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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Veterinary and International Affairs
Unit G5 – Veterinary Programmes

REPORT ON THE
**TASK FORCE MEETING OF THE
RABIES SUBGROUP**

Plovdiv, Bulgaria

15 – 16 March 2011

REPORT ON THE TASK FORCE MEETING OF THE RABIES SUBGROUP

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| OBJECTIVES | Assessment of the rabies situation in Bulgaria Recommendations for improvement and future actions |
| DATE OF MEETING | 15 – 16 March 2011 |
| LOCATION | Plovdiv, Bulgaria |
| AGENDA | In Annex |

PARTICIPANTS

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| Observers | Paola de Benedictis (IZSve, Padova, IT) Damyán Iliev (BFSA, BG) Darinka Ilieva (IVRZ of Rabies, Sofia, BG) Reneta Petrova (NRL for Rabies, Sofia, BG) Donka Popova (BFSA, BG) Tihomir Todorov (BFSA, BG) |
| European Commission | James Moynagh (DG SANCO, Head of Unit 04) Panayiotis Demetriou (DG SANCO) |

Welcome speech and presentation of new organisation of veterinary services in Bulgaria was given by Dr. Damyan Iliev, Chief Veterinary Officer of Bulgaria.

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

Hungary: ORV has started already in 1992. The number of rabies cases decreased from 1.600 in 1992 to only a few cases per year recently. Rabies cases were located near Austrian, Croatian and Serbian border. Until 2008 vaccination area was limited to trans-Danubian area. Since then the vaccination area was enlarged to the whole southern border of Hungary. In 2011, vaccination area is composed of 50 km wide vaccination belt along borders with Slovenia, Croatia, Serbia, Romania and Ukraine. If necessary, emergency vaccination will be conducted in an area of 50 km around the outbreak.

Austria: ORV has started in 1991 when there were more than 2.000 rabies cases detected per year. Since 2008, Austria has been free of rabies. ORV is still ongoing. Once per year a meeting is organised with all stakeholders regarding rabies situation in Austria and neighbouring countries. On this basis future vaccination strategy is adopted. Vaccination is still performed in southern part of the country, along the borders with Italy and Slovenia. This vaccination area presents the enlargement of the existing vaccination areas in those neighbouring countries. Vaccination is performed twice per year, in a density of 25 baits per square kilometre. Emergency vaccine stock is available.

Germany: ORV has started in 1983; the last ORV campaign was conducted in 2008; rabies eradication was a long process, mainly due to the federal organisation – responsibility of implementation of ORV program laid on each federal state; last rabies case was detected in February 2006;

France: in 1986, a pilot ORV has started; last rabies case was detected in December 1998; imported rabies cases are detected in dogs and cats; the last ORV campaign was conducted in 2005, in the bordering region with Germany; disease awareness is very important especially for people travelling to Northern Africa;

Italy: since 1997 Italy has been free of rabies; ORV has been performed until 2004; reoccurrence of rabies in 2008; last case in February 2011; implementation of ORV – emergency campaigns and in 2011 – regular ORV campaigns, spring and autumn.

Slovenia: ORV has started in 1988 with a pilot project of manual distribution of baits in a limited area. In 1995, aircraft distribution of baits has started. The number of rabies cases has decreased from 1.089 in 1995 to only few cases per year, all located in the bordering region with Croatia. In 2010, 16 cases were detected – 15 in foxes and 1 in cattle. Two ORV campaigns have been performed per year. Spring campaign is usually performed in late May and beginning of June while autumn campaign is performed in October and November. In both campaigns a total of 900.000 baits are distributed in a density of 22 – 26 per km². Fuchsoral (SADB19) baits are used.

After this short introduction the hosting country presented six presentations in relation to rabies in Bulgaria.

1. History and epidemiological evolution of rabies in Bulgaria, present situation

The first case of rabies was reported in Bulgaria in 1896. Until 1925, rabies was reported in 140 holdings throughout the country. In the period from 1925 to 1946, the number of rabies infected holdings increased from 140 to 1.011 with 2.285 rabies cases in total. The measures taken in the frame of Decree on rabies control, including compulsory vaccination of dogs, which was enforced in 1948, has resulted in decrease of stray dog population (from 1 mio to 120.000). At that time (in 1955), 10 regions were affected with 15 rabies cases in total. In the period from 1960 to 1973, 140 cases of rabies were reported, 73% of which were in dog population and the rest in livestock.

