

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate G – Veterinary and International Affairs
Unit G5: Food Chain and Animal Health Expenditure

SANTE/10146/2016

REPORT ON THE

TASK FORCE MEETING OF THE RABIES SUBGROUP

held in

Budapest, Hungary

15th – 16th October 2015

REPORT ON THE TASK FORCE MEETING OF THE RABIES SUBGROUP

OBJECTIVES Assessment of the rabies situation in Hungary

Recommendations for improvement and future actions

DATE OF MEETING 15 – 16 October 2015

LOCATION Budapest, Hungary

AGENDA In Annex I

PARTICIPANTS

Subgroup members Enel Niin (EE)

Martin Smreczak (PL)
Melinda Kocsis (HU)
Jedrt M. Wernig (SI)

Thomas Müller (FLI, Federal Reasearch Institute for

Animal Health, Wusterhausen, DE)

Florence Cliquet (ANSES, Nancy, FR)

Invited participants Budimir Plavsic (RS)

Mykola Ivanov (UA)

Cristian Siposean (RO)

Erika Papiernikova; Peter Korytar (SK)

Ivica Sucec (HR)

European Christophe Bertrand (DG SANTE, Unit G5)

Commission Pedro Rosado-Martin (DG SANTE, Unit G5)

Welcome speech was given by dr. Lajos Bognar, Chief Veterinary Officer of Hungary.

Introduction of Task Force, its objectives and composition of Rabies subgroup was given by the Commission.

Short information and update of rabies situation and eradication activities of participating MS and TC

<u>Croatia</u>: Croatia has started with ORV in 2011. At that time, more than 600 positive rabies cases were detected. With the implementation of regular ORV campaigns, the number of rabies cases significantly decreased to just one case detected in April last year. In 2015, no cases have been detected yet. ORV is implemented according to

the international standards and recommendations (aerial distribution, 2 campaigns per year, whole territory of Croatia, 25 baits/km²). Reliable quality control of vaccine baits was implemented. Insufficient vaccine titre was established in one of the consignments of vaccine baits and the whole consignment was rejected. Also inadequate vaccine storage conditions was detected on one occasion.

<u>Slovenia</u>: Last indigenous case of rabies was detected in January 2013. Vaccine induced case (SAD B 19) was diagnosed in November 2014. Slovenia fulfils the criteria of OIE for a rabies free country and the self - declaration of rabies free country according to OIE is in process. ORV will be continuously implemented depending on the rabies situation in the WB region.

Slovakia: More than 95,5 % of rabies cases were detected in red fox population, which represent the reservoir for rabies in Slovakia. Slovakia was declared as free of rabies in 2009. In 2013, 7 positive cases were detected in the bordering region with Poland. Determination of rabies virus showed high similarity with Polish and Ukrainian virus strain. After no cases in 2014, 4 new cases were detected again in 2015, in the same region close to Polish border. Aerial distribution of baits with the density of 25 baits/km2 is performed in two ORV campaigns per year. In addition manual distribution of baits around big cities is performed with the density of 18 baits per km2. The exchange of information on rabies between Poland and Slovakia exists but no co-operation of ORV activities is conducted to improve the situation on both sides of the borders.

Romania: The new multiannual rabies eradication programme was approved for the period 2014-2017. In 2014, only autumn ORV campaign was implemented. The vaccination area of 213.375 km² covered the whole territory of Romania, including bordering regions with Serbia, Moldova, Ukraine and Bulgaria. Both aerial and manual distributions of vaccine baits in the autumn campaign 2014 were implemented. Over 5,3 milion vaccine baits were distributed by fixed-winged aircrafts in a density of 25 baits per km². In addition, 75.000 vaccine baits were distributed in "non-flying" areas. Official controls are performed by local and central authorities. After 2014, when almost 1.000 rabies cases were detected, a significant decrease of rabies cases was detected. In 2015, until October, only 25 rabies cases were diagnosed. Improvement of rabies situation together with data from official controls performed provides reliable information on successful implementation of the approved rabies eradication programme.

<u>Serbia:</u> Serbia has started with implementation of ORV campaigns in 2010. Two ORV campaigns are performed per year, spring and autumn. Vaccination area covers the whole territory of Serbia. Baits are distributed in a density of 20 – 23 baits per km2, with fixed-wing aircraft, in flight line distance of 500 m. Distribution of vaccine baits is supported by computerised system. Rabies incidence has decreased since the beginning of ORV – from over 200 rabies cases per year to only 3 rabies cases in 2014.

