

The aim of this Brief is to shed light on the EC's decision to amend Annex III to the Biological Agents Directive<sup>1</sup> (BAD) to include SARS-CoV-2 and provide a detailed overview on why such biological hazard should be classified as belonging to Group 4.

## 1. Timeline

This brief timeline highlights the most salient events within the past month that culminated in the EC's decision to classify SarsCov2 as a mid-level hazard (Group 3) within the framework of the Biological Agents Directive 2000/54/EC.

- 27 April: National experts gather in an online meeting (Social partners were invited as observers).
- 29 April: Bureau meeting of the tripartite Advisory Committee.
- During the first week of May, the Commission adopted a draft proposal which was communicated to the Technical Progress Committee (TPC) of Member States.
- 13 May: the French newspaper *Le Monde* disclosed the EC's draft proposal<sup>2</sup> (the Commission did not share the document with the social partners in the tripartite Committee and refused to disseminate it to journalists).
- 14 May: the TPC adopted the draft proposal with minor modifications, such modifications were not communicated to the social partners.
- 20 May: EMPL Committee Meeting on the classification of SarsCov2. Mr Olsson (DG EMPL) presented the views of the Commission.
- 28 May: Commissioner for Jobs and Social Rights, Nicolas Schmit sent a letter to De Sutter (BE, Greens), Jongerius (NL, S&D) and other MEPs.
- 29 May: EC answers to questions of the MEPs.

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<sup>1</sup> <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32000L0054>

<sup>2</sup> [https://www.lemonde.fr/planete/article/2020/05/13/la-commission-propose-une-evaluation-controversee-de-la-dangerosite-du-coronavirus\\_6039557\\_3244.html](https://www.lemonde.fr/planete/article/2020/05/13/la-commission-propose-une-evaluation-controversee-de-la-dangerosite-du-coronavirus_6039557_3244.html)

- 3 June: EC adopts the Directive amending Annex III to Directive 2000/54/EC to include SARS-CoV-2 and classifies such biological agent in group 3.

## **2. The Precautionary Approach**

Article 2 of the 2000/54/EC directive reflects a precautionary approach. Some of the criterion laid out in the article could justify the classification in group 3, others in group 4.

Article 18§3 further reflects such a precautionary approach as it states:

*If the biological agent to be assessed cannot be classified clearly in one of the groups defined in the second paragraph of Article 2, it must be classified in the highest risk group among the alternatives.*

In case of doubts, we should, therefore, adopt the highest risk category. Such requirement is legally binding for the Commission in its delegated competence.

In 1997, after the outburst of the Bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, the Commission applied a precautionary principle. BSE was classified as a hazardous agent belonging to group 3 by the Commission (Directive 97/65/EC)<sup>3</sup> although there were different criteria which could justify the insertion in Group 2. Point 2 of the Annex to Directive (97/65/EC) explicitly mentions the need to adopt a precautionary approach.

## **3. Workers' protection is the key for determining the risk group**

The BAD is not about public health. It is instead, a Directive with the precise aim of protecting workers from risks related to exposure to biological agents at work, it is therefore an OSH Directive. This implies that scientific documentation must be interpreted on the basis of OSH. General public health arguments are not sufficient in this case. However, the EC has repeatedly handpicked scientific documentation solely considering the effects of SARS-CoV-2 on the general population.

When the Commission opted for Group 3, at the very end of April, there was already ample evidence on the following elements:

- a) Work is (and was) a crucial vector of contamination among the working-age group 20-64. Data deriving from various EU countries (mainly Italy, Spain, France, Germany and the UK) clearly shows that contagion in workplaces is soaring.
- b) Differences between occupational/sectoral groups in the morbidity and mortality statistics were highly visible (most of the data came first from the healthcare sector,

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<sup>3</sup> <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31997L0065>

at a later stage, data shows also the high risk in other occupational sectors such as bus drivers, meat industry, retail, specifically in supermarkets, and others).

