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Working Discussion Document

Guidelines to design an EU co-financed programme on eradication and control of Rabies in wildlife

This document is a staff working document for discussion purposes and does not necessarily represent the views of the European Commission

Content

1. Introduction

Rabies is a viral fatal disease that can affect both animals and humans and was previously widespread across Europe. In the European Union (EU), human rabies cases are nowadays rare thanks to the disappearance of dog-mediated rabies, the improvement of the situation in wildlife and the systematic application of post-exposure treatment in cases of contact between humans and suspect animals. This is mainly due to the EU co-funded oral rabies vaccination programmes, launched at the end of the 1980s, that have proved very successful as they have led to the steady eradication of rabies from several Member States (MSs). Between 2005 and 2014, the total number of rabies cases at EU level has decreased very significantly from 3,708 cases to 300 in the EU 28 (source rabies bulletin: http://www.who-rabies-bulletin.org/)

The eradication of rabies from Europe is now in sight. This is a unique situation in the world as the EU has achieved a level of rabies eradication that has never been experienced anywhere else before[1]. The disease is now confined to the east of the EU. In this area, a vaccination belt has been created through bilateral agreements between MSs and their respective neighbours outside the EU where rabies is still a threat[2].

The purpose of this document is to:

- provide guidance to the MSs and the neighbouring third countries to assist in the planning and implementation of rabies EU co-funded eradication programmes in wildlife and associated activities, and the improvement of the effectiveness of such programmes;
- accelerate the progress of eradication programmes;
- stimulate discussion on future strategy in relation to rabies eradication.

There is a general EU legislative framework for national eradication, control and surveillance programmes of certain animal diseases and zoonoses, including rabies. The main pieces of legislation are:

- Regulation (EU) No 652/2014 of the European Parliament and of the Council[3]: it *inter alia* lays down the procedures for co-financing national programmes for the eradication, control and surveillanceof animal diseases and zoonoses set out in Annex II thereto.

[1] In recent years, due to a high infection pressure from the Western Balkan (WB) countries, the EU is also financing cooperation activities on rabies (and CSF) with WB within the Instrument for Pre-accession Assistance (IPA).

[2] Third Countries that are at the moment being considered under this plan include Russia, Ukraine, and Belarus.

[3] Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the

- Commission Decision 2008/341/EC[4]: it *inter alia* lays down the requirements to be met by national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses in order to be approved and co-financed by the Union.
- Commission Decision 2008/425/EC[5] as amended by Commission Implementing Decision 2012/282/EU[6]: it sets out the requirements for the submission of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Union financing.
- Commission Implementing Decision 2014/288/EU[7]: it lays down the reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Union (intermediate and final reports).

In addition to these references, valuable work has been carried out by the Task Force (TF) for monitoring disease eradication established in 2000 and based on the reccommendations of the »White paper on Food Safety« (DOC/00/1-COM/99/719[8]).

The two main objectives of the TF are to advance with animal disease eradication and to improve the cost-benefit-ratio of animal disease eradication programmes cofinanced by the EU.

The TF is made up of representatives from all MSs with an EU co-financed eradication programme, invited private experts and the Commission. A Plenary Task Force meeting is held annually in Brussels.

Within the TF a subgroup for rabies was established in 2004 with its first meeting held in Klagenfurt, Austria.

Since 2010, the mandate of the TF has been extended to the neighbouring third countries, candidate countries, potential candidate countries and acceeding countries.

More information on the activities of the Task Force and the reports of the meeting (plenary and Subgroups) is available on the Commission website: http://s-sanco-europa/food/animal/diseases/index_en.htm

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Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1422457582211&uri=CELEX:32014R0652)

[4] Commission Decision 2008/341/EC of 25 April 2008 laying down Community criteria for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1422460876174&uri=CELEX:32008D0341

[5] Commission Decision 2008/425/EC of 25 April laying down standard requirements for the submssion by Member States of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Community financing http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1422460659402&uri=CELEX:32008D0425

[6] Commission Implementing Decision 2012/282/EU of 22 May 2012 amending Decision 2008/425/EC as regards standard requirements for the submission by Member States of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Union financing http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32012D0282

[7] Commission Implementing Decision 2014/288/EU of 12 May as regards the standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Union and repealing Decision 2008/940/EC http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1422460028593&uri=CELEX:32014D0288

8 http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1422457470283&uri=CELEX:51999DC0719

2. Requirements for rabies programmes

Oral rabies vaccination (ORV) has proven to be the most effective method to eliminate terrestrial rabies in wildlife. Proper planning, organisation and implementation of an ORV programme are vital for its success and require active involvement of a variety of stakeholders including veterinary and public health authorities, forest services, hunting societies, wildlife biologists, flight companies distributing the vaccines, vaccine producers, …etc.