<u>Ukraine</u>: Annually, over 1.000 rabies cases have been reported. More than half of rabies cases (56,8%) is detected in domestic animals. Vaccination of dogs is compulsory, while vaccination of cats and other domestic animals is obligatory only in the outbreaks. In the period of 2006 – 2008 ORV was implemented over the area of 16 regions. Annually, 9 million vaccine doses were distributed. In 2009 and following years, ORV area was reduced due to the economic constraints. Annually, still two ORV were conducted, in an area of app. 100.000 km2. The density of distributed vaccine was 15 – 20 bait per km2. In recent years, ORV is conducted by neighbouring EU MS in a vaccination belt along the common borders.

After this short introduction, the hosting country gave seven presentations in relation to rabies in Hungary.

1. Legal background of the control of rabies in Hungary

Hungarian veterinary authorities (NFCSO) have established solid legal framework for the implementation of an effective rabies eradication programme.

Under Act No XLVI of 2008 on the food chain and its official control (FCA), animal keepers are obliged to notify the competent authority and the private veterinarian of any suspicion, diseases or mortality in their animals.

Rabies is a compulsory notifiable disease under Decree No 113/2008 (VIII. 30.) of the Minister of Agriculture and Rural Development (MARD) on the rules of notification of animal diseases, which includes provisions for notification of rabies to the CA and to the EU.

In line with Decree No 81/2004(IX. 4.) of the MARD on the animal health measures for protection against specified zoonoses, the NFCSO reports the confirmed cases of rabies to the human health authorities.

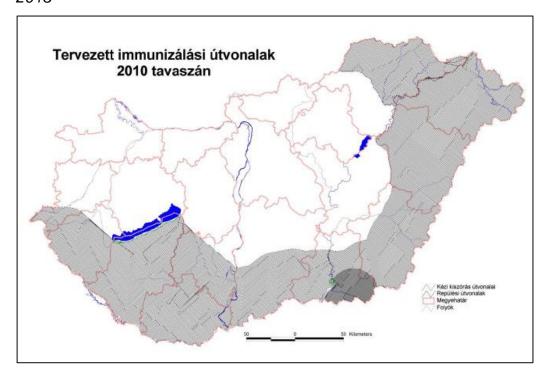
Decree No 164/2008 of the MARD on detailed rules of the protection against rabies includes provisions for:

- obligatory vaccination against rabies of all dogs
- · voluntary vaccination against rabies of other animals
- case definition
- notification and suspicion for rabies
- tasks of official veterinarian/district veterinary officer in case of rabies or suspicion of rabies
- procedures with suspected/ potentially rabies infected/ rabies-risky animals
- official observation of animals
- public health rules and
- wild animals.

2. History and epidemiological evolution of rabies in Hungary, present situation

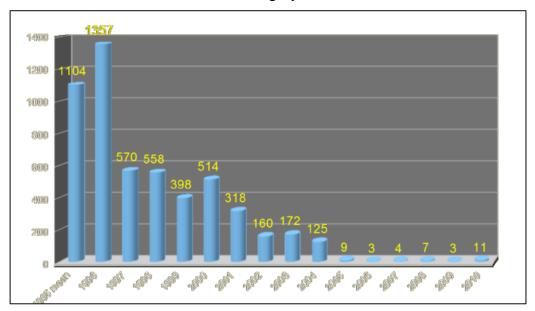
Rabies is a notifiable disease ever since 1928. At the beginning of 20th century, only dog-mediated rabies was present in Hungary. In the late 1930's Hungary became free of rabies. Wildlife mediated rabies occurred in Hungary in 1954 and spread throughout the country by the end of 1971. Decrease of red fox population with shooting was the first measure to combat rabies, though ineffective. In 1992, the first ORV was performed. Initially the ORV covered an area of 6.000 km2 in the NW part of Hungary. In the period between 1993 to 1996 ORV was conducted in this area two times per year. From 1996 to 2000, ORV was performed in Transdanubian area. Rabies was eliminated there by the end of 2000. In 2001, the area between rivers Tisa and Danube was included in ORV, and from 2004 the whole territory of Hungary was included in ORV. Due to the very favourable rabies situation and ORV activities in neighbouring countries, ORV area in Hungary has been limited to vaccination belt along the borders from Slovenia to Ukraine from 2008 until 2013.

