

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

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 2022, 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 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 in foxes and dogs and occasionally in other animals;
- most cases of rabies in domestic animals have been recorded in 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;
- vaccination of domestic animals in outbreak;
- compulsory vaccination of dogs and cats; identification and registration of dogs and cats

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

- 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.

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

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.

Therefore, we kindly ask you to reconsider your approach and to let at least for 2022 the samples for monitoring to be co financed for FAT to have a better overview regarding epidemiological situation of rabies in Romania.

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.

In Moldova, will be performed aerial and manual distribution for oral vaccination of foxes, on a buffer zone of 100 km distance from the border with Romania, in 35 raions (Anenii Noi, Basarabasca, Briceni, Cahul, Cantemir, Călărași, Căușeni, Cimișlia, Criuleni, Dondușeni, Drochia, Dubasari, Edineț, Fălești, Florești, Glodeni, Hîncești, Ialoveni, Leova, Nisporeni, Ocnița, Orhei, Rezina, Rîșcani, Sîngerei, Soroca, Strășeni, Șoldanești, Ștefan Vodă, Taraclia, Telenești, Ungheni, UTA Gagauzia, Chișinău Municipality, Bălți Municipality) also in 2 campaigns, spring and autumn. Area of aerial vaccination from Moldova is 23040 km².

By aerial distribution will be distributed yearly in 2 campaigns 1152000 baits.

In Ukraine, will be performed aerial and manual distribution for oral vaccination of foxes, on a buffer zone of 100 km radius from the border with Romania, in 5 regions (Odesa, Khmelnytsk, Ternopil, Chernivtsi, Ivano-Frankivsk) with 29 districts, also in 2 campaigns, spring and autumn. Area of aerial vaccination from Ukraine is 21530 km²/campaign.

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

By aerial distribution will be distributed yearly in 2 campaigns 1076500 baits and by manual distribution 58000 baits over an area of 1160 km²/campaign, where aerial distribution is not recommended to be performed.

In Romania:

The total number of foxes estimated for 2021 is 73306.

The total number of jackals estimated for 2021 is 19356.

In Moldova:

The total number of foxes estimated in 2021 is approximate at 36.000 animals

We intend to continue the ORV at least until 2024, because in 2021 we still have rabies cases and the rabies epidemiological situation of our neighbouring countries (Moldova and Ukraine) is not stabile yet.

Taking into consideration the request of the Moldova authorities for introducing in our programme all the area of Moldova for co financing the ORV, we will adapt the figures in this line. The major reason is to protect the east border of E.U. from Romania, because due to the small area of Moldova if the vaccination will be performed only into half of the country, the animals from the rest of the country could migrate into the area close to the border with Romania and could be a danger for reintroduction rabies into the EU.

ORV in Moldova should be performed in all the teritory, from the border of Romania inside Moldova at a distance of 100 km, excepting terittory of Trasnistria.

With Ukraine, we intend to restart negotiations for finalizing a protocol of collaboration for ORV after the E.C. STM planned to take place in Romania in November 2021, where both Ukrainian and Moldova competent authorities will attend.

Both ORV in Moldova and Ukraine should take place at least until 2024, to strenght the results of vaccination achieved in Romania.

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 programe included the oral rabies vaccination from 2011.

During 2014-2017 the oral rabies vaccination of foxes it was performed all over the teritory of Romania and the number of outbreaks in this period decreased after the vaccination as follows:

2011- 283

2012-405

2013 403

2014-161

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

2015-28

2016-4

2017-2

2018- 3

2019 -4

2020 -5

2021 – 1 case 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 programe 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 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 rabies is eliminated.

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

In 2021, 23 animals had positive results for rabies (from them 4 were foxes, 3 cats, 8 dogs, 7 cattles and 1 goat).

In 2020, 94 animals had positive results for rabies (from them were 18 foxes, 12 cats, 22 dogs, 37 cattles, 2 jackals and 3 other animals).

In 2019, 91 animals had positive results for rabies (from them 14 were foxes, 11 cats, 23 dogs, 32 bovines, 2 ferrets, and 9 other animals)

In 2018, 78 animals had positive results for rabies (from them 15 were foxes, 11 cats, 18 dogs, 30 bovines and 10 other animals).

In 2017, 59 animals had positive results for rabies (from them 13 were foxes, 7 cats, 13 dogs, 22 bovines and 4 other animals).

- the number of cases in Moldova, since 2016 until present is 424.
- 2016: 79 cases, 2017: 59 cases, 2018: 78 cases, 2019 :91 cases, 2020: 94 cases, 2021:23 cases

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.

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

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

The implementation of the Program in the years 2020-2021 for the buffer zone of 50 km from the border with Romania was co-financed by the EU and supported by Romania.

For Moldova, we intend to perform vaccination campaign into a 100 km buffer zone from the border with Romania, in the same technical conditions, like it is performed in Romania, for the period 2021-2024 (except for areas on the left bank of the Nistru river).

