„Regional action on animal disease eradication in the Western Balkans”
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COHERENT STRATEGY FOR RABIES CONTROL IN THE WESTERN BALKAN REGION

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Contents

1. Objective and purposes

The European Commission aims to facilitate the progressive alignment of the animal health status, the priorities for disease control intervention and the disease preparedness of the Western Balkans to higher EU standards. It will contribute to achieving the eradication of official disease freedom of the Western Balkan region. This will protect the EU and ensure a proper functioning of the internal market from the moment the Western Balkans are ready to join the EU.

The objective of this document is to support the competent authorities of the beneficiary countries to adopt a common strategy for rabies control with emphasis on regional approach in the Western Balkan countries, namely Albania, Bosnia and Herzegovina, Kosovo[1], Montenegro, North Macedonia and Serbia.

The project purpose is to ensure that the technical capacity of the beneficiary competent authorities is upgraded to ensure favourable animal health status for the whole region over long term.

2. Introduction

Rabies is a zoonotic disease of mammals still present in Europe with the red fox as its main vector and reservoir. Scientific advances have made it possible to develop oral vaccination for wildlife by incorporating rabies vaccines in baits for foxes. Oral vaccination by use of rabies vaccine baits has proved to be cost effective and durably efficient for controlling wildlife rabies. Thanks to the application of this method most infected European countries are (or have been) reported to be freed from rabies.

The Western Balkan countries have been engaged in oral vaccination programmes since around ten years, with the first programme implemented in Kosovo[1] in 2010. The EU had supported financially rabies eradication through pre-accession instruments (IPA), with IPA I which ended in 2014 and IPA II ended in 2020. During the same period, bordering EU countries (Romania and Bulgaria) then Croatia entered the European Union in 2009 and in 2013 respectively, and initiated large-scale rabies eradication programmes. Greece experienced the first rabies outbreak at the end of 2012 and started vaccination programmes in Autumn 2013.

In all these countries, oral vaccination has proved to be efficient for controlling terrestrial wildlife rabies, as the number of cases has dramatically decreased in the last years. The scientific knowledge is available for establishing efficient and adapted oral programmes aimed at eliminating terrestrial rabies from Europe, which is a priority for the European Union. Despite tremendous efforts of each of the six countries for fighting against this disease, the true rabies incidence is unknown, as the surveillance is not efficient nor effective in certain areas. Therefore, the absence of the disease is not demonstrated in the targeted animal population and the Western Balkan countries are still continuing using oral vaccination programmes as a protection measure. The sustainability of these programmes is not optimal, with campaigns not regularly performed.

It is necessary to consolidate the achievements on rabies control accomplished by the combined efforts of all countries/territories of the region, by establishing a rabies control strategy adapted

[1] *This designation is without prejudice to positions on status and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence.*

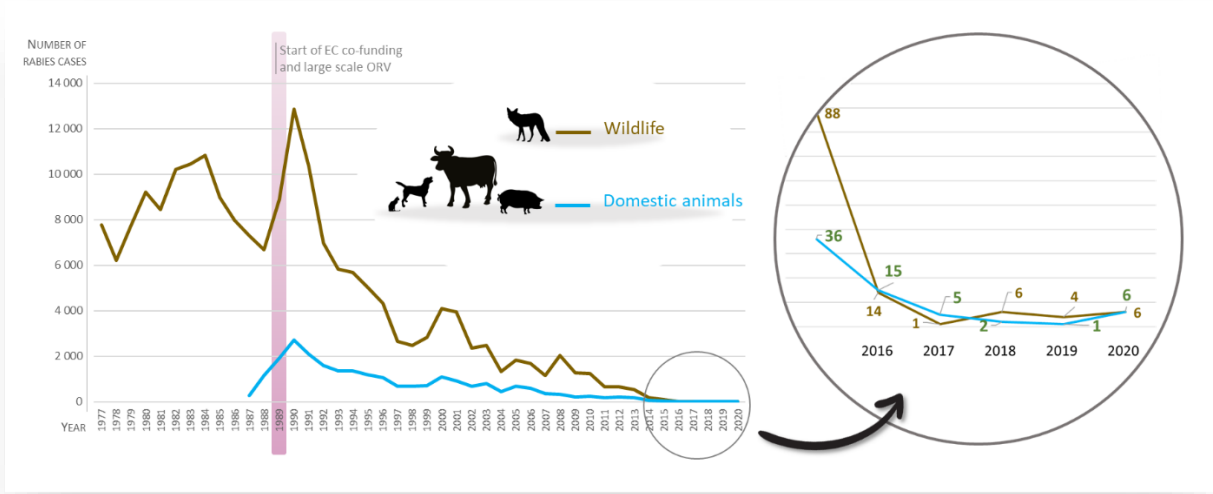
to the current context and based on a regional approach, the ultimate goal being to reach the rabies free status of the Western Balkan countries.

3. Background

3.1. Rabies in Europe

The implementation of oral vaccination programmes in the European Union (EU) has produced a dramatic decrease in the number of rabies cases in both domestic and wildlife animals over the last 30 years (Figure 1). This has led to the elimination of rabies in the Western, Northern and Central part of the EU. The disease is now confined to the Eastern part of the EU where it has been notified since 2016 only in 4 Member States: Lithuania, Poland, Hungary and Romania. In 2019, only 5 fives cases were reported in Poland (1 fox) and in Romania (2 foxes, 1 wild boar and 1 cattle). In 2020 (Figure 2), 12 cases of rabies were detected with 7 cases in Poland (5 foxes, 1 cattle and 1 dog) and 5 cases in Romania (1 fox, 2 bovines and 2 dogs), representing a sharp decrease compared to the situation in 2010, where there were more than 1500 cases in nine EU Member States.

The Figure 2 shows that, excepting a case recorded in a dog in Romania, the 11 other cases reported by Poland and Romania in 2020 were located close to the borders. The history of rabies elimination in infected Member States during the last decades has clearly demonstrated that the last rabies cases were often detected close to the borders, even if the neighbouring countries were also engaged in rabies control programmes.



Source: Rabies Bulletin Europe and Animal Disease Notification System

Figure 1: Evolution of rabies in the EU 1977 – 2020

The elimination of rabies in the EU is now in sight, the goal was to reach zero cases in wildlife and domestic animals in the EU by 2020. However, rabies elimination is still not achieved and the number of cases registered in 2020 in the EU was the highest since 2017 (Figure 1). In 2021, up to

30 April, an outbreak has been occurring in Poland with 19 rabies cases detected in foxes, in an area far from the border and where the last case was recorded in 2004. In Romania, one case was detected close to a border. This demonstrates how difficult is the final phase just prior to definitive and sustainable virus elimination, still not achieved in the EU despite regular vaccination campaigns.

The EU identified rabies elimination as a priority, and has provided since 1989 considerable financial and technical resources to the infected EU Member States, allowing regular and large-scale rabies eradication programmes. These programmes are usually annual or multiannual. The key elements of the rabies eradication programmes are rabies surveillance, oral rabies vaccination (ORV), quality control of vaccines as well as control of their distribution, and monitoring of the aerial vaccination effectiveness [1].

Source: Animal Disease Notification System and Plateforme Epidémiologie santé animale

Figure 2: Location of rabies cases in 2020 in Europe (RABV cases, excluding bat rabies cases)

3.2. Rabies in the Western Balkan and EU bordering countries

Wildlife rabies is present in the Western Balkans, with the red fox (*Vulpes vulpes*) being the reservoir and vector of the disease. According to information available from the Rabies Bulletin Europe, Western Balkan countries reported many rabies cases in the past. Rabies was continuously reported from several Western Balkan countries. The epidemiological situation from 2010 to 2019 is represented in the Figure 3. In 2010, the Rabies Bulletin Europe reported a total of 191 cases in wild and domestic animals. The first rabies case in North Macedonia was recorded in 2011 and the last reported case was in 2012. The first cases in Greece and in Albania were reported in 2012 and Kosovo[2] reported rabies case in 2013. In 2014, last cases were confirmed in

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Albania, Croatia, Bosnia and Herzegovina, Montenegro, Kosovo[3], Greece and Bulgaria. From 2015 until 2018, for four consecutive years, rabies was apparently detected only in Serbia (9 cases) and only within a small area very close to the border with Bosnia and Herzegovina. The last nine cases in this area were confirmed in foxes. In 2019, no rabies cases were reported in this area as well in the entire Western Balkan area.

In 2020, rabies was confirmed in a dog in Srebenica in Bosnia and Herzegovina, very close to the area where cases in foxes were reported in Serbia (Figure 4). The last case in Bosnia and Herzegovina was confirmed in dog within the same area where case was reported in 2014. This suggests that the rabies virus probably continues to circulate in an undefined area.

