



submitted for obtaining EU financial contribution

Annex I.a: Programme for the eradication of Rabies

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

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- 5) For simplification purposes you are invited to submit multi-annual programmes.
- 6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ROMANIA

Disease Rabies

Species : Fox

This program is multi annual :

Request of Union co-financing from beginning of : To end of:

Year for request

Contact data

Name : _____ Phone : _____

Email : _____ Your job type within the CA : _____

Submission Date
09/12/2022

Submission Number
1670582852132-19233



Standard requirements for the submission of programme for eradication, control and surveillance

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
- areas you envisage to continue vaccinating from 2020 onwards

(max. 32000 chars) :

For 2023, 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 vaccination of dogs and cats from backyards and also emergency vaccination will be done only for the domestic animals within the outbreaks.

Its objectives will take into account that:

- rabies develops in Romania both in animal population wildlife, especially in foxes and also in domestic animals population;
- rabies develops in foxes, dogs, cattles and occasionally in other animals;
- most cases of rabies in domestic animals have been recorded in dogs, cats and cattles;

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 rabies vaccination (ORV) 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;
- additional ORV of wildlife on a 50 km² radius area around each outbreak occurred;
- 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;
- vaccination of domestic animals in outbreak;

Standard requirements for the submission of programme for eradication, control and surveillance

- compulsory vaccination of dogs and cats; identification and registration of dogs and cats
- monitoring of animal movements

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 low 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.

Manual vaccination is performed by official veterinarians accompanied by the hunters to the den. Baits are carried out in refrigerated boxes and covered at the den with leaves and grass for being protected by eating by other species.

Manual distribution is performed by hunters together with official veterinarian following the established and approved procedure by CCA.

The forms from the procedure are filed in the field by the teams established above, and contains data regarding place, number, time, outdoor temperature, latitude, longitude.

Official controls are performed by veterinarians after finalising of the manual distribution concerning the bait uptake and integrity of the baits found in the field/den.

Additional ORV will be done on an area of 50km² radius around each outbreak occurred for trying to have an extra protection of wildlife susceptible to rabies and avoid spreading the infection. This measure was also highlighted to the Romanian CA by the expert team of the STM Regional Workshop on Rabies held in Bucharest 2 - 5 may 2022 at the E.C. initiative.

After 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 from suspect animals following clinical examinations and from those who are hunted, found dead or killed by car accidents.

Foxes sent for testing under the monitoring program are also tested for the presence of rabies virus. Although these animals are not considered indicator animals for rabies surveillance, in the past authorities have detected a number of rabies cases in this population, for example one case in 2019 and two cases in foxes in 2016.

For samples with inconclusive results, they are retested by one of the alternative techniques, other than the one by which the initial test was performed (ex. if the initial test was FAT, is retested by PCR technique, direct immunohistochemistry or cell culture isolation, according to provisions of the OIE Manual).

In Romania will be distributed by planes 10668750 baits in 2 campaigns yearly, spring and autumn, over all area of Romania. Area of aerial vaccination is about of 213.375 km²/campaign. Also, will be distributed by manual distribution 150800 baits in 2 campaigns early, spring and autumn, over a surfaces of 3015 km² / campaign, where aerial distribution is not recommended to be performed.

Additional ORV will be done on an area of 50km² radius around each outbreak occurred. An estimated number of 5 rabies outbreaks are estimated for 2023, the density of the baits distributed in these regions will be 30 baits/km², this means a max. number of 1.177.500 baits. (Total number of baits :[50*50*3.14

Standard requirements for the submission of programme for eradication, control and surveillance

(π)]*30*5= 1.177.500 baits). This vaccination will be done only in the case of confirmation of rabies outbreaks, by air, if the service provider of aerial services will accept to perform these flights. If not, baits will be distributed manually.

In Romania:

The total number of foxes estimated for 2022 is 76381.

The total number of jackals estimated for 2022 is 23042.

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) :

ROMANIA

The rabies eradication programme included the oral rabies vaccination from 2011.

During 2014-2020 the oral rabies vaccination of foxes it was performed all over the territory of Romania and the number of outbreaks in this period decreased after the vaccination as follows:

2011- 283

2012-405

2013 403

2014-161

2015 – 29 cases : 15 foxes, 4 cattle, 2 bisons, 4 cats, 2 wolves, 1 donkey, 1 dog

2016- 14 cases :1 dog, 2 cats, 7 cattle; wild: 4 foxes

2017 – 2 cases : 1 dog, 1 cattle

2018- 3 cases : 1 dog, 1 cattle; wild 1 fox.

2019- 4 cases : 1 cattle, wild- 2 foxes, 1 wild boar.

