed in Romania, for the period 2016-2017. Short summarise of the 50 km buffer zone:

- 25 regions (rayons) with a total surface of 17755,63 square km, (see attached table 1)
- Surface suitable for aerial distribution (without water and localities) is of 12625,41 square km, (see attached table 1)
  - 3. Description of the measures of the programme

#### 3.1. Notification of the disease

#### (max. 32000 chars):

#### 1.ROMANIA

Rabies prophylaxis under legislative aspects in Romania is regulated by the following Orders and Laws:

- Order No. 29/28.03.2008 for the approval of the sanitary veterinary norm regarding general measures for preventing and control of rabies in domestic and wild animals
- Government Decision No. 55/16.01.2008 for the approval of the strategic programme for surveillance,

control and eradication of rabies in foxes in Romania, with further modifications and completions;

- Government Decision No. 1156/2013 for the approval of veterinary actions included in the Program of the surveillance, prevention, control and eradication of animal diseases transmissible from animals to humans, animals and the environment, the identification and registration of bovine animals, swine, sheep, goats and equine of actions in surveillance and control program on food safety and related charges
- Order No.29/25.01.2014, The programme of the actions of surveillance, prevention, control, and eradication of animal diseases, of those transmissible from animals to man, for protection of animals and environment, of yearly identification and registration of bovines, swines, ovines and caprines, as well as of methodological norms of yearly applying of The programme of surveillance and control in the field of food safety.

According to the above mentioned rules, in Romania, the vaccination and registration of domestic dogs and cats is compulsory.

Disease notification

Rabies is a notifiable disease in Romania; it is notified at both local and central level accordingly to the NSVFSA President Order No.79/2008, approving the sanitary veterinary norm regarding the internal notification and the official declaring of some diseases transmissible to animals, as well as the procedure of stamping out of some notifiable diseases. Also, rabies is a notifiable disease at EU, accordingly to the Council Directive 82/894/EC.

The empowered free-practice veterinarian is obliged to notify the official veterinarian all suspected cases of rabies. Rabies suspicion is notified to the county SVFSD, and the samples are sent to the county sanitary veterinary laboratory which is authorised and acknowledged for the diagnosis of rabies. The official veterinarian responsible for animal health issues at the level of county SVFSD shall notify all suspect cases of rabies by rapid communication to the Director of Animal health and welfare directorate at the level of NSVFSA, using a notification report form for the notification of all confirmed cases of rabies to NSVFSA.

Following to confirmation of rabies, the county SVFSD and of the Bucharest Municipality shall notify all confirmed cases of rabies, by using a notification report form to NSVFSA.

Following to laboratory confirmation of rabies, the county SVFSD and of the Bucharest Municipality shall notify all confirmed cases of rabies, by using a notification report form to NSVFSA.

The situation concerning the cases of rabies is notified twice a year to OIE and quarterly to the European Institute for Rabies Control.

#### 2. MOLDOVA

Rabies prophylaxis under legislative aspects in Republic of Moldova is regulated by the following Orders and Laws:

- Law no. 221 of 19.10.2007 concerning sanitary veterinary activity
- Government Decision no. 494 of 06.05.1998 on the control and prevention of rabies
- Order MAIA no. 34 of 27.02.2006 on approval of sanitary veterinary norm on the announcement, declaration and notification of animal diseases.
- Order NFSA no. 258 of 22.10.2014 strategic program of actions surveillance, prevention and control of animal diseases prevention of transmission of diseases from animals to humans and protection of the environment

According to the above mentioned rules, in Republic of Moldova, the vaccination and catagraphy of domestic dogs is compulsory.

#### Disease notification

Rabies is a notifiable disease in Republic of Moldova; it is notified at both local and central level in accordance with the Order of Ministry of Agriculture no. 34 of 27.02.2006, on approval of sanitary veterinary norm on the announcement, declaration and notification of animal diseases.

The empowered free-practice veterinarian is obliged to notify the official veterinarian all suspected cases of rabies. Rabies suspicion is notified to the county FSDS, and the samples are sent to the Republican Veterinary Diagnostic Center (RVDC) which is responsible for the diagnosis of rabies. Final disease confirmation is done at the level of rabies NRL - RVDC.

The official veterinarian responsible for animal health issues at the level of county FSDS notify all suspect cases of rabies by rapid communication to the Head of Sanitary-Veterinary Surveillance Department at the level of NFSA, using a notification report form for the notification of all confirmed cases of rabies to NFSA.

Following to confirmation of rabies, the county FSDS notify all confirmed cases of rabies, by using a notification report form to NFSA.

If rabies is confirmed in a domestic animal, the owner is also notified and a complete file is issued in order to apply the control measures.

To prevent rabies in domestic animals, especially dogs, the municipality (districts) annually (October to December) records dogs belonging to individual owners, organizations, institutions and businesses operators.

Data record of dogs are used for appropriate charges and prophylactic immunization plans. All dogs on record are vaccinated once a year (October to December). The action is announced in the press and other mass media.

All the records regarding rabies vaccination are kept at the FSDS level and a summary is sent to NFSA. In order to prevent the introduction of rabies in dogs and cats in to the country by overseas or carried in transit through the territory of the republic of Moldova must be above 2 months old and have to be accompanied by an international certificate of vaccination, written in a international circulation language (English) which confirm rabies vaccination.

The situation concerning the cases of rabies is notified twice a year to OIE and quarterly to the Rabies-Bulletin-Europe (World Health Organization).

### 3.2. Target animals and animal population

(max. 32000 chars):

The target animals of this programme are foxes.

In Romania, the population of foxes for the year 2015 is estimated at 65.707 animals. In Moldova, the population of foxes for the year 2015 is estimated at 32.000 animals.

### 3.3. Tests used and sampling schemes

#### Describe:

- a. the tests used for surveillance and monitoring, when are to be used and in which animals
- b. the sampling schemes in each area of the programme for surveillance and monitoring

#### (max. 32000 chars):

#### 1. ROMANIA

Virological and serological tests used shall comply with the Manual of standards for diagnostic tests for OIE.

The most widely used test for rabies diagnosis which is recommended by both OIE and OMS. This test may be used directly on brain sample, and it can also be used to confirm the presence of rabies antigen in cell culture or brain tissues of mice that have been inoculated for diagnosis. The FAT test gives reliable results in more than 95-99% of cases.

For the diagnosis of rabies, the smears of a mixture of nervous tissue including the cerebral trunk are fixed in high-grade cold acetone and then stained with a drop of specific conjugate.

Those available commercially are either polyclonal conjugates specific of the entire virus or specific of nucleocapsid protein, or they may be prepared from a mixture of different monoclonal antibodies. The specific aggregates of nucleocapsid protein combin with fluorescein are identified by immunofluorescence. The specificity and sensitivity of these anti-rabies fluorescent conjugates against the local predominant virus variants shall be checked before use.

The number of animals estimated to be tested by IFD shall be recovered in chapter 7, point 7.1.1. The antirabies vaccination in foxes showed that from 1645 foxes that were shot in 2011 within the programme and checked by FAT, 51 of them were positive, in 2012 were tested by FAT 1645 foxes shot of which 45 were positive and in first semester 2013 were tested by FAT 546 foxes shot of which 44 were positive.

Taking into account the high incidence of rabies cases in Romania, and the fact that some infected foxes do not show any clinical/nervous symptoms when there are shot, there has been decided that all foxes shall be tested by FAT.

Jaw bone fragments and thoracic liquids from foxes to who results at FAT are negative, samples are sent to NRL for rabies for tetracycline marker and antibodies detection by ELISA, and FAT positive samples are sent to NRL to genotype them and differentiate between wild and vaccinated strains.

Immunoenzymatic assay (ELISA)

Immunoenzymatic assays allow a detection of post-vaccinal rabies antibodies from thoracic liquids originated from shot foxes.

According to OIE recommendations, the protective value of antibodies titer shall be greater or equal to 0,5 U.I./ml.

Whereas the recommendations regarding the sampling fraction of foxes for the detection of rabies antibodies level is not provided in UE normative acts, 6965 animals shall be examined every year, between 2015-2017.

Test for the detection of tetracycline marker

Vaccinal baits contain tetracycline as a marker that assures a long-term marking, by being stored at the level of bones and teeth where there is easily detected post-mortem.