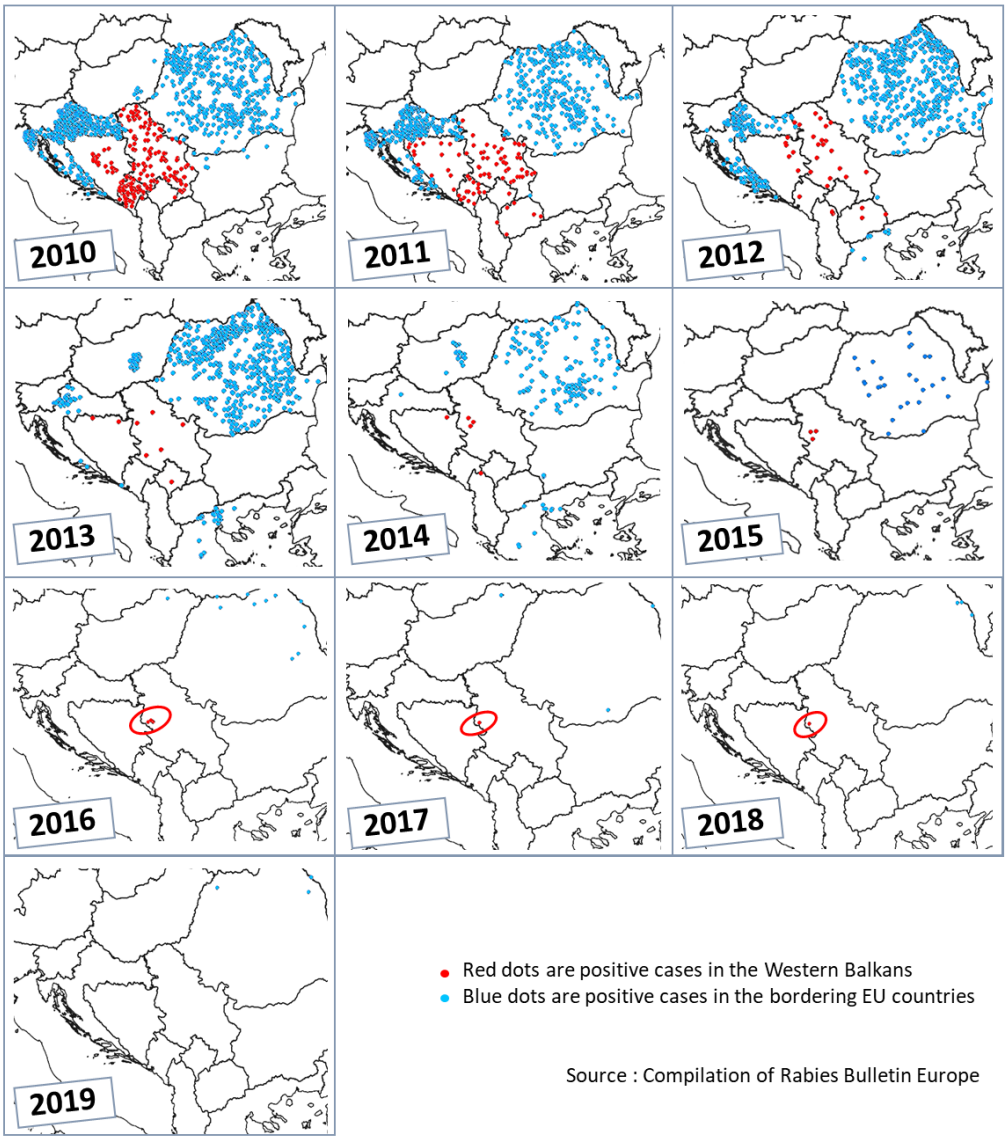

Figure 3: Rabies situation (RABV cases, excluding bat rabies cases) in the Western Balkans and in the neighbouring EU countries from 2010 to 2019

[3] *This designation is without prejudice to positions on status and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence.*

This event also confirms the lack of surveillance, as investigations in the infected area were very low, and a lack of adequate emergency measures.

Rabies epidemiological data of EU countries bordering Western Balkan countries (Figure 3) show also a rapid and high decrease of cases over the period 2010 – 2019. The last cases were reported in 2014 in Bulgaria, Croatia and Greece and in 2017 in Hungary. However, these countries are still not recognized as rabies free (no dossier of self-declaration submitted so far to the OIE). Romania is reporting several cases each year, most of them are located close to the borders with Moldova and Ukraine. Therefore, the available current epidemiological data suggest that the EU bordering countries present a very low risk of rabies introduction in a Western Balkan country.

Figure 4: Rabies case in Srebenica (Bosnia and Herzegovina) on 29 May 2020 (Source: ADNS)

IN CONCLUSION

- Western, Central and Northern European countries have become rabies free after implementation of years of ORV. In Europe, very few countries are still infected, the situation is under control and these countries are involved in regular and continuous ORV campaigns, which are the only way to eliminate durably the virus.
- The epidemiological situation in the Western Balkan countries is improving as the number of cases has dramatically decreased in the last years.
- The recent case detected in Bosnia and Herzegovina in 2020, close to the border with Serbia threatens the positive evolution in the region, after 6 years without any case in Bosnia and Herzegovina, and two years after the last case reported in Serbia.
- The available current epidemiological data suggest that the EU bordering countries present a very low risk of rabies introduction in a Western Balkan country. However, with the last case recorded in 2020 in Bosnia and Herzegovina, the data suggest that rabies is not under good control in the region. Resurgence of the virus in neighbouring countries could occur, including countries of the Western Balkan region or EU bordering countries.

3.3. Rabies control and eradication programmes: EU funding

Since several years, the EU has funded ORV programmes in territories or buffer zones of non-EU countries (Russian Federation, Belarus and Ukraine) as part of Member State programmes. Since 2016, the EU has also co-funded the costs associated with laboratory testing (serological tests, fluorescent antibody tests, virus characterization tests, biomarker detection and vaccine titration tests) in the case these tests are related to buffer zones in non-EU countries and have been performed in a laboratory of a Member State [2].

The EU is also co-funding ORV programmes in six countries or territories in the Western Balkans through the EU Instrument for Pre-Accession Assistance (IPA). From January 2007 onwards, the IPA replaces a series of EU programmes and financial instruments for candidate countries or potential candidate countries. In the Western Balkan countries, besides technical assistance for the transposition of EU Acquis and activities designed to strengthen inspection services and veterinary legislation, the IPA funds are generally used for the control and eradication of animal diseases including brucellosis, tuberculosis, anthrax, classical swine fever and rabies. As a result, since 2010, multi-annual oral rabies vaccination programmes for eliminating fox rabies have been launched in six Western Balkan countries. These programmes are established at the country level, and the beneficiary authorities and EU delegations of each country discuss the use of the IPA funds by establishing priorities in activities to be implemented. When IPA funds are insufficient, additional funding is provided by the national budgets. For rabies, and depending upon countries and years, IPA funds may support all the expenses linked to the rabies program control or may be used for purchasing the vaccine baits and their delivery in the fields, while the national budgets support expenses for rabies surveillance and ORV monitoring.

The key components of the IPA programmes for the control and eradication of animal diseases in the Western Balkan countries include the setting up and execution of disease surveillance, coordination and exchange of information on the situation and evolution trend of rabies programmes in the region, and regional and international cooperation between the involved national veterinary services.

The Table 1 summarizes the funding sources of the rabies control programmes in the six WB countries since 2010. Most of those countries have reinforced measures aiming to control the disease and have initiated oral vaccination programmes against rabies which started in Kosovo[4] in spring 2010 and autumn 2010 in Serbia. All countries have requested assistance from the EU IPA instrument since 2010. Montenegro and Serbia have vaccinated for 6 and 7 consecutive years, respectively, with the support of IPA instrument.

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Year	ORV Campaign	Funding by IPA funds					
		AL	BiH	KO[4]	MN	MK	SR
2010	ORV Spring	No	No	100%	No	No	No
	ORV Autumn	No	No	100%	No	No	100%
2011	ORV Spring	No	No	100%	No	100%	100%
	ORV Autumn	No	100%	100%	100%	100%	100%
2012	ORV Spring	No	100%	No	100%	100%	100%
	ORV Autumn	No	100%	100%	100%	100%	100%
2013	ORV Spring	No	100%	100%	100%	100%	100%
	ORV Autumn	No	100%	100%	100%	100%	100%
2014	ORV Spring	100%	100%	100%	100%		100%
	ORV Autumn	100%	100%	100%	100%		100%
2015	ORV Spring	100%	100%	100%	100%	100%	100%
	ORV Autumn	100%	100%		100%	100%	100%
2016	ORV Spring	100%	100%		100%	100%	100%
	ORV Autumn	100%	100%		100%	100%	100%
2017	ORV Spring	100%	100%		100%		100%
	ORV Autumn	100%	100%		100%	100%	No
2018	ORV Spring	100%	100%	100%	100%	100%	100%
	ORV Autumn	100%	No	100%	100%	100%	100%
2019	ORV Spring	No	No	100%	100%	100%	100%
	ORV Autumn	No	No	100%	100%		100%
2020	ORV Spring	No	100%	100%	100%	No	No
	ORV Autumn	100%	100%	100%	No	No	No
2021	ORV Spring ORV Autumn						

Caption

No	ORV not implemented.
Yes	ORV was implemented, but information on the funding not known.
100%	ORV was implemented and the funding was 100% (supply and distribution of baits) covered by IPA funds (link to detailed information about the funding of the ORV is provided).
ND	No data regarding whether ORV was implemented or not.

Table 1: Financial sources of ORV campaigns in the six Western Balkan countries from 2010 to 2020

IN CONCLUSION

- Annual IPA programmes for the control and eradication of rabies represents currently the main source of funding for the implementation of the control measures. ORV campaigns were not conducted in case IPA funds were not available.
- These programmes are established at the country level, and the beneficiary authorities and EU delegations of each country discuss the use of the IPA funds by establishing priorities in activities to be implemented, therefore rabies control may be considered as a lower priority at a certain time in certain countries.
- There is no coordination activities in the region in relation to the projects of ORV campaigns, and sharing of information is mainly limited to the GF TADs meetings.

3.4. Oral rabies vaccination programmes (ORV)

In Europe, the only efficient method to control rabies consists to use oral vaccination of wildlife by depositing vaccine baits containing a capsule or a plastic sachet filled with an attenuated anti-rabies liquid vaccine throughout the fox habitat, therefore almost everywhere, including > 2000 m altitude mountains since foxes can be found until 2500 m of altitude. The objective is to break the transmission of rabies virus by vaccinating a sufficient number of susceptible foxes by use of oral vaccine baits. The method has been used for the first time in 1978 in Switzerland in small areas then enlarged rapidly to Western Europe for field trial in the eighties. Oral immunization of wildlife through ORV has started to be used on large scales in the EU thanks to EU funding since 1989. This tool was rapidly proven to be the only efficient technique in controlling the disease. In the majority of Western and Central European countries, ten consecutive years of regular campaigns conducted twice a year without discontinuation, in Spring and in Autumn, was the minimum time for achieving the last case of rabies. In many countries, it took more time, in very few countries it took less time.

The Figure 5 presents the frequency of oral vaccination campaigns in the six beneficiary countries in the last ten years. The year of the occurrence of the last case in each country is also indicated in the Figure. Depending on countries, ORV campaigns were conducted on a regular way, during successive years. In other countries, ORV campaigns were carried out a certain time, then interrupted for more or less time, and started again, indicating gaps in the implementation of ORV in the region. The data clearly show that within a period of ten years, the 6 Western Balkan countries conducted ORV all together only at two periods: in Spring 2015 and in Spring 2018.

Moreover, the combination of the data on frequency of oral rabies vaccination and the last reported case suggests that for most countries, the last rabies case was recorded only after very few vaccination campaigns. Such rapid achievement of Zero case after one or two ORV campaigns has never been observed in an EU country, and such results are not expected in presence of an effective surveillance system. The previous experiences in the EU confirmed that at least six consecutive years with oral rabies vaccination campaigns were the minimum to reach the last case of the infection and associated with a robust surveillance scheme. To the best of the knowledge gained on rabies eradication programmes in Europe, only one EU country succeeded to sustainably eliminate rabies after six years with oral rabies vaccination campaigns. All other EU countries needed at least 10 years to detect the last rabies case. In the compilation of ORV campaigns conducted in the Western Balkans (Figure 5), it is clear that only two countries were enrolled for at least six consecutive years with oral rabies vaccination before the last case in 2018 was confirmed. It should be noted that the sanitary conditions due to COVID-19 pandemic in 2020 and 2021 did hamper the execution of the rabies control programme and certain countries were obliged to cancel ORV campaigns.