Picture 1: ORV belt in Hungary along the borders with nighbouring countries 2008 - 2013



Due to the effective ORV programme, the number of rabies cases significantly decreased over the years. In years 2011 and 2012, no rabies cases were detected in Hungary.

Picture 2: No. of rabies cases in Hungary 1995 – 2010



In September 2013, rabies re-occurred in Hungary. The case was detected outside (app. 40 km from the borders of ORV area) the vaccination area. The rabies virus was showed genetic relationship to Ukraine and Romanian virus strain. In 2013, the total of 24 rabies cases and in 2014, 23 rabies cases were confirmed.

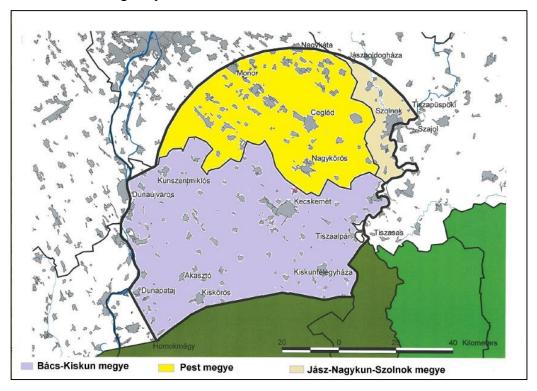
The last case was confirmed on 7th October 2014. Since then, no new rabies cases were detected.

3. Management of 2013 autumn outbreak in Hungary – emergency measures

On 12th September 2013 a red fox from the Kecskemét (Bács-Kiskun county) was diagnosed positive for rabies. The fox was killed at a farm. Information was provided to all counties, to the human health authority, the disaster management authority, the hunting authority and to the media.

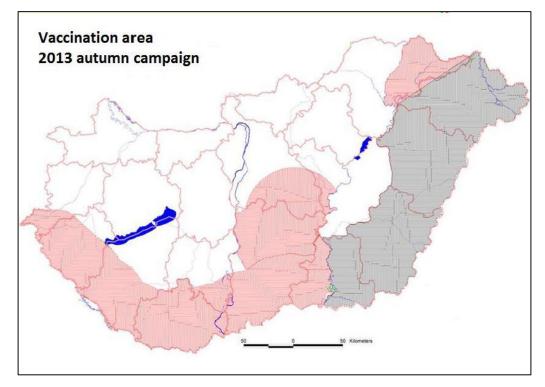
The measures, such as ban on animal movement in infected holdings, epidemiological investigation, to establish possible contacts, official observation for 90 days on affected holdings, preventive vaccination of cats and farm animals were implemented at the holding in question. Additionally, over 10.000 food producing animals were vaccinated. Extensive door-to-door control over the vaccination of dogs was performed in the area. Pasture of animals was banned and dog movements were restricted in the infected area. Activities for raising public and veterinary awareness were conducted.

Emergency ORV campaign was performed during regular autumn 2013 campaign. Area of emergency campaign was defined as an area of 50 km radius around the first outbreak. The new area was attached to the existing ORV area. In the new area ban on grazing and closure of dogs were ordered. All relevant stakeholders in the new area were informed about the measures and activities.



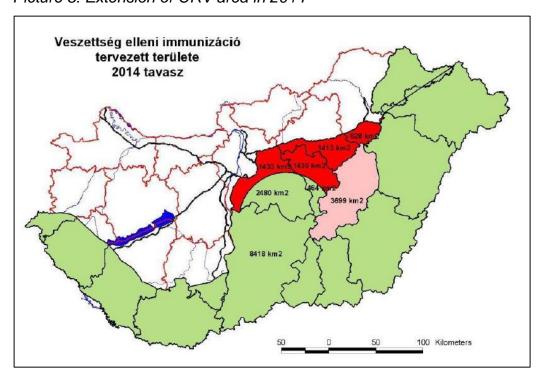
Picture 3: Emergency rabies vaccination area 2013

Picture 4: ORV area in autumn 2013



In December 2013 and early 2014, three cases of rabies were diagnosed outside the 2013 ORV area (including emergency vaccination area). Due to this, the ORV area was extended in spring 2014 and surveillance was strengthened. In the newly vaccinated /including the infected/ area, during the 2014 spring and autumn campaigns, a baiting density of 40 baits/km2 was applied with 500 m distance between the flight lines.