Wildlife mediated rabies was first detected in Bulgaria in 1974 in the northern part of the country. In the period from 1979 to 1981 no rabies cases were detected, the reason for this is still unknown. In 1982 rabies occurred again in the north. From 1988 to 1992, infection pressure was the highest. Altogether, 296 cases of rabies were detected, of which only 14 in the south of Bulgaria. On average 15 rabies cases were detected per year until 2007, then

after rabies have spread from north to south to the entire territory of Bulgaria. All regions are affected. Most of the cases are reported in spring. Cases are limited to wildlife (fox) and pasture animals.

2. Stray animal situation and management in Bulgaria

Stray dog population presented a social as well as economical problem. After the change of political system, the problem of stray dogs has been ignored for several years. With increased human populations in big cities and bad waste management the situation has worsened. Pets were kept under inappropriate conditions, abandoned or released and consequently uncontrolled reproduction has led to huge stray dog populations and problems accompanied.

In the period of 1986 to 2006, municipalities were responsible for stray dog population management. The main measure was mass killing of stray dogs. In Sofia alone 70.000 stray dogs were killed at that time. A lot of money was spent (2,5 mio €) with no results. It was impossible to cooperate with NGOs. Therefore, Bulgaria has undertaken a commitment to adopt the Animal Protection Act.

Echinococcosis is a major problem in the population of stray dogs. Among the EU Member States, Bulgaria is in the first place concerning the number of reported human cases of echinococcus. Bulgaria has prepared the National Echinococcosis Eradication Programme for the period 2004 - 2008. The number of human cases has decreased; however, the National Programme needs to be implemented also in the future. There arises the problem of funding the Programme and of the additional funding by the EU.

Whilst examining the problem of stray dogs, the moral and emotional dilemmas arising thereby need to be presented in the first place.

The sight of a multitude of emaciated, injured, mutilated and dead animals in the streets, and implementation of merciless measures for reducing the population of stray dogs are far from acceptable in a contemporary society.

The system of ensnarement and killing of stray dogs has proven ineffective and unacceptable, as have the capture and accommodation of dogs in shelters (migration of stray dog populations - unacceptable from the point of view of eradication of the disease, as migration may additionally contribute to the spread of the disease, animal shelters have been overcrowded,...). Despite all the measures implemented the number of stray dogs has not been decreasing.

A most stimulating solution with good results is the ABC – Animal Birth Control Programme. Within a 2-year period, the population of stray dogs has been reduced by 23 % under the application of the ABC Programme.

In the beginning of 2006, the population of stray dogs in Sofia was estimated at 20 000, and in 2009, at 8 500 stray dogs only.

Compulsory measures within the ABC Programme include the permanent identification and registration of animals, castration or sterilisation, and vaccination.

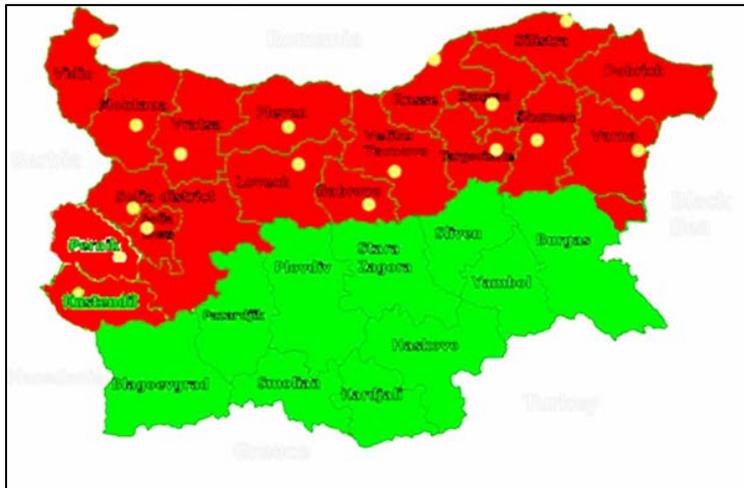
Within the ABC Programme, the national database for dogs has been set up and is managed by the Competent Authority.

In 2008, the new Animal Protection Act was passed, which introduces the public-private partnerships in this field.

3. Organisation of oral vaccination campaigns in Bulgaria

In 2009, the first ORV campaign was implemented. ORV plans are adopted annually and submitted to the European Commission for approval and co-financing. ORV is planned to be implemented for at least five consecutive years but not less than two years after the last rabies case.

Two campaigns, spring (March – May) and autumn (October – November) are conducted per year, the month in which ORV is to be implemented depends upon climatic conditions. Vaccination area consists of the territory of 19 regions (out of 28) in Burgas region only two provinces (Ruen and Pomorie) are included. The size of vaccination area is 63.000 km²; excluding “non flying” areas the size is 56.000 km².