2020- 5 cases : 2 dogs, 2 cattle; wild 1 fox

2021 - 5 cases : 4 cattles, 1 fox

2022 - 1 positive fox so far

In 2018 the oral vaccination was not performed (there was no available contract).

The efficiency of cost is showed by the results of the programme implementation.

A higher number of foxes sampled for evaluation of vaccination efficiency: 91.2% in 2020, 96,3% in 2019, 97,1% in 2017, 94% in 2016, 92% in 2015, 78.21% in 2014

Regarding the level of bait uptake and level of immunization, it can be seen an improvement, in 2019 – TTC – 75% and antibodies to rabies virus – 28,64%, in 2020 – TTC – 76,35% and antibodies to rabies virus – 36,72% and figures presented are almost at the same level like in the other Member States who are still implementing ORV programme.

Taking into consideration the above mentioned and the fact that during this period 2014-2020, we had interruptions in continuity of the programme implementations (2014 first campaign, 2018 – national legislation adoption and in 2021 problems regarding approving of the tender because of the delay of

Standard requirements for the submission of programme for eradication, control and surveillance

Grant Decision approving), we had a continuous decreasing of the number of rabies cases confirmed, this means that the ORV programme was implemented in a professional manner with good results.

Our major objectives are to eliminate the rabies cases and to maintain these results in order to achieve the free rabies status. After the achievement of free rabies status, we intend to carry on this programme, sufficient time, to eliminate any risk of reintroduction rabies from neighbouring countries, for this reason neighbouring countries where rabies evolves should be helped to implement the programme, until the risk of reintroduction of rabies is eliminated.

Anti-rabies vaccination of foxes by aerial distribution of vaccine baits and related activities shall be carried out for a period of 12 months, it will be carried out in "Campaign I" (March, April, May) "and" Campaign II "(September, October or November) on the entire territory eligible for distribution, the campaign being finished in maximum 30 calendar days, in weather conditions favorable for aerial distribution, with the possibility to extend the campaign by maximum 30 calendar days, only upon written consent from CCA (depending on the recommendations provided in the prospect by the vaccine baits producer regarding the minimum and maximum outside temperatures that the vaccine baits can be distributed at).

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 administrative areas are not used, describe the natural or artificial boundaries used to determine the geographical areas)

- vaccination and monitoring
- surveillance

Attach maps

(max. 32000 chars) :

The programme will be implemented in all the country, taking into account all eligible territory. The estimate eligible surface for aerial distribution it is 213.375 km² by distributing 25 vaccine baits/km².

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 low altitude, by avoiding the territories of localities, water surfaces, highways, etc.

After 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 from suspect animals following clinical examinations and from those who are hunted, found dead or killed by accident by cars.

Standard requirements for the submission of programme for eradication, control and surveillance

The oral rabies vaccination is implemented over all the territory of Romania, by aerial distribution and by manual distribution in areas with localities, rivers, public roads and around territories that are military facilities or close to the borders.

The passive surveillance in :

(1) The presence of animals with deviant behavior, or suspected of rabies, or dead carnivores must be reported immediately to the veterinarian, police or local city hall by any person who detected it.

(2) The empowered free practice veterinarian notifies the suspicion of rabies to the official veterinarian, to the county sanitary-veterinary and food safety directorate, respectively of Bucharest municipality.

The measures applied in case of rabies suspicion in animals from a holding or locality

1. The empowered free practice veterinarian shall take the following measures:

a) if the suspicion of rabies is caused by a wild animal, there is provided its killing, followed by the collection of samples, which are sent to the laboratory;

b) inspects the receptive animals;

c) draws up the catalog of receptive species;

d) isolates domestic animals that have bitten or scratched persons or other animals and takes them under observation for a 14 days period, in conformity with the instructions provided in national legislation..

(2) The official veterinarian of the zonal sanitary-veterinary circumscription shall take the following measures:

a) notifies the suspicion of rabies to the county sanitary-veterinary and food safety directorate, respectively of Bucharest municipality and to the family doctor who provides assistance within the locality;

b) draws up the preliminary epidemiological investigation;

c) draws up the plan of measures, supervises the animals and verifies the application of the plan in conformity with the instructions provided in national legislation;

d) provides the removal from surveillance, if during this period the bitten or scratched animal does not show clinical signs of rabies;

e) orders the killing, if during this period the animal under surveillance shows clinical signs of rabies;

f) the corpses of dead animals and of those that have been killed, are disposed of; in isolated or inaccessible areas, the disposal of corpses is carried out by neutralization and burial, complying with the measures to prevent the spreading of the disease;

g) lifts the restrictions imposed on the holding, if the suspicion of rabies is not confirmed.

