EXPLANATORY NOTE

1. BACKGROUND

The EU Occupational Safety and Health Directives lay down minimum requirements at EU level to protect workers against risks to which they are or can be exposed to at work. The **Framework Directive** (Council Directive 89/391/EEC) sets out the main principles of prevention and protection of occupational risks for all sectors of activity. These provisions are supported by a set of individual Directives, among them the **Biological Agents Directive** (Directive 2000/54/EC)[1]. This aims to protect workers against risks to their health and safety, including the prevention of such risks that arise or are likely to arise from exposure to biological agents at work.

Biological agents are microorganisms that may harm workers by causing an infection, an allergic reaction or exposing them to toxins. **Annex III** to Directive 2000/54/EC provides a list of agents known to infect humans, classified into four risk groups according to their level of risk of infection (see table below), which determines the protective measures to be put in place. In line with note 6 of Annex III, based on the latest scientific and epidemiological developments that have brought about significant changes, including the existence of new biological agents, the Annex should be amended to take into account new knowledge.

Group 1	Biological agent means one that is unlikely to cause human disease.
Group 2	Biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available.
Group 3	Biological agent means one that can cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available.
Group 4	Biological agent means one that causes severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.

In October 2019, **Commission Directive (EU) 2019/1833**[2] amended Annex III (together with other annexes) to Directive 2000/54/EC. This resulted in, amongst others, the addition of a large number of biological agents, including the Severe Acute Respiratory Syndrome-related coronavirus (SARS-virus) and the Middle East Respiratory Syndrome coronavirus (MERS-virus), which have both been classified as group 3 human pathogens. Other coronaviruses that are known to be pathogenic are currently classified as group 2 biological agents.

The field of infectious diseases is constantly evolving, with the identification and classification of biological agents being an ongoing activity. Following the **COVID-19** outbreak, caused by the coronavirus **SARS-CoV-2**, epidemiological research and clinical investigations are now

[1] Directive 2000/54/EC of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Council Directive 89/391/EEC), OJ L 262, 17.10.2000, p. 21.

[2] OJ L 279, 31.10.2019, pp. 54–79.

ongoing to identify and understand the virus, such as its transmission patterns, severity, clinical features and risk factors for infection. Based on the available knowledge and evidence of the new coronavirus, SARS-CoV-2 can be classified according to the risk group classification described in Directive 2000/54/EC.

2. GENERAL ASPECTS OF THE DRAFT DIRECTIVE

2.1 Annex III: Community classification

Based on the latest scientific evidence and clinical data available, SARS-CoV-2 can cause severe disease in a certain percentage of the infected population. It represents a serious hazard in particular to elderly workers and/or those with an underlying medical condition or chronic disease. While there is currently no effective prophylaxis or treatment available, considerable efforts are being made worldwide; a significant number of vaccine candidates have so far been identified and clinical trial for COVID-19 treatments are ongoing.

To gather technical and scientific views on the appropriateness of including SARS-CoV-2 in Annex III as well as its risk classification, the Commission organised an expert group meeting on 27 April 2020 with scientific experts from the Member States as well as observers from Norway, the Directorate-General for Health and Food Safety (DG SANTE), the European Centre for Disease Prevention and Control (ECDC), the World Health Organization (WHO) and the three interest groups of the tri-partite Advisory Committee on Safety and Health at Work (ACSH). Scientific experts from all Member States gave their opinions on the classification of SARS-CoV-2 (Belgium and Croatia were not present online, but provided comments in writing).

During the meeting, the experts unanimously agreed that there is a need for a technical update to Directive 2000/54/EC by adding SARS-CoV-2 to Annex III. All experts supported a risk classification of SARS-CoV-2 as a group 3 human pathogen. The experts made additional remarks, such as that attention should be given to the work carried out by non-propagative diagnostic laboratories and that it should be made possible for this work to be continued at facilities using procedures equivalent to containment level 2. This is in line with Article 16(1)(c) as well as guidance published by ECDC and WHO on laboratory biosafety guidance related to COVID-19, which various Member States are following. Further details on the remarks made by the experts can be found in the minutes of the Expert meeting. Norway, WHO, ECDC and DG SANTE also supported the classification of SARS-CoV-2 as a group 3 human pathogen in case of laboratory work involving viral propagation by culture or enrichment procedures and as a risk group 2 for non-propagative diagnostic laboratory work procedures.

