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Self-declaration of country freedom from infection with Rabies virus by Montenegro

Declaration sent to the World Organisation for Animal Health (WOAH) on 8 September 2022 by Mrs. Vesna Dakovic, WOAH Delegate for Montenegro, Food Safety, Veterinary and Phytosanitary Affairs.

1. Introduction

The aim of this declaration is to demonstrate that Montenegro fulfils the requirements of a country free from infection with rabies virus in compliance with Article 8.14.2. of the 2022 *Terrestrial Animal Health Code (Terrestrial Code)*. The self-declaration covers the whole territory of Montenegro and the populations of both domestic and wild animals.

The starting date of this self-declaration is 08.09.2022.

2. Notification of Rabies

According to the Veterinary Law and the Book of rules on the classification of infectious animal diseases (Annex 2), the method of reporting the occurrence or suspicion and resolving of infectious animal diseases (OG No. 92/17), rabies is a compulsory notifiable contagious disease in Montenegro.

In case of occurrence of rabies or when signs of the disease have been established giving rise to suspect that the animal has taken ill with or died of an infectious disease, the animal keeper is obliged to immediately notify, without delay, the nearest veterinary surgery or official veterinarian.

Any suspicion of rabies should be immediately, without delay, notified to the competent authority.

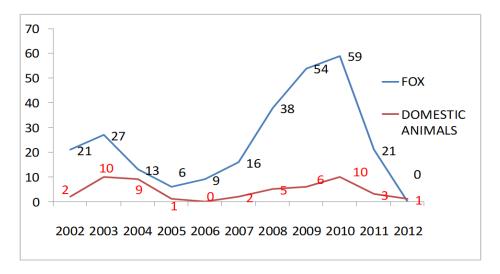
3. History and epidemiological evolution of the disease

Dog-mediated rabies was eradicated soon after World War II when compulsory vaccination of dogs against rabies was set into force (1947). Since then, vaccination of dogs against rabies has been mandatory.

The last case of human rabies in Montenegro was confirmed in 1963.

The first recorded case of wildlife-mediated rabies was in 1948 in the northern part of Montenegro. For several years the majority of rabies cases in wildlife population occurred in the north of Montenegro.

The last rabies case in wildlife population was detected in 2011, and in domestic animals (one cat) in 2012.



4. Measures in place to maintain freedom from infection in the country

4.1 Regulatory measures for the prevention and control of rabies, including rules on imports

The following legislative acts in Montenegro are applicable in case of rabies outbreaks:

- 1) Veterinary Law (OG No.30/12 and 48/15, 52/16, 43/18), Based on the Veterinary Law, in Chapter 4 ANIMAL HEALTH, Articles from 54 to 58 are prescribing the general and special preventive measures for prevention and eradication of diseases.
- 2) Rulebook on prevention, confirmation, control and eradication of rabies in animals (OG No. 53/2011), Rulebook on Measures to Prevent the Occurrence, Suppression and Eradication of Rabies in Animals is prescribing definition of rabies cases, obligation on vaccination and identification and more detailed measures for Suppression and Eradication of disease, Articles 4 to 7. Annex 3
- 3) Rulebook on the classification of infectious animal diseases, the method of reporting the occurrence or suspicion and resolving of infectious animal diseases (OG No. 92/17).
 - Detailed classification of animal diseases and measures for prevention of their occurrence, detection, control and eradication, the method of sampling and diagnostic examination and the scope of the infected and endangered area, are prescribed by The Rulebook on the Classification of Infectious Animal Diseases, Notification of the Occurrence or Suspicion of Infectious Animal Diseases and Eradication of Infectious Animal Diseases.
- 4) Book of rules on identification of dogs and cats (OG No. 60/2018): Rulebook on Dogs and Cats Identification is prescribing methods of identification and registration and detailed requirements for it. Identification of dogs and cats is subject to all newborn dogs and cats found in the territory of Montenegro, no later than 90 days from the date of birth, i.e. during the first vaccination against viral diseases or leaving the litter. Imported dogs and cats that are not permanently identified are also subject to identification, and identification is performed 15 days from the day of entry into Montenegro. Annex 4

- 5) Rulebook for non-commercial movement of pet animals (OG No. 42/2016): Rulebook for non-commercial movement prescribes rules for entry of animals in order to keep stable epidemiological situation regarding rabies, namely to minimize risk of importing disease through non-commercial movement. Annex 5
- 6) Programme of mandatory animal health protection measures (an example from 2020 mandatory health care measures 14 attached). Annex 6

In addition to the national legislation, Montenegro, as a WOAH member, follows international standards established in the *Terrestrial Code* and *Terrestrial Manual*.

4.2 Imports

Import rules

Provisions of the Veterinary Law and the Rulebook on requirements for non-commercial movement of pets (OG No.42/2016) regulate these issues (Annex 7). This Rulebook is in accordance with the provisions in the EU Regulation 576/2013.