In 2021, only Albania, Bosnia and Herzegovina and Kosovo[5] planned to carry out ORV in Spring and Autumn. The perspectives of ORV for the next years are unknown or unclear for the

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beneficiary countries as ORV implementation is closely linked to the IPA funding. Therefore it clearly appears that no long term planning is established in the current strategy.

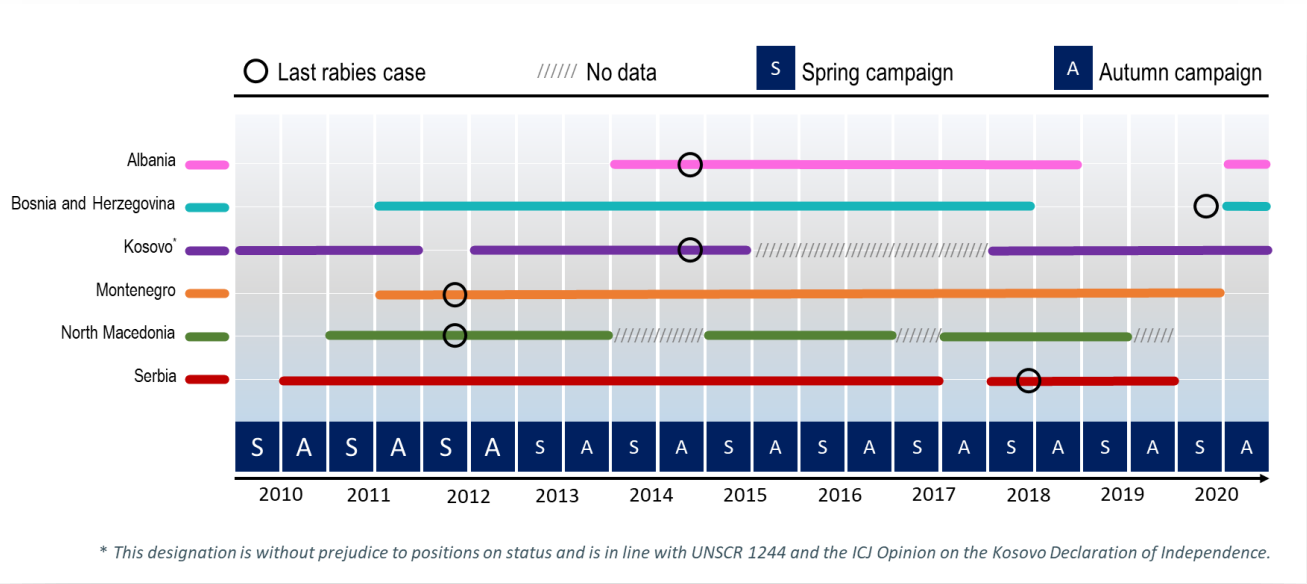


Figure 5: Frequency of oral vaccination campaigns in the WBs from 2010 to 2020

An analysis has recently been done regarding the quality of vaccine baits distribution near the political borders in the Western Balkan countries [3]. Bait distribution data with the geo-coordinates for Autumn 2018 oral rabies vaccination campaign (except for Bosnia and Herzegovina, it was Spring 2018) was requested from the Veterinary Competent Authorities of the beneficiary countries. The study zone was of 10 km on both sides of the border between each Western Balkan country. The conclusions of the report were that globally, the alignments of flight lines were satisfactory with just few hundred meters from the borders and the overall average vaccine bait density was considered as uniform. However, several more or less large areas remained unvaccinated at the borders, these are generally located in mountain areas (>2000-meter altitude).

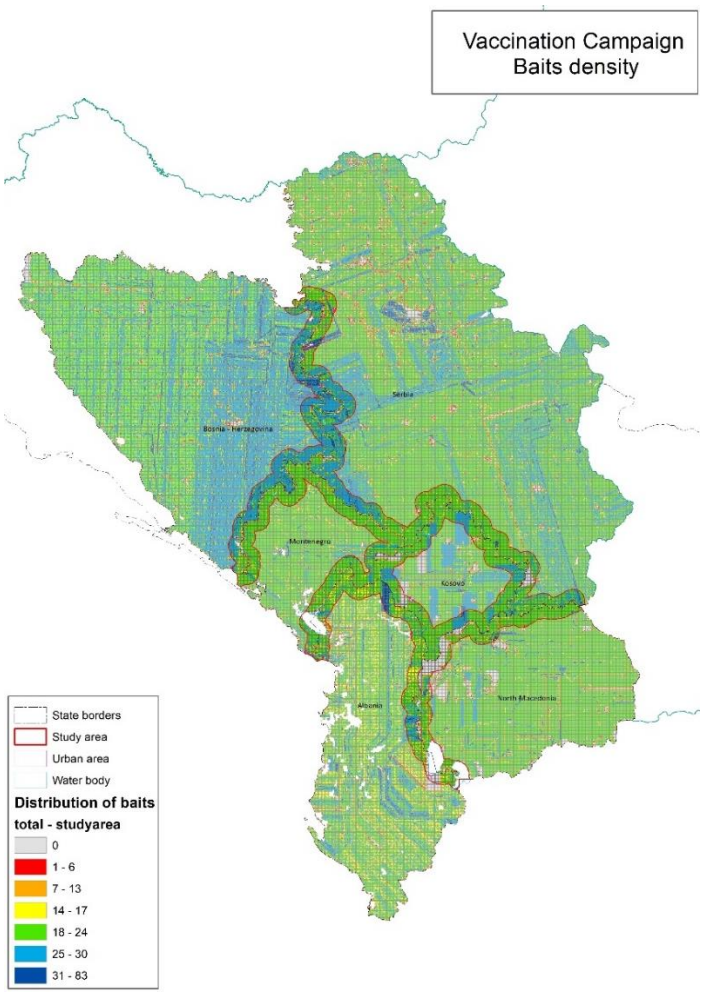
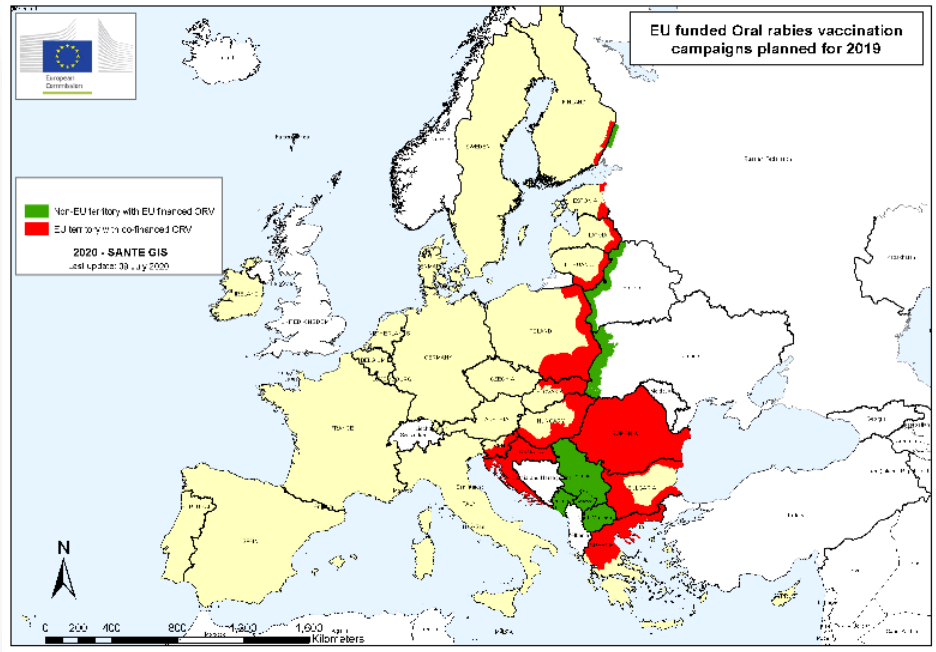


Figure 6: Rabies vaccine bait distribution in the Western Balkans in 2018 Autumn ORV (for Bosnia and Herzegovina information for 2018 Spring ORV campaign is presented)

As regard ORV in the European Union, the strategy is currently used in all Member States that are infected with rabies, within all the country or in certain infected areas. Oral vaccination is also used in rabies free Member States along the political borders with neighbouring infected countries (examples of Finland, Estonia or Latvia). EU countries bordering the Western Balkan countries - Bulgaria, Croatia, Greece, Hungary and Romania - are all engaged in eradication programmes in more or less large areas (Figure 7).



Source: Courtesy of Dr Rosado Martins, DG SANTE

Figure 7: Oral rabies vaccination campaigns planned in 2019

IN CONCLUSION

- ORV has been in use in the Western Balkan countries since 2010 and is also used in bordering EU Member States.
- The Western Balkan countries did vaccinate their territories without considering similar activities of the bordering countries of the region: within ten years (2010 – 2020), the 6 Western Balkan countries conducted ORV all together only at two periods: in Spring 2015 and in Spring 2018. There is no coordination in control measures among countries of the region.
- It seems that ORV was conducted in the Western Balkan region based on availability of financial support rather than based on perceived rabies risk and long-term planning.
- The combination of the data on frequency of oral rabies vaccination and the last reported case in each country, recorded after only very few vaccination campaigns, suggests that probably rabies cases are not detected because of a lack of surveillance.
- The analysis of bait distribution in the Western Balkan region suggest overall uniform bait distribution. The analysis demonstrated that near the political borders several more or less large areas remained unvaccinated at several borders. These were sometimes located in mountain areas (>2000-meter altitude).

3.5. Rabies surveillance

Rabies (passive) surveillance is the key element for assessing the rabies situation within the country and for planning, implementing and evaluating the success of any rabies eradication programme [4]. The objective is to be in a position for early detection of outbreaks to avoid rabies spread or re-infection [5].

The ultimate indicator of the efficacy of the control programme comes from surveillance data, i.e. a decrease in the incidence of animal rabies in the country. Surveillance must be [6] (Table 2):

- Based only on laboratory investigations on **found dead** and **suspect animals**. A **suspect animal** is an animal that show clinical signs or abnormal behaviour suggestive of rabies, or an animal found dead or road-killed, or an animal involved in human exposure (biting, scratching or licking on broken skin).
- Carried out on all mammal species, **wildlife and domestic**, **owned or ownerless**.
- Conducted continuously in time (**during all the year**) and space (**within all the country, irrespective of the vaccinated areas**).