The control of efficiency of vaccination shall be tested by tetracycline biomarker in the whole area of vaccination, from the mandibles (teeth and bones) of shot foxes, by microscopic examination in ultraviolet light.

This identification of tetracycline has an important role in monitoring the consumption of vaccinal baits by foxes.

Identification and characterization of specific genome of rabies virus

Materials and methods:

Biological material is represented by brain homogenate samples, confirmed by standard methods (direct imunofluorescence). They are selected for geographical distribution in order to cover as much as possible from Romanian territory or from the territory subject to oral vaccination of foxes.

All samples are initially homogenized using MagNa Lyzer instrument (Roche Applied Science), centrifuged and supernatant ones are collected.

RNA extraction is performed using commercially available kits, such as RNEasy Mini Kit (Qiagen) or High Pure RNA Isolation Kit (Roche Applied Science), according to manufacturer specifications, by using 200µl supernatant sample and the elution of RNA in 50µl final volume.

Reverse-transcription and amplification: the protocol is a conventional RT-PCR with primers specific of the nucleoprotein viral gene, generating an amplification product of 606bp (base pairs, Heaton et al.). The technology of amplification is specific of "single tube" technique- both the stage of reverse transcription and amplification are performed in the sane tube of reaction and there are used commercially available kits.

The final concentration for each reagent abd the thermic profile of reaction are those reccommended by the producer.

Electrophoresis is conducted in 2% agarose gel and TBE buffer (Tris-Borat-EDTA) concentration IX, stained with ethidium bromide.

Isolation and purification of amplicons in gel: we use commercial kits, according to manufacturer recommendations. Quantification of purified amplicons is carried out in a spectrofotometrical way. Direct sequencing is performed by means of Sanger technology- commercial kit BigDye Terminator Cycle Sequencing Kit version 1.1 or 3.1, and model 3130 Genetic Analyzer formed 4 capilars. Results obtained (generated sequencing) are compared with international data banks (GenBank, SUA) and the data bank of IDSA for the confirmation of rabies genome. For harmonization/processing, there are used dedicated programs (Bio Edit Sequence Alignment Editor, Clustal W), resulting in a final fragment of 322bp (base pairs).

Dendrograms were obtained also using available software (Mega Software version 4.0), using algorithmic Neighbor-Joining.

In the period 2011-2012 samples subjected to phylogenetic investigations were selected according to geographical distribution in order to cover the whole Romanian territory – therefore not all positive samples are tested, but only some of them that are relevant for spatial distribution.

All samples selected for phylogenetic investigations were sent to IDAH (NRL for rabies) and they were processed.

So far, all analyzed samples belong to the wild virus category, with high degree of genetic diversity (at least six lineages) - http://www.ncbi.nlm.nih.gov/pubmed/20178821. For quality assessment, NRL for rabies participate to intercomparative trials organised by Community Reference Laboratory, including phylogenetic analysis. During the two 2011 vaccination campaigns, there were not submitted positive samples to Community Reference Laboratory.

All positive detected cases from domestic and wild animals (samples) in vaccinated areas will be differentiated from the vaccine strain. The samples will be sent to IDAH (NRL for rabies) and they will be

processed as described above.

#### 2. MOLDOVA

Virological and serological tests used shall comply with the Manual of standards for diagnostic tests for OIE.

#### **FAT Tests**

FAT test is the most widely used test for rabies diagnosis which is recommended by both OIE and OMS. This test may be used directly on brain sample, and it can also be used to confirm the presence of rabies antigen in cell culture or brain tissues of mice that have been inoculated for diagnosis. The FAT test gives reliable results on fresh specimens within an hour in more than 95-99% of cases.

For the diagnosis of rabies, the smears of a mixture of nervous tissue including the cerebral trunk are fixed in high-grade cold acetone and then stained with a drop of specific conjugate. Anti-rabies fluorescent conjugates may be prepared in the laboratory.

Those available commercially are either polyclonal conjugates specific of the entire virus or specific of nucleocapsid protein, or they may be prepared from a mixture of different monoclonal antibodies. The specific aggregates of nucleocapsid protein are identified by their immunofluorescence. The specificity and sensitivity of these anti-rabies fluorescent conjugates against the local predominant virus variants shall be checked before use.

The number of animals estimated to be tested by FAT is 1050 every year, between 2016-2017.

### Immunoenzymatic assay (ELISA)

Immunoenzymatic assays allow a detection of post-vaccinal rabies antibodies from thoracic liquids originated from shot foxes.

According to OIE recommendations, the protective value of antibodies titer shall be greater or equal to 0,5 U.I./ml.

720 animals shall be examined every year, between 2016-2017.

### Test for the detection of tetracycline marker

Vaccinal baits contain tetracycline as a marker that assures a long-term marking, by being stored at the level of bones and teeth where there is easily detected post-mortem.

The control of efficiency of vaccination shall be tested by tetracycline biomarker in the whole area of vaccination, from the mandibles (teeth and bones) of shot foxes, by microscopic examination in ultraviolet light.

This identification of tetracycline has an important role in monitoring the consumption of vaccinal baits by foxes.

510 foxes will be shoot and tested every year, between 2016-2017.

#### 3.4. Vaccines used and vaccination schemes

#### Describe

- vaccine(s) to be used
- bait density to be achieved in each of the units of the programme
- number and period of the campaigns
- Vaccine distribution (if it is delivered by hand, clarify the reason and the areas covered)

#### (max. 32000 chars):

### 1. ROMANIA

Live rabies vaccines used for the oral vaccination of foxes shall fulfill the requirements of the European Pharmacopoeia monographs as well as the efficacy and safety recommendations of the OIE manual. Vaccine titers of each batch at release, shall be at least 10 times greater than the dose that assures the entire vaccinal protection of the experimental group (indicative of 100% protective dose). Each series of vaccine shall be put to test regarding the viral titer in conformity with the European

Each series of vaccine shall be put to test regarding the viral titer in conformity with the European Pharmacopoeia, OIE standards, WHO recommendations and the SCAHAW report for the oral vaccination of foxes against rabies, adopted on October, 23 2002.

Vaccine producers shall put to the availability of The Official Laboratories for the Control of Medicines detailed information on the stability of baits used in the field.

The Community Reference Laboratory shall perform additional tests or trials if required.

The proof of compliance about vaccine titer shall be demonstrated in certificates issued by the official quality control laboratories recognized by EDQM (European Directorate for the Quality of Medicines). The laboratory involved in the testing of rabies vaccine shall monitor viral titres from vaccinal baits before the beginning of vaccination campaign for all vaccine batches that shall be used in the vaccination campaign.

During the vaccination campaign, there shall be carried out a monitoring of viral titres in order to check the observance of storage requirements; the controlled batches shall be chosed at random.

The melting point of the bait casing shall be in conformity with OIE recommendations in order to ensure that the capsule of vaccine suspensions is still covered by the mixture of bait if exposed to such temperatures in the field, following distribution.

The Community Reference Laboratory shall perform additional tests or trials if required.

The transport, storage and distribution of vaccine baits will be done in the conditions of the temperature specified by the manufacturer in the product prospect.

The service provider of the storage vaccine baits sends daily to NSVFSA the thermogram cold storage and the delegates of the CSVFSA check daily the cold warehouse and thermograms of vaccine baits from the cold warehouse.

The use of tetracycline as a biomarker in the teeth and bones of foxes is recommended to evaluate vaccinal baits-uptake in animals.

The vaccines against rabies which are to be used in vaccination campaigns against rabies in foxes are presented as vaccine baits, administered by plane over the most important surface from the area established for vaccination, and manually, in the areas where the administration by plane is not possible.

The used vaccines shall be immunogenic, harmless and produced for the main susceptible species at rabies, so as to be used in most of the vaccination campaigns established during the year, irrespective of weather conditions.

The oral vaccination of foxes shall be carried out by distributing vaccine baits (25 baits/km2) by plane or by helicopter, on smooth surfaces or in case of areas where access is burdened, and around the localities, it is done manually (25 bites/km2) by the managers of the hunting founds, being assisted by the official vets. In areas with significant surfaces of water, vaccination shall be done manually.

In order to be appropriate for use in Romania, vaccines against rabies need to be authorized for trade in our country.