- c) Public health policies differ among Member States; however, all had a common denominator: the concern that workplace had to be considered at a very high-risk level and have thus imposed the forces closure of non-essential economic activities. Such policy initiatives have been unprecedented in the history of our Union, never have workplaces had to cease their activities due to a pandemic.

Further scientific evidence has consolidated the above-mentioned preliminary findings. Although we still lack the precise figures on the spread of the virus for each occupational sector. It is of no doubt that SARS-CoV-2 has been the most serious occupational health threat caused by a biological agent for the working age group 20-64, since the adoption of the BAD in 1990. The level of risk (measured by the number of exposed workers, the seriousness of diseases, and the high risk of spreading to the community) is certainly higher for SARS-CoV-2 than for the entire list of biological agents which are presently classified in Group 4 (see for example the report of Prof. Jean-Pierre Unger <sup>4</sup>).

#### **4. The argument on risk groups**

In the written answers to the question of the EP, the Commission has argued (pg. 6) that “data shows that a significant percentage of all deceased suffered from co-morbidities such as obesity, coronary heart disease, asthma, type 2 diabetes, peripheral arterial or neurodegenerative diseases. This is important to consider as the classification of the biological agents in Annex III is based on the effect of the agent on healthy workers (see introductory note 2 of Annex III)”.

However, this argument is biased. Scientific research indicates that there is a correlation between co-morbidity factors and fatal cases. By no means this entails that co-morbidity should be considered as a precondition for severe and fatal cases of COVID-19. On such point, the WHO has been categorical. The risk is higher for those with chronic diseases <sup>5</sup>. However, the risk is still high for adults without underlying medical conditions. Data from Belgium<sup>6</sup> for example, shows that for serious cases (i.e. hospitalized patients) in the age group 16-44, 72,4% and in the age group 45-64, 42,4% of cases was not associated with any co-morbidity factor. Only in the age group above 65, co-morbidity is highly associated with serious disease due to COVID-19 (about 89%). The data from Belgium is statistically significant as it is based on over 14,000 cases, with more than 5000 cases between the ages of 16 and 64.

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<sup>4</sup> <https://www.efbww.eu/stream/4b222e24-fc0a-4d34-b159-2d7988bea85e>

<sup>5</sup> [https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200311-sitrep-51-covid-19.pdf?sfvrsn=1ba62e57\\_10](https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200311-sitrep-51-covid-19.pdf?sfvrsn=1ba62e57_10)

<sup>6</sup> <https://covid-19.sciensano.be/fr/covid-19-situation-epidemiologique>

The Commission is thus misusing statistics on the general population without taking into account the categories of age which should be relevant for a workers' protection legislation. Data from Spain and Italy, with regards to morbidity and mortality in the healthcare sector has demonstrated that a significant number of workers have died or suffered the severe consequences of COVID-19. For most workers, no co-morbidity factor was established. We know by experience that the healthcare staff tends to be healthier than the average population of the same age and sex (in epidemiology, this is called the healthy worker effect). This means that data from occupational groups should be considered as even more alarming due to the comparatively better health of the workforce in the health care sector.

Data from the UK has shed light on another alarming aspect of SARS-CoV-2, Black, and minority ethnic (BME) groups have been hit the hardest by the virus, demonstrating that there is a very strong social health inequality attached to COVID-19. The interpretation of such data cannot be reduced to the working conditions alone as we must also consider housing conditions, access to public health, in-work-poverty and other non-work-related factors. However, BME workers are disproportionately working in the emergency occupations (often with precarious forms of work) with high levels of proximity.

## **5. The argument of “no practical difference”**

The Commission accepts that the scope of application of the BAD is covering all the workers exposed to biological agents (although this is not entirely true as domestic workers are not covered by the Directive).

The Commission has repeatedly used the rhetoric that entails that for most of the workforce, there is “no practical difference”. However, there is an omission in the Commission’s answers. Article 10§1-b of the directive states that there *is* a difference. It requires “written instructions” in case of “handling a group 4 biological agent”. In the case of Group 4, individuals who are handling the agent must receive written instructions. To illustrate, in the case of people working for testing the population (meaning the entire chain, from testing to the laboratory where the analysis will take place). Workers should receive written instructions on how to protect themselves and how to handle the agent correctly. In the case of Group 3, there is no obligation with regards to written instructions.