Anti-rabies vaccination of foxes by aerial distribution of vaccine baits and related activities shall be carried out in the 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 on the territory of the Republic of Moldova, the campaign being finished in maximum 15 calendar days, in weather conditions favorable for aerial distribution, with the possibility to extend the campaign by maximum 15 calendar days, solely upon written consent from ANSA (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).

An efficient achievement of the Programme will decrease the risk of spreading rabies at susceptible animals, domestic and wild, removing the danger of transmitting 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 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) :

ROMANIA

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.

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

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

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 annex no.4.

(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 annex no.4;

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.

MOLDOVA

For Moldova, we intend to perform vaccination campaign into a 100 km buffer zone from the border with Romania, in the same technical conditions, like it is performed in Romania, for the period 2021-2024 (except for areas on the left bank of the Nistru river).

Short summarise of the 100 km buffer zone:

- 35 regions (Anenii Noi, Basarabasca, Briceni, Cahul, Cantemir, Călărași, Căușeni, Cimișlia, Criuleni, Donușeni, Drochia, Dubasari, Edineț, Fălești, Florești, Glodeni, Hîncești, Ialoveni, Leova, Nisporeni, Onița, Orhei, Rezina, Rîșcani, Sîngerei, Soroca, Strășeni, Șoldanești, Ștefan Vodă, Taraclia, Telenești,

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

Ungheni, UTA Gagauzia, Chişinău, Bălţi) with a total surface of 30 440,5 square km.

- Surface suitable for aerial distribution (without water and localities) is of 23040 square km, (see attached table 1), mostly by plane distribution, 25 baits/ campaign/km² with a distance between flight lines of 500 meters and at a lower altitude, by avoiding the territories of localities, water surfaces, highways, etc.

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. The target of the foxes to be shot is 930 foxes divided in 2 campaigns.

The tests necessary for active and passive monitoring will be performed in the National Reference Laboratory of the Republic of Moldova (Republic of Veterinary Diagnostic Center).

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.

The objectives of the programme comprise :

- surveillance of rabies in wild animals population in Moldova
- control of rabies in fox population in Moldova
- monitoring of oral vaccination in fox population in Moldova
- efficiency of vaccination
- surveillance of rabies' prevalence in the population of domestic animals, including dogs and cats

Executive requirements

Passive Surveillance

Firm managers, owners of non-professional farms, hunting grounds administrators / managers, zoos, circuses, including itineraries and other spaces organized by law and housing animals; free practitioners empowered veterinarians, official veterinarians, decentralized institutions and non-governmental organizations.

Free practitioner empowered veterinary or official veterinarian.

If the official veterinarian decides on the existence of a risk point, all the susceptible animals in the outbreak shall be vaccinated according to the vaccination method recommended by the vaccine manufacturer in the instructions for use.

Virological examinations are carried out at the Republic of Diagnostic Veterinary Center of Moldova (CRDV).

All death / killed animals susceptible to rabies (on road, forest, non-commercial holdings, etc.), suspected or with clinical signs of rabies, as well as those shot to determine the effectiveness of rabies vaccination will be tested at CRDV.

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

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

(max. 32000 chars) :

ROMANIA

Rabies is notified according to the 2020/2002 Regulation.

MOLDOVA

1. AGREEMENT between the National Agency for Food Safety of the Republic of Moldova and the National Sanitary Veterinary and Food Safety Authority of Romania - on granting non-reimbursable financial assistance for the surveillance, control and eradication of fox rabies in the buffer zone established on the territory of the Republic of Moldova (RO no .25464 from 15.04.2019).
2. GOVERNMENT DECISION 185 of 15-03-2019 on the approval of the Plan of measures for surveillance, control and eradication of rabies in foxes in the Republic of Moldova for the years 2019–2023.
3. Order ANSA 182 of 26-04-2019 on the implementation of the Plan of measures for surveillance, control and eradication of rabies in foxes in the Republic of Moldova for the years 2019–2023. Order ANSA 52 of 04.03.2015 on the approval of sanitary-veterinary norms on general measures for the prevention and control of rabies in domestic and wild animals.
4. Program of strategic actions for the surveillance, prophylaxis and control of animal diseases, for the prevention of the transmission of diseases from animals to humans and for the protection of the environment (the year is approved).

Note: the terms of implementation of the regulatory framework listed above will be extended in conjunction with the new EU co-financing Decisions.

3.2. Target animals and estimation of the animal population

(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 73 000.

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 2456324 and cats 369015.

MOLDOVA

target populations for monitoring of ORV and rabies surveillance:

The objectives of the programme comprise :

- surveillance of rabies in wild animals population in Moldova
- control of rabies in fox population in Moldova
- monitoring of oral vaccination in fox population in Moldova
- efficiency of vaccination
- surveillance of rabies' prevalence in the population of domestic animals, including dogs and cats

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

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) :

ROMANIA

Regarding the disease monitoring, all the suspect animals from domestic species and the 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 send 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 collection of brain tissues, mandibula and thoracic liquid. The brain tissue its 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.