The trade authorization shall be performed in accordance with the NSVFSA Order no. 187/2007 (with subsequent amendments) regarding The Code of veterinary medical products, published in the Official Journal of Romania Part I, No. 804 bis/26.XI.2007 or in accordance with Regulation 726/2004/EC for establishing the Community procedures concerning authorization and surveillance of medicines for humans and veterinary use and for founding an European Agency for medicines, published in O. J. No. L 136, 30.04.2004.

The authorization conditions for vaccines against rabies are:

- To contain live attenuated vaccine strains;
- To be intended for oral immunization of foxes;
- The way of presentation shall be appropriate for aerial distribution

At delivery, every vaccine series shall be accompanied by the Official Analysis report, in accordance with the request of EDQM (European Directorate for the Quality of Medicines).

For the vaccination of livestock (dogs, cats and other domestic animals), the vaccine is used in accordance with national and EU legislation.

Vaccination of domestic carnivores (dogs and cats) – each animal shall be vaccinated against rabies from the age of three months with yearly revaccination according with the NSVFSA President Order No.29/2008 for the approval of the sanitary veterinary norm regarding general measures for preventing and control of rabies in domestic and wild animals and Commission Decision 94/275/EC on recognizing antirabies vaccines.

Prophylactic vaccination of dogs and cats in backyards and dogs from the sheepfold with inactivated vaccine is made by organizing mass vaccination campaigns, during autumn-winter, followed by completing vaccination.

Vaccination of domestic animals in the outbreak is done according to the national legislation in force.

#### 2. MOLDOVA

Live rabies vaccines used for the oral vaccination of foxes shall fulfill the requirements of the European Pharmacopoeia monographs as well as the efficacy and safety recommendations of the OIE manual. Vaccine titers of each batch at release, shall be at least 10 times greater than the dose that assures the entire vaccinal protection of the experimental group (indicative of 100% protective dose).

Each series of vaccine shall be put to test regarding the viral titer in conformity with the European Pharmacopoeia, OIE standards, WHO recommendations and the SCAHAW report for the oral vaccination of foxes against rabies, adopted on October, 2002.

Vaccine producers shall put to the availability of The Official Laboratories for the Control of Medicines detailed information on the stability of baits used in the field.

The proof of compliance about vaccine titer shall be demonstrated in certificates issued by the official quality control laboratories recognized by EDQM (European Directorate for the Quality of Medicines).

The laboratory involved in the testing of rabies vaccine shall monitor viral titres from vaccinal baits before the beginning of vaccination campaign for all vaccine batches that shall be used in the vaccination campaign.

During the vaccination campaign, there shall be carried out a monitoring of viral titres in order to check the observance of storage requirements; the controlled batches shall be choses at random.

The melting point of the bait casing shall be in conformity with OIE recommendations in order to ensure that the capsule of vaccine suspensions is still covered by the mixture of bait if exposed to such temperatures in the field, following distribution.

The transport, storage and distribution of vaccine baits will be done in the conditions of the temperature specified by the manufacturer in the product prospect/

The use of tetracycline as a biomarker in the teeth and bones of foxes is recommended to evaluate vaccinal baits-uptake in animals.

The vaccines against rabies which are to be used in vaccination campaigns against rabies in foxes are presented as vaccine baits, administered by plane over the most important surface from the area established for vaccination, and manually, in the areas where the administration by plane is not possible. The used vaccines shall be immunogenic, harmless and produced for the main susceptible species at rabies, so as to be used in most of the vaccination campaigns established during the year, irrespective of weather conditions.

The oral vaccination of foxes shall be carried out by distributing vaccine baits (25 baits/km2) by plane or by helicopter, on smooth surfaces or in case of areas where access is burdened, and around the localities, it is done manually by the managers of the hunting founds, being assisted by the official vets. In areas with significant surfaces of water, vaccination shall be done manually.

For the vaccination of livestock (dogs, cats and other domestic animals), the vaccine is used in accordance with national legislation.

Vaccination of domestic carnivores (dogs) – each animal shall be vaccinated against rabies from the age of three months with yearly revaccination according with the Moldova Government Decision 494/1998 Prophylactic vaccination of dogs in backyards and dogs from the sheepfold with inactivated vaccine is made by organizing mass vaccination campaigns, during autumn-winter, followed by completing vaccination.

Vaccination of domestic animals in the outbreak is done according to the national legislation in force.

### 3.5. Measures in case of a positive result

Please describe the measures taken and if reinforced vaccination, surveillance or monitoring is foreseen.

### (max. 32000 chars):

### 1. ROMANIA

When rabies is confirmed in domestic or wild animals, specific control measures are applied, in accordance with the NSVFSA President Order No. 29/28.03. 2008 for the approval of sanitary veterinary norm regarding general measures of prevention and control of rabies in domestic and wild animals.

For these cases the following procedure is applied:

A. Measures applied in case of rabies confirmation in animals from a holding, locality, area After rabies confirmation, the county SVFSD and of Bucharest municipality acts as follows:

- a) shall perform the final epidemiological enquire;
- b) shall establish the protection and the surveillance area;
- c) shall issue the control plan with deadlines and responsibilities;

The control measures in the protection area include:

- drawing up of epidemiological maps;
- put under observation the carnivores which were bitten or scratched by sick animals, if they were not vaccinated against rabies, or if they have less than 21 days since first vaccination,
- isolation by the rest of the animals of the vaccinated carnivores which have been bitten or scratched by the sick animal;
- placement under observation of all animals from that holding for 14 days, beginning with the contact moment;
- killing of all animals from that holding, in case they show clinical signs of rabies in this period of time of 14 days; animals which do not show clinical signs of rabies are released from observation;
- -inspection of carnivores from the protection area which have been bitten or scratched by the sick animal is performed by the free practice empowered veterinarian, for 14 days, and, if they don't show clinical signs are released from observation;
- interdiction of animal movements for the animals which were under observation for a period of at least 3 months.

The control measures in the surveillance zones include:

- a catagraphy of all dogs and cats;
- vaccination of dogs and cats with inactivated vaccine;
- surveillance and movement control of dogs and cats
- B. Measures applied in the hunting funds, in case rabies is confirmed in wild animals When rabies is confirmed, the county SVFSD and of Bucharest Municipality shall take the following measures:
  - a) they shall perform the epidemiological enquiry;
  - b) they shall establish and declare the infected area;
- c) they shall ask the managers of hunting grounds to evaluate the wild animal population, especially of the foxes;
  - d) they shall release the control measures plan with deadlines and responsibilities;
  - e) they shall release and implement a vaccination programme for foxes;
  - f) they shall ask for the organization of hunting campaigns for foxes, without using hunting dogs;
  - g) they shall order the banning of skinning of wild animals that were killed or found dead.

#### 2. MOLDOVA

When rabies is confirmed in domestic or wild animals, specific control measures are applied, in accordance with the Goverment Decision nr. 494 of 06.05.1998 on the control and prevention of rabies.

For these cases the following procedure is applied:

A. Measures applied in case of rabies confirmation in animals from a holding, locality, area After rabies confirmation, the FSDS acts as follows:

- a) shall perform the final epidemiological enquire;
- b) shall establish the protection and the surveillance area;

c) shall issue the control plan with deadlines and responsibilities;

The control measures in the protection area include:

- drawing up of epidemiological maps;
- euthanasia of carnivores which were bitten or scratched by sick animals, if they were not vaccinated against rabies, or if they have less than 21 days since first vaccination,
- isolation by the rest of the animals of the vaccinated carnivores which have been bitten or scratched by the sick animal:
- placement under observation of all animals from that holding for 14 days, beginning with the contact moment;
- killing of all animals from that holding, in case they show clinical signs of rabies in this period of time of 14 days; animals which do not show clinical signs of rabies are released from observation;
- -inspection of carnivores from the protection area which have been bitten or scratched by the sick animal is performed by the free practice empowered veterinarian, for 14 days, and, if they don't show clinical signs are released from observation;
- interdiction of animal movements for the animals which were under observation for a period of at least 2 months.

The control measures in the surveillance zones include:

- a cartography of all dogs and cats;
- vaccination of dogs and cats with inactivated vaccine;
- surveillance and movement control of dogs and cats
- B. Measures applied in the hunting funds, in case rabies is confirmed in wild animals When rabies is confirmed, the county FSDS shall take the following measures:
  - a) they shall perform the epidemiological enquiry;
  - b) they shall establish and declare the infected area;
- c) they shall ask the managers of hunting founds to evaluate the wild animal population, especially of the foxes;
  - d) they shall release the control measures plan with deadlines and responsibilities;
  - e) they shall release and implement a vaccination programme for foxes;
  - f) they shall ask for the organization of hunting campaigns for foxes, without using hunting dogs;
  - g) they shall order the banning of skinning of wild animals that were killed or found dead.

