Commission Directive (EU) 2020/739 of 3 June 2020 amending Annex III to Directive 2000/54/EC of the European Parliament and of the Council as regards the inclusion of SARS-CoV-2 in the list of biological agents known to infect humans and amending Commission Directive (EU) 2019/1833

COMMISSION DIRECTIVE (EU) 2020/739

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THE EUROPEAN COMMISSION,

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

Having regard to Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work[(1)], and in particular Article 19 thereof,

Whereas:

(1) The Union strives to maintain its high standards for ensuring adequate protection of workers' health, which is particularly relevant in the context of a global health pandemic. The outbreak of COVID-19, a new coronavirus disease, has affected all Member States since early 2020 and is causing major disruptions to all sectors and services, directly impacting the health and safety of all workers across the Union.

(2) More than ever, strict compliance with and application of national provisions transposing Union rules on safety and health at work are of utmost importance. Directive 2000/54/EC lays down rules to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work. It applies to activities in which workers are exposed, or are potentially exposed, to biological agents as a result of their work, and states the measures to be taken in the case of any activity likely to involve a risk of exposure to biological agents, to determine the nature, degree and duration of workers' exposure to such agents.

(3) Annex III to Directive 2000/54/EC sets out the list of biological agents known to infect humans, classified according to their level of risk of infection. In line with introductory note 6 in that Annex, that list should be amended to take into account the latest knowledge as regards scientific and epidemiological development that have brought about significant changes, including the existence of new biological agents.

(4) In October 2019, Commission Directive (EU) 2019/1833[(2)] amended Annex III to Directive 2000/54/EC, which resulted notably in the addition of a large number of biological agents, including the Severe Acute Respiratory Syndrome-related

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coronavirus (SARS-virus) and the Middle East Respiratory Syndrome coronavirus (MERS-virus).

(5) The virus 'severe acute respiratory syndrome coronavirus 2' or, in short, 'SARS-CoV-2', which caused the outbreak of COVID-19, shows great similarities with the SARS-virus and the MERS-virus. Considering the epidemiological and clinical data currently available concerning the virus' characteristics such as its transmission patterns, clinical features and risk factors for infection, SARS-CoV-2 should be added to Annex III to Directive 2000/54/EC as a matter of urgency, to ensure the continued adequate protection of workers' health and safety at work.

(6) SARS-CoV-2 can cause severe human disease among the infected population, presenting in particular a serious hazard to elderly workers and those with an underlying medical problem or chronic disease. While there is no vaccine or effective treatment currently available, considerable efforts are being deployed internationally and a significant number of vaccine candidates have so far been identified. Taking into account the latest scientific evidence and clinical data available as well as advice provided by experts representing all Member States, SARS-CoV-2 should therefore be classified as a risk group 3 human pathogen. Several Member States, as well as EFTA States and other third countries, have started taking measures regarding the classification of SARS-CoV-2 in risk group 3.

(7) In March 2020, the World Health Organization published biosafety guidance for laboratories concerning the new coronavirus and the testing of clinical specimens of patients infected with SARS-CoV-2[(3)]. The guidance specifies that non-propagative diagnostic laboratory work, such as sequencing, can be conducted at a facility using procedures equivalent to at least containment level 2 (Biosafety Level 2, BSL-2), while propagative work involving SARS-CoV-2 should be conducted at a containment laboratory with air pressure negative to atmosphere (Biosafety Level 3, BSL-3). To ensure sufficient capacity as well as continuity of the vital work carried out by diagnostic laboratories across the Union, this should be made clear in Annex III to Directive 2000/54/EC.

(8) In the light of the severity of the global COVID-19 pandemic and taking into consideration that every worker has the right to a healthy, safe and well-adapted working environment, as provided by Principle 10 of the European Pillar of Social Rights[(4)], this Directive should provide for a short transposition period. Based on a wide consultation, a transposition period of 5 months was considered to be appropriate. In the light of the exceptional circumstances, Member States are encouraged to implement this Directive before the deadline for transposition, where possible.

(9) Directive (EU) 2019/1833 also amended Annex V and Annex VI to Directive 2000/54/EC, which lay down containment measures and levels for laboratories, animal facilities and industry. To provide workers with the appropriate levels of protection, the date for transposition of the amendments to those Annexes as regards exposure to SARS-CoV-2 should also be brought forward.

(10) The Commission will continue to closely monitor the situation regarding the COVID-19 outbreak, including the development of a possible vaccine and the availability of further

technological and scientific data and evidence concerning SARS-COV-2. On this basis, the Commission would review, if necessary, the risk group classification as established through the adoption of this Directive.

(11) Consideration was given to the need to maintain the existing levels of protection for workers who are exposed, or are potentially exposed, to biological agents through their work, and to ensure that the amendments only take into account scientific developments in the area, requiring adjustments at the workplace that are merely technical in nature.

(12) In preparing this Directive, the Commission was assisted by experts representing Member States, who provided technical and scientific support. Moreover, the tripartite Advisory Committee for Safety and Health at Work was consulted concerning the purely technical adjustments to Directive 2000/54/EC in the context of the SARS-CoV-2 outbreak.

(13) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents[(5)], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(14) The measures provided for in this Directive are in accordance with the opinion of the committee established by Article 17 of Council Directive 89/391/EEC[(6)],

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2000/54/EC is amended as set out in the Annex to this Directive.

Article 2

In Article 2 of Directive (EU) 2019/1833, paragraph 1 is replaced by the following:

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 November 2021 at the latest. However, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the amendments to Annexes V and VI to Directive 2000/54/EC, insofar as they relate to the biological agent SARS-CoV-2, by 24 November 2020 at the latest.

They shall forthwith communicate to the Commission the text of the provisions referred to in the first subparagraph.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 24 November 2020 at the latest. They shall forthwith communicate to the Commission the text of those provisions.