## **6. The argument of “no flexibility”**

The Commission has reiterated in the answers to the questions submitted by the European Parliament that, if Group 4 is adopted, there is no flexibility regarding the rules of Annex VI.

We believe this argument not to be truthful. The implementation of legislation can perfectly modify the wording of any Annex and introduce, if needed, new flexibility clauses. The last

modification of BAD in October (Directive 2019/1833<sup>7</sup>), modified the different Annexes simultaneously. Such an option, meaning the modification of the Annexes, should have been considered and proposed to the experts, the social partners and Member States. Instead, the EC has continuously repeated that the classification in Group 4 of COVID-19 would have dramatic consequences on the production of a vaccine and other public health needs.

In sum, if there is any concern regarding the lack of flexibility in Annex V or Annex VI, specific adaptations can be introduced by the same Act under which SARS-CoV-2 will be classified. The reluctance of the Commission is instrumental and should not be regarded as a legal argument.

## **7. Transparency, social partners' consultation and democracy**

Considering the three events (as per the Timeline in Section 1 in the present Brief): Mr Olsson's intervention in the EMPL Committee Meeting on May 20, Mr Schmit's letter on May 28 and the EC's answers on May 29, we strongly believe that the Commission is building an *a posteriori* justification of the process.

On May 20, the debate on the substantial aspects was refused. The Commission blamed the "misrepresentation" by journalists and centered the arguments on risk management issues. Apparently, there was virtually no room for discussion since the experts "unanimously agreed". On May 28, Commissioner Schmit gave more details on the substance of the argument sustaining the classification in Group 3. On May 29, the Commission provides us with more information. Although, this may be regarded as a step forward as it shows a higher degree of democratic control of the decision-making process, we still have to remember that prior to May 20 the process was completely obscure. In our opinion, the oral and written questions that the Members of the EP have demanded from the EC mark an important step forward in guaranteeing transparency and accountability in the democratic process. However, there are still many aspects on which the EC should shed some light.

The lack of transparency and background documentation is not a mere procedural technicality. We need full transparency in order to understand what has been asked to the experts. We know from experience (see for example the case on Glyphosate), that questions to the experts can be asked with a lingering bias without fully explaining the legal implications of the entirety of the articles included in BAD. The EC is legally bound to respect the BAD in the implementing legislation process, in such, Article 18 §3 is a key element for providing an answer.

Finally, the main argument put forward by the EC for the insertion of COVID-19 in Group 3 and not in Group 4 has been informed by risk management measures. This impression is supported

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<sup>7</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019L1833>

by Annex II of the EC's answers: most of the addendums are not related to the risk level for the entire workforce. Instead, they contain very specific provisions for scientific laboratories.

## 8. Main Takeaway Points

- The precautionary approach laid out in Article 18§3. In case of doubt, the highest risk category should and must be applied.
- The need to avoid double standards between the level of protection of workers and the level of protection for the general population.
- The fact that any worker who has been affected (even if asymptomatic) could transmit the disease to other individuals. This is not a theoretical argument. It has been documented in the USA in slaughterhouses<sup>8</sup> and in Poland in the mining industry<sup>9</sup>. Clusters appeared at the workplace and spread the disease to the community.
- The lack of transparency. Without the EP's intervention, the Commission would have never explained how the process was organized. In a completely unprecedented case such as the current COVID crisis, full transparency from the public authority must be at the forefront in order to obtain the support from the population. In addition, the role of the Parliament is crucial for maintaining a democratic balance of power.

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<sup>8</sup> <https://www.theguardian.com/world/2020/may/02/meat-plant-workers-us-coronavirus-war>

<sup>9</sup> <https://www.climatechangenews.com/2020/05/12/covid-19-outbreak-polish-coal-mines-heaps-pain-struggling-sector/> and <https://www.mining-technology.com/uncategorised/83-of-new-polish-covid-19-cases-hit-mining-heartland-silesia/>