3. Description of the disease control strategy of the eradication programme in accordance with Article 32 of Commission Delegated Regulation (EU) 2020/689

3.1. Notification of the disease

(max. 32000 chars) :

Rabies is notified according to the 2002/2020 Regulation.

3.2. Target animals and estimation of the animal population

Standard requirements for the submission of programme for eradication, control and surveillance

(max. 32000 chars) :

ROMANIA

The target wild species of animals for the oral vaccination are the foxes. The estimated number of foxes according to the Ministry of Environment, Water and Forests is 76381.

The target animals in domestic to be vaccinated are represented by the dogs and cats (annual census).

The estimation of population for domestic animal species : dogs 2429479 and cats 378238.

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 and details on the collection of dead animals

(max. 32000 chars) :

Regarding the disease monitoring, all suspect animals of domestic species and wild animals found dead are going to be tested by FAT.

For samples with inconclusive results, they are retested by one of the alternative techniques, other than the one by which the initial test was performed (ex. if the initial test was FAT, is retested by PCR technique, direct immunohistochemistry or cell culture isolation, according to provisions of the OIE Manual). The positive samples are genotyped.

Vaccination monitoring: After 45 days from the end of the vaccination the foxes are going to be shot, in a number of 4 foxes /100 km² and the samples are sent to the laboratory in order to perform the monitoring of vaccination. The tests performed in the framework of monitoring are: FAT – the negative samples are going to be tested for tetracycline detection and ELISA for antibody detection.

In order to perform the monitoring of vaccination, the foxes brought to the laboratory are sampled by collecting brain tissues, mandibles and thoracic liquid. The brain tissue is used to perform FAT tests in order to detect the presence of rabies virus. The positive samples are brought to the Reference National Laboratory for Rabies for confirmation in order to perform the sequencing. The negative samples for FAT are tested for tetracycline detection and antibody detection by ELISA.

According to the national strategy, regional labs receive foxes from hunters, perform FAT and after that send samples for monitoring of the effectiveness of ORV (samples for antibody detection and Tetracycline) to the designated labs. NRL for Rabies technical coordinates regional labs in terms of trainings, Proficiency Test organizer and provider and performs confirmation tests of the FAT positive samples found to regional labs. NRL provides internal controls to the regional labs when they are required.

Standard requirements for the submission of programme for eradication, control and surveillance

3.4. Vaccines used and vaccination schemes

Describe

- vaccination of kept animals in the framework of the eradication programme
 - vaccine(s) to be used
 - targeted population
- vaccination of wild animals:
 - definition/demarcation of the vaccination area
 - frequency and expected dates of the vaccination campaigns
 - vaccine bait(s) to be used
 - vaccine bait distribution method and designed vaccine bait density
 - vaccination of stray dogs with the vaccine(s) to be used and the targeted population

(max. 32000 chars) :

In Romania, the rabies vaccination in domestic animals is targeting the dogs and cats. The vaccine used is the product used according to the requirements in Reg 576/2003, Annex III. The rabies vaccine must: (a) be a vaccine, other than a live modified vaccine, and fall into one of the following categories: (i) an inactivated vaccine with at least one antigenic unit per dose (World Health Organization recommendation) ; or (ii) a recombinant vaccine expressing rabies virus immunizing glycoprotein in a living viral vector; (b) if administered in a Member State, have received a marketing authorization in accordance with: Regulation 2019/6/EC, (i) Article 5 of Directive 2001/82 / EC; or (ii) Article 3 of Regulation (EC) No 726/2004; (c) if administered in a territory or third country, have received approval or license from the competent authority and meet at least the requirements set out in the relevant part of the rabies chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organization for Animal Health.

Vaccination of wild animals:

- definition/demarcation of the vaccination area.

The vaccination is performed over the whole territory of Romania from 2013;

- frequency and expected dates of the vaccination campaigns

2 campaign/year; 1 spring campaign (March/April/May) & 1 autumn campaign (September, October, November)

- vaccine bait(s) to be used.

During 2014-2020 it was used Lysvulpen.

- vaccine bait distribution method and designed vaccine bait density.

The vaccine baits are distributed both by aerial distribution and manual distribution.

The vaccine baits density foreseen is 25 baits/km

- vaccination of stray dogs with the vaccine(s) to be used and the targeted population.

The stray dog's population managed by local councils that deal with the establishment of shelters for these dogs and the animals are vaccinated in this shelters.

3.5. Measures in case of a positive result

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

Standard requirements for the submission of programme for eradication, control and surveillance

(max. 32000 chars) :

All the suspected animals are tested by FAT and in case of confirmation of the disease there are several measures to be applied.