2.1 Design, implementation and duration of ORV campaigns

Proper planning, design and implementation of ORV campaigns as well as coordination of campaigns between neighbouring regions or countries are vital to their success.

It requires involvement of all stakeholders at a national level. Well-planned and synchronised campaigns may also reduce costs.

When planning and implementing an ORV campaign, emphasis should be placed on:

- objectives, roles and responsibilities of stakeholders;
- chain of command;
- infrastructure;
- estimated costs (budgetary requirements) and funding;
- duration and timing;
- biology of target wildlife population;
- determination of vaccination areas;
- vaccine baits to be used ;
- modes of vaccine bait distribution;
- bait densities and distribution patterns to be applied (flight line distance);
- storage of vaccine baits;
- rabies surveillance and monitoring of ORV campaigns.

As a general rule, a long-term, large-scale approach is the most effective strategy, and:

- there must be a guarantee that the ORV campaign can be sustained for at least six years to increase the chance of elimination; and
- it must not be ceased any earlier than two years after the last confirmed case of rabies in a given region, provided appropriate surveillance and monitoring remained in place during these two years.

2.2 Vaccines

All rabies vaccines used for oral immunization of wild animals are based on live replication-competent vaccine viruses. Methods to develop such attenuated vaccines are by

conventional in vivo and/or in vitro passaging, monoclonal selection mutants, recombination using another viral vector expressing the rabies virus glycoprotein or site-directed mutagenesis (reverse genetics).

In the EU, all rabies vaccines used for oral vaccination of foxes need to fulfil the requirements of European Pharmacopoeia monograph [Rabies vaccine (live, oral) for foxes and racoon dogs- Vaccinum rabiei perorale vivum ad vulpem et nyctereutem], i.e. efficacy, safety and stability, and need to be licensed or registered.

Vaccine baits should contain a biomarker (usually tetracycline) to monitor the bait up-take in the target species.

Vaccines for ORV currently available and authorised in the EU market are made of the following strains:

- SAD B19 (live attenuated);
- SAD Bern (live attenuated);
- SAG 2 (live attenuated);
- V-RG (live recombinant).

If a MS applies for funding of an ORV programme to be carried out in a neighbouring third country where vaccines are to be used that have not been granted marketing authorisation in the EU, the vaccine should have, at least, a marketing authorisation in the third country and meet the requiremens of the relevant chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE)[9].

If ORV campaigns do not show progress and there is a suspicion that this might be due to a lack of efficacy of the vaccines in the field, then additional tests should be undertaken to assess the rabies vaccine quality.

2.3 Quality Control of vaccines

In general, quality criteria of vaccine baits include stability testing of both vaccine (vaccine characteristics including vaccine titre, genetic and thermo stability) and bait casing (appearance, melting point and temperature stability).

As ORV campaigns are also to be conducted in close vicinity of human settlements, a number of minimum criteria and precautions have to be considered to minimize the risk of humans to come in contact with vaccine baits including mechanical stability of the vaccine bait, warning labels on blisters and other risk mitigating measures.

Cold chain as specified by the manufacturer (usually -20°C or less) has to be maintained while vaccine baits are stored, transported and delivered directly to the customer. Maintenance of the cold chain

[9] http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.13_RABIES.pdf

has to be documented using calibrated temperature loggers or equivalent equipment and written evidence has to be provided upon request. Storage under any other conditions prior to distribution in the field may have a serious negative impact on the vaccine titre.

The vaccine viral titre of all batches should therefore be verified right before the campaigns by the competent authority. Such tests should be performed in qualified laboratories, preferably accredited to EN ISO/IEC 17025 with documented, validated methods and appropriate standards.

The results of these tests are to be reported to the Commission yearly using Table C of Annex VI to Implemeting Decision 2014/288/EU.

