



**2020/2672(RPS)**

11.6.2020

# DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 112(4) of the Rules of Procedure

on the 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 (D067174/03 – 2020/2672(RPS))

## **Committee on Employment and Social Affairs**

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**B9-0000/2020**

**European Parliament resolution on the 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 ((D067174/03 – 2020/2672(RPS))**

*The European Parliament,*

- having regard to 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<sup>1</sup>,
- 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<sup>2</sup>, and in particular Article 19 thereof,
- having regard to Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work<sup>3</sup>,
- having regard to the opinion delivered on 14 May 2020 by the committee referred to in Article 17 of Directive 89/391/EEC,
- having regard to point (b) of Article 5a(6) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>4</sup>,
- having regard to Rule 112(2), (3) and (4)(c) of its Rules of Procedure,

***EU principles***

- A. whereas in accordance with Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities;
- B. whereas Principle 10 of the European Pillar of Social Rights, proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to a healthy, safe and well-adapted working environment, whereas workers' right to a high level of protection of their health and safety at work and to a working environment that is adapted to their professional needs and that enables them to prolong their participation in the labour market includes protection from exposure to biological agents at work;

***The COVID-19 pandemic***

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<sup>1</sup> OJ L 175, 4.6.2020, p. 1.

<sup>2</sup> OJ L 262, 17.10.2000, p. 21.

<sup>3</sup> OJ L 183, 29.6.1989, p. 1.

<sup>4</sup> OJ L 184, 17.7.1999, p. 23.

- C. whereas on 11th March 2020 the World Health Organization (WHO) declared the COVID-19 outbreak to be a pandemic;
- D. whereas from 31 December 2019 until 8 June 2020, 1 143689 cases of COVID-19 were reported in the Union, including 128107 deaths; whereas, although the peak of the outbreak has passed in several Member States, the numbers of people infected with COVID-19 and the number of deaths registered continue to increase on a daily basis<sup>5</sup>;

***Classification in groups 3 and 4 under the Biological Agent Directive: criteria***

- E. whereas point (a) of the first paragraph of Article 2 of Directive 2000/54/EC provides for a definition of ‘biological agents’ and the second paragraph of that Article classifies biological agents into four risk groups, according to their level of risk of infection and on the basis of criteria laid down in that Directive;
- F. whereas according to point 3 of the second paragraph of Article 2 of Directive 2000/54/EC, a biological agent in risk group 3 means one that can cause severe human disease, that can present a serious hazard to workers, that may present a risk of spreading to the community but for which there is usually effective prophylaxis or treatment available;
- G. whereas according to point 4 of the second paragraph of Article 2 of Directive 2000/54/EC, a biological agent in group 4 means one that causes severe human disease, that is a serious hazard to workers, that may present a high risk of spreading to the community and for which there is usually no effective prophylaxis or treatment available;
- H. whereas Article 18(3) of Directive 2000/54/EC provides that if a biological agent to be assessed cannot be classified clearly in one of the four groups defined in the second paragraph of Article 2, it must be classified in the highest risk group among the alternatives;
- I. whereas the assessment of a biological agent must be based on all criteria in a balanced and weighted manner; whereas no standalone criterion should be singled out as a determining factor with more weight than that provided for in the legislation;
- J. whereas a classification as a group 4 biological agent entails in consequence that:
- according to Article 10(1) of Directive 2000/54/EC, employers are required to provide written instructions and, if appropriate, display notices for workers handling a group 4 biological agent,
  - according to Article 13(1) of Directive 2000/54/EC, prior notification is to be made to the competent authority of the use for the first time of each subsequent group 4 biological agent,
  - according to point (b) of Article 16(1) of Directive 2000/54/EC, the handling of a group 4 biological agent in laboratories must be carried out only in working areas

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<sup>5</sup> Source: ECDC

corresponding to at least containment level 4;