Samples	Animals	Sample size	Sample submitted to laboratory analysis	Period for sampling
SURVEILLANCE **Found dead or suspect animals (all domestic and wild species)**	Animals sampled throughout the country (even those non vaccinated)	No sample size	Brain	During all the year
MONITORING **Hunted wild animals (foxes)**	Animals sampled throughout vaccinated areas	4 animals /100 km^2 annually	Blood and teeth (canine) or bone	3 weeks after vaccination for at least 2 – 3 months

Source: EFSA Development of harmonized schemes for monitoring and reporting of rabies in animals in the European Union, 2010

Table 2: Rabies surveillance and monitoring of oral rabies vaccination

The exact number of animals to collect for surveillance (also named passive surveillance) cannot be pre-determined. To be effective, the EC and OIE recommend that an effective network be in place [7] nationally and locally to allow the collection of samples on all the territory. It is of utmost importance to motivate all official veterinarians of all unit areas to ensure the sampling of a significant number of found dead and suspect animals to be analysed for rabies to detect as much as possible the positive cases.

More animals are collected better is the surveillance and more cost-effective are the control measures. To summarize, "**No surveillance = no control**" resumed the WHO Team Leader of the Zoonotic Neglected Tropical Diseases unit (WHO, Geneva).

The public plays a major role to identify the dead (road-kills for example) and suspect animals whereas the hunters are generally in charge of collecting or/and killing these animals. Awareness campaigns should be conducted on a regular basis to obtain close collaboration between the general public, veterinary services and hunters. The objective is to sensitize them on the importance of reporting any found dead or suspect case to the official veterinarians/hunters.

Data collected during the project and from the GF-TAD meeting of 2020 [8] on passive surveillance conducted by the beneficiary countries are reported in Table 3. As mentioned in several reports [8, 9, 10, 11, 12, 13] and despite all efforts of the veterinary authorities to undertake rabies surveillance, the surveillance pressure is largely insufficient in the region, with a number of samples tested for rabies diagnostic too low, hence hampering the freedom status declaration.

	AL	BiH	KO[6]	MN	MKD	SR
2017	0	40	2	12	5	206
2018	0	35	/	13	2	115
2019	0	21	/	11	2	98
2020 (not complete year)	0	8	1	6	7	39
Total	**0**	**29**	**1**	**17**	**9**	**137**

Source: SGE RAB2: Second meeting of the Standing Group of Experts on Rabies for Europe, 13 July 2020 (Teleconference)

Table 3: Number of tested animals in the frame of passive surveillance in the WB countries from 2017 to 2020

Resurgence of rabies occurred in May 2020 in Bosnia and Herzegovina on a dog. As a result of this outbreak, very few animals in Bosnia and Herzegovina (7 foxes) and in Serbia were investigated in the infected area. This confirms the above conclusions and the necessity to continue with oral rabies vaccination (no emergency vaccination was conducted nor Spring vaccination due to COVID-19 restrictions and administrative constraints, both in Bosnia Herzegovina and in Serbia).

IN CONCLUSION

- Rabies surveillance, which is the key pillar of the program to assess the effectiveness of the control measures is ineffective:
  - Animal sampling too low, and sampling is decreasing along the years.
  - Uneven location of samples tested.
  - Epidemiological data not analysed to improve the control programme or to rapidly adapt the ORV campaign.
- The true rabies situation in all regions is therefore unclear:
  - Rabies situation in the region unknown (is the region still infected? Or rabies free?).
  - High risk hampering to detect rabies at an early stage.
  - Impossibility to declare the region or some areas as free of rabies (so obligation to continue vaccination in the whole territory).

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3.6. Vaccination monitoring

The objective of the monitoring is to sample wild carnivores (foxes and jackals) in vaccinated areas to evaluate the efficacy of ORV campaigns in terms of bait consumption (bait uptake by the target species) and herd immunity against rabies.

For the purpose of the monitoring, animals are hunted homogenously through vaccinated areas and killed (Table 2). The quasi totality of these animals is healthy, therefore not suspect for rabies [6].

The following tests are carried out on those animals:

- Rabies diagnosis using WHO/OIE reference tests [7, 14],
- Testing of fox sera for rabies antibodies in blood samples to evaluate the immunity of fox population against rabies,
- Analysing for the occurrence of the biomarker (tetracycline) incorporated in the bait from bones and teeth from foxes.

The recommended sample size for rabies monitoring is to test 4 foxes per 100 km^2 annually, i.e. 2 foxes per 100 km^2 after each campaign in vaccinated areas.

The hunters play a major role in collecting foxes generally transported to the veterinary services or/and regional or national laboratory(ies). This requires a monitoring network in all vaccinated areas.

The Table 4 summarizes the results of ORV monitoring in the beneficiary countries. The analysis of the results demonstrate that the monitoring is not homogenously conducted in the region over years. Furthermore, interruptions in ORV, creating breaks in the vaccination coverage of foxes, hamper a rigorous analysis of the results. Several reports [9, 11, 13] underline the weakness of the monitoring, such as a number of tested animals below the recommended target, an uneven distribution of the sampling within vaccinated areas or a lack of reliability in the results (as samples might be not properly identified).

		AL	BiH	KO[7]	MN	MKD	SR
		(% positive results)					
2019	Tetracycline	-	-	-	78	26	82
	2019 ELISA	-	-	-	43	36	27
2020	Tetracycline	-	-	-	70	96	86
	2020 ELISA	-	-	-	28	45	33

Table 4: Bait uptake and sero-conversion rates in foxes in the Western Balkan countries in 2019 and 2020

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IN CONCLUSION

- ORV monitoring is globally insufficient to reliably assess the effectiveness of the vaccination programmes:
  - Animal sampling below the recommended sample size.
  - Uneven location of samples tested.
  - As ORV campaigns are not regularly performed, difficult to interpret the data.

3.7. Reporting of epidemiological data on rabies

Collection of epidemiological data regarding rabies is crucial as it is forming the basis to the national authorities to have knowledge on rabies incidence and geographical distribution of the cases, to undertake decisions regarding control measures. Such data are also important to estimate the real costs of the programme control (for animals) and prevention (for humans) [6]. The last case detected in a dog in 2020 In Bosnia and Herzegovina was reported on time at the EC through ADNS.

As a basic rule, all existing information systems request data from the passive surveillance, i.e. only found dead and suspect animals (those with positive and negative results) and not the data from monitoring. Mixing of data from passive surveillance and data from monitoring of rabies vaccination campaigns, as it can be the case in Western Balkan countries, makes the assessment of the situation highly difficult or even impossible. Monitoring data do not give a picture of the epidemiological situation because sampled animals were healthy, so no suspect being rabid.

Reporting data of rabies diagnosis to international organizations, i.e. positive and negative results, mean that the data have been collected, processed and analysed. No data reporting suggests that the data from the diagnostic laboratories are not analysed nor used.

Within the last 10 years, only one of the 6 Western Balkan countries regularly reported positive and negative cases to Rabies Bulletin Europe. All countries reported data to Rabies Bulletin Europe only in 2013. In the last two years, except Serbia, Rabies Bulletin Europe did not receive any data from other countries.

IN CONCLUSION

- The surveillance data, which correspond to the positive and negative results of laboratory diagnostic analysis, are poorly disseminated to international bodies. In particular, 5 of the 6 Western Balkan countries do not regularly report the data to the Rabies Bulletin Europe. This lack of data sharing seems to be the reflect of limited interest or capacities to analyse the available data, hence suggesting a neglected priority to rabies control programmes.

4. Strategy of rabies control and elimination

The Western Balkan countries have all been enrolled in oral vaccination programmes since at least ten years. The global principles of the method are known from the authorities and the results of the campaigns demonstrate a success in the reduction of rabies incidence. Furthermore, a number of recent documents [10, 11, 12] have been specifically elaborated by rabies experts for planning and implementing multi-annual vaccination programmes in different countries of the region. These documents are still valid and contain many important recommendations to guarantee the sustainability and the success of rabies control programmes.

The available data from the national authorities of each beneficiary country seem suggesting a satisfactory epidemiological situation in the region. However, as the level of the surveillance is quite low in all the region, the true situation is indeed unknown (is the region free or not? Are some countries free or not?) and the authorities might not be able to detect rabies at an early stage. “They reasoned that the insufficient number of samples is as a result of improving the rabies situation in the country, and thus there is a decreased number of indicator animals” [13]. Indeed, this reasoning is right only if passive surveillance is effective and efficient.

At the start of application of control programmes, the evolution and decrease of rabies incidence is visible, as many cases are easily recorded, even with a non-optimal surveillance. Most European countries met difficulties at the final stage of elimination, as last cases of rabies were more difficult to detect, effective surveillance is then crucial. Resurgence of rabies cases were due to:

- Too small vaccination zone around residual foci,
- Oral vaccination stopped too early after the last recorded case or not applied on a regular basis (twice a year),
- Delayed or lack of coordination between neighbouring countries,
- Procurements for oral vaccines: Missing campaigns,
- Inappropriate strategy in the fields (flight lines, bait dropping, etc),
- Inappropriate passive surveillance and monitoring of the vaccination efficacy (not enough samples, samples analysed years after the campaigns, etc).

In Western Europe, a network with rabies contact points of Belgium, France, Germany, Luxembourg and Switzerland has been created at the end of the 1990s, when residual foci were still reported and more difficult to eliminate, to meet regularly for discussing the control strategies, the common objective being to achieve the rabies free status of the involved countries. The 6 Western Balkan countries are strongly encouraged to adopt the same way of working, which was highly effective.

At the present time, the surveillance data are insufficient in Western Balkan countries to prove the rabies free status of the region:

- Hence some countries of the region are not in a position to prepare a self-declaration dossier to the OIE to declare its free rabies status,
- Hence ORV campaigns should continue in all beneficiary countries as a cost-benefit measure to avoid the extension of the eventual residual foci, to avoid introduction of rabies from a bordering country, and to avoid spread of rabies in a bordering country, including EU countries,
- All the countries of the region must absolutely gather their efforts on rabies passive surveillance to be able to detect in time and space any positive case.

It is clear that this situation where ORV is used nearly “blindly“ to compensate for the lack of surveillance cannot be prolonged for a long time as ORV is an expensive method and cumbersome to organize and implement. The objective of the following sections is to address recommendations adapted to the current context, and aiming to achieve the rabies elimination in the 6 Western Balkan countries.