### B. General information

- 1. Organisation, supervision and role of all stakeholders involved in the programme Describe :
  - competent authorities (CA) involved in the implementation of the programme and their responsabilitities
  - other steakholders involved in the implementation of the programme, their role and their communication channels with the CA.

(max. 32000 chars):

#### 1. ROMANIA

The main institutions implicated in the application of the programme for control, monitoring and eradication of rabies are:

National Sanitary Veterinary and Food Safety Authority (NSVFSA), County Sanitary Veterinary and Food Safety Directorates (CSVFSA), Institute for Diagnosis and Animal Health (IDAH), Ministry of Environment, National Administration of Forests, District Forest Ranges, Associations of Hunters and Fishers of Romania and Private Hunting Associations, Institute for Control of Biological Products and Medicines for Veterinary Use.

National Sanitary Veterinary and Food Safety Authority is the central veterinary structure of Romania which is responsible to supervise and coordinate the implementing of the programme.

NSVFSA is also responsible for assuring funds to cover the needs created by implementation of the programme.

At county level, the departments responsible for the programme implementation are all the County Sanitary Veterinary and Food Safety Directorates.

NSVFSA, invested as central unit responsible for acquisition of services of foxes vaccination is responsible for organizing the tender and for the monitoring and evaluation of vaccination efficacy and the activities of vaccination shall be conducted under the coordination of the company which was selected as winner of tender.

CSVFSD shall verify the transport and vaccine storage conditions, monitor vaccine circulation within the territory, control the training of personnel in charge with vaccination and participate at manual vaccination at dens.

Institute for Diagnosis and Animal Health

- It coordinates and administrates the testing capacity of the county laboratories, the training of personnel in order to apply the diagnosis methods;
- Coordinates the diagnostic activity for rabies;

- Draws up epidemiological reports, based on the interpretation of the results regarding rabies;
- The National Reference Laboratory for rabies uses the diagnostic methods in accordance with OIE
- It cooperates through the National Reference Laboratory (NLR) with The Community Reference Laboratory for rabies for the typization and sub-typization of wild strain rabies viruses.

The Institute for the Control of Biological Products and Medicines for Veterinary Use The main responsibilities are:

- authorizes marketing of immunological products used for immunization against rabies in Romania;
- it performs the quality control of all vaccine baits against rabies, in conformity with European Pharmacopoeia, OIE Diagnostic Manual and the SCAHAW report, for the oral vaccination of foxes against rabies, adopted on October, 23 2002;
- provides consultation regarding immunological veterinary medicinal products used for the immunization against rabies in Romania;

Ministry of Environment and Forests manages The National Administration of Forests, and The Associations of Hunters and Fishermen of Romania and supervises The Private Hunting Associations.

The National Administration of Forests

The main responsibilities are:

- it assures the maintenance of foxes population within reasonable limits, by performing the seasonal hunting according to the approved hunting percentage, it authorizes additional hunting percentage to the already approved hunting quota, in order to observe the present Programme;
- it assures, by the personnel from hunting funds, the achievement of sampling and their transport to laboratory for the accomplishing of laboratory surveillance for the diagnosis of rabies, and for the assessment of post-vaccinal immunization, according to the approved programme;

The National Administration of Forests estimates each year the fox population and establishes the annual the number of foxes proposed to be hunted (hunting quota).

The Associations of Hunters and Fishermen of Romania and The Private Hunting Associations The main responsibilities are:

- monitoring and evaluation of the density of foxes population from Romania's hunting funds;
- monitoring and control of the implementation of measures which are the tasks of the administrators of hunting funds;
- cooperating with CSVFSD for the implementation of the programme;

The hunting associations of Romania organize hunting sessions following the completion of vaccination campaigns, assuring the transport of the samples (shot foxes) collected by the personnel in charge with sampling at the level of the county laboratories within the CSFSD.

#### 2. MOLDOVA

The main institutions implicated in the application of the programme for control, monitoring and eradication of rabies are:

National Food Safety Agency (NFSA), Food Safety District Subdivisions (FSDS), Republican Veterinary Diagnostic Center (RVDC), Ministry of Environment, Agency "Moldsilva", District Forest Ranges, Associations of Hunters and Fishers of Republic of Moldova.

National Food Safety Agency is the central veterinary structure of Republic of Moldova which is responsible to supervise and coordinate the implementing of the programme.

NFSA is also responsible for assuring funds to cover the needs created by implementation of the

programme.

At county level, the departments responsible for the programme implementation are all the Food Safety District Subdivisions.

NFSA, invested as central unit responsible for acquisition of services of foxes vaccination is responsible for organizing the tender and for the monitoring and evaluation of vaccination efficacy and the activities of vaccination shall be conducted under the coordination of the company which was selected as winner of tender.

FSDS shall verify the transport and vaccine storage conditions, monitor vaccine circulation within the territory, control the training of personnel in charge with vaccination and participate at manual vaccination at dens.

Republican Veterinary Diagnostic Center

- -In the Republican Veterinary Diagnostic Center is the National Reference Laboratory for Rabies
- It coordinates and administrates the testing capacity of the county laboratories, the training of personnel in order to apply the diagnosis methods;
- Coordinates the diagnostic activity for rabies;
- Draws up epidemiological reports, based on the interpretation of the results regarding rabies;
- The National Reference Laboratory for rabies uses the diagnostic methods in accordance with OIE
- give the marketing authorization for the immunological products used for immunization against rabies in Republic of Moldova;
- it performs the quality control of all vaccine baits against rabies, in conformity with OIE Diagnostic Manual ;
- provides consultation regarding immunological veterinary medicinal products used for the immunization against rabies in Republic of Moldova;

The Moldosilva Agency

Moldsilva is the agency responsible for the hunting grounds in the forest.

The main responsibilities are:

- it assures the maintenance of foxes population within reasonable limits, by performing the seasonal hunting according to the approved hunting percentage,
- it authorizes additional hunting percentage to the already approved hunting quota, in order to observe the present Programme;
- it assures, by the personnel from hunting funds, the achievement of sampling and their transport to laboratory for the accomplishing of laboratory surveillance for the diagnosis of rabies, and for the assessment of post-vaccinal immunization, according to the approved programme;

The Society of Hunters and Fishermen of Republic of Moldova

The Society of Hunters and Fishermen of Republic of Moldova is responsible for the hunting grounds, except the ones in the forests.

The main responsibilities are:

- monitoring and evaluation of the density of foxes population from Republic of Moldova hunting funds;
- monitoring and control of the implementation of measures which are the tasks of the administrators of hunting funds;

it assures, by the personnel from hunting funds, the achievement of sampling and their transport to laboratory for the accomplishing of laboratory surveillance for the diagnosis of rabies, and for the assessment of post-vaccinal immunization, according to the approved programme.

### 2. Legal basis for the implementation of the programme

(max. 32000 chars):