- K. whereas the third paragraph of Annex VI to Directive 2000/54/EC, which provides for containment for industrial processes, provides for groups 2, 3 and 4 biological agents that it may be appropriate to select and combine containment requirements from different categories on the basis of a risk assessment related to any particular process or part of a process; whereas Annex V to Directive 2000/54/EC, which relates to indications concerning containment measures in laboratories, provides in its first paragraph that the measures contained in that Annex are to be applied according to the nature of the activities, the assessment of risk to workers, and the nature of the biological agent concerned;
- L. whereas according to point 6 of Annex III to Directive 2000/54, the list of classified biological agents reflects the state of knowledge at the time that it was devised, and is to be updated as soon as it no longer reflects the latest state of knowledge;
- M. whereas Annex I to Directive 2000/54/EC sets out an indicative list of activities referred to in Article 4(2) of the Directive and includes, in points 4 and 5, work in healthcare and work in clinical, veterinary and diagnostic laboratories; whereas the first paragraph of Annex I to Directive 2000/54/EC provides that where the results of the risk assessment show an unintentional exposure to biological agents, there may be other work activities, not included in that Annex, which should be considered;

### ***Classification of SARS-CoV-2***

- N. whereas in Directive (EU) 2020/739 of 3 June 2020, the Commission decided as a matter of urgency to add SARS-CoV-2, the enveloped RNA coronavirus that causes COVID-19, to Annex III to Directive 2000/54/EC in order to ensure the continued adequate protection of workers' health and safety at work but classified it as a risk group 3 human pathogen;
- O. whereas infections of SARS-CoV-2 have been proven to be a full-body assault, causing damage well beyond the respiratory system<sup>6</sup>; whereas new infections of SARS-CoV-2 were confirmed in previously infected patients who had recovered and were clear of the virus<sup>7</sup>;
- P. whereas people of all ages can be infected with SARS-CoV-2; whereas older people and people with pre-existing conditions (such as cardiovascular disease, diabetes and cancer) appear to be the most at risk of fatal consequences or of becoming severely ill as a result of SARS-CoV-2 infections; whereas there have been cases of people of all age groups with no pre-existing illness, including young people<sup>8</sup> who died or suffered severe health problems or damage as a result of SARS-CoV-2 infections;
- Q. whereas, in addition to respiratory sequelae, such as lung fibrosis, severe COVID-19 may lead to cardiovascular sequelae, such as myocardial injury, arrhythmias,

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<sup>6</sup> The Great Invader: How COVID-19 Attacks Every Organ - *Medscape* - Apr 23, 2020

<sup>7</sup> Source: <https://www.reuters.com/article/us-health-coronavirus-southkorea/south-korea-reports-more-recovered-coronavirus-patients-testing-positive-again-idUSKCN21V0JQ>

<sup>8</sup> Severe Disease Not Uncommon in Kids Hospitalized With COVID-19 - *Medscape* - May 27, 2020

cardiomyopathy and heart failure<sup>9</sup>;

- R. whereas transmission of SARS-CoV-2 occurs through droplets, aerosols, and, possibly, the oral–fecal or fecal–droplet route<sup>10</sup>; whereas available studies also show that SARS-CoV-2 can be detected in the air, up to three hours after aerosolisation<sup>11</sup> and can survive for hours or days on surfaces and objects, depending on the material from which they are made<sup>12</sup>; whereas persons can therefore also catch SARS-CoV-2 infections by touching their mouth, nose, or eyes after touching such contaminated surfaces or objects<sup>13</sup>;
- S. whereas SARS-CoV-2 can also be transmitted from infected persons when they are prodromal (namely, before the onset of symptoms) or asymptomatic (namely, when they are infected but symptoms never develop)<sup>14</sup>; whereas SARS-CoV-2 transmission in the absence of symptoms reinforces the value of adopting the highest precautionary and protective measures in order to minimise the risk of spreading SARS-CoV-2 by infected persons who are infectious but do not exhibit symptoms;
- T. whereas new analyses indicate that SARS-CoV-2 have a reproduction number (the average number of secondary infections produced by a single infectious case in a population where everyone is susceptible and used to measure the transmission potential of a communicable disease) higher than SARS-CoV-1 and is thus more infectious than SARS-CoV-1<sup>15</sup>; whereas super-spreading events (when few infected persons have been responsible for a disproportionate number of transmissions) have been reported<sup>16</sup>;
- U. whereas COVID-19 is the first new occupational disease to be described in this decade; whereas increasing data confirmed that the workplace is an essential vector of contagion<sup>17</sup> and that the levels of mortality and of severe morbidity in the age group 20