2.4 Regular ORV campaigns

2.4.1 Vaccination areas

The vaccination area should be as large as possible and preferably should include the entire rabies affected (endemic) area. However, where the budget is limited, the minimum vaccination area to start with should comprise at least 5.000 km². In this case, depending on the level of success and the available budget, a rapid enlargement of the vaccination areas in consecutive years should be considered.

When defining vaccination areas in consecutive years, consideration should be given to:

- the rabies situation in a given country;
- the rabies situation and ongoing ORV campaigns in neighbouring countries or regions;
- the geographical characteristics of a given area, e.g. natural barriers (such as big rivers, lakes, and higher mountains ranges); and
- the patterns of movement of target wildlife population.

The use of administrative borders should be avoided.

It is advisable to start implementing ORV campaigns in areas where benefit can be obtained from already implemented ORV campaigns or in rabies free areas to prevent further spread of disease. In the latter case, vaccination areas should be designed in such a way that they cover at least a 50 km belt ahead of the rabies front. However, the vaccination area should be as large as epidemiologically justified.

2.4.2 Timing

Oral rabies vaccination of foxes and/or raccoon dogs should be carried out twice a year, in spring and in autumn. Spring and autumn vaccination campaigns should be preferably conducted from the end of March to the beginning of June and from late September until the end of October.

In order to decide the best moment to vaccinate, two factors should be considered:

- prevailing climatic conditions and local seasonal weather conditions: vaccination campaigns

performed at temperatures below 0°C, or at temperatures higher than the melting point of the bait should be avoided;

- biological cycle of target species as the outcome of spring campaigns is influenced by regional differences in time periods when target species give birth to their offspring, maternally transferred immunity and accessibility of baits for fox and raccoon dog cubs due to behavioural patterns. Spring campaign should be carried out as late as feasible as in early spring a large segment of the young fox and raccoon dog population can not be vaccinated effectively as a result of maternally transferred immunity and limited acces to baits due to their behavioural pattern.

2.4.3 Distribution pattern

Aerial distribution of baits using fixed-winged aircrafts or helicopters is the method of choice.

Manual distribution of baits should only be used as a complementary method to aerial distribution. It should be conducted in limited areas where aerial distribution is difficult, such as suburban and urban areas, no-flight zones, and densely populated areas.

The classical flight pattern consists of parallel flight lines set approximately 500 metres apart.

The distribution pattern of baits should take into account habitat and landscape features. Under certain circumstances, e.g. extreme topographical features (fragmented landscapes) or persistent residual foci, deviation from parallel flight line patterns might be acceptable provided that the requested bait density per km² (see paragraph 2.4.4) is guaranteed.

The use of GPS systems, computer-supported recording of flight routes and co-ordinates of bait droppings during aerial distribution are necessary for quality control and detailed analysis of data.

For manual distribution of baits an equivalent recording of bait placements should be used.

In case the territory covered in the MS or third country is smaller than 20.000 square kilometres per campaign computer-supported recording of flight routes may be considered as enough for the purposes of quality control.

Furthermore, GIS technology should be made available in order to transform the data recorded during bait distribution into bait density maps. These maps allow for a proper evaluation of the bait distribution required and enable to establish the appropriateness of bait coverage both in terms of territory and density. Accordingly, additional flights could be required in order to guarantee appropriate bait coverage in some areas.

This information concerning the flight routes and the coordinates of the bait release (exact time point and geographical coordinates of each bait released) should be compiled by the competent authorities (CAs) on a regular basis (daily basis recommended). This information should be assessed by the CAs and reported to the Commission on a yearly basis using Table B of Annex VI to

Implementing Decision 2014/288/EU.

Recommeded formats for the data to be compiled are:

- For the flight tracks: shapefile[10];
- For the dropping data: text or csv file[11].

2.4.4 Baiting density

Based on experience, the minimum bait density to be applied should not be less than 20 baits/km².

In case of high population densities, setbacks, and persisting residual foci, an increased bait density of up to 25-30 baits/km² in combination with reduced flight line distance or adapted flight line patterns should be considered as a corrective action.

2.5 ORV buffer zones in rabies free areas

To prevent (re) infection of rabies free areas from a neighbouring infected area and depending on the control measures taken in the neighbouring affected area, the establishment of ORV buffer zones (cordon sanitaire) along the border (preferably natural) with the infected area should be considered. A precondition for the establishment of such buffer zones is the proper identification and demarcation of rabies free areas.

The ORV buffer zone should be at least 50 km wide and needs to be maintained as long as the rabies situation persists in neighbouring affected areas. In case that appropriate natural or artificial physical barrier exists to limit the movements of reservoir animals, the depth of ORV buffer zone may be reduced to 20 km as a minimum.

Whenever possible the ORV buffer zones should also be established in the neighbouring affected region as this will guarantee the maintenance of a “rabies-free” status for the yet uninfected or free area.

However, in order to make the programme more cost efficient and to maintain the ORV buffer zone in areas free of rabies bordering with rabies endemic areas, the following derogations to the recommended standards (two vaccination campaigns/year and parallel flight line distances of 500 metres) may be acceptable:

- One single annual ORV campaign could be performed, preferably in autumn.
- The parallel flight line distances may be increased up to 1000 metres.

When considering these derogations to the recommended standards, infection pressure in the non-free area and the density of reservoir species should be considered and properly assessed.

ORV should be continued as long as rabies infection persists in neighbouring areas.

[10] In projection WGS84 (code EPSG:4326)

[11] With the following fields: ID;TIME;DATE;LAT;LON(with the longitude and latitude in decimal degree format)

2.6 Emergency ORV campaigns

In case of recurrence or re-infection of rabies in a free area, swift reaction is crucial to avoid further spread of the disease. In such a situation, in addition to enhanced surveillance in a sufficiently large area, emergency ORV campaigns have to be conducted.

An emergency vaccination area with a radius of at least 50 km around the outbreak should be established, taking into account natural and artificial barriers.

In general, emergency vaccination has to be carried out without delay irrespective of the climate conditions.

Short interval baiting (4 to 6 weeks) of the defined vaccination area could be considered at the beginning of the operations. ORV campaigns can be modified to the regular cycle (spring/ autumn) provided that previous emergency campaigns have resulted in a significant improvement of the situation. Depending on the situation, enlargement of the vaccination area for any forthcoming ORV campaign should be included in the strategy.

It is strongly recommended to establish an »emergency rabies vaccine stock« to avoid delays in vaccine delivery should urgent action be needed.

2.7 Rabies surveillance

Rabies surveillance is the key parameter for assessing the rabies situation within the country and for planning, implementing, improving the performance and evaluating the success of any rabies eradication programme.

Rabies surveillance should be:

- Laboratory based. Emphasis should be given to investigation of suspect animals (domestic and wild) also called as »indicator animal[12]s« (risk-based or targeted approach). Healthy hunted animals should be excluded from surveillance and be used for monitoring of the efficiency of ORV campaigns only.
- Conducted continously in time and space, e.g. before, during and after implementation of ORV campaigns.
- Performed not only in vaccination areas but in neighbouring areas to the infected ones and in rabies-free areas and, to allow for early detection of spread of rabies or of re-infection.

The exact number of animals to be sampled for rabies surveillance can not be predetermined. However, maximum efforts should be made to detect and test as many animals as possible.

For proper epidemiological evaluation, stratification of data should be considered. Therefore, basic data such as date of sampling, geo-location, age (in case of foxes or raccon dogs) and results of

[12] Suspect or indicator animals are animals that show clinical signs or abnormal behaviour suggestive of rabies, animals found dead, road-kills and animals involved in human exposure.

laboratory investigations should be collected.

For obtaining as much as possible suspect animals to be analysed for surveillance, it is important to conduct disease awareness campaigns on a regular basis to obtain close collaboration with the general public, veternary services and hunters. Permanent information and feedback on surveillance and ORV campaigns should be guaranteed. Furthermore, regular trainings should also be organised for the professionals involved in the rabies control programme.

For rabies surveillance, laboratory tests should be performed in line with the relevant chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE.

The fluorescent antibody test FAT[13] test is routinely used. It is crucial for routine rabies diagnosis to follow a diagnostic hierarchy:

- FAT-positive result: presence of lyssavirus infection proven.
- FAT-negative result: absence of lyssavirus infection proven.
- FAT-inconclusive result: further confirmation using recommended techniques (RTCIT[14], RT-PCR[15]).
- FAT-negative result in a context of human exposure: further confirmation using recommended techniques (RTCIT, RT-PCR).
- Autolysed or putrified samples: use FAT and further confirmation using recommended techniques (RTCIT and RTPCR).