In case of confirmation of the disease in domestic animals:

(1) After having confirmed the rabies, the county sanitary-veterinary and food safety directorate, respectively of Bucharest municipality carries out the following:

- a) draws up the final epidemiological investigation;
- b) establishes the protection area and the surveillance area;
- c) elaborates the measurement plan with deadlines and responsibilities.

(2) Measures in the protection area include:

- (i) the elaboration of epidemiological maps;
- (ii) euthanasia of carnivores that have been bitten or scratched by sick animals, if they have not been vaccinated against rabies or if they are less than 21 days old, in the case of the first vaccination;
- (iii) isolation by the rest of the animals of the vaccinated carnivores which have been bitten or scratched by the sick animal;
- (iv) the surveillance of all animals on the holding for a period of 14 days from the moment of contact;
- (v) euthanasia of animals mentioned in point (iv) if it shows clinical signs of rabies during this period; animals that show no clinical signs of rabies after this period are removed from surveillance;
- (vi) the inspection of carnivores in the protection area, which have been bitten or scratched by the sick animal, shall be carried out by the empowered free practice veterinarian for a period of 14 days, after which the animals shall be removed from surveillance;
- (vii) the ban on the estrangement of animals that have been under surveillance for a period of at least 3 months.

(3) Measures in the surveillance area include:

- (i) performing the catagraphy of dogs and cats;
- (ii) carrying out supplementary vaccinations in dogs and cats with inactivated vaccine;
- (iii) monitoring and restricting the movement of dogs and cats.

Confirmation of rabies in wild animals:

Measures applied in hunting grounds, in case of confirming the presence of rabies in wild animals

After having confirmed rabies, the county sanitary-veterinary and food safety directorates, respectively of Bucharest municipality, initiate the following activities:

- a) carry out the epidemiological investigation;
- b) establish and declare the infected area;
- c) request the administrators of the hunting funds to assess the population of wild animals, especially foxes;
- d) elaborate the measurement plan with deadlines and responsibilities;
- e) elaborate and implement a fox vaccination program;
- f) request the organization of hunters for the fox species, without using hunting dogs;
- g) provide the ban on skinning wild animals killed or found dead.

Yes, measures for supplement vaccinations and surveillance are going to be put in place.

Measures applied in hunting grounds, in case of confirming the presence of rabies in wild animals

After having confirmed rabies, the county sanitary-veterinary and food safety directorates, respectively of Bucharest municipality, initiate the following activities:

Standard requirements for the submission of programme for eradication, control and surveillance

- a) carry out the epidemiological investigation;
- b) establish and declare the infected area;
- c) request the administrators of the hunting funds to assess the population of wild animals, especially foxes;
- d) elaborate the measurement plan with deadlines and responsibilities;
- e) elaborate and implement a fox vaccination program;
- f) request the organization of supplementary huntings from hunters for the fox species, without using hunting dogs;
- g) provide the ban on skinning wild animals killed or found dead.

Additional ORV will be done on an area of 50km² radius around each outbreak occurred. An estimated number of 5 rabies outbreaks are estimated for 2023, the density of the baits distributed in these regions will be 30 baits/km, this means a max. number of 1.177.500 baits.

3.6 Awareness campaigns and other measures

- *Awareness campaigns :*
 - *Please describe the awareness raising campaigns to be implemented*
- *Other measures :*
 - *Please describe measures to be implemented to reduce the contact with infected animals*
 - *Please describe coordinated measures with other Member States or third countries, where relevant*

(max. 32000 chars) :

Before each vaccination campaign are organized awareness campaigns using printed materials (posters) posted in public places (this is coordinated by the central competent authorities).

Awareness campaign is composed by two actions for each campaign:

- making 3 types of posters : warning materials (68575), informative materials (68575), chronological informative materials (5000). In Romania, is a number of approximately 13715 localities, in every locality are posted a number of 5 warning materials, 5 informative materials and chronological materials at the level of townhalls.

The cost of purchase of services to print leaflets and posters is approximated at 0.13 euro/poster.

Also all the neighbouring counties and all the authorities involved in rabies eradication program are informed by writing means before each campaign.

Before every ORV campaign, awareness campaign is performed by posting of posters and leaflets. Additionally, press communicates are released before every start of ORV campaigns and every public institution is informed about the scope of vaccination of wildlife. Neighbouring countries are also informed.

Standard requirements for the submission of programme for eradication, control and surveillance

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 responsibilities
- other stakeholders involved in the implementation of the programme, their role and their communication channels with the CA.