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<sup>9</sup> <https://www.ecdc.europa.eu/en/2019-ncov-background-disease>

<sup>10</sup> Gupta S, Parker J, Smits S, Underwood J, Dolwani S. Persistent viral shedding of SARS-CoV-2 in faeces - a rapid review [published online ahead of print, 2020 May 17]. *Colorectal Dis.* 2020;10.1111/codi.15138. doi:10.1111/codi.15138

<sup>11</sup> Bahl P, Doolan C, de Silva C, Chughtai AA, Bourouiba L, MacIntyre CR. Airborne or droplet precautions for health workers treating COVID-19? [published online ahead of print, 2020 Apr 16]. *J Infect Dis.* 2020;jiaa189. doi:10.1093/infdis/jiaa189

<sup>12</sup> Fiorillo, L.; Cervino, G.; Matarese, M.; D'Amico, C.; Surace, G.; Paduano, V.; Fiorillo, M.T.; Moschella, A.; La Bruna, A.; Romano, G.L.; Laudicella, R.; Baldari, S.; Ciciù, M. COVID-19 Surface Persistence: A Recent Data Summary and Its Importance for Medical and Dental Settings. *Int. J. Environ. Res. Public Health* 2020, *17*, 3132.

<sup>13</sup> Lotfi M, Hamblin MR, Rezaei N. COVID-19: Transmission, prevention, and potential therapeutic opportunities [published online ahead of print, 2020 May 29]. *Clin Chim Acta.* 2020;508:254-266. doi:10.1016/j.cca.2020.05.044

<sup>14</sup> Mohammadi M, Meskini M, do Nascimento Pinto AL. 2019 Novel coronavirus (COVID-19) overview [published online ahead of print, 2020 Apr 19]. *Z Gesundh Wiss.* 2020;1-9. doi:10.1007/s10389-020-01258-3

<sup>15</sup> Viceconte G, Petrosillo N. COVID-19 R0: Magic number or conundrum?. . 2020;12(1):8516. Published 2020 Feb 24. doi:10.4081/idr.2020.8516

<sup>16</sup> *ibid.*

<sup>17</sup> Koh D. Occupational risks for COVID-19 infection. *Occup Med (Lond).* 2020;70(1):3-5. doi:10.1093/occmed/kqaa036

to 64 are strongly correlated with occupational factors<sup>18</sup>; whereas SARS-CoV-2 has caused severe and fatal diseases at a larger scale in the Union than most other biological agent included in the list of Annex III to Directive 2000/54/EC;

- V. whereas very high levels of contagion and fatality rates have been registered among workers and professionals in the healthcare sector<sup>19</sup>; whereas several other occupations or sectors have been identified as highly affected by COVID-19, such as workers in the food-processing, retail, cleaning and transport sectors; whereas frontline workers are often women and are often low paid, and not protecting them entails a huge social inequality; whereas infected workers who are generally in contact with the public have contracted SARS-CoV-2 and have played a major role in disseminating SARS-CoV-2 infections; whereas workplace clusters have contributed to a high risk of spreading to the community<sup>20</sup>;
- W. whereas SARS-CoV-2 is causing severe and fatal diseases among healthy workers with no pre-existing diseases according to national statistics on the age group 16 to 64<sup>21</sup>;
- X. whereas in recital 6 of Directive (EU) 2020/739, the Commission explicitly states that there is no vaccine or effective treatment currently available for SARS-CoV-2 infections;
- Y. whereas social distancing, disinfection and protective equipment could be considered to be elements of prophylaxis but do not necessarily qualify as an overall effective prophylaxis, but rather as part of a delaying strategy that aims to slow down the spread of SARS-CoV-2 to ensure that seriously ill people can continue to receive optimal treatment and that Member States' health services are not overburdened<sup>22</sup>; whereas a vaccine could qualify as truly effective prophylaxis considering the nature of SARS-CoV-2;
- Z. whereas, in general, many factors complicate efforts to calculate a case fatality rate while an outbreak is still evolving;
- AA. whereas, in the case of SARS-CoV-2, due to limited testing capacity, underreporting and operational shortcomings of various Member States in clarifying whether people who died with symptoms of COVID-19 were previously infected or not, it is possible that the currently reported numbers of deaths and infections are an underestimation of the real overall impact of SARS-CoV-2 in the Union;
- AB. whereas, as SARS-CoV-2 emerged recently (end of 2019), there is still limited and uncertain scientific knowledge on its overall consequences on human health, including