Picture 5: Extension of ORV area in 2014



4. Outcome of the analysis of the 2013-2014 rabies epidemic and the effectiveness of measures in Hungary

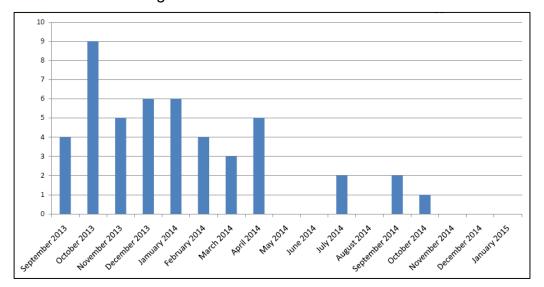
In total, 47 rabies cases were detected in 2013 – 2014, out of which 43 cases (91 %) were detected in wildlife and 4 cases (9%) in domestic animals.

Table 1: Summary of cases 2013 - 2014

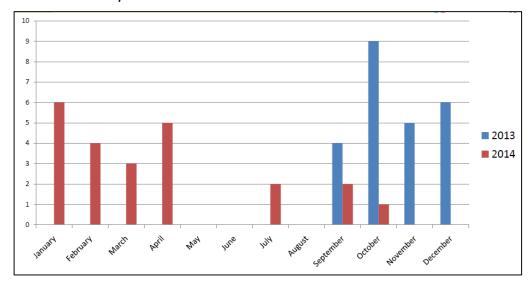
Species	No. of cases	%	Dom/wild	No. of cases	%
Fox	42	89	wild	wild 43	91
Roe deer	1	2	Wild		
Cattle	2	4			
Goat	1	2	domestic	domestic 4	9
Dog	1	2			
Total	47	100		47	100

The number of cases was increasing from September 2013 to January 2014, then it started decreasing to October 2014, when the last case was confirmed.

Picture 6: Decreasing no. of cases

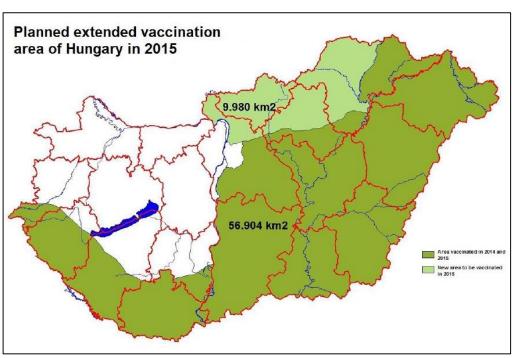


Picture 7: Comparison 2013 vs. 2014



Following the reoccurrence of rabies in Hungary, experts of the VDD and of the AHAWD Epidemiology Unit worked together on the assessment of the results. Following the in-depth evaluation of the rabies situation it was concluded that during the whole 2014 less cases were confirmed that in 3,5 month period in 2013. Following the two outbreaks in December 2013 and February 2014, which were the farthest from the primary outbreak, no further geographical spread was observed. No rabies cases occurred in the area vaccinated every year since 2004 and the disease did not spread to the west side of the Danube, to the east of river Tisza or to the north of Highway E71 (M3). Between the first outbreak in 2013 and the last in 2014, 13 months have elapsed. No cases have been detected after 3 consecutive ORV campaigns in the new area. The awareness campaign resulted in an increased number of samples from passive surveillance. Provisions for emergency vaccine stock was arranged in the frame of the ORV contract for similar emergency situations in the future which will allow for early and swift response. Based on the evaluation of the situation, the ORV area has been modified. The ORV area was enlarged to the border with Slovakia at the North.

Picture 8: ORV area for 2015



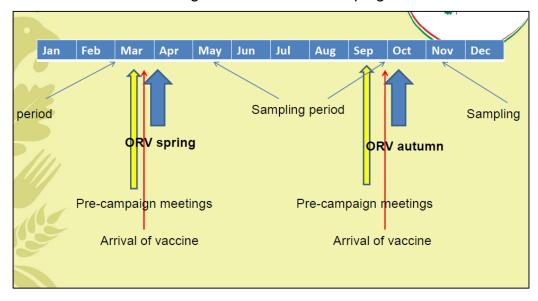
5. Organisation and implementation of oral vaccination campaigns in Hungary

First ORV campaign was conducted in 1992. In the period of 2004 – 2006, ORV was extended to the whole territory of Hungary, with the support of PHARE funds. Since 2007, rabies eradication programme is approved and co-financed by the EU in the frame of veterinary fund.