Based on the suggestions put forward by experts at the meeting, and in line with Article 2 of Directive 2000/54/EC, the Commission therefore considers it appropriate to classify SARS-CoV-2 as a **risk group 3** human pathogen and that a footnote is added to the proposed SARS-CoV-2 entry in Annex III to Directive 2000/54/EC. It reads as follows:

> ‘In line with Article 16(1)(c), non-propagative diagnostic laboratory work involving SARS-CoV-2 should be conducted at a facility using procedures equivalent to at least containment level 2. Propagative work involving SARS-CoV-2 should be conducted at a containment level 3 laboratory with air pressure negative to atmosphere.’

2.2 Transposition period

In addition to the risk classification of SARS-CoV-2 and its inclusion in Annex III to Directive 2000/54/EC, and in light of the severity of the COVID-19 pandemic as well as taking into consideration the adequate level of workers’ protection, the Commission considers it appropriate to set a shorter transposition period for Member States to implement the

proposed measures. This point was also discussed at the Expert meeting of 27 April 2020 and further considered during a wide consultation process involving, amongst others, the three interest groups of the ACSH. Based on this wide consultation, a transposition period of **5 months** following the date of entry into force of the new directive is considered to be appropriate.

During the 2019 technical update, Commission Directive (EU) 2019/1833 also amended elements of **Annexes V and VI to Directive 2000/54/EC**, which lay down containment measures and levels for laboratories, animal facilities and industry. The transposition period of this directive runs until 20 November 2021.

To provide workers with the appropriate levels of protection against risks to their health and safety from exposure to SARS-CoV-2, the Commission proposes to adjust, and solely as regards exposure to SARS-CoV-2, the date of transposition of the relevant elements updating Annexes V and VI. The purpose of this adjustment is to align it with the inclusion of SARS-CoV-2 in Annex III. This thus means that a transposition period of **5 months**, following the date of entry into force of the new directive, will also apply to the implementation of the updated elements applicable to SARS-CoV-2, of the containment measures set out in Annexes V and VI and as amended by Commission Directive (EU) 2019/1833.

3. LEGAL BASIS, CONSULTATION AND PROCEDURE

3.1 Legal basis

The legal basis of the draft Directive is Article 153(2) of the Treaty on the Functioning of the European Union and Article 19 of Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work.

This Directive is an instrument of the EU's action in the field of the control of occupational risks arising from exposure to biological agents at work.

It is adopted in accordance with the procedure provided for in Article 17 of Council Directive 89/391/EEC (regulatory procedure with scrutiny) in order to take account of technical progress and new findings. It is designed to amend non-essential elements of the Annexes to Directive 2000/54/EC.

3.2 Consultation process

The preparation and adoption of this draft Directive has entailed extensive consultation with the relevant stakeholders.

While drawing up the draft measures, the Commission was thus assisted by experts representing the 27 Member States, who provided technical and scientific support, as well as representatives from Norway, DG SANTE, ECDC, WHO and the three interest groups of ACSH.

The Commission also consulted the ACSH, consisting of representatives of the three interest groups (governments, employers and workers), which discussed the draft measures during the Bureau meeting on 29 April 2020. The ACSH Bureau issued a statement on the technical update of the above-mentioned Directive on 29 April 2020.

Finally, the draft measures were also put forward during an interservice consultation (ISC) process with relevant Directorates General of the European Commission.

3.3 Procedure: Technical Progress Committee

Taking into account the latest technical progress and recent findings, the technical update of Directive 2000/54/EC is adopted in accordance with the procedure provided for in Article 17

of Council Directive 89/391/EEC (regulatory procedure with scrutiny). This procedure is designed to amend non-essential elements of Annex III to Directive 2000/54/EC.

Given the urgency of the matter (the outbreak of COVID-19 caused by SARS-CoV-2), the urgency procedure of the regulatory procedure with scrutiny will be used, to which Articles 17(1) and (3) of Council Directive 89/391/EEC refer. The details of the procedure are laid down in particular in Article 5a(6) of Council Decision 1999/468/EC. Under this procedure, the Commission is assisted by the Technical Progress Committee (TPC), composed of representatives of the Member States. Accordingly, the draft Commission Directive to update Annex III to Directive 2000/54/EC will be discussed during a meeting of that committee, which is planned for 14 May 2020.

During the meeting, the representatives of the Member States to the Technical Progress Committee meeting need to hold a corresponding mandate to vote on the opinion on the technical update. If the Committee agrees with the draft measures at the meeting, the Commission will adopt them and they will be implemented immediately. The Commission will communicate them without delay to the European Parliament and to the Council. They have 1 month to reject the measures on a limited number of grounds. If they oppose, the Commission will repeal the measures. However, it may keep the provisional measures if need be for health protection reasons. In that case, it must submit an amended text to the Committee without delay. The provisional measures will then remain applicable until the definitive instrument is adopted.