The contractor for ORV is selected through public tender. The contract is signed for one calendar year and includes two ORV campaigns. Contractor has to follow the program prepared by the competent authority. It includes detailed provisions for no. and location of airports to be used during campaigns, timing, baiting density, flight lines, vaccine bait,...

Contractor has to provide for purchase of baits, transportation and storage facilities with maintaining of cold-chain and also for media campaign. The information should be given on the purpose of ORV, the area on which ORV will be conducted, timeframe and safeguard measures to be taken by public during campaign. After the completion of ORV contractor has to prepare reports with detailed data and maps on flying routs, baiting density,...

In 2009 and 2010 campaigns, Lysvulpen, BIOVETA, vaccine baits have been used. Distribution of baits was performed with fixed-winged aircraft from four airports. Baiting density was 20 baits per km², flying altitude – 150 – 200 m, speed 150-200 km/h, altitude 1200m asl, parallel flights in a distance of 500m.



Aerial distribution of the vaccine baits is done by using a fully automated system supported by computer and GPS which allows also recording of flight lines and positions (location) and amount of dropped baits.

4. Control of OV campaigns in Bulgaria, challenges and obstacles faced, cooperation with stakeholders

Rabies eradication program is approved by the Minister of agriculture. Control over the implementation of the program is assigned to the CVO. For managing the ORV central operational unit was established and regional operational units in the regions with ORV. Duties of central operational unit are to organize, control and coordinate the implementation of ORV throughout the country; to organise and control laboratory control of ORV; to report to the CVO of the progress of ORV and to prepare all the necessary documentation and reports for EC – for co-financing.

Duties of the regional operational units: organising and monitoring of ORV at the airport and preparing the relevant documentation for inspection; organising sampling and transport of

samples to the lab for monitoring the efficiency of ORV; daily reporting to the central operational unit.

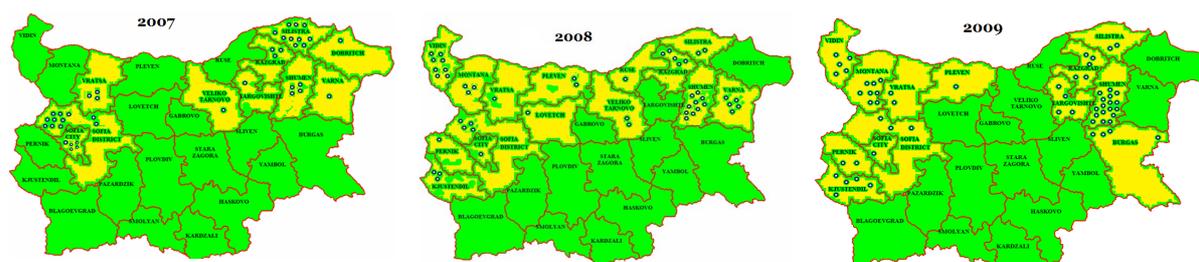
Storage of vaccine baits: the whole stock of vaccines is stored at the central storage facility. The first control is performed by central operational unit upon arrival of the vaccines in the central storage facility. Baits are delivered to the airports using refrigerated lorries. The cold chain must be maintained until the loading of baits in the aircraft. A person is appointed for implementation of control at regional level. Daily logs contain data on temperature, control of transport of vaccine baits, vehicles, flight parameters (time, baits). Daily logs are maintained and signed by the appointed person (veterinarian).

Epidemiological team is established at central as well as at regional level to deal with the data on ORV.

Difficulties: The main difficulty is to secure the necessary funds, therefore 2010 autumn campaign was not performed; sufficient funds are allocated for both 2011 campaigns. Collection of samples – in 2009 and 2010 only 10% of planned (8 foxes/100 km²) no. of samples were collected.

5. Results of rabies surveillance and monitoring since the introduction of oral vaccination

Rabies surveillance



In the period from 2007 – 2009 the number of rabies cases has increased. Rabies has spread from north towards south and east.

| Cases | Infected regions | Domestic | Wildlife | Total |
|-------|------------------|----------|----------|-------|
| 2007 | 10 | 14 | 26 | 40 |
| 2008 | 15 | 10 | 39 | 49 |
| 2009 | 13 | 10 | 49 | 59 |
| 2010 | 4 | 4 | 2 | 6 |

The rabies eradication program has been approved and cofinanced by the EU since 2009. Maximum amount of the EU financial contribution has been set to 1,1 mio € in 2009, 1,87 mio € in 2010 and 1,8 mio € in 2011.