Virus characterization is recommended to either identify occurring rabies virus strains in a given endemic region or to be able to distinguish field from vaccine strains in vaccination areas.

Laboratories should work in accordance with quality assurance schemes following the requirements of ISO/IEC 17025 (2005+Ap1:2007) and should follow the national requirements to guarantee biosafety of the staff (confinement facilities, workers' equipements and pre exposure vaccination and rabies antibody testing every six months).

NRLs for rabies should also participate in the periodic inter-laboratory proficiency test for rabies diagnosis organised by the EU Reference Laboratory (EURL) for rabies (see paragraph 2.10).

It should be noted that the similar basic principles of rabies surveillance should be applied in non-EU countries which are being vaccinated under an EU approved programme.

2.8 Monitoring of ORV

Monitoring the effectiveness of ORV is based on three main pillars:

- determination of bait-uptake by detecting the presence of biomarker,

[13] Fluorescent antibody test
[14] Rabies tissue-culture infection test
[15] Reverse transcription polymerase chain reaction

- determination of seroconversion by detecting rabies specific antibodies in target animals (foxes and raccoon dogs) sampled in vaccination areas, and
- enhanced rabies surveillance in all animals species (wild and domestic): decrease in rabies incidence is the key index for the success of an ORV programme.

For investigations in the first two pillars, sampling should focus on animals from the hunting bag; here, it is considered as sufficient to test 4 animals per 100 km2 annually from vaccinated areas. Sampling should be conducted homogeniously to avoid bias in results to be obtained. Whenever possible blood/body fluid and teeth/bone tissue samples for serological testing and detection of biomarker, respectively, should be taken from the same animal.

To assess the immune response due to vaccination, seroneutralisation tests such as RFFIT[16] and FAVN[17] test should be used. However, those tests are sensitive to cytotoxicity, virucidal effects and bacterial contamination particularly with poor quality samples. Alternative serological assays are commercial direct or indirect rabies ELISA test kits validated for field samples of wild animal origin. When using those tests attention should be paid in terms of sensitivity and specificity. The EURL for rabies serology should be contacted for further information and for possible interest in inter-laboratory serological testing.

For proper epidemiological evaluation of ORV, stratification of data should be considered. Therefore, basic data such as date of sampling, geo-location of hunted animals, age and results of laboratory investigations should be collected.

It should be noted that similar level of monitoring should be applied in non-EU countries which are being vaccinated under an EU approved programme.

2.9 Vaccination of other animals

Vaccination of grazing animals is highly recommended in areas where rabies is endemic, regardless whether it is subject to EU-funding or not.

Vaccination of grazing animals is higly recommended also in at-risk areas. Vaccination of transhuman animals should also be considered when moving from and to infected and at-risk areas.

2.10 EU reference laboratory for rabies

The EURL for rabies (ANSES- Nancy rabies and wildlife laboratory, France)) was designated in 2008 by means of Commission Regulation (EC) No 737/2008 amended by Commission Regulation (EU) No 415/2013[18].

[16] Rapid fluorescent focus inhibition test

[17] Fluorescent antibody virus neutralisation test

[18] Commission Regulation (EU) No 415/2013 of 6 May 2013 laying down additional responsibilities and tasks for the EU reference laboratories for rabies, bovine tuberculosis and bee health, amending Regulation (EC) No

Its work has been valuable to improve the control of rabies throughout the EU. Its role is focused on:

- Coordination of the methods employed in the MSs for diagnosing rabies;
- Harmonisation of diagnostic techniques throughout theEU;
- Organisation of workshops with NRLs and training of experts;
- Technical assistance to the Commission;
- Research and scientific advice.

3. Enhancing the effectiveness of rabies eradication programmes

For effective rabies eradication programmes, adequately organised veterinary services, competent authorities and involvement of all stakeholders concerned are prerequisites.

The main issues to be considered regarding rabies eradication programmes, based on the experience and the conclusions and recommendations of the TF Rabies subgroups, are the following:

- The need for an instrument at EU level that supports long-term planning and allows to secure the necessary budget at national level.
- Increased cooperation and collaboration on ORV implementation with neighbouring countries including non-EU countries.