The List of countries with a favorable situation as regards rabies, which is currently laid down in <u>Annex II to Regulation (EU) No. 577/2013</u>, as last amended by Commission Implementing Regulation (EU) 202/2016, and the import rules are as following:

Pet animals are allowed to non-commercial movement if:

- a. animals are identified in the prescribed way,
- b. animals are accompanied with a passport,
- c. animals are vaccinated against Rabies,
- d. are older than 12 weeks on the day of the vaccination,
- e. 21 days have expired since vaccination,
- f. animals underwent testing for titer of specific neutralising rabies antibodies,
- g. the testing must be performed at least 30 days after the vaccination and three months before noncommercial movement,
- h. animals underwent Echinococcus multilocularis treatment in the prescribed manner,
- i. are accompanied by a veterinary certificate on animal health status.

Other imports (other captive, feral, wild and laboratory mammals and other susceptible domestic species (camelids, ruminants, equids, suids) are in compliance with *Terrestrial Code* (Articles 8.14.5. to 8.14.10.) and relevant EU legislation, including all veterinary certificates harmonized.

4.3 Vaccination of domestic animals

To prevent the occurrence of rabies, dogs and cats are vaccinated with an inactivated vaccine in order to constantly maintain active immunity against the rabies virus.

Vaccination of dogs and cats against rabies is carried out in accordance with the Rulebook on measures to prevent, detect, control and eradicate rabies in animals ("Official Gazette of Montenegro", No. 53/11), the instructions of Administration and the vaccine producer.

Dogs and cats older than three months are vaccinated once a year with an inactivated rabies vaccine, with revaccination, according to the vaccine producer instructions.

Vaccination of dogs less than three months of age may be carried out if there are justified reasons, according to the instructions of the vaccine producer.

Administration provides the vaccine for the purposes of vaccination of dogs, vaccination in case of rabies in the infected and endangered area and for dogs and cats in registered shelters for abandoned animals (pets).

Dogs identified by the appropriate microchip (verification of its functionality) are vaccinated or in the case of unidentified dogs, vaccination is carried out after application of the microchip, and data on marking (microchip number) and vaccination are entered in the dog passport printed by Administration.

Vaccination of dogs against rabies, identification - application of microchips and issuance of passports as well as entry of data in the Register of Pets is done in accordance with the instructions of Administration.

If necessary, other domestic susceptible animals are vaccinated, by order of the official veterinarian.

4.4 Oral vaccination programme in foxes

To eradicate rabies in foxes and other wild animals, oral rabies vaccination (ORV) has been carried out by Administration for Food Safety, Veterinary and Phytosanitary Affairs (AFSVPA) with the support of the European Union, since 2011, twice per year, except in 2021 (when no ORV was carried out). We continued with vaccination in 2022, and already have an agreement for 2023.

Vaccination is carried out by distribution of vaccines (bait) from airplanes in the entire territory of Montenegro, except in urban areas, on water areas and in the area of military zones. Lysvulpen vaccine (attenuated vaccine) for oral immunisation of foxes against rabies is being used for the vaccination. The vaccine is produced by Bioveta.

Lysvulpen vaccine has been tested both by the producer and the independent laboratory. Lysvulpen was tested by laboratory prior to shipping to Montenegro (full set of parameters) as well as after its delivery (titer only) to the warehouse close to Podgorica. Every time, the vaccine complied in all prescribed parameters.

Sampling has been done under presence of representative of monitoring team and Administration for Food Safety, Veterinary and Phytosanitary Affairs.

5. Surveillance and monitoring

5.1. Early warning system and rabies awareness

Rabies surveillance, control and eradication programme in wildlife and domestic animals are in place, since 2011, including compulsory oral vaccination of wildlife population, compulsory vaccination of dogs, and an ongoing system of rabies surveillance and monitoring and rabies awareness. Examples of awareness campaigns are provided here below and in annexes:

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https://www.gov.me/clanak/193055--promocija-kampanje-za-podizanje-svijesti-o-kontroli-populacije-pasa-lutalica

https://www.gov.me/dokumenta/0c1581a4-0e97-4a75-8bc8-e19d8141b380

file:///C:/Users/Admin/Downloads/Letak.pdf

https://www.gov.me/clanak/161340--kampanja-za-podizanje-svijesti-o-kontroli-populacije-pasa-lutalica

https://www.gov.me/dokumenta/487da537-b53a-46cf-9b19-c67ff3444567

Annex 8

Annex 9

Annex 10

Annex 11

A 42

Annex 12

Annex 13

Diagnostic and other measures are in place to timely detect and suppress the occurrence of rabies.

Other measures are referred to official veterinarian's record and measures he is prescribing depending on current situation.

