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COMMISSION IMPLEMENTING DECISION (EU) 2021/788

of 12 May 2021

laying down rules for the monitoring and reporting of infections with SARS-CoV-2 in certain animal species

(notified under document C(2021) 3293)

(Text with EEA relevance)

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Article 1

Subject matter and scope

This Decision lays down detailed harmonised rules for the monitoring and reporting by Member States of cases of infection with SARS-CoV-2 in certain animals.

That monitoring and reporting shall cover outbreaks of infection with SARS-CoV-2 in kept and wild animals of the species listed in Annex I (the animals), and shall cover the whole territory of the Member States.

Article 2

Sampling framework for monitoring

Member States shall take the necessary measures to ensure that the competent authorities make appropriate arrangements for:

(a) the sampling and testing for SARS-CoV-2 of animals kept in establishments, with more than 500 adult breeders at the beginning of the cycle, in accordance with the sampling scheme set out in Annex II.

(b) the sampling and testing for SARS-CoV-2 of kept and wild animals in accordance with the sampling scheme set out in Annex III.

Article 3

Monitoring virus evolution

1. In the case of detection of the SARS-CoV-2 virus in animals, Member States shall ensure that official laboratories carry out phylogenetic analysis in the presumed index case of each outbreak to characterise the virus.

2. Member States shall ensure that viruses sequenced from animals in accordance with paragraph 1 are phylogenetically compared to already known sequences and the results of such studies transmitted to the Commission in accordance with Article 4.

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Article 4

Reporting

1. Member States shall submit a report to the Commission within three days from the date of the first confirmation on their territory of the infection of animals with the SARS-CoV-2 virus.

2. Member States shall submit a follow-up report:

(a) on a weekly basis in the case of further outbreaks of new infections with SARS-CoV-2 in animals after the first confirmation referred to in paragraph 1;

(b) when there are relevant updates on the epidemiology of that disease and its zoonotic implications.

3. The reports provided for in paragraphs 1 and 2 shall include for each outbreak of SARS-CoV-2 in animals, the information set out in Annex IV.

4. Where relevant, Member States shall submit a report to the Commission on a monthly basis as regards the results of the phylogenetic analysis and the results of the studies referred to in Article 3.

5. The reports provided for in paragraphs 1 and 2 shall be communicated in an electronic format to be determined by the Commission in the framework of the Standing Committee on Plants, Animals, Food and Feed.

Article 5

Information by the Commission

1. The Commission shall inform the Member States in the framework of the Standing Committee on Plants, Animals, Food and Feed of the reports submitted by the Member States in accordance with Article 4.

2. The Commission shall publish on its website, for information purposes only, an updated summary of the information contained in the reports submitted by the Member States in accordance with Article 4.

Article 6

This Decision shall apply until ►M1 31 March 2023 ◄.

Article 7

Commission Implementing Decision (EU) 2020/2183 is repealed.

Article 8

This Decision is addressed to the Member States.

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ANNEX I

List of animal species subject to monitoring and reporting

1. Minks (*Neovison vison*) and all other animals belonging to species of the family *Mustelidae*;

2. Raccoon dogs (*Nyctereutes procyonoides*).

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ANNEX II

Sampling and testing for SARS-CoV-2 of animals kept in establishments, with more than 500 adult breeders at the beginning of the cycle

The competent authority shall ensure that one of the following sampling schemes is followed:

SECTION 1

Default sampling scheme

(a) Target population: in each establishment keeping animals, samples shall be taken from every dead and sick animal from each epidemiological unit until the number of animals in the expected sample size is reached; in the absence of dead or sick animals, samples shall also be taken from random live animals to reach the expected sample size.

(b) Sampling frequency: samples shall be taken weekly.

(c) Sample matrix: oropharingeal swabs shall be taken from live or dead animals.

(d) Diagnostic tests: tests shall be taken for the detection of SARS-CoV-2 virus genome.

(e) Design prevalence to determine the expected sample size: within each establishment, the sample size shall be based on a 5 % prevalence with 95 % confidence.

SECTION 2

First alternative sampling scheme

Based on a positive outcome of a risk assessment, carried out by the competent authority, which considers the sensitivity of alternative sampling methodologies to be equivalent to oropharingeal swabs as referred to in point (c) of Section 1 and the existence of risk mitigating measures for the occurrence of SARS-CoV-2 in the target population in the establishment, the Member States may decide to use the following alternative sampling scheme instead of the default sampling scheme set out in Section 1:

(a) Target population: in each establishment keeping animals, samples shall be taken from every dead animal and sick animals as soon as they are identified, from each epidemiological unit until the expected sample size is reached; in the absence of dead or sick animals, samples shall also be taken from random live animals to reach the expected sample size.

(b) Sampling frequency: samples shall be taken every two weeks.

(c) Sample matrix: oropharingeal swabs shall be taken from dead animals; from live animals either oropharingeal or conjunctival or saliva swabs shall be taken or a combination of such swabs shall be taken; in addition, another option may be added to the swabs matrix, by using expiration air directly collected from all animals by using electronic air collector tools.

(d) Diagnostic tests: tests for the detection of SARS-CoV-2 virus genome shall be carried out.

(e) Design prevalence to determine the expected sample size: within each establishment the sample size shall be based on a 20 % prevalence with 95 % confidence.

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SECTION 3

Second alternative sampling scheme

Where a risk assessment has been carried out by the competent authority with a positive outcome, and the risk assessment covers the result of SARS-CoV-2 sampling and testing of workers of an establishment and the existence of risk mitigating measures for the occurrence of SARS-CoV-2 in the target population in the establishment, the Member States may decide to rely solely on the sampling scheme for the monitoring of animals provided by Annex III.

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ANNEX III

Sampling scheme for the monitoring of kept or wild animals

The competent authority shall ensure that the following sampling schemes set out in Section 1 and Section 2 are followed.

SECTION 1

Monitoring in establishments keeping animals

1. The target populations for the sampling shall be the following:

   (a) In each establishment keeping animals where there is an increased mortality compared to the baseline mortality rate of that specific production period or animals with clinical signs related to SARS-CoV-2: every dead animal or animals with clinical signs related to SARS-CoV-2, from each epidemiological unit until the expected sample size is reached.

   (b) In each establishment keeping animals where the competent authority has been informed that cases of SARS-CoV-2 have been detected in the workers of that establishment or their families: every dead animal or animals with clinical signs related to SARS-CoV-2, from each epidemiological unit until the expected sample size is reached.

2. Sampling frequency: sampling shall be carried out every time an animal suspected of being infected with SARS-CoV-2 is identified as indicated in the target population referred to in point 1.

3. Sample matrix: oropharingeal swabs shall be taken from dead or live animals referred to in point 1.

4. Diagnostic tests: tests for the detection of SARS-CoV-2 virus genome shall be carried out.

5. Design prevalence to determine the expected sample size for the target population referred to in:

   (i) point (1)(a): within each establishment, the sample size shall be based on a 50 % prevalence with 95 % confidence;

   (ii) point (1)(b): within each establishment, the sample size shall be based on a 5 % prevalence with 95 % confidence.

SECTION 2

Monitoring in all other kept or wild animals

1. The target populations for the sampling shall be for all other kept or wild animals excluding those kept in establishments: animal suspected of being infected with SARS-CoV-2 which have died, or were found dead, or animals with clinical signs related to SARS-CoV-2.

2. Sampling frequency: sampling shall be carried out every time an animal suspected of being infected with SARS-CoV-2 is identified as indicated in the target population referred to in point 1.

3. Sample matrix: oropharingeal swabs shall be taken from dead or live animals referred to in point 1.

4. Diagnostic tests: tests for the detection of SARS-CoV-2 virus genome shall be carried out.

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5. Design prevalence to determine the expected sample size: sampling of all reported animals that have died, or were found dead, or animals with clinical signs related to SARS-CoV-2; in case more than 5 animals were found dead in the same place or presumed to belong to the same epidemiological unit, the sample size shall be limited to 5 randomly selected animals.

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ANNEX IV

Information to be contained in the reports provided for in Article 4 in relation to outbreaks of infection with SARS-CoV-2 in animals *('susceptible species')*

1. Date of reporting;

2. Member State;

3. Type of report (first confirmation report/weekly-follow-up report);

4. Total number of outbreaks in the Member State included in the report;

5. For each outbreak provide:

   (a) Serial number of each outbreak in the Member State;

   (b) Region and approximate geographical location of the establishment or other place where animals were kept or located;

   (c) Date of suspicion;

   (d) Date of confirmation;

   (e) Diagnostic method(s);

   (f) Date of estimation of introduction of the virus in the establishment or place;

   (g) Possible source of the virus;

   (h) Control measures taken (details [1]);

   (i) Number of susceptible animals on establishment or at the place (by susceptible species);

   (j) Number of animals clinically or subclinically affected on establishment or at the place (by susceptible species; in case an exact figure is not available, an estimate must be provided);

   (k) Morbidity: number of animals (by susceptible species) clinically affected, with signs resembling COVID-19, on establishment or at the place in relation to the number of susceptible animals with a summary description of the clinical signs (in case an exact figure is not available, an estimate must be provided);

   (l) Mortality: number of animals (by susceptible species) that have died on establishment or at the place (in case an exact figure is not available, an estimate must be provided);

6. Data on molecular epidemiology, significant mutations;

7. Where relevant, non-personal epidemiological data on human cases in the Member State directly related to animal outbreaks referred to in Article 4(1) and (2);

8. Other relevant information.

[1] Movement control inside the Member State; surveillance within containment or protection zone; traceability; quarantine; official disposal of carcasses, by-products and waste; stamping out; control of wildlife reservoirs; zoning; disinfection; vaccination of animals permitted (if a vaccine exists); no treatment of affected animals and other relevant measures.