3.1 Organisation

An adequate organisation of the competent authorities (Veterinary Services) and others involved in the rabies eradication programme is necessary. An appropriate legal basis for the implementation of rabies control strategies included ORV is needed.

Central, regional and local Veterinary Services as well as the NRL for rabies should be involved in planning and carrying out ORV campaigns and the associated activities such as grazing animal vaccination, dog vaccination, stray dog control and management, disease awareness programmes and laboratory testing.

The roles and responsibillities of all those involved in the organisation and implementation of the programme should be clearly defined well in advance. Regular meetings should be scheduled according to the approved programme and its progress.

Rabies eradication requires a long term planning including allocation of financial resources for the whole duration of the programme. This represents the main obstacle in proper and regular implementation of ORV in most of theMSs.

To secure the necessary budget for continous and un-interrupted implementation of the programme,

737/2008 and repealing Regulation (EU) No 87/2011 (http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1422531996722&uri=CELEX:32013R0415)

several actions have already been taken by the EU:

- Multi-annual programming;
- The possibility to increase the level of co-financing of the measures up to 75 % of eligible costs, instead of the normal 50%, under one of the following conditions:
    - Cross-border activities implemented together by two or more Member States in order to control, prevent or eradicate animal diseases;
    - Member States whose gross national income per inhabitant based on the latest Eurostat data is less than 90% of the Union average.
- Introduction of 100% co-financing for organization of ORV campaigns in third countries bordering EU;
- Additional measures may be included among eligible measures (e.g.: vaccination of grazing animals; awareness campaigns).

3.2 Epidemiological analyses

Epidemiological analysis is a fundamental basis for proper planning, implementation and evaluation of ORV programmes. It helps decision makers check the success of interventions and take corrective actions by adapting the rabies control strategy, if necessary.

Therefore, permanent and continuous collection of rabies (surveillance) and ORV related (monitoring) data is an essential prerequisite. The collection and evaluation of such minimum baseline data / information, e.g. species, date of finding, exact location (ideally geographical coordinates) where the animal was found, date of submission, results of laboratory testing (rabies diagnosis, serology, bait-uptake, etc.), require the set-up of a country specific computerised rabies database with the latter comprising of individual animal based datasets rather than cumulative ones. Such data form the basis for descriptive epidemiological analysis, including mapping, or for more sophisticated epidemiological approaches, including applicable predictive modeling of rabies and ORV interventions and cost-benefit analysis.

Because storage, management and evaluation of data from rabies surveillance and monitoring are complex tasks, a responsible epidemiological unit with adequate expertise needs to be in place.

This unit should gather all relevant data at national level, run the national rabies database and provide regular analysis, maps and reports to responsible authorities on the:

- epidemiological rabies situation, e.g. spatial-temporal rabies dynamics, trends by species and rabies virus variant;
- monitoring of the ORV campaign, e.g. spatial-temporal bait-uptake and seroconversion;
- other ORV related information, e.g. densities of target species and bait competitors upon

request.

The evaluation of ORV campaigns should also contain a detailed assessment of the bait distribution in order to identify sub-optimally or non-vaccinated areas that may lead to corrective actions, such as manual distribution of baits. These reports should form the basis of data reporting to EU or other international organizations (World Health Organisation, WHO, and OIE) and should be standardized so that the reports prepared for one party could also be used for all other parties.

3.3 Training and disease awareness

Continuous education and training of veterinarians, medical staff responsible for post-exposure prophylaxis, hunters, wildlife biologists and flight service operators performing aerial distribution of vaccine baits on the cornerstones of the implemented ORV programme, related issues as well as responsibilities, duties, competencies, competent jurisdictions, and chain of commands as appropriate are strongly recommended.

Training should include basic knowledge on rabies epidemiology, e.g. clinical signs of rabies, actions to be taken in a case of suspicious cases of rabies and safety measures to be applied in case of human exposure with vaccine baits as well as orgnisational aspects of sampling for monitoring of ORV campaigns.

For information of the public a communication plan needs to be in place for increasing community awareness from a local to national level and to raise awareness about the timing and location of ORV campaigns, and what the public should do if they or their pets encounter ORV baits. Special emphasis should be given to appropriate information of children.