Roles and responsibilities are clearly assigned to each stakeholder within the programme. In previous years, ORV programme was prepared on annual basis, for 2015 and 2016 it was approved as multiannual programme. Two ORV campaigns per year are planned over the area of 66.884 km2. Lysvulpen vaccine baits (Bioveta, Czech Republic) will be distributed using aerial and manual distribution.

Aerial distribution is supported by computer and GPS system which allows for recording of flying lines and recording of bait distribution. Distance between flight lines is 1000 m. The density of distributed baits is on average 20 bait per km2. The direction of flight-lines is rotated for 90° in the next campaign.

Manual distribution of baits, which represent only a small proportion (2% of all baits) is used for distribution of vaccine baits in non-flying areas (holiday area, oil and power plants and railway transfer zones). It is performed by qualified wildlife biologists, using GPS planning and recording.



Picture 9: Timetable of organisation of ORV campaigns

A number of controls over the implementation of the ORV are performed:

- daily telephone contact
- at least one CA control and one county/district control at the cold storage
- at least one CA control and one county/district control on each airfield
- daily reporting of GPS (data sent to the CA)

At the end of each campaign, closing meeting is organised in order to evaluate the campaign. Final report should be provided by the contractor for ORV to the CA.

Table 2: ORV activities in 2013, 2014

Year	ORV	Area covered by ORV (km2)	Flight distance/ Bait density	No. of baits distributed	No. of campaigns	Total no. of vaccines baits distributed
2013	Regular	41.045	1.000 m 20 baits/km2	820.900	2	1.641.800
	New ORV area (Emergency)	6.999	1.000 m 20 baits/km2	139.860	1	139.860
	Total 2013					1.781.660
2014	Regular	41.045	1.000 m 20 baits/km2	820.900	2	1.641.800
	New ORV area (Emergency)	15.859	500 m 40 baits/km2	634.360	2	1.268.720
	Total 2014					2.910.520
2015	Regular	66.884	1.000 m 20 baits/km2	1.337.680	2	2.675.360
	Total 2015					2.675.360

6. <u>Effectiveness of monitoring of OV in Hungary, organisation, implementation and results</u>

Rabies surveillance is divided to active surveillance and passive surveillance. In the frame of active surveillance, healthy foxes shot for monitoring of effectiveness of ORV from the vaccination area are tested (FAT, tetracycline detection, serology). The minimum number of foxes tested in the frame of active surveillance should not be less than 4 foxes per 100 km2 (2 foxes per 100 km2 per campaign) for the whole territory of Hungary. The number required is broken down by county and by hunting organisation. So according to the plan, each hunting organisation is required to sample 1 fox per 50km2 per campaign.

Preparatory meetings are organized on county level before the start of each campaign with the participation of the hunters and the county veterinary service. These meetings play an important role in the education of hunters and are considered to be a key element in the successful implementation of the programme.

Sample size is determined and a decision is issued for each hunting organisation by the CGO, which is legally binding for hunters. Sampling period starts 30 days after the end of ORV campaign and lasts approximately 4 months. CA controls the submission of samples. In case of non-implementation of sampling, hunters are penalized (warning or fine).

Passive surveillance is targeted to indicator animals (found dead, diseased animals, clinical signs of rabies, in-contact animals) from the whole territory of Hungary. For this purpose FAT and MIT tests are used.

Monitoring of efficiency of ORV (active surveillance) is performed by VDD, Veterinary laboratories in Budapest (NRL), Debrecen and Kaposvar. The bait up-take is monitored by detection of biomarker (bone polishing of the mandible), seroconversion rate is followed with AB ELISA test and FAT test is used for monitoring the rabies incidence.

Table 3: Monitoring of ORV efficiency results 2013 – 2015 (red fox)

Hunting year	Test	Type of Sample	Tested	Positive
2013/2014	FAT	Brain	2.005	4 (0,2%)
	Detection of biomarker	Mandibule	1.927	1.312 (68%)
	AB - ELISA	Blood	901	197 (22%)
	FAT	Brain	2.521	0
2014/2015	Detection of biomarker	Mandibule	2.510	1.744 (69%)
	AB - ELISA	Blood	2.085	733 (35%)
2015/2016 (ongoing)	FAT	Brain	1.132	0
	Detection of biomarker	Mandibule	814	598 (73%)
	AB - ELISA	Blood	763	383 (50%)

According to the age structure of the hunted and tested foxes, the majority of samples belongs to young foxes (one year old or younger).

An improvement was observed in seroconversion rates and also in bait-uptakes in recent years.