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<https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/causesofdeath/bulletins/coronaviruscovid19relateddeathsbyoccupationenglandandwales/deathsregistereduptoandincloding20april2020>

<sup>19</sup> Source: Hoe Gan W, Wah Lim J, Koh D. Preventing intra-hospital infection and transmission of COVID-19 in healthcare workers [published online ahead of print, 2020 Mar 24]. *Saf Health Work*. 2020;10.1016/j.shaw.2020.03.001. doi:10.1016/j.shaw.2020.03.001

<sup>20</sup> <https://polandin.com/48064594/miners-in-covid19struck-silesia-undergo-mass-testing>

<sup>21</sup> <https://covid-19.sciensano.be/fr/covid-19-situation-epidemiologique>

<sup>22</sup> Kähler, Christian & Hain, Rainer. (2020). Flow analyses to validate SARS-CoV-2 protective masks About distance rules, mouth-nose protection, particle filtering respiratory protection, filter materials and mask manufacturing.

in the long term; whereas there is growing evidence of the long-term health impacts of SARS-CoV-2 on persons infected, including kidney failure, inflammation of the heart muscle and arrhythmias, liver damage, cognitive impairment, psychosis and mood disorder, and will need treatments for the rest of their lives;

AC. whereas it is in particular still unclear from a scientific viewpoint whether SARS-CoV-2 is capable of lying dormant in the body for many years (as is the case of some other enveloped RNA viruses) and revive back in a different form, thus possibly continuing to seriously affect human health in the future;

AD. whereas coronaviruses have high mutation rates<sup>23</sup>;

### ***Laboratories***

AE. whereas the WHO Extended Biosafety Advisory Group (BAG) repeatedly recommended revising the WHO Laboratory Biosafety Manual (LBM) (third edition) adopted in 2004, considering its revision to be both a necessity and a priority in order to take into full account the most advanced technologic and scientific developments in such a fast-evolving field; whereas the WHO never revised its LBM and in its Laboratory biosafety guidance related to coronavirus disease (COVID-19), interim guidance, of 13 May 2020, it took as a reference its outdated LBM; whereas in recital 7 of Directive (EU) 2020/739, in order to establish the biosafety level for SARS-CoV-2 related propagative and non-propagative diagnostic laboratory work, the Commission took as a benchmark the WHO Laboratory biosafety guidance related to coronavirus disease (COVID-19) delivered on 19 March 2020 which is, in turn, affected by the outdated prescriptions of the WHO LB (third edition) dated 2004;

### ***Procedural considerations***

AF. whereas the Commission fixed a transposition period of five months for Member States to implement Directive (EU) 2020/739;

AG. whereas in accordance with Article 5a(6) of Decision 1999/468/EC in the event of opposition by the European Parliament or the Council, the Commission must repeal Directive (EU) 2020/739; whereas if warranted on health protection, safety or environmental grounds the Commission may however provisionally maintain the directive in force until it is replaced by a definitive instrument; whereas in that event the Commission must without delay submit a new draft instrument on the basis of the TFEU;

1. Opposes Directive (EU) 2020/739;
2. Considers that Directive (EU) 2020/739 is not compatible with the aim and the content of Directive 2000/54/EC;
3. Underlines the lack of effective prophylaxis or treatment for COVID-19 and that point 6 of Annex III to Directive 2000/54/EC provides that the list of classified biological