3.4 Collaboration and cooperation between MSs and TC

Eradication and control of rabies needs a multi-disciplinary approach. Eradication programmes should be implemented, if possible, in the infected countries covering large areas and for a sufficient duration (large scale, long-lasting). When different inconsistent strategies are implemented in the same area (in own country, in bordering countries), there is a risk of failure of the rabies eradication programmes.

Different countries can be considered as one region. The infection dynamics can be similar in these countries. Co-ordination of eradication and control strategies within a country and among neighbouring countries is needed.

Collaboration between the competent authorities is essential. There should be continuous exchange of information on the rabies situation. Moreover, the cross-border cooperation for the implementation of ORV should be encouraged.

TF meetings should be used for the promotion of cross-border cooperation, especially when a

programme is run in a border area with third countries.

4. Conclusions

- An important step towards rabies elimination in the EU was made with the general implementation of ORV programmes in the infected MSs and neighbouring third countries, with the support of the EU co-financing. The rate of co-financing was increased at the level of 75% for certain Member States[19] and up to of 100%, in the neighbouring non-EU countries. This has led to a more favourable rabies situation in the EU.
- Competent authorities have established solid legal frameworks for the control of rabies following international guidelines and good collaboration between central/regional authorities and stakeholders.
- Fruitful collaboration has been established between the MSs and most of the neighbouring non-EU countries on the coordination and exchange of information on ORV activities and epidemiological situation. The system of rabies surveillance and ORV monitoring has been implemented and improved.
- Quality criteria and quality assurance for oral rabies virus vaccines have been defined and implemented, respectively to prevent potential vaccine based deficiencies due to inappropriate storage, transportation and distribution.
- EU-RL and the subgroup rabies of the task force are playing a crucial role in improving the quality of the ORV campaigns and related activities.
- NRLs for rabies have generally appropriate facilities, trained staff and are adequately equipped. They work in close cooperation with CAs and regional labs, where appropriate. The NRLs have established WHO/OIE recommended standard laboratory techniques for rabies surveillance and ORV monitoring. When necessary, additional trainigs for staff were provided by EURL.
- The NRLs participates in international proficiency testing and inter-laboratory comparison tests as organized by the EU-RL for rabies. Furthermore, the NRLs have established good collaboration with WHO Collaborating Centres and OIE-Reference Laboratories for rabies as well with NRLs of neighbouring countries.
- A lot of resources have been allocated in establishing communication and education systems to ensure high disease awareness and thus, full involvement and collaboration between all authorities and stakeholders, necessary for the progress of rabies eradication.

[19] Member States whose gross national income per inhabitant based on the latest Eurostat data is less than 90% of the Union average.

5. Recommendations

- The ORV programmes in MSs should be conducted for a period long enough and to sufficient extent in relation to the density of the target species in the area to increase the chance of elimination of rabies. A large-scale approach is the most effective strategy, and there must be a guarantee that the ORV programme can be sustained for at least six years and be ceased not earlier than two years after the last confirmed case of rabies.
- An area should not be considered as free of rabies unless robust surveillance data indicates the absence of the disease.
- Special attention should be given to maintain the sufficient sample size of animals of all susceptible species (wild and domestic) submitted for rabies surveillance (suspect cases, indicator animals) to be able to adequately assess the rabies situation.
- Measures should be taken to maximize sample collection in all target species for monitoring of ORV campaigns, e.g. bait-uptake and seroconversion in healthy hunted animals to get the adequate assessment of the efficiency and efficacy of ORV.
- Epidemiological analysis of rabies surveillance and ORV monitoring data should be given high priority.
- Virus titer of all batches of rabies vaccine baits should be monitored before and during ORV campaigns to ensure that vaccine baits have been properly stored and handled, as the interruption of cold chain and storage under unappropriate conditions may have a serious negative impact on the vaccine titre.
- Manual distribution of vaccine baits should be considered only in areas where aerial distribution is difficult or not feasible.
- Education and frequent exchange of information with hunter associations is crucial to obtain their cooperation.
- Efforts should be made to continue with the good collaboration with MSs and neighbouring non-EU countries on ORV activities, where such collaboration already exists.
- It is desirable to establish or reinforce cooperation and/or partnership on rabies with the neighbouring non-EU countries not yet involved in ORV campaigns. The final aim is creating a vaccination belt along the borders for mutual benefit so that the risk of disease spread or reintroduction is minimized.