#### 1. ROMANIA

- OIE Diagnostic Manual and the SCAHAW report, for the oral vaccination of foxes against rabies, adopted on October, 23 2002
- Order No. 29/28.03.2008 for the approval of the sanitary veterinary norm regarding general measures for preventing and control of rabies in domestic and wild animals
- Government Decision No. 55/16.01.2008 for the approval of the strategic programme for surveillance, control and eradication of rabies in foxes in Romania, with further modifications and completions;
- Order No.29/25.01.2014, The programme of the actions of surveillance, prevention, control, and eradication of animal diseases, of those transmissible from animals to man, for protection of animals and environment, of yearly identification and registration of bovines, swines, ovines and caprines, as well as of methodological norms of yearly applying of The programme of surveillance and control in the field of food safety.
- NSVFSA President Order No.79/2008, approving the sanitary veterinary norm regarding the internal notification and the official declaring of some diseases transmissible to animals, as well as the procedure of stamping out of some notifiable diseases,
- requirements of the European Pharmacopoeia monographs as well as the efficacy and safety recommendations of the OIE manual,
- The proof of compliance about vaccine titer shall be demonstrated in certificates issued by the official quality control laboratories recognized by EDQM (European Directorate for the Quality of Medicines), NSVFSA Order no. 187/2007 (with subsequent amendments) regarding The Code of veterinary medical products, published in the Official Journal of Romania Part I, No. 804 bis/26.XI.2007 or in accordance with Regulation 726/2004/EC for establishing the Community procedures concerning authorization and surveillance of medicines for humans and veterinary use and for founding an European Agency for medicines, published in O. J. No. L 136, 30.04.2004,
- Government Decision No. 1156/2013 for the approval of veterinary actions included in the Program of the surveillance, prevention, control and eradication of animal diseases transmissible from animals to humans, animals and the environment, the identification and registration of bovine animals, swine, sheep, goats and equine of actions in surveillance and control program on food safety and related charges,
- Government Decision No. 1214/2009 specifies the beneficiaries of compensations (under art. 4), the method of compensation and the source of the funds for disease control operations and describes the basis for this calculation (covered in art. 4 and Appendix no. 2),
- Decision Number 722/2012/UE
- Decision Number SANTE/VP/2015/RO/SI2.700828,
- monitoring of animal movements in conformity with CE Reg. no.576/2013 and 577/2013 regarding animal health requirements regulating trade and imports of animals, semen and embryos in Community that are not subject to animal health requirements established by the Community norms provided in Annex A, point I to Directive 90/425/EEC.
- Procedure reagarding antirables vaccination at foxes (advertising campaign, transport, storage, distribution, and testing of the efficiency of the antirables vaccin for oral vaccination of foxes,

#### 2. MOLDOVA

Measures regarding bio-security and infrastructure in the holdings involved are foreseen in the following national legal bases:

- Law no. 221 of 19.10.2007 concerning sanitary veterinary activity
- Government Decision no. 494 of 06.05.1998 on the control and prevention of rabies
- Order MAIA no. 34 of 27.02.2006 on approval of sanitary veterinary norm on the announcement, declaration and notification of animal diseases.
- Order NFSA no. 258 of 22.10.2014 strategic program of actions surveillance, prevention and control of animal diseases prevention of transmission of diseases from animals to humans and protection of the environment

According to the above mentioned rules, in Republic of Moldova, the vaccination of domestic dogs is compulsory anualy.

Moldavian Sanitary Veterinary Agency (ANSA) and Romanian National Sanitary Veterinary and Food Safety Authority (NSVFSA) have an agreement for institutional cooperation in the sanitary veterinary and food safety domain.

By recognizing the importance of bilateral cooperation in areas of mutual interest, National Sanitary Veterinary and Food Safety Authority in Romania and the National Food Safety in Moldova signed an institutional cooperation protocol in the field of sanitary veterinary and food safety field in order to establish joint actions for surveillance, prevention, control and eradication of animal diseases, those transmitted from animals to humans, diseases with major economic impact, and supervision and control of food safety.

3. Historical data on the epidemiological evolution of the disease

#### Provide:

- a. a concise description of the following indicators
  - number of rabies cases (excluding bat cases) compared to previous year
  - number of rabies cases in previously(last year) case free areas compared to previous year
  - % of seroconversion in target species (juveniles/aldut separately) compared to previous year
  - % of vaccine uptake in target species (juveniles/adult separately) compared to previous year
- b. an assessment of the evolution of the indicators along the years is requested as well as obstacles and contraints identified that hamper the progress of eradication.

(max. 32000 chars):

#### 1. ROMANIA

- Rabies cases in 2014 169 cases
- Rabies cases in 2015 (untill 29 may 2015) 20 cases
- Seroconversion at foxes for 2013 was of 28.35 %
- Seroconversion at foxes for 2014 was of 32,52%.

#### 2.MOLDOVA

In year 2014, 140 animals had positive results for rabies (from them 32 were foxes),

in 2013 - 109 animals were positive (from them 22 were foxes),

in 2012 - 184 animals were positive (from them 26 were foxes),

in 2011 - 58 animals were positive(from them 16 foxes ) and

in 2010 - 111 animals were positive (from them 28 foxes i).

4. Control on the implementation of the programme

Describe the system to control the implementation of the programme (flight tracks, bait distribution, cold chain and official controls to be performed on the vaccine)

(max. 32000 chars):

1. Technical specification regarding handling of the vaccine

When handling vaccine baits it must be strictly respected storage conditions and transport and cold chain requirements specified by the manufacturer.

The vaccine should be transported from field to place of storage at a temperature of -20°C in refrigerated containers for being sufficiently protected against excessive ambient temperature. Also, the vaccine is stored in a dark place at a temperature of -20 °C or less.

Until applied manually or by plane, the vaccine should not be exposed to temperatures above + 15°C. At temperatures above + 30°C, the coating can melt bait and vaccine titers decrease failing to ensure the effectiveness of vaccination. The vaccine can be distributed throughout the year, when temperatures are in the range 0°C - +25°C.

The area where vaccination is to be properly marked and those people must be adequately informed by information posters, warning and informational materials chronological.

2. The service provider must have at least 14 airplanes equiped with automaticly distribution equipment to ensure the distribution of rabies vaccine baits throughout the eligible area of Romania within 30 days, in favorable weather conditions.

Automaticly distribution equipment must be linked to GPS which must record place, date, time (hour, minute, seconds), altitude, speed for every bait distributed.

Main obligation of the service provider are:

- To distribute by air 25/Km2 vaccine baits across the entire surface of 213.375 km² estimated eligible / campaign, with the plan of distribution lines set at a distance of 500 m each, with a maximum speed of

flight 180km / h at a maximum altitude of 150 m.

- Do not distribute vaccine baits from air to surface areas or localities less than 500 m from these water bodies (rivers, lakes, rivers), highways, roads European, national and county. To prepare and implement a strategy to enable a uniform distribution on all the surface with a density of 25 baits / km² (mountains, hills, valleys, plains, Delta, etc.)
- Comply with the specifications in the package insert regarding atmospheric temperature conditions on the distribution of vaccine baits.
- to transmit the recorded data in real time to a server provided to the contracting authority by the service provider. In this regard, the service provider must have a server software program compatible with ArcGIS version 9.1, which will be operated by representatives ANSVSA to view and check the recorded data in real time and after campaign;
- to save all data in an encrypted file, in order to prevent a possible manipulation of data recorded. To decode the data, it is necessary to have a decoding algorithm (key). Only the manufacturer / supplier of automatic distribution of baits will have access to this decoding key to decrypt the data that are saved on the storage device of the automatic data distribution baits.
- -- Each aircraft must be equipped with a GPS device for recording flight routes and speed aircraft other than those provided in the automatic distribution of baits;
- Each aircraft must be equipped with HD movie camera located inside the aircraft and shooting direction throw automated device baits. The cameras will record each individual flight, the provider is obliged to keep all these records and make them available daily to ANSVSA;
- 3. Reception of distribution of vaccine baits air

Compliance with the maximum period established specification requirements is mandatory.

The reception and payment of services will be based on the following documents submitted in paper and electronic (CD / DVD):

- a) documentation distribution during the campaign:
- The minutes of the periodic meetings with the beneficiary;
- Reports on the work of air distribution in accordance with Annex. 8;
- Copies daily mission orders drawn up and approved by the flight operator for every airplane part and copy of the technical log sheets stamped and signed by all parties involved in its preparation;
- Notifications of non-conformities found and the action taken to remedy ordered by the beneficiary, if any;
- b) maps with flight routes when vaccine baits were distributed and distribution geographical coordinates of each vaccine baits;
- c) raw data, data storage device crypted of the automatic distribution of vaccine baits regarding the geographical position of vaccine bait dropped, which will be provided daily to the beneficiary exactly in the format in which extract the electronic file for each airplane in part;
- d) The data decrypted from the storage device of the automatic distribution of vaccine baits regarding the baits geographical position of vaccine, which will be provided to the recipient at the end of the vaccination campaign with the official address of the manufacturer / supplier of automatic distribution of baits.