Table 4: Improvement of bait uptake and seroconversion rates

Year	Bait uptake	Seroconversion
2007	70%	29,70%
2008	66%	30,79%
2009	60%	28,82%
2010	59%	24,36%
2011	65%	31,28%
2012	72%	38,81%
2013	71%	24,77%
2014	69%	35,16%
2015 spring campaign	73%	50,20%

In the recent years, after the re-occurrence of rabies in Hungary, the number of animals tested in the frame of passive surveillance significantly increased due to the intense disease awareness campaign.

Table 5: Passive surveillance 2014 – 2015

Year	Total number of FAT tests	Passive surveillance	Number of positive samples
2013	4.074	1.297	24
2014	4.868	2.313	23
2015 September	2.314	691	0

7. Presentation of tasks of laboratory, rabies-related investigations in NRL

The Hungarian NRL for Rabies has established WHO/OIE recommended standard laboratory techniques for rabies surveillance and ORV monitoring. The NRL participates in annual international inter-laboratory comparison tests.

For routine rabies diagnosis, FAT test is used. Additionally, histopathology and MIT (Mouse inoculation test) are used, the latter only in case of human exposure. For further diagnostics of rabies also RT – PCR (since 2004), real-time RT-PCR (since 2009), sequencing (since 2011), immuno-histochemistry and virus isolation are used.

To evaluate the efficiency of ORV, the bait up-take and immune response are monitored by detection of biomarker in the bones of the lower jaw and with ELISA (Bio pro) test respectively. Additionally, age determination of hunted foxes is performed.

Vaccine bait titration is conducted in an OMCL laboratory (OCABR procedure, quality testing during campaigns). The laboratory is accredited according to MJA by EDQM.

8. Conclusions and recommendations by the TF Subgroup for rabies

After the presentations and rich discussion, the TF made several conclusions and proposed recommendations for improvement of rabies eradication programme in Hungary.

Conclusions

- 1. Hungarian veterinary authorities have established solid legal framework for the control of rabies in line with international guidelines.
- Considerable efforts have been made to decrease the incidence of rabies following the reinfection in 2013. The source of reinfection in 2013 remains unclear. Emergency response of Veterinary Services was rapid and very effective. Vaccination areas have been modified several times to tackle different epidemiological situations.
- Emergency vaccine stock has been established.
- 4. There is good collaboration between central/regional authorities, hunting societies and other stakeholders. Official supervision during planning, implementation and evaluation of ORV campaigns is well organised.
- 5. Vaccination of dogs is compulsory in Hungary; while vaccination of cats and livestock depends on the epidemiological situation.
- 6. No human case of rabies has been reported since 1994
- 7. Rabies surveillance and monitoring of ORV campaigns meet international standards.
- 8. Rabies awareness and vigilance in the country is high thanks to effective communication and education campaigns.
- 9. The Hungarian NRL for Rabies has established WHO/OIE recommended standard laboratory techniques for rabies surveillance and ORV monitoring. The NRL participates in annual international proficiency tests.
- 10. Vaccine bait titration is conducted in an OMCL laboratory (OCABR procedure, quality testing during campaigns). The laboratory is accredited according to MJA by EDQM.
- 11. Like in neighbouring countries, the golden jackal is a species of rising concern, mainly due to the increasing populations in a number of countries in the region. The role of this species in rabies epidemiology is unknown. Some of the Member States concerned would welcome the inclusion of this species among the target species of ORV monitoring eligible for Community co-financing.

Recommendations

- 1. Frequent exchange of information, coordination of program and appropriate communication should be intensified with the neighbouring countries, in particular with Ukraine.
- 2. The use of the classical flight-line pattern of 500 meters as recommended in the 2015 EFSA report should be preferably used, in particularly in areas bordering endemic neighbouring countries.
- 3. Confirmation of rabies diagnosis in animals with FAT-inconclusive or negative results, the latter in combination with human exposure, using the Rabies Tissue Culture Infection Test (RTCIT) should be established to meet international requirements. Further use of the Mouse Inoculation

(MIT) and Immuno Histological Tests are strongly discouraged (latter method is also not recommended by the OIE).

General recommendations

- 1. Research on bait-uptake and seroconversion in golden jackals in particular in areas with a high abundance of this species in the region is encouraged.
- 2. Regular exchange of information regarding rabies situation and ORV activities between MS and neighbouring third countries (governed by the EC) should be conducted to facilitate rabies eradication (elimination) from the EU and the neighbourhood.