MOLDOVA

Laboratory tests used, including the procedure in place in case of FAT inconclusive results,

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 WHO. 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

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 1300 every year , between 2022-2024.

Immunoenzymatic assay (ELISA)

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

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

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

930 animals shall be examined every year, between 2022-2024.

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.

930 foxes will be shoot and tested every year, between 2022-2024.

Laboratory investigations:

a) in case of suspicion of disease:

- Exam by FAT or intracerebral inoculation of mice / inoculation on cell cultures, when FAT is negative for human exposure.

Confirmation of the disease is performed by an FAT exam in accordance with the OIE diagnostic manual.

b) in the case of domestic and wild carnivorous found dead:

- FAT exam with release of analysis bulletin.

Viral strains circulation surveillance (by PCR / sequencing):

Samples are taken from all wild and domestic animals at IFD and transmitted from the Republican Center for Veterinary Diagnosis of the Republic of Moldova to the Rabies NRL – Institute for Diagnostic and Animal Health (IDAH), Romania.

Executive requirements

Passive Surveillance

Firm managers, owners of non-professional farms, hunting grounds administrators / managers, zoos, circuses, including itineraries and other spaces organized by law and housing animals; free practitioners empowered veterinarians, official veterinarians, decentralized institutions and non-governmental organizations.

Free practitioner empowered veterinary or official veterinarian.

If the official veterinarian decides on the existence of a risk point, all the susceptible animals in the outbreak shall be vaccinated according to the vaccination method recommended by the vaccine manufacturer in the instructions for use.

Virological examinations are carried out at the Republic of Diagnostic Veterinary Center of Moldova (CRDV).

All death / killed animals susceptible to rabies (on road, forest, non-commercial holdings, etc.), suspected or with clinical signs of rabies, as well as those shot to determine the effectiveness of rabies vaccination will be tested at CRDV.

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

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 577/2003, 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: (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.

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

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

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 chosen 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.

Vaccination of domestic carnivores (dogs) – each animal shall be vaccinated against rabies from the age of three months with yearly revaccination according with the Programs of strategic actions for the surveillance, prophylaxis and control of animal diseases, for the prevention of the transmission of diseases from animals to humans and for the protection of the environment (the year is approved). 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 are foreseen.

(max. 32000 chars) :

ROMANIA

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.

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

(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:

- 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.

MOLDOVA

2. MOLDOVA

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

When rabies is confirmed in domestic or wild animals, specific control measures are applied, in accordance with the GOVERNMENT DECISION 185 of 15-03-2019 on the approval of the Plan of measures for surveillance, control and eradication of rabies in foxes in the Republic of Moldova for the years 2019–2023.

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 grounds, 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.

The targeted species for rabies surveillance in Moldavia are: fox (passive and active), dog, cat, sheep, goat, cattle, pigs and other wild animals (any wild animal susceptible to rabies with clinical signs or found dead).

Samples are taken from all wild and domestic animals at IFD and transmitted from the Republican Center for Veterinary Diagnosis of the Republic of Moldova to the Rabies NRL – Institute for Diagnostic and Animal Health, Romania

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

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 manufacturing of posters is 10% and cost of distribution is 90%. Total cost of awareness campaign for 1 poster is 1.26 euro. It means that the cost for manufacturing of 1 poster is 0.13 euro and cost of distribution is 1.13 euro.

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

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

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

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 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).

The Associations of Hunters and Fishermen of Romania and The Private Hunting Associations

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

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.

MOLDOVA

Actions undertaken for the fulfillment of the objectives:

- oral vaccination of foxes by airplane distribution in order to obtain an territory free of rabies;
- 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 Moldova;
- 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.
- annual vaccination of 70% of dog and cat populations;

vaccination of other domestic animals in outbreak;

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 23040 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.

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.

2. Legal basis for the implementation of the programme

(max. 32000 chars):

ROMANIA

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

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

completions, Order no 35/2016 with the subsequent modification and completions.

MOLDOVA

1. AGREEMENT between the National Agency for Food Safety of the Republic of Moldova and the National Sanitary Veterinary and Food Safety Authority of Romania - on granting non-reimbursable financial assistance for the surveillance, control and eradication of fox rabies in the buffer zone established on the territory of the Republic of Moldova (RO no .25464 from 15.04.2019).
2. GOVERNMENT DECISION 185 of 15-03-2019 on the approval of the Plan of measures for surveillance, control and eradication of rabies in foxes in the Republic of Moldova for the years 2019–2023.
3. Order ANSA 182 of 26-04-2019 on the implementation of the Plan of measures for surveillance, control and eradication of rabies in foxes in the Republic of Moldova for the years 2019–2023. Order ANSA 52 of 04.03.2015 on the approval of sanitary-veterinary norms on general measures for the prevention and control of rabies in domestic and wild animals.
4. Program of strategic actions for the surveillance, prophylaxis and control of animal diseases, for the prevention of the transmission of diseases from animals to humans and for the protection of the environment (the year is approved).