In the frame of monitoring FAT, ELISA-AB and biomarker detection tests are performed. Samples are taken by official veterinarian in accordance with the requirements of the Instruction for sampling approved by Director General of NVS, when the whole fox carcass has been submitted by the hunter.

Monitoring of ORV (IF, ELISA AB, TTC)

| | IF | | ELISA - AB | | Biomarker (TTC) | |
|------|--------|----------|------------|----------|-----------------|----------|
| | Tested | Positive | Tested | Positive | Tested | Positive |
| 2009 | 417 | 7 | 235 | 40 | 300 | 39 |
| 2010 | 158 | 0 | 69 | 14 | 167 | 15 |

6. Presentation of rabies related activities in the rabies NRL

NRL for "Rabies in animals" in Sofia is a structural unit of the National Reference Center for Animal Health. It was designated as NRL under the Law on Veterinary Activity in 2003 by the Minister of Agriculture and Food. Three veterinarians are employed at the NRL (virologist, pathomorphologist and expert in rabies diagnostic), all trained at rabies diagnostics.

NRL for Rabies is accredited by the Executive Agency "BAS" BDS according to ISO 17025:2006. Diagnostic methods used in the NRL:

- Fluorescent antibody test – FAT (accredited method)
- FAT- antirabies nucleocapsid conjugate, BioRad, France
- Mouse inoculation test –MIT (confirmatory method, accredited)
- For monitoring of ORV:
 - o ELISA for detection of antibody against rabies virus in fox serum (accredited method), BioRad, France
 - o Detection of biomarker (tetracycline)
 - o Genotyping of field isolates of rabies virus in areas held by oral to distinguish vaccine strains from field; in cooperation with the EU-RL.

Other rabies-related activities of NRL: storage, maintenance and typing of rabies virus isolates; introduction of other standard methods related to rabies diagnosis and serology; training of official vets on sending samples to the laboratory; cooperation with EURL on rabies and participation in inter-laboratory control (ring and proficiency testing) organized by EURL.

Detailed data on tests performed by NRL is included in the ppt presentation, annexed to this report.

7. Conclusions and recommendations by the TF Subgroup for rabies

Conclusions

1. Bulgaria made an important step towards rabies control by launching ORV in 2009. Since then, three ORVs have been carried out in the northern part of the country. Due to financial constraints autumn ORV in 2010 was not performed.
2. Bulgarian authorities have established solid legal framework for the control of rabies following international guidelines, and collaboration between central/regional authorities and stakeholders.
3. Bulgarian authorities together with NGOs have developed an impressive program for reducing stray dog populations by ABC including neutering and implementation of national dog register and electronic identification of dogs.
4. Bulgarian authorities made considerable efforts to decrease the incidence of rabies in domestic animals by strengthening controls on the implementation of mandatory vaccination of dogs.
5. In the case of detection of rabies mandatory vaccination of all domestic animals is implemented in the affected area.
6. No human case of rabies has been reported for more than 40 years.
7. NRL has established WHO/OIE recommended standard laboratory techniques for rabies surveillance and ORV monitoring.
8. A new Agency for risk assessment has recently been set-up.

Recommendations

1. Bulgarian authorities should ensure long term financial backing for uninterrupted continuation of the ORVs even in times of financial difficulties especially considering availability of the EU co-financing at the rate of 75%.
2. Bulgarian authorities should be proactive and ensure flexible management of the program in order to react quickly to the epidemiological developments.
3. Because rabies surveillance is the key index for evaluation of ORV success the Bulgarian authorities should increase efforts to enhance rabies surveillance by focusing on indicator animals (suspect animals, road-kills, found-dead) across the country.
4. Measures should be taken to maximize sample collection in all target species including jackals for monitoring of ORV campaigns. Education and frequent information of hunters has shown to be effective to achieve cooperation.
5. Epidemiological analysis of rabies surveillance and ORV monitoring data should be given high priority. One of the basic preconditions is to set-up a national rabies database.
6. Frequent exchange of information, coordination of program and appropriate communication should be established with the neighboring countries.
7. Virus titer of all batches of rabies vaccine baits should be monitored before and during ORV campaigns.
8. To avoid persistence of rabies in large areas where aerial distribution is not possible arrangements for manual distribution should be considered.
9. Given the experience of other MSs Bulgaria should consider expanding ORV in altitudes above 1200 m.
10. In order to obtain reliable results in bait uptake detection, a training for tetracycline test analysis could be organized in the NRL