The decoded data will be transmitted to the recipient in electronic format (CD / DVD) as a summary table in excel format which shall include the following:

- i) The number of the bait in the order disposing of their flight;
- ii) longitude of throwing bait (the geographical coordinates projection system compatible with ArcGIS software owned by ANSVSA and decimal degrees format, eg longitude: 23.123456);

- iii) Latitude throw bait (coordinate projection system compatible with ArcGIS software owned by ANSVSA and decimal degrees format, eg latitude: 45.123456);
- iv) Date and time of each distribution baits;
- v) The outdoor temperature since throwing baits on each flight;
- vi) Altitude throw bait site;
- vii) Speed of the aircraft in the moment of bait s distribution
- e) Daily transmission electronically to the email address of the contracting authority subsequently communicated, routes flown in ".shp" coordinate system WGS 1984 extracted from the GPS board the means of flight and the number of kilometers traveled for the actual distribution of baits;
- f) Sending daily copy of the following documents signed by the service provider, and pilots:
- i) the service provider's daily schedules showing proposed flight date and route;
- ii) books flight pilots who carried out flights for aerial distribution of vaccine baits;
- iii) aircraft logbook records from giving information about date flight crew during flight, route, aircraft maintenance, etc.
- g) Summary on oral rabies vaccination of foxes / campaign in accordance with Annex. 10.
- 4. Official control in rabies vaccination

Is performed at the level of four structures:

- a. National Sanitary Veterinary and Food Safety Authority (NSVFSA);
- b. County Sanitary Veterinary and Food Safety Directorate (CSVFSD)
- c. Institute for Diagnostic and Animal Health (IDAH);
- d. Institute of Control of Biological Products and Veterinary Medicines (ICBPVM)

The NSVFSA role in official control is to:

- performs the reception of the vaccine baits when entering into the storehouse and verify their conformity, consulting the accompanying documents;
- before subsequent contracting, evaluates the equipments from the cold storehouses and fulfilling of the adequate storage conditions for vaccine baits;
- assists in sampling of samples of vaccine and inspections of the batches of vaccine baits
- schedules the teams for monitoring the aerial distribution of vaccine baits
- monitors the way of fulfilling the manual distribution
- monitors the risk points and eventually unconformities appeared in the process of vaccination
- ask for fixing of weakness points discovered in the vaccination process

The CSVFSD role in official control is to:

- helps with personnel for monitoring teams of aerial distributions of vaccine baits
- daily verifying of the vaccine storehouses if they fulfill the storage conditions and order the improvements of unconformities
- supervise, asses and verify the conformity of aerial distributions of vaccine baits
- supervise, asses and verify the conformity of manual distribution of vaccine baits, by inspections
- monitors the risk points and eventually unconformities appeared in the process of vaccination

The IDAH role in official control is to:

- evaluates the vaccination efficacy by lab tests, accordingly with the assumed vaccination programme of rabies in foxes
- monitors the testing capacity of regional laboratories regarding the rabies
The ICBPVM role in official control is to:
<ul> <li>verifying the conformity of documents the vaccine which are delivered by contractors</li> <li>controls the batches of vaccine which will be used in the vaccination process.</li> </ul>
Same procedures will be applied in Moldova also, Romanian authorities will control and implement all necesary for assuring that the vaccination programme will be done as it is stipulated in the technical specifications of the programme.

### C. Targets

### 1. Tests to be carried out for the monitoring of the vaccination effectiveness

Targets for year: 2016

Country	Region	Animal Species	Type of test	Test description	Number of tests	Expected number of positive results	% positive	
ROMANIA	all country	Fox	serological test	ELISA	8535	4250	50	X
ROMANIA	all country	Fox	presence of biomar	Tetracycline in bones	8535	6800	80	X
MOLDAVIA	50 km from the	Fox	serological test	ELISA	510	153	30	X
MOLDAVIA	50 km from the	Fox	presence of biomar	Tetracycline in bones	510	255	50	X
		I.	J	Totals:	18 090	11 458		
						Add a ne	ew row	
		Total tests Serolog	gical (VNT,FAVN	I,ELISA) in MS	8 535			
				ts Serological	0			
Total tests presence of biomarker (Tetracycline in bones) in MS					8 535			
		Total tests presen	0					

Targets for year:	2017
-------------------	------

Country	Region	Animal Species	Type of test	Test description	Number of tests	Expected number of positive results	% positive	
ROMANIA	all country	Fox	serological test	ELISA	8535	5120	60	X
ROMANIA	all country	Fox	presence of biomar	Tetracycline in bones	8535	7250	85	X
MOLDAVIA	50 km from the		serological test	ELISA	510	204	40	X
MOLDAVIA	50 km from the	Fox	presence of biomar	Tetracycline in bones	510	306	60	X
			1	Totals:	18 090	12 880		
						Add a no	ew row	
		Total tests Serolog	gical (VNT,FAVN	I,ELISA) in MS	8 535			
				ts Serological	0			
	(Other) in MS Total tests presence of biomarker (Tetracycline in bones) in MS							
		Total tests presen	0					

### 2. Surveillance tests to be carried out

Targets for year:

2016

Country	Region	Animal Species	Category	Test description	Number of tests	Expected number of positive results	
ROMANIA	all country	Fox	Hunted animals (a	FAT	7945	30	X
ROMANIA	all country	Fox	Suspect or dead a	Virus characterisation test	400	20	X
ROMANIA	all country	wild animals	Suspect or dead ar	FAT	275	10	X
ROMANIA	all country	wild animals	Suspect or dead a	Virus characterisation test	35	5	X
ROMANIA	all country	Dogs	Suspect or dead a	FAT	300	10	X
ROMANIA	all country	Dogs	Suspect or dead a	Virus characterisation test	90	5	X
ROMANIA	all country	cats	Suspect or dead ar	FAT	200	5	X
ROMANIA	all country	cats	Suspect or dead ar	Virus characterisation test	40	2	X
ROMANIA	all country	horse	Suspect or dead ar	FAT	15	1	X
ROMANIA	all country	horse	Suspect or dead ar	Virus characterisation test	5	0	X
ROMANIA	all country	bovine and buffalc	Suspect or dead ar	FAT	220	10	X
ROMANIA	all country	bovine and buffalc	Suspect or dead a	Virus characterisation test	40	5	X
ROMANIA	all country	sheep and goat	Suspect or dead aı	FAT	180	10	X

ROMANIA	all country	sheep and goat	Suspect or dead aı	Virus characterisation test	20	3	X
ROMANIA	all country	pigs	Suspect or dead aı	FAT	15	2	X
ROMANIA	all country	pigs	Suspect or dead aı	Virus characterisation test	5	1	X
MOLDAVIA	50 km from the border of I	Fox	Hunted animals (a	FAT	510	50	X
MOLDAVIA	50 km from the border of I	Fox	Suspect or dead aı	Virus characterisation test	40	20	X
MOLDAVIA	50 km from the border of I	wild animals	Suspect or dead aı	FAT	50	25	X
MOLDAVIA	50 km from the border of I	wild animals	Suspect or dead aı	Virus characterisation test	15	5	X
MOLDAVIA	50 km from the border of I	dogs	Suspect or dead aı	FAT	80	50	X
MOLDAVIA	50 km from the border of I	dogs	Suspect or dead aı	Virus characterisation test	55	20	X
MOLDAVIA	50 km from the border of I	cats	Suspect or dead aı	FAT	50	25	X
MOLDAVIA	50 km from the border of I	cats	Suspect or dead aı	Virus characterisation test	20	10	X
MOLDAVIA	50 km from the border of I	horses	Suspect or dead aı	FAT	10	2	X
MOLDAVIA	50 km from the border of I	horses	Suspect or dead aı	Virus characterisation test	4	2	X
MOLDAVIA	50 km from the border of I	bovines	Suspect or dead aı	FAT	40	15	X
MOLDAVIA	50 km from the border of I	bovines	Suspect or dead aı	Virus characterisation test	25	5	X
MOLDAVIA	50 km from the border of I	Sheep and goat	Suspect or dead aı	FAT	40	10	X
MOLDAVIA	50 km from the border of I	Sheep and goat	Suspect or dead aı	Virus characterisation test	6	3	X

MOLDAVIA	50 km from the border of I	pigs	Suspect or dead aı	FAT	10	2	X
MOLDAVIA	50 km from the border of I		Suspect or dead aı	Virus characterisation test	2	1	X
ROMANIA	all country	Fox	Suspect or dead aı	FAT	150	25	X
MOLDAVIA	50 km from the border of I	Fox	Suspect or dead aı	FAT	50	20	X
	·			Total	10 942	409	
					Add a new ro	w	
			Tot	al tests FAT in MS	9 300		
Total tests Virus characterisation tests in MS					635		
			Total	I tests Other in MS	0		