(max. 32000 chars):

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.

CCA issued Service Notes in which highlighted the importance and obligation of each regional veterinary directorate to increase the samples taken from all the indicator animals. Additionally, official controls have been done from CCA to LCA during 2022, which led to an intensified surveillance in all counties. The results obtained due to this increased surveillance are reflected into a higher number of rabies cases detected until 24.11.2022. (3 dogs in Suceava county, 3 cattles in Botosani county and 10 cattles, 2 foxes hunted and 3 foxes found dead in Iasi county).

On line trainings are organized periodically, last one in 24.11.2022 when official controls were performed into the field in some areas from Iasi and Suceava counties, where rabies cases were detected in last period.

At this moment, a number of at least 30-40 samples in the framework of passive surveillance (wild animals) in each county were taken, from different hunting grounds.

This strategy will be kept each year and depending on the issues encountered, it will be improved accordingly.

Standard requirements for the submission of programme for eradication, control and surveillance

For 2023, Service Notes will be sent to LCA starting with the beginning of the year, in which it will be highlighted the importance and obligation of each regional veterinary directorate to collect samples from all the indicator animals in the framework of passive surveillance and that it has to be done all over the year and in all hunting grounds from all counties.

Additionally, official controls will be performed from CCA in the field during 2023, in order to assure a correct implementation of the measures taken accordingly to the programme and especially for an intensified surveillance in all counties. In outbreaks, all the measures will be taken by LCA in the coordination of CCA. (ex. hunting of foxes in the hunting grounds due to the confirmation of outbreaks with the origin of infection most probably the wildlife reservoir, restrictions of movements, etc)
Targets for Monitoring of the effectiveness of vaccination and bait uptake will be transmitted from CCA to LCA with a schedule for hunting period and will be strictly controlled to be taken from most of all hunting grounds.

Trainings with hunters will be performed by CSVFSD, to remind them their obligations for collecting indicator animals for rabies surveillance and monitoring of the effectiveness of vaccination.

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 Efsa document "Update on oral vaccination of foxes and raccoon dogs against rabies" - 2015;
- 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).

Standard requirements for the submission of programme for eradication, control and surveillance

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. Legal basis for the implementation of the programme

(max. 32000 chars) :

Regulation 429/2016, Regulation 689/2020, Regulation 690/2021

National legislation:

Government Decision no. 55/2008, Order no. 29/2008 with the subsequent modification and completions, Order no 35/2016 with the subsequent modification and completions.

3. Historical data on the epidemiological situation, including:

a. a concise description of the following indicators:

- number of confirmed cases by listed animal species (excludes bat cases), during at least the past 5 years
- maps indicating the distribution of confirmed cases referred before per year, during at least the past 5 years
- disease control strategy and results of control measures, during at least the past 5 years
- number of rabies cases in previously (last year) free areas compared to previous year
- % of seroconversion in target species (juveniles/adult 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 constraints identified that hamper the progress of eradication.

(max. 32000 chars) :

During the last 5 years, the epidemiological situation showed a decrease in number of rabies confirmation cases.

2015 – 29 cases : 15 foxes, 4 cattle, 2 bisons, 4 cats, 2 wolves, 1 donkey, 1 dog

2016- 14 cases :1 dog, 2 cats, 7 cattle; wild: 4 foxes

2017 – 2 cases : 1 dog, 1 cattle

2018- 3 cases : 1 dog, 1 cattle; wild 1 fox.

2019- 4 cases : 1 cattle, wild- 2 foxes, 1 wild boar.

2020- 5 cases : 2 dogs, 2 cattle; wild 1 fox

2021 - 5 cases : 4 cattles, 1 fox

2022 - 1 positive fox so far

The control strategy measures in case of rabies outbreaks is comprising the following measures: vaccination of animals, placing susceptible animals under observation, movement restrictions, rabies post exposure treatment for the humans who were in contact with the affected animals, decision for vaccination of domestic species from the outbreak, vaccination of dogs and cats from the protection zone and from the surveillance zone.

Standard requirements for the submission of programme for eradication, control and surveillance

The measures applied in hunting grounds in case of confirming the presence of rabies in wild animals
After having confirmed rabies, the county sanitary-veterinary and food safety directorates, respectively of Bucharest municipality, initiate the following activities:

- a) carry out the epidemiological investigation;
- b) establish and declare the infected area;
- c) request the administrators of the hunting funds to assess the population of wild animals, especially foxes;
- d) elaborate the measurement plan with deadlines and responsibilities;
- e) elaborate and implement a fox vaccination program;
- f) request the organization of hunters for the fox species, without using hunting dogs;
- g) provide the ban on skinning wild animals killed or found dead.

