

## ANNEX II

### 3. CASE DEFINITIONS OF COMMUNICABLE DISEASES

#### 3.39. SEVERE ACUTE RESPIRATORY SYNDROME (SARS)

##### **Clinical Criteria**

Any person with fever or a history of fever

AND

At least one of the following three:

- Cough
- Difficulty in breathing
- Shortness of breath

AND

At least one of the following four:

- Radiographic evidence of pneumonia
- Radiographic evidence of acute respiratory distress syndrome
- Autopsy findings of pneumonia
- Autopsy findings of acute respiratory distress syndrome

AND

No alternative diagnosis which can fully explain the illness

##### **Laboratory Criteria**

*Laboratory criteria for case confirmation*

At least one of the following three:

- Isolation of virus in cell culture from any clinical specimen and identification of SARS-CoV using method such as RT-PCR
- Detection SARS-CoV nucleic acid in at least one of the following three:
  - At least *two* different clinical specimens (for example, nasopharyngeal swab and stool)
  - The same clinical specimen collected on *two* or more occasions during the course of the illness (for example, sequential nasopharyngeal aspirates)
  - *Two* different assays or repeat RT-PCR using a new RNA extract from the original clinical sample on each occasion of testing
- SARS-CoV specific antibody response by one of the following two:
  - Seroconversion by ELISA or IFA in acute and convalescent phase serum tested in parallel
  - Four-fold or greater rise in antibody titre between acute and convalescent phase sera tested in parallel

*Laboratory criteria for a probable case*

At least one of the following two:

- A single positive antibody test for SARS-CoV
- A positive PCR result for SARS-CoV on a single clinical specimen and assay

##### **Epidemiological Criteria**

At least one of the following three:

---

**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2018/945, Division 3.39.. (See end of Document for details)

---

- Any person with at least one of the following three:
  - Employed in an occupation associated with an increased risk of SARS-CoV exposure (for example, staff in a laboratory working with live SARS-CoV/SARS-CoV-like viruses or storing clinical specimens infected with SARS-CoV; persons with exposure to wildlife or other animals considered a reservoir of SARS-CoV, their excretions or secretions, etc.)
  - Close contact<sup>(1)</sup> of one or more persons with confirmed SARS or under investigation for SARS
  - History of travel to, or residence in, an area experiencing an outbreak of SARS
- Two or more health-care workers<sup>(2)</sup> with clinical evidence of SARS in the same health-care unit with onset of illness in the same 10-day period
- Three or more persons (health-care workers and/or patients and/or visitors) with clinical evidence of SARS with onset of illness in the same 10-day period and epidemiologically linked to a healthcare facility

#### **Case Classification for the inter-epidemic period**

Also applies during an outbreak in a non-affected country or area

- A. Possible case
  - Any person meeting the clinical criteria with an epidemiological link
- B. Probable case
  - Any person meeting the clinical criteria with an epidemiological link and meeting the laboratory criteria for a probable case
- C. Nationally confirmed case
  - Any person meeting the clinical and the laboratory criteria for case confirmation where the testing has been performed at a national reference laboratory
- D. Confirmed case
  - Any person meeting the clinical and the laboratory criteria for case confirmation where the testing has been performed at a WHO SARS verification and reference laboratory

#### **Case Classification during an outbreak**

Applies during an outbreak in a country/area where at least one person has been laboratory confirmed by a WHO SARS verification and reference laboratory

- A. Possible case
  - Any person meeting the clinical criteria
- B. Probable case
  - Any person meeting the clinical criteria with an epidemiological link to a nationally confirmed or a confirmed case
- C. Nationally confirmed case
  - Any person meeting the clinical and the laboratory criteria for case confirmation where the testing has been performed at a national reference laboratory
- D. Confirmed case

---

**Changes to legislation:** There are currently no known outstanding effects for the Commission  
Implementing Decision (EU) 2018/945, Division 3.39.. (See end of Document for details)

---

One of the following three:

- Any person meeting the clinical and the laboratory criteria for case confirmation where the testing has been performed at a WHO SARS verification and reference laboratory
- Any nationally confirmed case with an epidemiological link to a chain of transmission where at least one case has been independently verified by a WHO SARS Reference and Verification Laboratory
- Any person meeting the clinical criteria and with laboratory criteria for probable case with an epidemiological link to a chain of transmission where at least one case has been independently verified by a WHO SARS Reference and Verification Laboratory

---

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2018/945, Division 3.39.. (See end of Document for details)*

---

- (1) A close contact is a person who has cared for, lived with, or having had direct contact with the respiratory secretions, body fluids and/or excretions (e.g. faeces) of cases of SARS.
- (2) In this context the term 'health-care worker' includes all hospital staff. The definition of the health care unit in which the cluster occurs will depend on the local situation. Unit size may range from an entire health care facility if small, to a single department or ward of a large tertiary hospital.

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2018/945, Division 3.39..