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<sup>23</sup> Cui J, Li F, Shi Z-L. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol. 2019;17(3):181–192.

agents is to reflect the state of knowledge at the time that it was devised;

4. Believes that, in light of the precautionary principle, given the absence of effective prophylaxis or treatment for SARS-CoV-2 and the little and uncertain scientific knowledge on its overall consequences on human health, which prevents its clear classification in risk group 3, SARS-CoV-2 would be more correctly classified in risk group 4 in order to ensure the highest possible levels of protection of workers' health and safety, minimising the risks of further infections and deaths, and a possible second wave of infections;
5. Considers that the classification of SARS-CoV-2 in risk group 4 is further corroborated by the requirement laid down in Article 18(3) of Directive 2000/54/EC, which requires a biological agent to be classified in the highest risk group among the alternatives, if it cannot be classified clearly in one of the groups defined in the second paragraph of Article 2;
6. Highlights the fact that the transposition period of five months for Member States to implement the Directive is not in line with the very high risks to human health posed by SARS-CoV-2 and the urgent need to ensure the rapid adoption of the highest levels of precautionary and protective measures in all workplaces; calls on the Commission to provide for a shorter transposition period in its new draft instrument;
7. Underlines the paramount importance of implementing the most stringent precautionary and protective measures in all workplaces, carefully assessing all risks related to the nature, degree and duration of workers' exposure to SARS-CoV2 in order to prevent another increase of the number of infections, the impact of which could result in additional devastating social and economic consequences in the whole Union; recalls the fact that workers have the right to the best available protection and should not unnecessarily put their life and health on the line;
8. Highlights that the strongest protection of all workers in contact with the public, including workers and professionals in the healthcare sector, is essential to ensure the highest levels of health and safety in all work environments and it is crucial for the activation of key mechanisms to reduce possible SARS-CoV-2 transmission, morbidity and mortality in the general population;
9. Stresses that Member States must ensure adequate financial support for microenterprises, small and medium-sized enterprises, taking into full account possible additional operational and administrative costs for them arising from the adoption of the most stringent precautionary and protective measures in all workplaces related to the classification of SARS-CoV-2 in risk group 4;
10. Recalls that the classification of SARS-CoV-2 in risk group 4 would give the right to written workplace instructions and display notices; stresses that written instructions provide for a higher level of protection of particularly vulnerable workers; considers it to be important that workers exposed to SARS-CoV-2 are provided with written instructions, whether they are intentionally or unintentionally exposed;
11. Insists that the Commission when defining laboratory biosafety levels for SARS-CoV-2 related propagative and non-propagative diagnostic laboratory work must ensure an assessment based on the most recent and advanced technologic and scientific

developments going beyond the prescriptions of the WHO Laboratory biosafety guidance related to coronavirus disease (COVID-19), interim guidance, of 19 March 2020, which is affected by the outdated prescriptions of the WHO LBM (third edition) dated 2004;

12. Highlights the fact that Directive 2000/54/EC and its annexes V and VI provide flexibility when public health needs justify an adaptation of specific measures; stresses that Parliament aims to combine the highest available protection of workers while maintaining the functioning of laboratories in the combat of SARS-CoV-2;
13. Stresses that once a vaccine and/or medical treatments have been found and sound new scientific data shows their efficacy for the protection of human health, a revision of the classification of SARS-CoV-2 can take place;
14. Calls on the Commission in close cooperation with the legislators and the social partners to assess whether Union health and safety legal acts are adequate to provide the highest available protection for workers in pandemic situations, and if necessary to revise the legal acts accordingly;
15. Calls on the Commission to repeal Directive (EU) 2020/739 and to submit a new draft instrument to the Committee without delay;
16. Calls on the Commission to provisionally maintain Directive (EU) 2020/739 in force until it is replaced by a definitive instrument in accordance with Article 5a(6) of Decision 1999/468/EC as this is warranted on health protection and safety grounds; calls on the Member States to transpose Directive (EU) 2020/739 while it remains in force provisionally
17. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.