We do not have any free rabies declared in 2021.

• % of seroconversion in target species (juveniles/adult separately) compared to previous year.

In 2020, the seroconversion in adult foxes was 39% and in juvenile foxes was 34%.

In 2019 the seroconversion in adult foxes was 35 %and 23% in juvenile foxes.

• % of vaccine uptake in target species (juveniles/adult separately) compared to previous year.

In 2020, the uptake in adult foxes was 81% and in juvenile 74%.

In 2019, the uptake for the vaccine baits for adult foxes was 79% and for young foxes 71%.

In 2021 ORV was not implemented in Romania.

National legislation is in force since 2008. Modifications were done to the legislation so far, and in this moment, is it for consultation with ministries a new proposal for modification of Government Decision no.55/2008 which should assure an uninterrupted ORV until rabies eradication.

4. Control on the implementation of the programme and Intermediate targets

4.1 Control on the implementation of the programme

Describe the system to control the implementation of the programme:

- flight tracks
- methods to be used to assess the correct vaccine bait distribution
- strategy to monitor the effectiveness of the vaccination as regards serology and vaccine bait uptake in the targeted animal population, the sampling schemes, with details on the collection of dead animals, and diagnostic methods
- measures to ensure the maintenance of the quality of the vaccine bait before it is distributed particularly as regards titration of the vaccine baits and controls of the cold chain (official controls to be performed on the vaccine)

4.2 Intermediate targets of the eradication programme:

- expected annual decrease of the number of outbreaks
- expected number of confirmed outbreaks in areas with outbreaks during the previous year
- expected percentage of sero-conversion in targeted animal populations
- expected percentage of vaccine uptake in animals of the targeted species

(max. 32000 chars):

4.1.
- Methods to be used to assess the correct vaccine bait distribution.
NSVFSA has implemented a very strict program based on very technical requirements, in the sense that

Standard requirements for the submission of programme for eradication, control and surveillance

all flights and the distribution of vaccine baits by air distribution were very strictly controlled by cross checkings: at the aerodromes, at the NSVFSA level and through a server online where all the information related to the flight and the distribution of the baits were made available to us in real time system.

Like a short description, all flight routes were scheduled before the flights were performed by the air operator, using special aviation software. Subsequently, after the flights, the flight routes performed by the planes were downloaded at the aerodromes by our colleagues from local level, at the same time they were sent on an online server to which the NSVFSA representatives had access. Any traces of fraud were eliminated because there were at least 2 places where this data were stored and subsequently verified for compliance. These flight routes are downloaded from the flight GPS of each aircraft and actually represent the flight corridor performed by each aircraft.

In addition to the flight routes, we also downloaded data on the aerial distribution of vaccine baits, which normally, after being verified in the GIS system, should have coincided as lines with the flight route performed, which happened.

The distribution of baits its also monitored on the online server GPSL which allows viewing online the process of distribution. The crypted and decrypted data is analysed during the campaign and at the end of the campaign and maps are drawn up.

During the verification process of the air distribution, in the middle of campaign, if are identified gaps in the bait distribution GIS verification, request for additional coverage with baits is transmitted to the service provider, Accordingly to the contract, the service provider is obliged to respect this request.

- Strategy to monitor the effectiveness of the vaccination as regards serology and vaccine bait uptake in the targeted animal population, the sampling schemes, with details on the collection of dead animals, and diagnostic methods.

The monitoring of the vaccination is performed 45 days after the vaccination by shooting the established number of foxes and sampled, These foxes are tested regarding rabies virus presence by FAT, then the negative samples are detected for vaccine marker and then tested for ELISA.

- Measures to ensure the maintenance of the quality of the vaccine bait before it is distributed particularly as regards titration of the vaccine baits and controls of the cold chain (official controls to be performed on the vaccine).

The vaccine is transported from the manufacturer to the storage site at a temperature of -20°C or lower, with means of transport (refrigerated road trains) equipped with cold production facilities and temperature monitoring and recording devices.

Until applied by hand or by airplane, the vaccine should be stored at -20°C or lower.

The storage conditions of the vaccine and the maintenance of the cold chain are checked daily by the staff of the County Sanitary Veterinary and Food Safety Directorates appointed to be part of the Technical Commission for verifying the rabies vaccination campaign in Romania, regardless of whether or not activities are scheduled. air distribution.

Each batch of rabies vaccine baits shall be accompanied by the analysis report issued by the manufacturer, the serial certificate for veterinary medicinal products issued by the manufacturer, the official batch certificate for immunological veterinary medicinal products issued by the competent authority of a EU Member State according to the requirements of the EDQM (European Directorate for Quality Medicine), as well as the analysis bulletin for testing the stability of the viral titer in field conditions.