To succeed, the strategy proposed is based on a regional approach. Considering the small geographical size of the beneficiary countries and the high number of borders, the rabies situation of one country is tightly linked to the situation in bordering countries (a rabid animal is able to move from its territory and it is admitted that the disease progresses by 20 to 60 kilometres a year). Considering also that the Western Balkan countries are close to rabies elimination, the strategy requires absolutely coordination and cooperation at the regional level, as well as with the neighbouring EU Member States. It should focus on the development of a formal, long-term and sustainable collaboration, at least for the harmonization of rabies elimination programmes (planning, surveillance, reporting). All actions recommended should be undertaken by all the 6 countries of the region. It is also proposed that templates of the report recommended below be harmonized for the six countries. A regional approach is supported by the GF-TADs (namely OIE, FAO and EC).

The 6 Western Balkan countries will become rabies free, according to the OIE definition, when, with an adequate surveillance system no rabies case has been reported in non-flying mammals for a period of two successive years. During these last two years, control measures will have to be maintained, i.e. ORV will be implemented.

4.1. Framework – Advocacy - Funding

Rabies is a transboundary disease and political or administrative borders are not barriers to rabies spread.

Following contacts from the European Commission (DG SANTE and DG Near are mainly involved in the process), the EU delegations of each country provide continuous support and funding for oral rabies vaccination and it is recommended to continue until rabies elimination is achieved within all the region, by securing budget for several successive years of vaccination. A minimum of 4 years is recommended to reach this objective. A budget should be secured from the EU delegations of the beneficiary countries for this period. The national budgets are generally sufficient to support passive and active surveillance but not for implementation of the oral rabies vaccinations. The EU delegations and the national competent authorities of each country should closely cooperate; in particular, the elimination of rabies should be a priority of competent authorities in all the beneficiary countries, hence efforts should be undertaken in the implementation of the programmes to strictly adhere with the existing recommendations, including those regarding passive surveillance.

In the Western Balkan countries, veterinary competent authorities are the principally responsible for the implementation of rabies control programmes. However, rabies control is a multidisciplinary long-term activity involving the collaboration of a range of public institutions and non – governmental organizations, as well as the involvement of the general public which is essential and crucial for effective control.

A major factor for the success of rabies control programmes is the political prioritization associated to a certain stability in the institutional framework, with a budget secured for several years and with a trained and competent staff. The chain of commands should be well established,

agile and fluid, with the roles, responsibilities and duties clearly identified and known at both on national and local levels for all stakeholders.

Besides the importance for each country to have an *ad hoc* National Committee for Rabies Control with representatives of all relevant institutions involved in rabies control, as well as an identified coordinator, the regional approach requires the nomination of a rabies contact (the coordinator seems to be the most appropriate), to share and exchange epidemiological information and on experiences as well as to enhance the coordination among the countries (and also with the neighboring EU countries). The coordinators should have the technical authority to take decisions or to refer for decision which should be taken rapidly

Regular meetings should be organized with all coordinators of the beneficiary countries. It is proposed to create a network named for example Rabies WeB network (for Western Balkans' network).

The GF-TADs for Europe has expanded its activities in 2019, with the creation of a new Standing Group of Experts on Rabies (SGE RAB). The countries involved are Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Greece, Hungary, Kosovo[8], Montenegro, North Macedonia, Romania, Serbia, Slovakia and Slovenia. The main objective of the SGE RAB is to coordinate the oral rabies vaccination activities with the overall goal to accelerate the final eradication of rabies. It is planned that the SGA RAB under the GF-TADs umbrella will meet again regularly (annual basis). These meetings are good opportunities to share information and to discuss results achieved and further steps of the regional strategy aiming to rabies elimination as well as to stimulate regional cooperation.

Through the creation of the Rabies WeB network with regular meetings and exchange of information, and meetings of GF-TAD, cooperation with international organizations as well as with the Member States could be improved.

The multi-year strategic plan described below will require continuous and pre-allocated financial resources to be developed and implemented.

4.2. Rabies surveillance

The surveillance is in place in Western Balkans and needs major improvements, the ultimate objectives being to:

- Increase the number of samples submitted to the diagnostic laboratories.
- Ensure that the found dead and suspect animals for rabies diagnosis are sampled within all the areas of each country.
- Ensure that the sampling is also highly efficient close to the borders.

To achieve this objective of improvement, the organization and manpower of the current functioning system should be adapted in each of the beneficiary countries. To be effective and efficient, a network should be officially established, nationally and locally, with identified persons, identified tasks and activities do be done at each level (national or regionally) and reported, with the goal to collect all suspect and found dead animals [4]. If such a manpower network is in place

[8] *This designation is without prejudice to positions on status and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence.*

and functioning, the laboratory receives samples. Most of Member States are rabies free and most of them have a surveillance still in place, even with no sample size assigned.

Specific actions to be conducted are summarized in the Table 5. It is crucial to nominate a rabies coordinator in each country, and also to continuously evaluate the ORV programme [4], with the contribution of an epidemiologist (the coordinator may assume this activity if trained with basic epidemiology).

The data from diagnostic analysis are the pillar of the passive surveillance [6], they should be collected, analysed and interpreted regularly to constitute epidemiological data. The Annex 1 is an example of representation of data analysis from the passive surveillance (two tables for reporting positive and negative cases and one figure of data analysis). Positive and negative cases are recorded on maps for all samples (ideally annual maps should be updated regularly and contain dots – e.g. red dot for each positive case and green dot for each negative case, thanks to GPS coordinates or municipality of the samples). The figure of the Annex 1 records the geographical origin (per region/district) of the samples collected during passive surveillance in Montenegro from 2010 to 2020. Such representation is sufficient to analyse the data and present many advantages: it allows to clearly, easily and rapidly assess that every part of the country has been accurately covered by surveillance, to detect any possible gaps and to study along years the trend in the surveillance pressure.

Such maps, particularly those representing dots for each found dead or suspect animal collected, are excellent ways for evaluating if the sample size for passive surveillance is acceptable or not. In certain European countries, in areas not sufficiently covered by passive surveillance for a certain period (around two months), the veterinary services of the concerned areas were contacted (most time by the coordinator) and strongly invited to improve the surveillance pressure.

ACTIONS	ADVANTAGES	INDICATORS OF SUCCESS
Nominating a rabies technical coordinator of veterinary services responsible of the planning and implementation of the control programme.	▪ Enhancing motivation of all participants and efficiency of the network. ▪ Reporting the epidemiological data to ADNS (positive cases) and to the RBE (positive and negative cases).	▪ Regular meetings and contacts with other coordinators of the region (transparent communication and exchanges of data). ▪ Regular exchanges with bordering EU countries. ▪ Increase in the number of submitted samples for passive surveillance and monitoring. ▪ Epidemiological data available in international websites.
Nominating an epidemiologist in charge of collecting and collating the data from the laboratories. A model of Table as well as mapping are reported in Annex 1.	▪ Analysing and interpreting the data (of rabies surveillance and monitoring) on time [4].	▪ Monthly exchange of data among the WeB network (passive surveillance), for example, using the models of map and table as presented in Annex 1). ▪ Epidemiological data available in international websites.

Organizing trainings of all national and local professionals (stakeholders, hunter associations and veterinary inspectors) on passive surveillance objectives. Such trainings could be held by international experts in each country [4].	▪ Increasing the knowledge on rabies. ▪ Stressing the need of collecting found dead and suspect animals only (and not hunted foxes). ▪ Learning how to complete properly the submission forms, without omitting the localization of the finding (municipality or GPS coordinate).	▪ Increase in the number of submitted samples for passive surveillance. ▪ Samples collected within all the territory. ▪ Early detection of suspect cases.
Organizing awareness campaigns for public focusing particularly on rabies surveillance prior to the two annual vaccination campaigns, by using different means available (written press, radio, Internet, posters, etc…) [4].	▪ Increasing the knowledge on rabies. ▪ Stressing the need of collecting found dead and suspect animals ▪ Collaboration with the general public	▪ Increase in the number of submitted samples for passive surveillance. ▪ Samples collected within all the territory. ▪ Early detection of suspect cases.
Organizing the collection of animals found dead in the field; in particular, arranging with road authorities the collection of road killed animals throughout all the country [4, 6].	Road kills animals are an important part of rabid animals (when rabid, the animals lose the sense of direction).	▪ Increase in the number of submitted samples for passive surveillance. ▪ Samples collected within all the territory. ▪ Early detection of suspect cases.
▪ **Organizing the transport of samples to the laboratory** within the whole territory. ▪ **Identifying clearly the samples collected** (place of collection, GPS coordinate if possible), as well as the type of sampling: passive surveillance [4].	▪ Safe transport of the animal samples ▪ Laboratories receive good quality samples. ▪ Laboratories know that samples are for the passive surveillance.	▪ All found dead and suspect animals received at the laboratory. ▪ Reliable results of the laboratory for diagnostic analysis.
Typing the virus strain of positive cases by using molecular biology tools [4, 6, 7, 14].	Distinction of field rabies virus from vaccine-associated case	Knowledge on the circulating strains in the region and possibly source of reinfection in case of outbreak

Table 5: Passive surveillance: main actions to undertake in each country

4.3. Oral rabies vaccination programmes

ORV programmes should be conducted for a sufficient time within all the six beneficiary countries. The strategy proposes to plan 4 consecutive years of ORV in each country, with two vaccination campaigns per year and following the existing recommendations [6, 7, 15, 16]. This 4-year period includes the two additional years of ORV after the last case is recorded. A discontinuity of vaccination in one country could compromise the success of the strategy.

The strategy implies absolutely that passive surveillance becomes efficient in all beneficiary countries, if not, the ORV campaigns will have to be maintained for a longer period. The Table 6 records the main common actions to be conducted.