Note: the terms of implementation of the regulatory framework listed above will be extended in conjunction with the new EU co-financing Decisions.

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

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 monitoring

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 did not have any free rabies areas until this time.

- % 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%..

description of rabies epidemiological situation over the last 5 years,

MOLDOVA

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

In 2021, 23 animals had positive results for rabies (from them 4 were foxes, 3 cats, 8 dogs, 7 cattles and 1 goat).

In 2020, 94 animals had positive results for rabies (from them were 18 foxes, 12 cats, 22 dogs, 37 cattles, 2 jackals and 3 other animals).

In 2019, 91 animals had positive results for rabies (from them 14 were foxes, 11 cats, 23 dogs, 32 bovines, 2 ferrets, and 9 other animals)

In 2018, 78 animals had positive results for rabies (from them 15 were foxes, 11 cats, 18 dogs, 30 bovines and 10 other animals).

In 2017, 59 animals had positive results for rabies (from them 13 were foxes, 7 cats, 13 dogs, 22 bovines and 4 other animals).

Rabies in Humans.

The last death Rabies case in human was registered in 2003 (Drochia district - the bite caused by a marten), 2016 (Causeni district - the bite caused by a dog) and 2019 (in Goieni Noi a suburb of Chisinau- the bite caused by a dog).

Due to the wrong policies regarding the regulation of animal maintenance and in particular the management of stray dogs, there are approximately 5,000 addresses registered by citizens at medical centers with dog bites caused by the application of prophylaxis protocols.

Republic of Moldova has a surface of approximately 33803,5 km² of which 4431 km² is covered by forests. The self declared 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 2021 is approximate at 36.000 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- 2 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.

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

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 2020 it carried out for the first time the aerial rabies vaccination of foxes in 2 campaigns, being applied also the manual distribution of vaccine baits around the rabbinical localities.

They were fully distributed in 2020- 1086277 vaccine baits distributed by air and 147600 vaccine baits distributed manually.

In 2021, due to the late completion of the tender procedures (various unjustified appeals of economic agents), only the autumn campaign took place.

They were fully distributed in 2021- 616825 vaccine baits distributed by air and 52200 vaccine baits distributed manually.

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.

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 monitoring

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 monitoring

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.

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 target animal is 40% - 50 %.

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

The expected percentage is 85%-90%.

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

C. Targets

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

Targets for year: **2021**

Country	Region	Animal Species	Type of test	Test description	Number of tests	Expected number of positive results	% positive
MOLDOVA	all country	Fox	serological test	ELISA	465	200	43
MOLDOVA	all country	Fox	presence of biomarker	Tetracycline in bones	465	400	86
Totals :					930	600	
					Add a new row		
Total tests Serological (FAVN) in MS					0		
Total tests Serological (FAVN) in TC					0		
Total tests Serological (ELISA) in MS					0		
Total tests Serological (ELISA) in TC					465		
Total tests Serological (Other) in MS					0		
Total tests Serological (Other) in TC					0		
Total tests presence of biomarker (Tetracycline in bones) in MS					0		
Total tests presence of biomarker (Tetracycline in bones) in TC					465		
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 monitoring

Targets for year: **2022**

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	4000	47 X
ROMANIA	all country	FOX	presence of biomarker	Tetracycline in bones	8535	7000	82 X
MOLDOVA	all country	FOX	serological test	ELISA	930	450	48 X
MOLDOVA	all country	FOX	presence of biomarker	Tetracycline in bones	930	750	81 X
UKRAINE	100 km buffer zone	FOX	presence of biomarker	Tetracycline in bones	862	700	81 X
UKRAINE	100 km buffer zone	FOX	serological test	ELISA	862	400	46 X
Totals :					20 654	13 300	
					Add a new row		
					0		
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					1 792		
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					1 792		
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 monitoring

2. Surveillance tests to be carried out

Targets for year: 2021

Country	Region	Animal Species	Category	Test description	Number of tests	Expected number of positive results
ROMANIA	all country	Fox	Suspect or dead animals	FAT	1200	2
ROMANIA	all country	Fox	Suspect or dead animals	Virus characterisation test	2	2
ROMANIA	all country	Dogs	Suspect or dead animals	FAT	98	0
ROMANIA	all country	cats	Suspect or dead animals	FAT	47	0
ROMANIA	all country	domestic ruminant	Suspect or dead animals	FAT	139	0
ROMANIA	all country	domestic ruminant	Suspect or dead animals	FAT	2	0
ROMANIA	all country	wild species	Suspect or dead animals	FAT	36	0
Moldova	all country	Fox	Hunted animals (active s	FAT	465	3
MOLDOVA	all country	Fox	Suspect or dead animals	FAT	50	4
MOLDOVA	all country	Dogs	Suspect or dead animals	FAT	100	10
MOLDOVA	all country	cats	Suspect or dead animals	FAT	40	5
MOLDOVA	all country	domestic ruminant	Suspect or dead animals	FAT	90	18
MOLDOVA	all country	pigs	Suspect or dead animals	FAT	10	0