Concerning early warning system, it is prescribed in our legislation Veterinary Law (Articles 51 and 53) and Rulebook On Prevention, Confirmation, Control And Eradication Of Rabies In Animals (OG No. 53/2011), as well as Rulebook On The Classification Of Infectious Animal Diseases, The Method Of Reporting The Occurrence Or Suspicion And Resolving Of Infectious Animal Diseases (OG No. 92/17).

5.2. Passive surveillance

To monitor the presence of rabies, animals suspected of having rabies are collected and examined as so-called "animal indicators".

Collection of wild carnivores that are found dead or killed is carried out by hunting organisations during regular hunting activities and upon notification by citizens and delivered to veterinary clinics.

Veterinary clinics pack, label, and properly store samples (heads and body fluids or whole carcass) of these and other indicator animals and deliver them with instructions to the Diagnostic Veterinary Laboratory for examination, in accordance with the professional instructions of the Administration.

The specialist veterinary laboratory receives samples and examines the presence of rabies virus antigens in indicator animals using the FAT method (fluorescent antibody technique).

5.3. Surveillance aimed at evaluating the efficiency of the ORV programme

After the oral vaccination, the success of the oral vaccination is monitored, as well as the presence/absence of the rabies virus antigen in the fox population (active monitoring of rabies in wild animals). It is necessary to catch and examine four healthy foxes for every 100 km2 of territory (the area where the vaccines were distributed). Hunters shoot foxes from different parts of the hunting areas to allow spatial variations, in accordance with the Administration's sampling plan, which is submitted to the Hunting Association.

Hunters deliver hunted foxes to veterinary clinics, which deliver the sample with instructions to the Diagnostic Veterinary Laboratory for examination.

The Diagnostic veterinary laboratory uses the fox samples to assess their age and examine the level of antibodies to the rabies virus with an ELISA test and the presence of tetracycline biomarkers in the teeth/bones. If these findings are positive, it is considered that the fox has consumed the bait and has been vaccinated. At the same time, Diagnostic Veterinary Laboratory tests the same fox samples for the presence/absence of FAT rabies virus antigens.

Before the implementation of the ORV, the majority of rabies cases were detected in red fox (Vulpes vulpes) population, which was the main reservoir of rabies.

As a result of this strategy, no case of indigenously acquired rabies virus infection has been confirmed in Montenegro during the past ten years. There were never imported cases of rabies in Montenegro.

The implementation and results of adequate laboratory-based rabies surveillance and ORV monitoring have proven the efficiency of the rabies eradication programme in Montenegro.

5.4. Results

Table: Surveillance data 2018-2022

Year	Number of tested animals – passive surveillance (FAT)			Number of tested animals (foxes) – active surveillance (FAT)	
	negative	species	positive	negative	positive
2018.	13	4 cats, 4 dogs and 5 foxes	0	325	0
2019.	11	1 cat, 6 dogs and 4 foxes	0	354	0
2020.	8	1 cat, 4 dogs, 2 foxes and 1 cow	0	284	0
2021.	2	2 foxes	0	146*	0
2022.	7	3 dogs, 2 foxes, 1 cat and 1 weasel	0	12*	0

Decrease in the number of foxes tested in 2021 and 2022 is due to the absence of the ORV campaign in 2021 **

6. Conclusion

- 1. Rabies is a compulsorily notifiable disease in Montenegro. In addition, any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1. of the *Terrestrial Code*;
- 2. All susceptible animals showing clinical signs suggestive of rabies are subjected to appropriate field and laboratory investigations;
- 3. Rabies surveillance, control and eradication programme in wildlife and domestic animals, in accordance with Chapter 1.4 and Article 8.14.12, has been in place for at least 24 months, including compulsory oral vaccination of wildlife population, compulsory vaccination of dogs, ongoing rabies vaccination monitoring, rabies awareness programmes and an early warning system.
- 4. Regulatory measures for the prevention of infection with rabies virus are implemented in accordance with the relevant recommendations in the *Terrestrial Code*, including Articles 8.14.5 to 8.14.10
- 5. No case of indigenously acquired rabies virus infection has been confirmed in Montenegro during the past ten years.

The WOAH Delegate of Montenegro declares that the country complies with the requirements for a country free from rabies as of 08.09.2022. in compliance with the provisions of Chapter 1.6. and Article 8.14.2. of the *Terrestrial Code* (2022 edition), and the declaration is consistent with the information provided in WAHIS.

Statement to be included in the self-declaration document.

I, the undersigned, <u>Vesna Dakovic</u>, the Delegate of <u>Montenegro</u>, to the World Organisation for Animal Health (WOAH, founded as OIE), takes responsibility for the self-declaration of freedom from <u>infection</u> <u>with Rabies virus</u>

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Drawn up on 07.10.2022.

Member concerned.

Signature of the Delegate: