

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)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC ⁽¹⁾, and in particular Articles 4(5) and 9(1) and Article 11, third paragraph, thereof,

Whereas:

- (1) Since 2020, infections with the SARS-CoV-2 virus in minks have been reported in certain Member States and third countries, and it has been established that human-to-mink and mink-to-human transmission can occur. Furthermore, one Member State has reported human COVID-19 cases infected with the SARS-CoV-2 virus variants related to mink.
- (2) On 12 November 2020, the European Centre for Disease Prevention and Control (ECDC) published, with the contribution of the European Food Safety Authority (EFSA), a Rapid Risk Assessment on the detection of new SARS-CoV-2 variants related to mink ⁽²⁾ (the ECDC Rapid Risk Assessment).
- (3) The ECDC Rapid Risk Assessment concluded that the overall level of risk to human health posed by SARS-CoV-2 mink-related variants can be determined as ranging from low for the general population up to very high for medically vulnerable individuals with occupational exposure. The ECDC Rapid Risk Assessment also indicated that further investigations are needed to assess whether SARS-CoV-2 mink-related variants may have an impact on the risk of reinfection, reduced vaccine efficacy or reduced benefit from treatment.
- (4) To decrease the risk posed to public health, the ECDC Rapid Risk Assessment recommends that national authorities should consider implementing measures aimed at mink farms, mink farm workers and communities in contact with mink farms. Those measures should cover human testing, sequencing and characterisation of antigenic properties and virus infectivity as well as animal monitoring and surveillance of mink farms in order to prevent the spread of SARS-CoV-2 variants from animals to humans.
- (5) On 20 January 2021, the World Health Organization (WHO), the World Organisation for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO) issued a joint tripartite risk assessment on emerging threats at the human-animal-ecosystems interface, which addressed SARS-CoV-2 in animals used for fur farming ⁽³⁾. The risk assessment recommends that the testing of animals for SARS-CoV-2 should be risk-based and should only be considered in the broader response to COVID-19 within a 'One Health' approach, incorporating an early warning and surveillance system based on case definitions in farm workers and animals as appropriate. In accordance with the risk assessment, in SARS-CoV-2 outbreaks involving fur farms, sequencing of viruses from human cases and minks, including phylogenetic analysis and comparison of genetic sequences, is recommended to understand the direction of infection (namely, whether animal to animal, animal to human, human to animal or human to human) and to identify and assess any mutations occurring.
- (6) On 18 February 2021, EFSA, with the contribution of ECDC, published the scientific report on the monitoring of SARS-CoV-2 infection in mustelids ⁽⁴⁾ (the EFSA report). The EFSA report indicates that SARS-CoV-2 spreads very efficiently within mink farms once introduced, by direct and indirect contact. Infected humans were likely at the

⁽¹⁾ OJ L 325, 12.12.2003, p. 31.

⁽²⁾ European Centre for Disease Prevention and Control. Detection of new SARS-CoV-2 variants related to mink – 12 November 2020. ECDC: Stockholm; 2020.

⁽³⁾ https://www.oie.int/fileadmin/Home/MM/GLEWS_risk_assessment_fur_animals_SARS_CoV_2.pdf

⁽⁴⁾ EFSA Scientific Report 'Monitoring of SARS-CoV-2 infection in mustelids'. DOI 10.2903/j.efsa.2021.6459

origin of the introduction of SARS-CoV-2 infection into farms. The EFSA report concludes that carrying out surveillance on workers at mink farms is an important step in enabling the early detection of infection. The EFSA report also indicates that raccoon dogs (*Nyctereutes procyonoides*) are also susceptible to SARS-CoV-2.

- (7) The EFSA report recommends that all mink farms that are not yet infected should be considered at risk of infection, as the human disease is widespread and therefore the monitoring objective of choice should be early detection.
- (8) In line with the EFSA report, one of the monitoring objectives should be the monitoring of the SARS-CoV-2 virus evolution. Genetic analysis is important to characterise the SARS-CoV-2 virus and to detect possible virus mutations and to identify the origin and the source of the virus. Detecting possible virus mutations is of particular relevance for public health, in order to identify new variant viruses early that may have an impact on diagnostics, transmission, severity or vaccine effectiveness.
- (9) Kept and wild raccoon dogs should be considered susceptible to SARS-CoV-2 infection. The OIE, in its Guidance on working with farmed animals of species susceptible to infection with SARS-CoV-2 ⁽⁵⁾, has called on countries to monitor susceptible animals for SARS-CoV-2 infection, such as mink and raccoon dogs, as well as humans in close contact with them, adopting a 'One Health' approach. Monitoring programmes concerning zoonoses should be established by the Commission for laying down detailed rules for the monitoring of this specific zoonotic agent as Directive 2003/99/EC provides for such monitoring in view of collecting coordinated data, make data easier to compile and compare and better identification of the risks, and thus enabling further action where appropriate. The recitals of that Directive mention that zoonoses transmitted through sources other than food, especially from wild animal and pet animal populations, are a matter of concern. In addition, they mention that the collection of data on the occurrence of zoonoses and zoonotic agents in animals, food, feed and humans is necessary to determine the trends and sources of zoonoses. They also mention that priority should be given to those zoonoses posing the greatest risk to human health, but that the monitoring systems should also facilitate the detection of emerging or newly emerging zoonotic diseases and new strains of zoonotic organisms.
- (10) In order to enable further risk assessment under the 'One Health' approach and to inform and identify possible risk-management options as regards the risks arising from the circulation of SARS-CoV-2 mink-related variants in animals of the family *Mustelidae* and in raccoon dogs, an efficient, harmonised monitoring and reporting system allowing for the collection and exchange of all relevant information should be established without delay.
- (11) In order to facilitate implementation and to focus resources on higher risk groups, the monitoring system laid down in this act should cover all kept *Mustelidae* and raccoon dogs, but prioritise establishments with over 500 adult breeders for active monitoring activities and accordingly rules for the sampling and testing for SARS-CoV-2 of animals in those prioritised establishments should be set out in Annex II to this act. In parallel, passive monitoring should be ensured in all kept and wild *Mustelidae* and raccoon dogs to ensure investigation of specific situations, and accordingly rules for a sampling scheme for the passive monitoring of all such kept or wild animals should be set out in Annex III to this act.
- (12) Given the urgency to further assess the risk posed by the epidemiological situation in the Union as regards the occurrence of SARS-CoV-2 in minks and other animals of the family *Mustelidae* and in raccoon dogs as well as to assess the viability of the measures, Member States should allocate the required resources for setting up a monitoring system and submit to the Commission regular reports on the occurrence of that infection in kept or wild animals of the family *Mustelidae* and in raccoon dogs. Article 3 of Directive 2003/99/EC provides for the publication of data by the Member States. To ensure proper risk communication within the Union, the Commission should publish on its website, for information only, a summary of the information collected as regards SARS-CoV-2, given the importance of risk communication for that virus.
- (13) To enable reporting, in a structured manner, of occurrences of SARS-CoV-2 in minks and other animals of the family *Mustelidae* and in raccoon dogs, this Decision should establish the model report, the minimum information requirements and the format for data by outbreak and by species susceptible to the SARS-CoV-2 virus. This model report should be used for reporting purposes for that virus.

⁽⁵⁾ Guidance on working with farmed animals of species susceptible to infection with SARS-CoV-2, Version 1.2. 16 November 2020. Taken from https://www.oie.int/fileadmin/Home/MM/Draft_OIE_Guidance_farmed_animals_cleanMS05.11.pdf

- (14) Commission Implementing Decision (EU) 2020/2183 ⁽⁶⁾ lays down rules concerning certain protective measures in relation to reporting infection with SARS-CoV-2 in minks and other animals of the family *Mustelidae* and in raccoon dogs and applies until 20 April 2021. Implementing Decision (EU) 2020/2183 is based on Article 9(4) of Council Directive 89/662/EEC ⁽⁷⁾, and on Article 10(4) of Council Directive 90/425/EEC ⁽⁸⁾. The measures laid down in that Implementing Decision have been shown to be effective and similar measures should be laid down in this Decision.
- (15) It is urgent to collect the required data for further assessing the risks for human health, for enabling early warning of occurrences of SARS-CoV-2 in minks and other animals of the family *Mustelidae* and in raccoon dogs, and for monitoring the virus evolution.
- (16) For disease monitoring purposes, the general principles for calculating the sample size set by the OIE Terrestrial Animal Health Code ⁽⁹⁾ refer to the need to calculate sample size based on factors such as the size of the population, the design of the survey, the expected prevalence and possible clustering, the level of confidence desired and the performance of the tests used. The EFSA report identifies specific design prevalence percentages for SARS-CoV-2, to achieve a given confidence ratio, which are used to set the design prevalence described in Annex II. These design prevalence and confidence levels directly impact, together with other factors, the expected sample size. These principles should be taken into account in the sampling scheme laid down in this Decision.
- (17) Considering the current epidemiological situation of SARS-CoV-2 in minks and other animals of the family *Mustelidae*, this Decision should apply until 31 March 2022. In case there are changes in the epidemiological situation, the duration of period of application of this Decision will be reviewed by the Commission.
- (18) Implementing Decision (EU) 2020/2183 should be repealed and replaced by this Decision.
- (19) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

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.

⁽⁶⁾ Commission Implementing Decision (EU) 2020/2183 of 21 December 2020 concerning certain protective measures in relation to reporting infection with SARS-CoV-2 in minks and other animals of the family *Mustelidae* and in raccoon dogs (OJ L 433, 22.12.2020, p. 76).

⁽⁷⁾ OJ L 395, 30.12.1989, p. 13.

⁽⁸⁾ OJ L 224, 18.8.1990, p. 29.

⁽⁹⁾ OIE Terrestrial Animal Health Code (2019 edition); Chapter 1.4. on Animal health surveillance, Article 1.4.4.

*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.

*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 31 March 2022.

Article 7

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

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 12 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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: oropharyngeal 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 oropharyngeal 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: oropharyngeal swabs shall be taken from dead animals; from live animals either oropharyngeal 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.

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.

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: oropharyngeal 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: oropharyngeal 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: 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.

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.