Upon receipt of the rabies vaccination baits, the Technical Commission for the verification of the rabies vaccination campaign against foxes in Romania verifies the batch documents, as well as the thermogram certifying the maintenance of the refrigeration chain from the moment of loading in the car until arriving at the aerodrome.

Standard requirements for the submission of programme for eradication, control and surveillance

Also, at the reception of the baits, samples are taken from all the series of baits received in order to verify the viral titer.

The testing is performed at the Institute for the Control of Biological Products and Veterinary Medicines (ICPBMV).

The transport of the samples to ICPBMV is done in refrigerated bags with carbonic ice.

ROMANIA

4.2

- expected annual decrease of the number of outbreaks.

Yes, if we want to keep as low as possible the number of cases. (2 cases per year).

- expected number of confirmed outbreaks in areas with outbreaks during the previous year, at the border with Moldova and Ukraine.

Probably 1 outbreak in each of these areas.

- expected percentage of sero-conversion in targeted animal populations.

The expected sero conversion in targeted animal is 40% - 50 %.

- expected percentage of vaccine uptake in animals of the targeted species.

The expected procentage is 85%-90%.

Standard requirements for the submission of programme for eradication, control and surveillance

C. Targets

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

Targets for year: **2023**

Country	Region	Animal Species	Type of test	Test description	Number of tests	Expected number of positive results	% positive	
ROMANIA	all country	Fox	presence of biomarker	Tetracycline in bones	8535	7400	87	X
ROMANIA	all country	Fox	serological test	ELISA	8535	3800	45	X
Totals :					17 070	11 200		
						Add a new row		
Total tests Serological (FAVN) in MS					0			
Total tests Serological (FAVN) in TC					0			
Total tests Serological (ELISA) in MS					8 535			
Total tests Serological (ELISA) in TC					0			
Total tests Serological (Other) in MS					0			
Total tests Serological (Other) in TC					0			
Total tests presence of biomarker (Tetracycline in bones) in MS					8 535			
Total tests presence of biomarker (Tetracycline in bones) in TC					0			
Total tests presence of biomarker (Other) in MS					0			
Total tests presence of biomarker (Other) in TC					0			

Standard requirements for the submission of programme for eradication, control and surveillance

2. Surveillance tests to be carried out

Targets for year : **2023**

Country	Region	Animal Species	Category	Test description	Number of tests	Expected number of positive results	
ROMANIA	all country	Fox	Suspect or dead animals	FAT	1800	1	X
ROMANIA	all country	Fox	Suspect or dead animals	Virus characterisation test	1	1	X
ROMANIA	all country	Fox	Hunted animals (active s	Virus characterisation test	1	1	X
ROMANIA	all country	Dogs	Suspect or dead animals	FAT	100	1	X
ROMANIA	all country	Dogs	Suspect or dead animals	Virus characterisation test	1	1	X
ROMANIA	all country	cattle	Suspect or dead animals	FAT	100	2	X
ROMANIA	all country	cattle	Suspect or dead animals	Virus characterisation test	2	2	X
ROMANIA	all country	cats	Suspect or dead animals	FAT	50	0	X
ROMANIA	all country	jackals	Suspect or dead animals	FAT	200	0	X
ROMANIA	all country	other wild animals	Suspect or dead animals	FAT	50	0	X
ROMANIA	all country	all species	Suspect or dead animals	PCR tests	100	0	X
ROMANIA	all country	all species	Suspect or dead animals	Virus isolation test	100	0	X
				Total	2 505	9	




Standard requirements for the submission of programme for eradication, control and surveillance

		Add a new row
	Total tests FAT in MS	2 300
	Total tests FAT in TC	0
	Total PCR tests in MS	100
	Total PCR tests in TC	0
	Total tests Virus characterisation tests in MS	5
	Total tests Virus characterisation tests in TC	0
	Total tests Virus isolation tests in MS	100
	Total tests Virus isolation tests in TC	0
	Total other tests MS	0
	Total other tests TC	0

3

Wildlife oral vaccination to be carried out

Targets for year : **2023**

Country	Region / area	Products used	Number of doses	Size of the vaccination area (km ²)	
ROMANIA	all country aerial distribution (2 cam 	SAD Bern strain	10668750	213 375	X
ROMANIA	all country manual distribution (2 ca 	SAD Bern strain	150800	3 015	X
ROMANIA	additional outbreaks vaccination (es 	SAD Bern strain	1177500	39 250	X
Total			11 997 050		
				Add a new row	