Targets for year: 2017

Country	Region	Animal Species	Category	Test description	Number of tests	Expected number of positive results	
ROMANIA	all country	Fox	Hunted animals (a	FAT	7945	10	X
ROMANIA	all country	Fox	Suspect or dead aı	Virus characterisation test	400	10	Х
ROMANIA	all country	wild animals	Suspect or dead aı	FAT	275	5	X
ROMANIA	all country	wild animals	Suspect or dead aı	Virus characterisation test	35	2	X

ROMANIA	all country	dogs	Suspect or dead a	FAT	300	5	X
ROMANIA	all country	dogs	Suspect or dead a	Virus characterisation test	90	3	X
ROMANIA	all country	cats	Suspect or dead ar	FAT	200	5	X
ROMANIA	all country	cats	Suspect or dead a	Virus characterisation test	40	2	X
ROMANIA	all country	horse	Suspect or dead a	FAT	15	0	X
ROMANIA	all country	horse	Suspect or dead ar	Virus characterisation test	5	0	X
ROMANIA	all country	bovine and buffalc	Suspect or dead a	FAT	220	5	X
ROMANIA	all country	bovine and buffalc	Suspect or dead a	Virus characterisation test	40	2	X
ROMANIA	all country	sheep and goat	Suspect or dead a	FAT	180	10	X
ROMANIA	all country	sheep and goat	Suspect or dead a	Virus characterisation test	20	3	X
ROMANIA	all country	pigs	Suspect or dead a	FAT	15	1	X
ROMANIA	all country	pigs	Suspect or dead ar	Virus characterisation test	5	1	X
MOLDAVIA	50 km from the border of I		Hunted animals (a	FAT	510	40	X
MOLDAVIA	50 km from the border of I	Fox	Suspect or dead a	Virus characterisation test	40	15	X
MOLDAVIA	50 km from the border of I		Suspect or dead a	FAT	50	20	X
MOLDAVIA	50 km from the border of I	wild animals	Suspect or dead a	Virus characterisation test	15	5	X
MOLDAVIA	50 km from the border of I	Dogs	Suspect or dead ar	FAT	80	40	X

						////////	
MOLDAVIA	50 km from the border of l		Suspect or dead ar	Virus characterisation test	55	15	X
MOLDAVIA	50 km from the border of		Suspect or dead a	FAT	50	20	X
MOLDAVIA	50 km from the border of		Suspect or dead a	Virus characterisation test	20	5	Х
MOLDAVIA	50 km from the border of		Suspect or dead a	FAT	10	2	X
MOLDAVIA	50 km from the border of		Suspect or dead a	Virus characterisation test	á	1	X
MOLDAVIA	50 km from the border of		Suspect or dead a	FAT	40	10	X
MOLDAVIA	50 km from the border of	bovines	Suspect or dead a	Virus characterisation test	25	3	X
MOLDAVIA	50 km from the border of		Suspect or dead a	FAT	40	10	X
MOLDAVIA	50 km from the border of		Suspect or dead a	Virus characterisation test	6	3	X
MOLDAVIA	50 km from the border of		Suspect or dead a	FAT	10	2	X
MOLDAVIA	50 km from the border of		Suspect or dead a	Virus characterisation test	2	1	X
ROMANIA	all country	Fox	Suspect or dead a	FAT	150	10	X
MOLDAVIA	50 km from the border of		Suspect or dead a	FAT	50	15	X
				Total	10 942	281	
					Add a new ro	w	
			Tot	al tests FAT in MS	9 300		
		Total tests	Virus character	isation tests in MS	635		

Total tests Other in MS 0
---------------------------

#### Wildlife oral vaccination to be carried out 3

Targets for year: 2016

Country	Region / area	Products used	Number of doses	Size of the vaccination area (km²)	
ROMANIA	all country/aerial vaccination	SAD Bern strain	10668750	213 375	X
ROMANIA	all country/manual vaccination	SAD Bern strain	150800	6 030	X
MOLDAVIA	aerial vaccination/50 km from	SAD Bern strain	635000	12 700	Х
MOLDAVIA	manual vaccination/50 km fro	SAD Bern strain	93000	3 720	Х
	_	Total	11 547 550		
				Add a new row	
Oral vaccine	and baits made of SAD E	Bern strain in MS	10 819 550		
Oral vac	cine and baits made of Sa	AG2 strain in MS	0		
Oral vaccine	e and baits made of SAD	B19 strain in MS	0		
	Oral vaccine in neighl	bourin countries	728 000		

Targets for year:

2017

Country	Region / area	Products used	Number of doses	Size of the vaccination area (km²)	
ROMANIA	all country/aerial vaccination	SAD Bern strain	10668750	213 375	X
ROMANIA	all country/manual vaccination	SAD Bern strain	150800	6 030	Х
MOLDAVIA	aerial vaccination/50 km from	SAD Bern strain	635000	12 700	Х
MOLDAVIA	manual vaccination/50 km fro	SAD Bern strain	93000	3 720	Х
	_	Total	11 547 550		
				Add a new row	
Oral vaccine	and baits made of SAD [	Bern strain in MS	10 819 550		
Oral vaco	cine and baits made of S	AG2 strain in MS	0		
Oral vaccine	e and baits made of SAD	B19 strain in MS	0		
	Oral vaccine in neighl	bourin countries	728 000		

#### (max. 32000 chars):

In Romania will be distributed by planes 10668750 baits in 2 campaigns yearly, spring and autumn, over all area of Romania. Also, will be distributed by manual distribution 150800 baits in 2 campaigns early, spring and autumn, over a surfaces of 6030 square km, where aerial distribution is not recommended to be performed.

(max. 32000 chars):

In Moldova, we intend to perform aerial and manual distribution for oral vaccination of foxes, on a buffer zone of 50 km radius from the border with Romania, in 25 counties, also in 2 campaigns, spring and autumn. Area of vaccination from Moldova is almost half of country. By aerial distribution will be distributed yearly in 2 campaigns 635000 baits and by manual distribution 93000 baits over an area of 3720 square km, where aerial distribution is not recommended to be performed.

#### 4 Official control of oral vaccines to be carried out

Targets for year: 2016

Country	Number of batches distributed	Number of batches controlled by the CA (virus titration)	
ROMANIA	28	28	X
MOLDOVA	6	6	Х
Total	34	34	
		Add a new row	
Vaccine tit	ration tests in MS	28	

Targets for year: 2017

Country	Number of batches distributed	Number of batches controlled by the CA (virus titration)	
ROMANIA	28	28	X

MOLDOVA	6	6	Х
Total	34	34	
		Add a new row	
Vaccine tit	tration tests in MS	28	

## D. Detailed analysis of the cost of the programme

## 1. Costs of the planned activities for year:

2016

The blocks are repeated multiple times in case of first year submission of multiple program.

To facilitate the handling of your cost data, you are kindly requested to:

- 1. Fill-in the text fields IN ENGLISH
- 2. Limit as much as possible the entries to the pre-loaded options where available.
- 3. If you need to further specify a pre-loaded option, please keep the pre-loaded text and add your clarification to it in the same box.