The objectives are to eliminate the infection and to maintain a sufficient vaccination coverage of fox populations (around 70%) until rabies free status is achieved, to prevent the re-emergence of the disease

ACTIONS	ADVANTAGES	INDICATORS OF SUCCESS
▪ **Planning ORV within all the countries for a 4 consecutive year period (to be discussed during a regional meeting with the coordinators and EU delegations, and during a GF-TAD meeting).** ▪ **Each country prepares with the EU delegations the administrative dossiers to ensure annual dedicated budget, secures annual national budget and prepares the public tendering procedure.** ▪ **Exchanging through the coordinator' network the dates of the ORV campaigns, sharing this information with the EU bordering countries.** ▪ **Field visit of the coordinator during each campaign, with different places at each campaign.**	▪ All countries know that they are all enrolled at the same level for ORV for a 4-year period ▪ All information for the implementation of the ORV in the region is shared among all countries, including EU bordering countries ▪ Visits of the coordinator enhances the motivation and support of the vaccination team	Sustainability of ORV programmes implemented for a 4-year period in the 6 countries.
Technical parameters of ORV common for all the region [6, 7, 15, 16, 17] (to be discussed during a regional meeting with the coordinators): ▪ Bait density: 20 baits/km2 ▪ Flight lines: ≤ 500m ▪ Eventual manual bait distribution ▪ Use of GPS.	Harmonization of the ORV protocols within the region to adhere to the existing recommendations.	Uniform distribution of baits in the whole region
Timing of vaccination ▪ Spring campaign in April-May ▪ Autumn campaign in October-November	Timing is adjusted to the prevailing climatic conditions to: ▪ Avoid adverse impact of high and low temperatures: high temperatures and direct exposure to sun and freezing temperatures and snow coverage ▪ Avoid prolongation of the bait distribution due to the bad climatic conditions not suitable for flying	Vaccine used at its full potency
Vaccination at high altitudes (until 2500m [18])	No gap in the vaccination area No risk of rabies foci at high altitudes	No resurgence of rabies from high altitude' areas
Vaccination along the borders [4, 16, 17]: ▪ **Increasing of the bait density (25 baits/km2) in a ≥10 km depth** ▪ **If possible, synchronisation of the ORV at both sides of the borders** ▪ **Detailed assessment of the flight lines to assure that no gaps remain in border area** ▪ **If possible, overlapping of the vaccinated areas by crossing the borders (on a ≈10 km depth or even less: it is important that the flight lines** were agreed before the start of the campaign to assure that there are no gaps.	Ensuring a buffer zone along all the political borders of the Western Balkans.	No re-infection from the bordering non-EU and EU countries.

Evaluations of each campaign [4, 6]: ○ **Evaluation of the aerial distribution of vaccine baits [3, 10]** ○ **Epidemiological surveillance of rabies (see section 4.2)** ○ **Monitoring of vaccination** (see section 4.5.)	▪ Following each vaccination campaign to check bait distribution homogeneity (no gap in bait' dropping), overall bait density, uniformity of distribution, distribution in non-target areas, and similar, according to established standards . ▪ Done on a regular basis (monthly) for the two last points to possibly adapt the future strategies within the region or within a particular area.	▪ Short report of ORV after each campaign from each country, shared among the WeB network. ▪ Monthly exchange of data among the WeB network (passive surveillance), for example, by using the models of map and table as presented in Annex 1). ▪ Report of the monitoring after each campaign from each country, shared among the WeB network.

Table 6: Main common actions recommended for ORV strategy
(implying a robust passive surveillance in place in the beneficiary countries)

The regional cooperation should at least include coordination of the ORV campaigns (timing, particularly at the borders, duration and information exchange). Indeed, despite various geographical and ecological conditions, in all European countries the same common rules have been (more or less) strictly followed to ensure the success of rabies eradication programmes. These common rules concern the general strategy, the method of vaccination, the choice of the vaccine and the methods for programme evaluation. Therefore, a regional approach for planning and implementing ORV is scientifically feasible.

Oral vaccines used for wildlife immunization are based on live replication-competent vaccine viruses which are derivatives of the original SAD (Street Alabama Dufferin) strain. Currently, two marketed vaccines are authorized in the European market [15]:

- The Lysvulpen vaccine (Bioveta, Czech Republic), is an attenuated strain of the rabies virus SAD Bern composed of two dominant subpopulations of viruses, namely SAD Bern and SAD B19 "like"viruses.
- The Rabitec vaccine (CEVA Santé Animale, France), is a genetically modified organism (GMO), attenuated rabies vaccine. The vaccine strain SPBN GASGAS is a recombinant rabies virus derived by site directed mutagenesis from SAD B19 strain by three targeted genetic modifications. This vaccine has been in use since December 2017.

These vaccines comply with the requirements of the European Pharmacopoeia and with national regulations for veterinary biologicals, regarding efficacy, safety and potency of the vaccine virus and to genetic strain stability.

The vaccination area should also include high mountains. In Italy, the identification of rabies foci at high altitudes (1500m – 2000m) stressed that sources of re-infection may persist if vaccination activities are not accurately planned, even at high altitudes, so it was decided to increase the flight altitude to 2300m to eliminate rabies foci at those altitudes [18]. In the Western Balkan countries, there are several high mountains, including certain that are at the borders, which should be considered in the planning and implementation programmes.

A key point of the vaccination, besides uniform bait distribution within all the territories, is dealing with the vaccination at the borders. In view of the available epidemiological data in the region, borders may be considered as "risk areas". Therefore, the best way would be, whenever feasible, to establish bilateral collaborations with the neighboring countries [4, 16, 17] to authorize

overlapping flight lines across the borders to ensure that they are efficiently covered by ORV (no gap, i.e. no blank vaccination pockets). If not possible, an increase in the bait density should be used (25 baits/km^2), however this will not hamper gaps of bait dropping very close to the borders from each side of the countries as the aircraft avoid flying at the proximity of the borders.

Data of the automatic records during each ORV should be compulsory analyzed after each day of ORV, in order to control the distribution patterns of the bait dropping accordingly to the technical specifications and the special conditions of the tender.

At the end of each campaign, a concise but precise report summarizing all steps and possible constraints of the campaign is established by the coordinator of each country and shared within the WeB network. It is also essential to share this report with the pilots engaged for ORV and also with all institutions of the National Rabies Control Committee, including the EU delegation of each country.

It is of utmost importance to evaluate the rabies control vaccination programme to possibly adapt the future strategies. The evaluation of oral vaccination campaigns efficacy consists in continuous investigations in time and space for passive surveillance to assess rabies incidence and to check bait uptake and rabies immunity in the target species (vaccination monitoring). It is proposed that template forms (such as ones of the Annex 1) are monthly shared through the WeB network.

4.4. Rabies outbreak management – Emergency vaccination

A recent rabies case was detected in May 2020 in Bosnia and Herzegovina, close to the border with Serbia, three years after the last case recorded in the region in Serbia in 2018 (close to the border with Bosnia and Herzegovina).

Several specific actions are proposed on a regional approach, i.e. each country should possibly update the legislation regarding outbreak management and emergency vaccination requirements. These actions are reported in the Table 7 and concern investigations aiming to detect any found dead or suspect animal around the infected area. The current prophylactic measures carried out regarding the management of a positive case are not reported here (such as observation of suspected domestic animals, isolation of animals, etc).

Regarding emergency oral vaccination, the EC [17] and EFSA [16] recommend that “In case of re-emergence of rabies in foxes in an area where rabies has been previously eliminated, vaccination should be implemented immediately, whatever the period of the year, except under extreme climatic conditions which would severely hinder bait and vaccine stability. An emergency vaccination area with a radius of at least 50 km around the outbreak should be established”.
In case of an outbreak detected close to a political border, rapid communications and collaboration with the neighbouring country has to be established. Each country should have an annual dedicated budget for emergency vaccination. Control measures within the zone and across the border(s) should be coordinated by both countries [16].

ACTIONS	ADVANTAGES	INDICATORS OF SUCCESS
▪ **Defining a protection zone around the positive case, i.e. a zone where the passive surveillance will be reinforced immediately and for a long time**. ▪ **Conducting (strengthened) awareness of the public in the zone to report any found dead or suspect animal to the veterinary services [4].** ▪ **Conducting investigations in the delimited zone to collect any found dead or suspect animal.**	Detect rapidly any rabid animal to avoid rabies transmission to other animals and to limit the spread of rabies.	Significant number of animals from the zone tested at the laboratory for rabies diagnostic.
Communicating to all rabies coordinators of the region the positive case as well as investigations around the case.	▪ Intensify passive surveillance depending on the location of the case. ▪ Detect rapidly any rabid animal to avoid rabies transmission to other animals.	Exchange of information on a very regular basis, particularly on laboratory results on the sampled animals of the zone.
Immediate ORV campaign to be performed within a radius of at least 50 km around the outbreak with a minimum of 5000km² [16] and short interval baiting [16].	Avoid the spread of rabies and detect rapidly any rabid animal to interrupt rabies transmission to other animals	No animal tested positive within the infected zone
Coordination of activities (ORV) with the bordering country(ies) in case of an outbreak close to border(s) [17]..	Avoid the spread of rabies in the bordering country and detect rapidly any rabid animal to interrupt rabies transmission to other animals	▪ Significant number of found dead and suspect animals from the zone and in the neighbouring country tested at the laboratory for rabies diagnostic. ▪ No positive animal tested within the infected zone and in the neighbouring country

Table 7: Compulsory elements of rabies outbreak management: main actions to undertake in each country

4.5. Vaccination monitoring

Hunters are the key persons involved in collection of the samples in the fields for laboratory testing. They are generally engaged in rabies surveillance (killing any wild and domestic suspect animals), as well as in rabies monitoring (hunting foxes and jackals for assessing the efficacy of the oral vaccination campaigns). They shoot foxes, (may be trained to) perform (or not, depending on countries) blood samples on killed foxes then collate and package foxes in plastic bags (together with the blood sample) in all vaccinated areas.

The hunters should be perfectly aware to differentiate surveillance from monitoring sampling (see section 4.2.) and the coordinator should be in regular contacts with them. The Table 8 records the main common actions to be conducted.

ACTIONS	ADVANTAGES	INDICATORS OF SUCCESS
The coordinator and the epidemiologist (see section 4.2.) of each country **remind regularly to the hunter** associations by visiting them in the field the following points: ▪ Hunting foxes and jackals from vaccinated areas ▪ The number of animals to be hunted per hunting ground and per campaign ▪ Reminder of definition of a suspect animal versus animal hunted for the monitoring.	▪ Motivation of the hunters for collecting foxes. ▪ Responsibilisation of local stakeholders and knowledge increase.	All vaccinated areas well covered by the monitoring (4 foxes or jackals collected per 100 km^2 annually).
▪ **The transport of fox/jackal carcasses** [4] to the laboratory is properly organized within the whole territory. ▪ **Samples are clearly identified** [4] (place of hunting, GPS coordinate if possible), as well as the type of sampling: monitoring.	▪ Safe transport of the animal carcasses ▪ Laboratories receive good quality samples. ▪ Laboratories know that samples are for the monitoring assessment.	▪ All hunted animals received at the laboratory. ▪ Reliable results of the laboratory for tetracycline serology assessments.
Evaluation of each campaign by the epidemiologist [4]: ▪ Determination of the percentage of bait uptake, distinguishing juveniles from adults (if possible) ▪ Determination of the percentage of immunized animals, distinguishing juveniles from adults (if possible) ▪ Analysis done for each region (Excel file with a table for each region) ▪ Mapping the collected samples from each campaign.	The proper analysis of results for each vaccinated region allows to identify eventual deficiencies (lack of samples, problem of transport, insufficient bait uptake, etc…). This greatly help for undertaking appropriate corrective actions.	▪ Report of the monitoring 6 months after each campaign and from each country, shared among the WeB network, detailing bait uptake and immunisation rates in the different regions, as well as a map with the geographical location of the samples collected.

Table 8: Main common actions recommended for vaccination monitoring
(implying a robust passive surveillance in place in the beneficiary countries)

4.6. National and Regional Reference Laboratories for Rabies

Depending on the countries, one or several laboratories are in charge of the rabies diagnostic of found dead and suspect animals and of the testing of samples for the monitoring (tetracycline detection and serological test).

The laboratories are using different WHO/OIE reference diagnostic techniques [7, 15]. Besides the Fluorescence Antibody Test, which is the gold standard method for primary rabies diagnosis, it is recommended to use molecular biology tools as confirmatory tests (in case of inconclusive FAT result or in case of human exposure) since they have been recommended by both WHO and OIE since 2018 (conventional RT-PCR, and Real time PCR). Sequencing for typing virus isolates is also important for differentiation between vaccine and field strain and for conducting phylogenetic analysis of virus isolates. This is particularly useful in case of resurgence of the disease, to help understanding the source or the origin of the strain for conducting the epidemiological investigation.

Where applicable, it is advised that national reference laboratories regularly conduct evaluations of the regional laboratories to assess the reliability of their results, by organizing inter-laboratory testing or proficiency testing.

Most of the beneficiary laboratories (5 out of 6 in 2016 and 2019, 4 out of 6 in 2017) participate regularly to the proficiency tests for rabies diagnosis organized by the European Union Reference Laboratory (EURL) for rabies and all obtained satisfactory results. Participation of national reference laboratories should be the rule as soon as a regional laboratory of the same country is asking for participation. The participation of the beneficiary countries to the proficiency tests for tetracycline detection organized by the EURL for rabies was less important, with only two countries participating and succeeding to the test.

The EURL for rabies should be contacted for providing support, training and advice as well as standard operating procedures. The European Union Reference Laboratory (EURL) for rabies can also help for confirming a case or sequencing a virus strain. The EURL did receive the dog strain isolated in BiH, it was a field rabies virus isolate belonging to the cosmopolitan clade. The genetic analysis showed that the sample grouped within the sub-group formed by Western European rabies virus samples (WE), from Serbia, Slovenia and BiH samples isolated from 1986-2006, respectively.

The national reference laboratories of the beneficiary countries should work all together, by exchanging reagents, materials and protocols thanks to the creation of a network of all national reference laboratories of the region.

4.7. Reporting of epidemiological data on rabies [6]

Most epidemiological data are those from the national and regional rabies reference laboratories:

Surveillance data: rabies diagnosis results (positive and negative cases) [6]. The results regarding those positive and negative cases are compulsorily reported from the laboratory to the regional and national authorities on a daily basis by e-mail. In case of positive case, the laboratory must immediately report (by e-mail) the result to the competent authority.

Monitoring data: data from the laboratory should be sent to the authority on a monthly basis:

- Bait uptake in target species (foxes/jackals): table detailing for each municipality the total number of tested animals and number of positive results for bait uptake.
- Immunity of target species: table detailing for each municipality the total number of tested animals and number of positive results for serology.

Other data can possibly be obtained from the hunting associations, corresponding to the density of foxes if known in certain areas (thanks to allocated compensations planned during implementation of monitoring of rabies control programme). Data on fox hunting bags are a good indicator of fox population density.

Regarding the regional approach, in the previous sections it was proposed the following reporting for each country to share among the WeB network:

- Monthly reports of passive surveillance data.
- Report after each ORV to summarize the implementation of the campaigns (surface vaccinated, number of baits distribute, duration, eventual problems, etc…).
- Report for monitoring data obtained six months after each ORV campaign.

It is recommended to use similar templates for all countries that have been previously discussed and decided through meetings organized by the coordinators.

Regarding the reporting to the international bodies, it concerns only passive surveillance data. Immediate notification of cases should be submitted to the Animal Disease Information System

(ADIS) and to the OIE World Animal Health Information System (OIE-WAHIS). The reporting to the Rabies Bulletin Europe is also highly recommended on a quarterly basis [6]. The tables presented in Annex 1 are sufficient for sending the data to the Rabies Bulletin Europe.

4.8. Public awareness and trainings

To increase the number of found dead and suspect animals to be tested for passive surveillance purposes, it is of utmost importance to achieve a close collaboration with the general public, who is implicated in the discovery of found dead and suspect animals.

Awareness campaigns are organized in each beneficiary country which delivers the key messages and information regarding rabies and ORV to the different media supports.
Organizing awareness campaigns prior to the two annual campaigns for the public, including rural populations, by using different means available (written press, radio, Internet, posters, etc…) focusing particularly on rabies surveillance and the need to call veterinary services in case of suspect animal finding, on the fact that a dead animal is a suspect animal, on general public awareness regarding rabies risks, on promoting responsible ownership, as well as on oral vaccination implementation.

The improvement of the passive surveillance requires also trainings in the beneficiary countries, for all stakeholders involved in the rabies control programme, at the national and local levels and on a regular basis (once per year): at least for field veterinary inspectors, regional official veterinarians and veterinarian staff, hunter associations and municipalities (to collect and notify found dead animals).

4.9. Vaccination of pets

In Europe, rabies is maintained in wildlife. Domestic animals may be infected and might present a risk for humans. Vaccination of domestic carnivores by the parenteral route, particularly dogs, and possibly identification, should be part of the rabies control programmes of the Western Balkan countries.

Potent inactivated vaccines are marketed, and certain vaccine producers have recently lightened the protocol of injection from one annual injection to one injection the first and the second year, then a vaccination 3 years apart.

4.10. Control of dog population

Municipalities are generally in charge of the stray dog management, which should be part of the rabies control programme. Stray dogs are at high risks of contact with potentially infected foxes and are living in close proximity to people.

Depending on the countries, different ways are used to manage the populations (reproductive control measures, removal and handling of dogs in dedicated facilities (shelters), capture and return of marked and vaccinated dogs, rehoming or release), however these methods are used on small scales, generally only in urban settings.

The World Animal Health Organization has recently updated a chapter of the Animal Health Code [19] describing practical measures for the control of stray dogs. The Delegated regulation (EU) 2020/689 supplementing the Regulation (EU) 2016/429 (Animal Health Law) requires now the possibility of stray dog vaccination as part of the rabies control programme [5, 20].

Projects regarding the management of stray dogs require long term multidisciplinary involvement of many governmental and non-governmental institutions, as well as the general public, and necessitate important budget. In the frame of the strategy proposed for eliminating rabies, the priority should be given to the measures regarding surveillance and ORV. Awareness campaigns dedicated to the public should raise the notion of responsible ownership and to educate people for reducing dog bites.

5. Recommendations

♦ The recommendations detailed below are classified according to the national and regional sides (Tables 9 (a) to 9 (e)).

I. Surveillance	
NATIONAL side	Making **control of rabies disease a political priority** in each country: ▪ **Having a clear chain of command** at the national and local levels: who is doing what and when. ▪ **Nominating a coordinator** of the control programme (from planning to implementation and evaluation). ▪ Building a **National Committee for Rabies Control**. ▪ **Working closely with the EU delegation**.
	Organizing regular trainings of all national and local professionals (stakeholders, hunter associations and veterinary inspectors) on passive surveillance.
	Organizing regular awareness campaigns for the general public focusing particularly on rabies surveillance by using different means available (written press, radio, Internet, posters, etc…).
	Organizing the **collection of animals found dead** in the field to the laboratory; in particular, arranging with road authorities the collection of road-killed animals throughout all the country.
	Identifying clearly the samples collected in the field, as well as the type of sampling: passive surveillance *versus* monitoring.
	Increasing collaboration with the EURL for rabies (for support for typing for example, trainings, etc…).
	Evaluating the programme on a very regular basis.
REGIONAL side	Making **control of rabies disease a political priority**: ▪ **Building a rabies network** involving all coordinators of the region (named for example Rabies WeB network).
	Organizing regular meetings (at least one every six months) within the network to exchange data and to share experiences. These meetings could be chaired by different countries on a rotational basis.
	Organizing awareness campaigns for all stakeholders of the control programme.
	Exchanging on a monthly basis surveillance data among the WeB network.
	Demonstrating the activities, discussing shortcomings and agreeing on mitigation measures during an annual Coordination meeting.

Table 9 (a): Surveillance

II. ORV campaigns	
NATIONAL side	**Planning ORV within all the countries for a 4 consecutive year period**.
	Preparing with the EU delegations of the administrative dossiers to ensure annual dedicated budget and secures annual national budget and **preparing the public tendering procedure (vaccines planned for the current vaccination and emergency stock).**
	Supporting the field activities (ORV) by regular visits of the coordinator during each campaign, with different places at each campaign.
	Harmonizing the technical parameters of ORV for all the region (2 vaccinations per year, bait density, flight lines, manual distribution, etc…).
	Vaccinating in all areas, including at high altitudes (until 2500 m) and close to the borders.
	Assessing the quality of bait distribution according to established standards and preparing ORV report.
REGIONAL side	**Exchanging** through the coordinator' network the dates of the ORV campaigns, **sharing** this information with the EU bordering countries.
	Vaccination along the borders: ▪ **Increasing of the bait density (25 baits/km2) in a ≥10 km depth** ▪ If possible, **synchronisation of the ORV at both sides of the borders** If possible, **overlapping of the vaccinated areas by crossing the borders** (on a ≈10 km depth or even less.
	Sharing of ORV reports among the WeB network after each campaign from each country.
	Establishing bilateral collaborations with the neighboring countries (including Member States).

Table 9 (b): ORV campaigns

III. Emergency situation management	
NATIONAL side	**Defining a protection zone around the positive case**, i.e. a zone where the passive surveillance will be reinforced immediately and for a long time**.**
	Conducting an awareness of the public in the zone to report any found dead or suspect animal to the veterinary services.
	Conducting investigations in the delimited zone to collect any found dead or suspect animal.
	Performing immediate ORV campaigns (thanks to the emergency stock available) within a radius of at least 50 km around the outbreak with a minimum of 5000km^2 and possibly additional short interval baiting**.**
REGIONAL side	**Communicating to all rabies coordinators of the region the positive case as well as investigations around the case.**
	Coordinating activities (ORV) with the bordering country(ies) in case of an outbreak close to border(s).

Table 9 (c): Emergency situation management

IV. Monitoring	
NATIONAL side	**Reminding the hunters (by the coordinator) some technical points** linked to the monitoring (proper identification of the samples, number of samples to get and location, etc…)**.**
	Organizing the safe transport of fox/jackal carcasses to the laboratory within the whole territory.
	Evaluating each campaign (rabies incidence in mammals, bait uptake and immune status in the target species) by the epidemiologist.
REGIONAL side	**Reporting monitoring data 6 months after each campaign from each country, shared among the WeB network (**detailing bait uptake and immunisation rates in the different regions, as well as a map with the geographical location of the samples collected).

Table 9 (d): Monitoring

V. Others	
National Reference Laboratory	**Creating a network with all National Reference Laboratories of the region.**
	Typing rapidly any positive sample to possibly investigate the origin of the infection.
Reporting of data to international organizations	**Reporting to existing international databases surveillance data** (rabies diagnosis results (positive and negative cases**).**
Public awareness and trainings	**Organizing awareness campaigns** for the general public before each ORV**.**
	Organizing for the general public **in case of rabies outbreak.**
	Organizing annual awareness campaigns for all stakeholders.
Vaccination of pets	**Organizing effective vaccination of pets and accessible dogs as well as identification.**
Stray dog management	**Adopting measures to reduce the risk of human bites (awareness).**
	Organizing vaccination of accessible stray dogs.
	Improving responsible ownership notion.

Table 9 (e): Others

- The recommendations regarding the funding are summarized in the Figure 8.

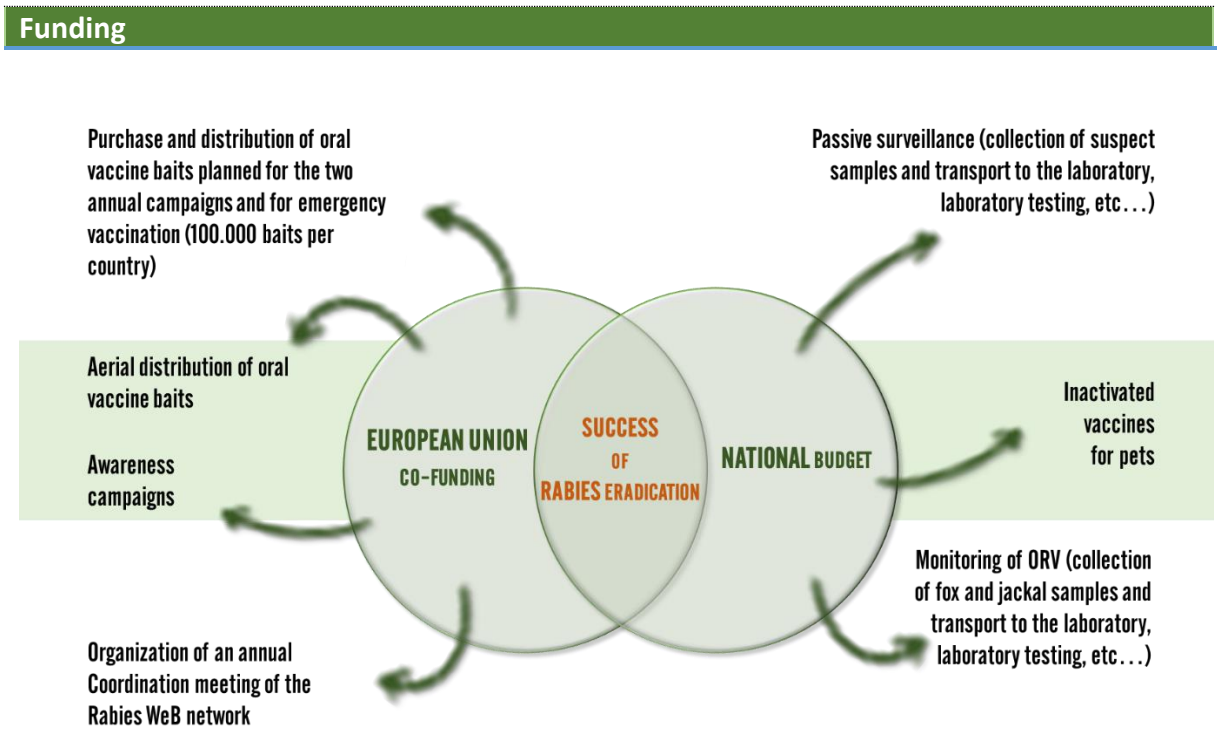

Figure 8: Funding

- The Table 10 records the possible consequences if the recommendations of the report are not used, suggesting clearly that the cost-benefit of such scenario will be the weak point. Therefore, conducting the ORV programme for a period of 4 consecutive years appears as the most sustainable and cost-benefit way to prove and guarantee rabies elimination in the Western Balkan countries.

If no change in rabies control		
	CONSEQUENCES	**REPERCUSSIONS**
NATIONAL and REGIONAL sides	▪ Continuation of the disorganized ORV programmes in all countries over a long period. ▪ If no regular vaccination campaign twice a year, this first point could even be indefinite. ▪ Constant risk of rabies re-infection.	▪ This does not make sense, ▪ Expensive, ▪ Low efficacy, ▪ Long lasting "strategy".
	▪ Continuation of isolation of biting animals and suspect animals according to the legislation on suspect animals.	▪ One or two cases might be detected, like the one of Srebenica in 2020. ▪ Or no case could be detected as a result of too poor surveillance.
	▪ Increased risk for human exposure. ▪ Contaminated people to be submitted to a post-exposure treatment.	▪ Very expensive. ▪ Highly cumbersome for people.
EU bordering countries	▪ EU neighbouring countries will have to pursue a buffer zone vaccination for an extended period. ▪ More generally, the heavy legislation on rabies will have to continue to be applied.	▪ Expensive, ▪ Risk of rabies resurgence, ▪ Constraining.

Table 10 – Consequences and repercussions if no change in rabies control

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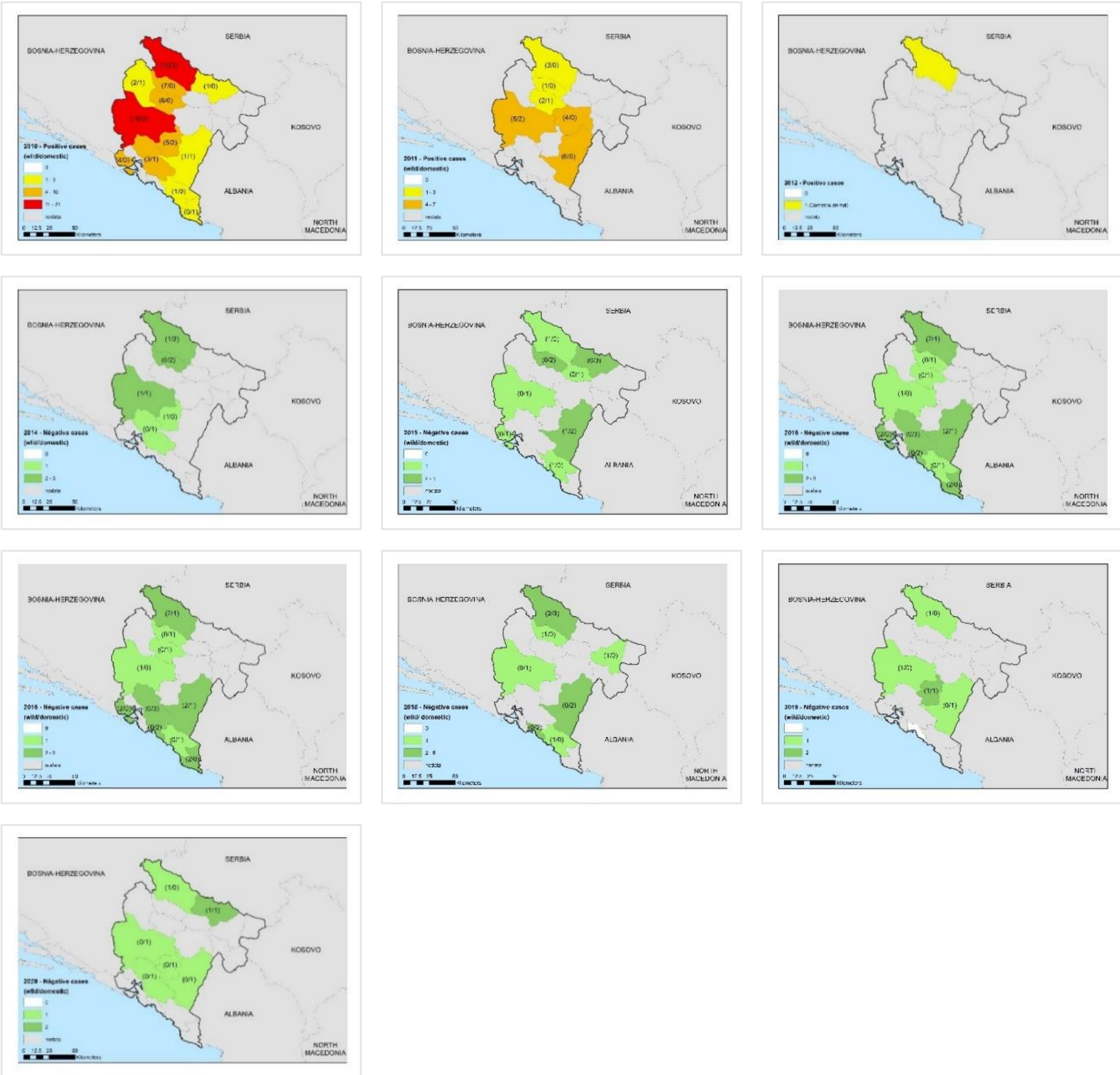
Annex 1

Passive surveillance in Montenegro from 2010 to 2020: Location of positive and negative cases
(in 2010 and 2011, only positive cases are known; no data in 2013)



Template model for registration of laboratory results of the passive surveillance

	2020			Negative cases																				
Municipality	Domestic animals								Wildlife															
	dog	cat	cattle	equine	goat sheep	pig	stray dog	other	subtotal	fox	racoon dog	racoon	wolf	badger	marten	other mustelides	other carnivores	wild boar	roe deer	red deer	jackal	other	subtotal	total
									0														0	0
									0														0	0
									0														0	0
									0														0	0
									0														0	0
									0														0	0

	2020			Positive cases																				
Municipality	Domestic animals								Wildlife															
	dog	cat	cattle	equine	goat sheep	pig	stray dog	other	subtotal	fox	racoon dog	racoon	wolf	badger	marten	other mustelides	other carnivores	wild boar	roe deer	red deer	jackal	other	subtotal	total
									0														0	0
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Figures

Tables