Standard requirements for the submission of programme for eradication, control and surveillance

Oral vaccine and baits made of SAD Bern strain in MS	11 997 050		
Oral vaccine and baits made of SAG2 strain in MS	0		
Oral vaccine and baits made of SAD B19 strain in MS	0		
Oral vaccine and baits made of SAD Clone attenuated in MS	0		
Oral vaccine and baits made of SPBN GASGAS strain in MS	0		
Total Vaccines distributed	11 997 050		
Purchase and distribution of oral vaccine and bait in neighbouring TC	0		

(max. 32000 chars) :

In Romania for the rabies oral vaccination of foxes will be distributed by planes 10668750 baits in 2 campaigns yearly, spring and autumn, over all area of Romania. Area of aerial vaccination is about of 213.375 km²/campaign. Also, will be distributed by manual distribution 150800 baits in 2 campaigns early, spring and autumn, over a surfaces of 3015 km² / campaign, where aerial distribution is not recommended to be performed. Additional ORV will be done on an area of 50km² radius around each outbreak occurred. An estimated number of 5 rabies outbreaks are estimated for 2023, the density of the baits distributed in these regions will be 30 baits/km², this means a max. number of 1.177.500 baits. (Total number of baits : $[50*50*3.14(\pi)]*30*5= 1.177.500$ baits). This vaccination will be done only in the case of confirmation of rabies outbreaks, by air, if the service provider of aerial services will accept to perform these flights. If not, baits will be distributed manually.

4 Official control of oral vaccines to be carried out

Targets for year: **2023**

Country	Number of batches distributed	Number of batches controlled by the CA	Number of virus titrations performed	
ROMANIA	30	30	30	X
Total	30		30	

Standard requirements for the submission of programme for eradication, control and surveillance

	Add a new row	
Vaccine titration tests in MS	30	
Vaccine titration tests in TC	0	

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 reimbursement/payment claim to the EU. Describe the financial flows/circuits followed.

Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who performs the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

(max. 32000 chars):

The sampling for the hunted foxes is performed by the hunting grounds associations, the regional veterinary services (state budget) is receiving the invoices and paying the compensation.

Standard requirements for the submission of programme for eradication, control and surveillance

For the passive surveillance also the compensations are paid from the 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):

The testing of the vaccine is paid from the national budget. The sampling and testing related to rabies diagnostic are also paid from the state budget; for passive surveillance the samples are collected by the official veterinarians and send to the laboratories in order to perform the diagnostic tests. The regional laboratories are performing the FAT tests and some regional laboratories and NRL are performing the monitoring of the vaccination and virus identification. (also state budget).

c) Implementing entities - **compensation**

(max. 32000 chars):

The compensation for sampling of the animals brought to the laboratories are also from the state budget and the compensations in case of culling of the animals are paid from the state budget only, not claimed for cofinancing.

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

(max. 32000 chars):

The vaccination of domestic animals is performed by the private veterinarians and paid from the state budget, not claimed for cofinancing. The oral vaccination of wild species is performed by a service provider, paid from the state budget and then subject for cofinancing. The local and central competent authorities are monitoring the activities performed in the framework of the oral vaccination.

Standard requirements for the submission of programme for eradication, control and surveillance

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

(max. 32000 chars):

The awareness campaign is implemented by the service provider and checked by the local veterinary authorities; also paid from the state budget until the approval of the cofinance.

Additional vaccination around outbreaks, which we are proposing to be implemented from 2023, like a measure for trying to stop the spreading of the virus from the residual virus animals carrier. The vaccine will be delivered from the same service provider who performs the ORV by the request of the CCA, after the confirmation of an outbreak.

2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursement will be claimed are financed by public funds.

yes

no

3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

Additional vaccination around outbreaks, which we are proposing to be implemented from 2023, like a measure for trying to stop the spreading of the virus from the residual virus animals carrier. The vaccine will be delivered from the same service provider who performs the ORV by the request of the CCA, after the confirmation of an outbreak.

Standard requirements for the submission of programme for eradication, control and surveillance

Additional ORV will be done on an area of 50km² radius around each outbreak occurred. An estimated number of 5 rabies outbreaks are estimated for 2023, the density of the baits distributed in these regions will be 30 baits/km², this means a max. number of 1.177.500 baits. (Total number of baits : $[50*50*3.14(\pi)]*30*5= 1.177.500$ baits). This vaccination will be done only in the case of confirmation of rabies outbreaks, by air, if the service provider of aerial services will accept to perform these flights. If not, baits will be distributed manually.

Standard requirements for the submission of programme for eradication, control and surveillance

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
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