1. Monitoring / surveillance									
Cost related to	<u>Specification</u>	Unit	Number of units	Unitary cost/ceiling in EUR	Total amount in EUR	Union funding requested			
Monitoring	Serological test(VNT/FAVN/ELISA)	Individual wild animal	8 535	15.24	130 073,4	yes	X		
Monitoring	presence of biomarker(Tetracycline in bones)	Individual wild animal	8 535	5	42675	yes	X		
Surveillance	FAT	Individual wild animal	9 300	13.09	121 737	yes	X		
Surveillance	Virus characterisation test	Individual wild animal	635	40	25400	yes	X		
Surveillance	Other tests	Individual wild animal	0	0	0	no	X		
Sampling	delivery of wild animals	Individual wild animal	8 535	12	102 420	yes	X		
					Add a new	v row			

2. Vaccination							
Cost related to	Specification	Unit	Number of units	Unitary cost/ceiling in EUR	Total amount in EUR	Union funding requested	
Oral vaccine and baits in MS	SAD Bern strain vaccine and bait	Vaccine dose or bait	10 819 550	0.28	3,029,474	yes	X
Distribution of oral vaccine per dose in MS	SAD Bern strain vaccine and bait	Vaccine dose or bait	10 819 550	0.35	3,786,842.5	yes	X
Purchase and ditribution of oral vaccine and baits in neighbouring third countries	Oral vaccine dose or bait	Vaccine dose or bait	728 000	0.95	691,600	yes	X
Vaccine titration tests in MS	Number of batches controlled by the CA	Batch	28	100	2800	yes	X
3.Other costs							
Cost related to	Specification	Unit	Number of units	Unitary cost/ceiling in EUR	Total amount in EUR	Union funding requested	
Live stock parental vaccination	Animals vaccinated for emergency into the outbreak	animal	7 000	0.7	4900	yes	X
Live stock parental vaccination	Administering costs for emergency vaccination	animal	7 000	1.5	10500	yes	X
inspection in the field	supervision and inspection on the spot	pieces	16	300	4800	yes	X
training sessions	training sessions for vaccination campaign	people trained	90	150	13500	yes	X
Awarness campaign in Romania	typing and distributtion of posters for population awaren		284 300	1.33	378,119	yes	X
Awareness campaign in Moldova	typing and distributtion of posters for population awaren	poster	22 890	1.33	30443.7	no	X
Monitoring in buffer zone 50 km Moldavia	Serological test (ELISA)	test	510	15.24	7772.4	yes	X
Monitoring in buffer zone 50 km Moldavia	presence of biomarker (Tetracycline in bones)	test	510	5	2550	yes	X
Surveillance in buffer zone 50 km Moldavia	FAT	test	840	15	12600	yes	Х

	Total				Add a new 8 471 007,00 €	/ row	
Sampling in passive surveillence in Romania	delivery of animals (foxes and jackals)	animals	1 200	50	60000	yes	X
Sampling	delivery of wild animals	animal	510	12	6120	no	X
Surveillance in buffer zone 50 km Moldavia	Virus characterisation test	test	167	40	6680	yes	X

## 1. Costs of the planned activities for year:

2017

The blocks are repeated multiple times in case of first year submission of multiple program.

To facilitate the handling of your cost data, you are kindly requested to:

- 1. Fill-in the text fields IN ENGLISH
- 2. Limit as much as possible the entries to the pre-loaded options where available.
- 3. If you need to further specify a pre-loaded option, please keep the pre-loaded text and add your clarification to it in the same box.

1. Monitoring / surveillance									
Cost related to	<u>Specification</u>	Unit	Number of units	Unitary cost/ceiling in EUR	Total amount in EUR	Union funding requested			
Monitoring	Serological test(VNT/FAVN/ELISA)	Individual wild animal	8 535	15.24	130 073,4	yes	X		
Monitoring	presence of biomarker(Tetracycline in bones)	Individual wild animal	8 535	5	42675	yes	X		
Surveillance	FAT	Individual wild animal	9 300	13.09	121 737	yes	X		
Surveillance	Virus characterisation test	Individual wild animal	635	40	25400	yes	X		

Sampling	delivery of wild animals	Individual wild animal	8 535	12	102 420	yes	X
					Add a new	row	
2. Vaccination							
Cost related to	Specification	Unit	Number of units	Unitary cost/ceiling in EUR	Total amount in EUR	Union funding requested	
Oral vaccine and baits in MS	SAD Bern strain vaccine and bait	Vaccine dose or bait	10 819 550	0.28	3,029,474	yes	X
Distribution of oral vaccine per dose in MS	SAD Bern strain vaccine and bait	Vaccine dose or bait	10 819 550	0.35	3,786,842.5	yes	X
Purchase and ditribution of oral vaccine and baits in neighbouring third countries	Oral vaccine dose or bait	Vaccine dose or bait	728 000	0.95	691,600	yes	X
Vaccine titration tests in MS	Number of batches controlled by the CA	Batch	28	100	2800	yes	X
3.Other costs							
Cost related to	Specification	Unit	Number of units	Unitary cost/ceiling in EUR	Total amount in EUR	Union funding requested	
Live stock parental vaccination	Animals vaccinated for emergency into the outbreak	animal	7 000	0.7	4900	yes	X
Live stock parental vaccination	Administering costs for emergency vaccination	animal	7 000	1.5	10500	yes	X
inspection in the field	supervision and inspection on the spot	pieces	16	300	4800	yes	X
training sessions	training sessions for vaccination campaign	people trained	90	150	13500	yes	X
Awareness campaign in Romania	typing and distributtion of posters for population awarer	poster	284 300	1.33	378,119	yes	X
Awareness campaign in Moldova	typing and distributtion of posters for population awarer	poster	22 890	1.33	30443.7	no	X
Monitoring in buffer zone 50 km Moldavia	Serological test (ELISA)	test	510	15.24	7772.4	yes	X

	Total				8 471 007,00 €		
					Add a nev	v row	
Sampling in passive surveillence in Romania	delivery of animals (foxes and jackals)	animal	1 200	50	60000	yes	X
Sampling	delivery of wild animals	animal	510	12	6120	no	X
Surveillance in buffer zone 50 km Moldavia	Virus characterisation test	test	167	40	6680	yes	X
Surveillance in buffer zone 50 km Moldavia	FAT	test	840	15	12600	yes	X
Monitoring in buffer zone 50 km Moldavia	presence of biomarker(Tetracycline in bones)	test	510	5	2550	yes	X

#### 2. 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 reimbursment/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 perform 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):

Hunter associations with the help of the 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)

- 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):

regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget

c) Implementing entities - compensation

#### (max. 32000 chars):

Rabies is included on the list of the diseases for which the government assures the compensation of farmer's losses in case control measures are applied. The legal measures and provisions regarding the compensation of owners for the killing of slaughtered, killed animals and animals which represent sources of contamination and also compensation for animals killed or affected in some other way in the process of killing on the infected premises are covered in Government Decision (GD) No. 1214/2009 with subsequent amendments.

Government Decision No. 1214/2009 specifies the beneficiaries of compensations (under art. 4), the method of compensation and the source of the funds for disease control operations and describes the basis for this calculation (covered in art. 4 and Appendix no. 2).

Appendix no. 1 of Government Decision No. 1214/2009 with further modifications and completions presents the list of diseases for which compensations are granted.

In case of confirmation of an outbreak of rabies, compensations are granted for animals of economic interest and the animals receptive of rabies from sanitary-veterinary zoo gardens, others than wild carnasieres. The compensation will be paid to the owner, by market value.

d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?

#### (max. 32000 chars):

Vaccine is provided by the contractor, who in this case is Bioveta a.s. from Czech Republic.

Distribution of the vaccine is done by 3 aviation company from Bulgaria, Czech republic and Serbia. In total they have 25 airplanes.

Vaccine and distribution of the vaccine is paid by the state budget and will be reimbursed by the E.U.

For the vaccine and action of distribution of the vaccine for the new provision, buffer zone for Moldova, will be mandatory to do another tender or additionaly contract for the 2016-2017 period. We will make all the efforts to can finalise and implement vaccination in Moldova.

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

#### (max. 32000 chars):

National sanitary Veterinary and Food Safety Authority is the responsible for implementing oral vaccination in Romania. Same entity will be responsible also for implementing vaccination in Moldova, if E.U. will approve the programme and we will be able to finalise accordingly to the Romanian legislation and Moldova legislation, especially the fiscal and economical part.

2 Co-financing rate (see provisions of applicable Work Programme)
The maximum co-financing rate is in general fixed at 50%. However based on provisions of Article 5.2 and 5.3 of the Regulation (EU) No 652/2014, we request that the co-financing rate for the reimbursement of the eligible costs would be increased:
Up to 75% for the measures detailed below
☑Up to 100% for the measures detailed below
Please explain for which measures and why co-financing rate should be increased to 100% (max 32000 characters)
For the vaccination in Romania area we request co-financing at 75% and 100 % for vaccination in third countries, Moldova, as it is stipulated into the Decision Number SANTE/VP/2015/RO/SI2.700828.
3. Source of funding of eligible measures
All eligible measures for which cofinancing is requested and reimbursment will be
The suggestion of the suggesti
$\boxtimes yes$
$\square$ no

#### **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 **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) 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
7041_4386.xls	7041_4386.xls	29 kb
7041_4387.jpg	7041_4387.jpg	783 kb
7041_4388.bmp	7041_4388.bmp	1187 kb
7041_4389.xls	7041_4389.xls	32 kb
	Total size of attachments :	2031 kb