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

MOLDOVA	all country	wild animals	Suspect or dead animals	FAT	12	2	X
MOLDOVA	all country	all species	Suspect or dead animals	Virus characterisation test	40	42	X
							X
							X
Total					2 331	88	
Add a new row							
Total tests FAT in MS					1 522		
Total tests FAT in TC					767		
Total PCR tests in MS					0		
Total PCR tests in TC					0		
Total tests Virus characterisation tests in MS					2		
Total tests Virus characterisation tests in TC					40		
Total tests Virus isolation tests in MS					0		
Total tests Virus isolation tests in TC					0		
Total other tests MS					0		
Total other tests TC					0		

Targets for year : **2022**

Country	Region	Animal Species	Category	Test description	Number of tests	Expected number of positive results

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

ROMANIA	all country	Fox	Suspect or dead animals	FAT	1200	1	X
ROMANIA	all country	Fox	Suspect or dead animals	Virus characterisation test	1	0	X
ROMANIA	all country	Dogs	Suspect or dead animals	FAT	40	0	X
ROMANIA	all country	cats	Suspect or dead animals	FAT	40	0	X
ROMANIA	all country	domestic ruminant	Suspect or dead animals	FAT	100	0	X
ROMANIA	all country	wild species	Suspect or dead animals	FAT	20	0	X
MOLDOVA	border 100 km	Fox	Hunted animals (active s	FAT	930	4	X
MOLDOVA	border 100 km	Fox	Suspect or dead animals	FAT	4	4	X
MOLDOVA	border 100 km	Dogs	Suspect or dead animals	FAT	150	5	X
MOLDOVA	border 100 km	cats	Suspect or dead animals	FAT	80	3	X
MOLDOVA	border 100 km	domestic ruminant	Suspect or dead animals	FAT	150	5	X
Moldova	border 100 km	pigs	Suspect or dead animals	FAT	10	0	X
MOLDOVA	border 100 km	wild animals	Suspect or dead animals	FAT	20	4	X
MOLDOVA	border 100 km	all species	Suspect or dead animals	Virus characterisation test	25	25	X
UKRAINE	border 100 km	Fox	Hunted animals (active s	FAT	862	3	X
UKRAINE	border 100 km	Fox	Hunted animals (active s	Virus characterisation test	3	3	X
UKRAINE	border 100 km	Fox	Suspect or dead animals	FAT	100	10	X
UKRAINE	border 100 km	Fox	Suspect or dead animals	Virus characterisation test	10	10	X
UKRAINE	border 100 km	Dogs	Suspect or dead animals	FAT	60	10	X

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

UKRAINE	border 100 km	Dogs	Suspect or dead animals	Virus characterisation test	10	10	X
UKRAINE	border 100 km	cats	Suspect or dead animals	FAT	50	5	X
UKRAINE	border 100 km	cats	Suspect or dead animals	Virus characterisation test	5	5	X
UKRAINE	border 100 km	cattle	Suspect or dead animals	FAT	30	2	X
UKRAINE	border 100 km	cattle	Suspect or dead animals	Virus characterisation test	2	2	X
							X
Total					3 902	111	
Add a new row							
Total tests FAT in MS					1 400		
Total tests FAT in TC					2 446		
Total PCR tests in MS					0		
Total PCR tests in TC					0		
Total tests Virus characterisation tests in MS					1		
Total tests Virus characterisation tests in TC					55		
Total tests Virus isolation tests in MS					0		
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*

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

Targets for year: **2021**

Country	Region / area	Products used	Number of doses	Size of the vaccination area (km ²)	
Other	Moldova (autumn campaign) aerial	SAD Bern strain	576000	23 040	X
Other	Moldova (autumn campaign) manual ⁺	SAD Bern strain	46500	1 860	X
		Total	622 500		
				Add a new row	
		Oral vaccine and baits made of SAD Bern strain in MS	0		
		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 GAGAS strain in MS	0		
		Total Vaccines distributed	0		
		Purchase and distribution of oral vaccine and bait in neighbouring TC	622 500		

Targets for year: **2022**

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
Moldova	Moldova (2 campaigns) aerial distri ⁺	SAD Bern strain	1152000	23 040	X
ROMANIA	all country manual distribution (2 ca ⁺)	SAD Bern strain	150800	3 015	X
UKRAINE	border 100 km (2 campaigns) aeri ⁺	SAD Bern strain	1076500	21 530	X

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

UKRAINE	border 100 km (2 campaigns) mant. SAD Bern strain	58000	1 160	X
Total				
		13 106 050		
			Add a new row	
	Oral vaccine and baits made of SAD Bern strain in MS	10 819 550		
	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	10 819 550		
	Purchase and distribution of oral vaccine and bait in neighbouring TC	2 286 500		

(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.

(max. 32000 chars) :

In Moldova, will be performed aerial and manual distribution for oral vaccination of foxes, on a buffer zone of 50 km radius from the border with Romania, in 35 raions, also in 2 campaigns, spring and autumn. Eligible area of aerial vaccination from Moldova is 23040 km2. By aerial distribution will be distributed yearly in 2 campaigns 635000 baits. In Ukraine, in 2021 we don't have any agreement for the oral rabies vaccination at the buffer zone. If it is going to be signed an Agreement, the oral rabies vaccination of foxes will include the aerial and manual distribution of vaccine baits, on a buffer zone of 100 km radius from the border with Romania, in 5 regions (Odesa, Khmelnytsk, Ternopil, Chernivtsi, Ivano-Frankivsk) with 29 districts, also in 2 campaigns, spring and autumn. Area of aerial vaccination from Ukraine is 21530 km2/campaign. By aerial distribution will be distributed yearly in 2 campaigns 1076500 baits and by manual distribution 58000 baits over an area of 1160 km2/campaign, where aerial distribution is not recommended to be performed.

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

4 Official control of oral vaccines to be carried out

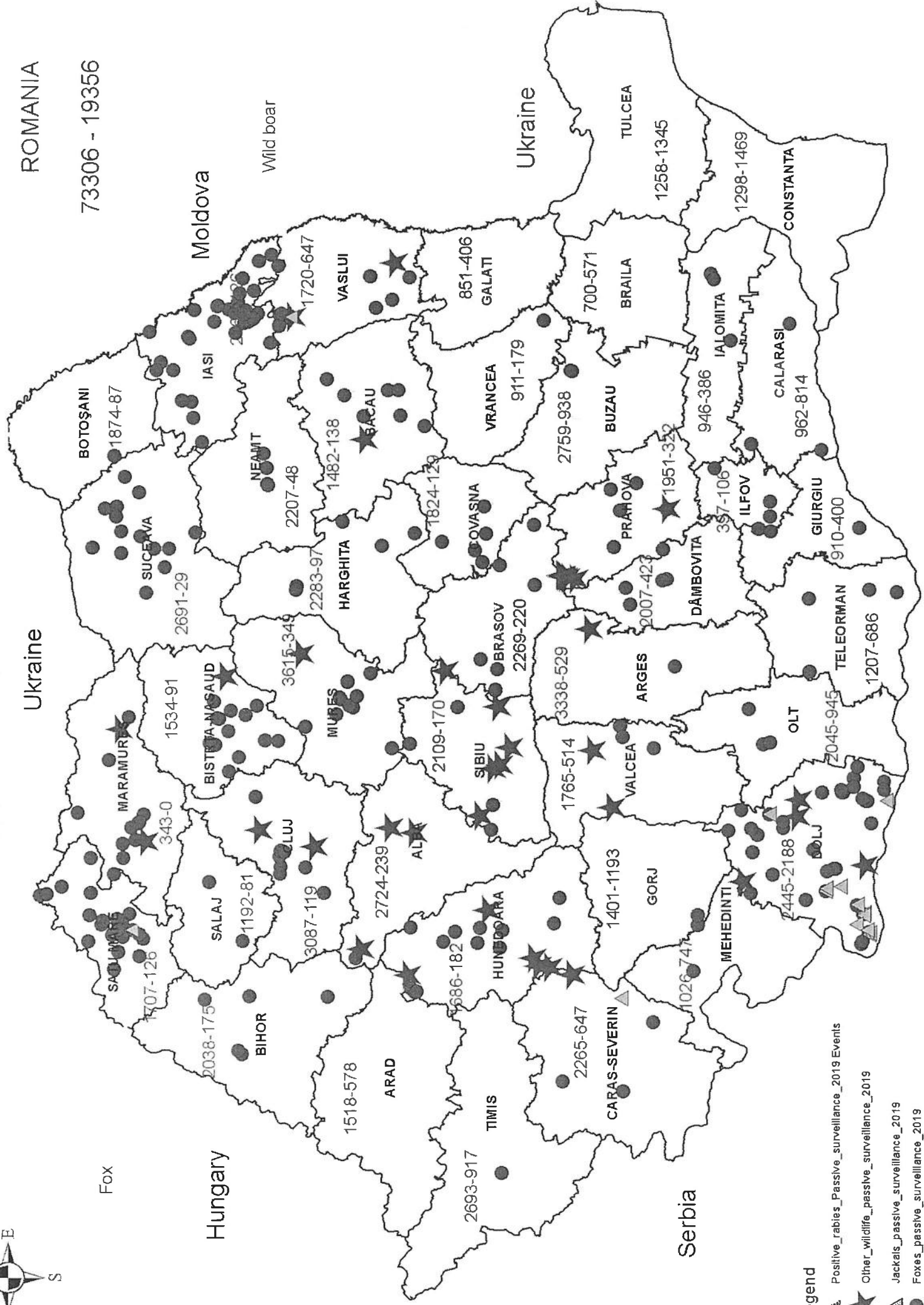
Targets for year: 2021

Country	Number of batches distributed	Number of batches controlled by the CA	Number of virus titrations performed
Moldova	2	2	2
Total	2		2
Add a new row			
	Vaccine titration tests in MS		0
	Vaccine titration tests in TC		2

Targets for year: 2022

Country	Number of batches distributed	Number of batches controlled by the CA	Number of virus titrations performed
ROMANIA	30	30	30
Moldova	4	4	4
UKRAINE	4	4	4
Total	38		38
Add a new row			
	Vaccine titration tests in MS		30
	Vaccine titration tests in TC		8

PASSIVE SURVEILLANCE III WIIU 2019



- Legend**
- ▲ Positive rabies_Passive_surveillance_2019 Events
 - ★ Other_wildlif_passive_surveillance_2019
 - ▲ Jackals_passive_surveillance_2019
 - Foxes_passive_surveillance_2019

ROMANIA
73306 - 19356

Moldova

Wild boar

Ukraine

Ukraine

Fox

Hungary

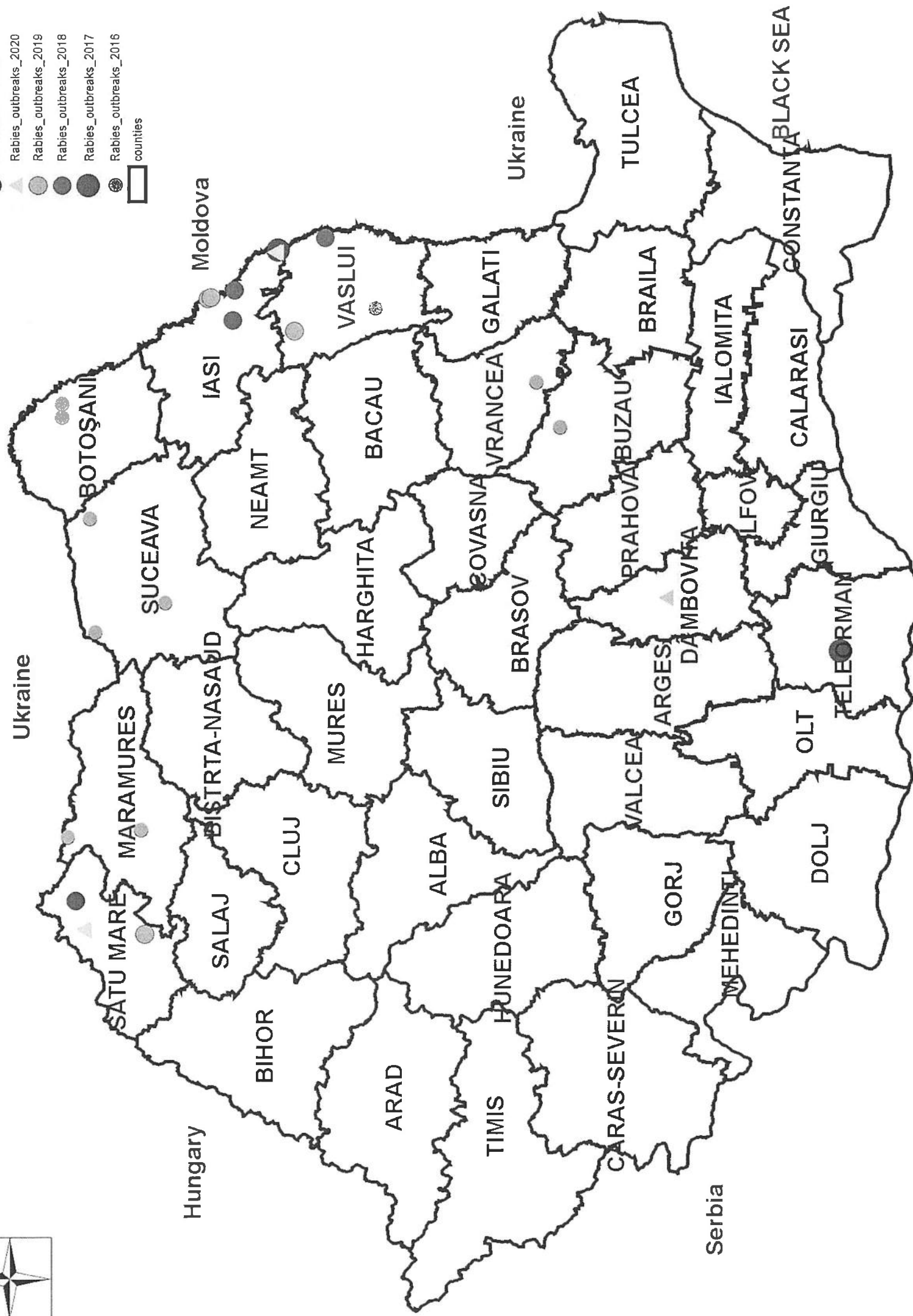
Serbia

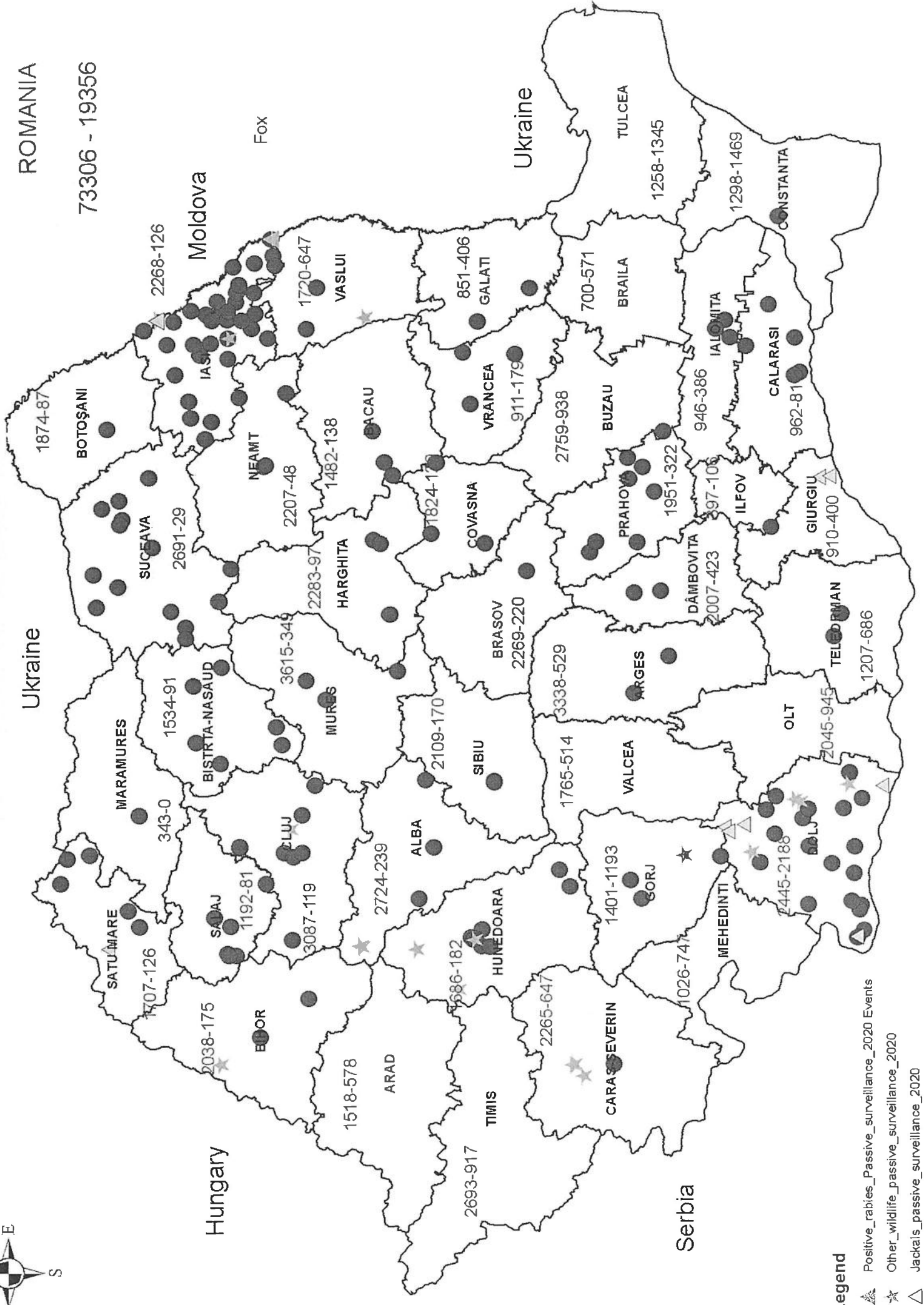
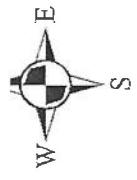
Legend

▲ Positive rabies_Passive_surveillance_2019 Events
 ★ Other_wildlif_passive_surveillance_2019
 ▲ Jackals_passive_surveillance_2019
 ● Foxes_passive_surveillance_2019



- Rabies_outbreaks_2021
- Rabies_outbreaks_2020
- Rabies_outbreaks_2019
- Rabies_outbreaks_2018
- Rabies_outbreaks_2017
- Rabies_outbreaks_2016
- counties





ROMANIA
73306 - 19356

Moldova

Fox

Ukraine

Ukraine

Hungary

Serbia

Legend

-  Positive_rabies_Passive_surveillance_2020 Events
-  Other_wildlife_passive_surveillance_2020
-  Jackals_passive_surveillance_2020

