european trade union institute

# Classification of the SARS CoV2 (the Covid-19 virus) in the Biological Agents Directive: group 3 or 4?

## Introduction

This note draws your attention to a pressing and highly sensitive issue. Due to the COVID-19 outbreak, occupational safety and health (OSH) prevention needs to be strengthened. The Commission has thus decided to revise the Biological Agents Directive (BAD, 2000/54/EC) on the protection of workers from risks related to exposure to biological agents at work and include COVID-19.

In the directive, biological agents are listed and ranked in four groups from the lowest danger (group 1) to the highest (group 4). All stakeholders have agreed that that SARS CoV2 must be included as hazardous biological agent in this directive. The conflictive issue regards the classification. The ETUC has vocally supported the option to introduce SARS CoV2 in the highest risk group, group 4. This is based on clear legally binding criteria that can be found in Article 2 of the Directive (you can find more details in the annex to this letter).

However, on Thursday 14th of May, the European Commission under the recommendation of the Technical Progress Committee (TPC) that is composed by national experts has decided not to classify COVID-19 in the highest risk group of biological agents. The TPC, that has informed the EC's decision is composed of highly regarded Public Health experts, however such experts reason at the basis of statistics that apply to the general population. The classification of COVID-19 in the 2000/54/EC Directive, however, regards workers.

Specific workers, such as *inter alia*, healthcare professionals, have been severely exposed to COVID-19, a lot more exposed than the general population. This is why, in our opinion, a Public Health lens when determining the danger of COVID-19 on the workplace cannot be adopted. In addition, due to the complete lack of transparency it is unclear what criterion such experts have applied in determining the level of hazard level for COVID-19 on the workplace. The decision of the EC has been proposed as a merely 'technical' decision. However, politically, a classification which categorises SARS-CoV2 as a mid-level hazard sends an inadequate message as regards the priority to be given to occupational health policies while national governments are progressively easing the more stringent measures and economic activities are resuming. Finally, we would also like to stress the lack of transparency and breach in the

democratic process that this decision has entailed, and we thus request an action on behalf of the EP. The Commission has neglected to consult not only the social partners, but also EP and their Members on a decision that will impact all workers in the European Union and will have a defining long-term effect on occupational health and safety legislation.

The COVID-19 crisis is Europe's most serious health crisis since the Second World War. The European Union should thus have a decisive role in protecting all workers. By adequately protecting the workers, the EU could contribute to a balanced exit strategy. Preliminary research depicts a dramatic image on the effects of COVID-19 on the world of work, resulting in important health social inequalities. Workers in the frontline include a lot more women than men and also include many professions that are among the more precarious ones, like for example cleaners. To illustrate, in Spain, according to the data provided by the Instituto Carlos III, COVID-19 is very clearly an occupational risk in the healthcare sector. The analysis conducted in early May shows that around 31,000 professionals, of which, 23,178 are women have been infected due to the lack of effective personal protective equipment. Another study conducted by the University of Antwerp, UHasselt and KU Leuven, shows that in Belgium, 51% of the participants in the study who received a COVID-19 diagnosis have a strong suspicion or certainty that they have contracted the infection at work. The very heavy price paid by female workers as well as workers in precarious jobs in all phases of the crisis cannot be overlooked.

With regards to risk management, the challenge is to combine a high level of protection for workers and to secure the activities linked with the pandemic situation. We are fully aware that we need flexibility. But a balanced solution means that the level of danger is recognized (inclusion of SARS Cov2 in group 4) and all the possible risk management measures of protection are adopted. We would like to stress that the classification in group 4 does not affect the return to work and the Directive does not ban any activity independently from the classification in a specific group. The classification means that employers have to take into account the relevant information in the risk assessment.

To conclude, we believe that the classification in group 3 represents a serious symbolic attack on the world of work. As citizens, we have been asked to give up fundamental freedoms. As workers, we are told that we are exposed merely to a medium-level biological risk.

## 1) Background: Directive 2000/54/EC

The Directive is based on three pillars, an approach commonly taken in European occupational health legislation.

a) Classification based on characteristics specific to each biological agent as set out in Annex III to the Directive. This classification was amended by Commission Directive 2019/1833 which must be transposed into national law by 20 November 2021 at the latest. It is based on a scale with four levels, ranging from group 1 (where the hazard to humans is considered non-existent) to group 4 (the highest level of hazard).

Such classification may not, under any circumstances, be linked to risk-management considerations, whether this is due to technical impossibility in one field or high cost in another.

In this respect, a comparison should be made with chemical risks, where the enhanced health and safety measures set out in the Carcinogens Directive play no role at all in the harmonised European classification scheme. The difference is of a different kind. For chemicals, no classification is set out in the occupational health rules. Consequently, the resulting consequences for the protection of public health and for occupational health are not addressed in the same legislative instrument. However, European law takes account of an intrinsic hazard of a certain level which requires, in all sectors, measures of increasing intensity depending on the classification. Accordingly, the classification of a carcinogenic substance as C-1A or C-2 leads, downstream, not to identical responses but to an equivalent level of concern for public health and occupational health. In other words, the principle of consistency must be observed.

In European law, there is no legislative classification for biological agents other than the one for the purposes of occupational health. However, it is up to the Commission and the Member States to ensure a certain level of consistency between the concern raised by a biological agent with respect to public health (which does not result in a formal classification) and occupational health. This requirement to ensure consistency is reflected by the criteria set out in Article 2 of Directive 2000/54. Most of the criteria relate to public health. However, one criterion implies that the classification is also based on the specific impact of biological agents on workers. Thus, in group 3, the agent "can present a serious hazard to workers" while in group 4, the agent "is a serious hazard to workers". In other words, the choice to be made in classification must necessarily be based on two factors: the general concern that this agent raises for public health and the specific aspect of occupational health.

b) Health and safety measures are provided by the Directive itself. Some apply to all biological agents. Essentially, these are Articles 3 and 4 of the Directive which apply to biological risk one of the essential principles of the Framework Directive: risk assessment. Other health and safety measures are assessed on a scale. Accordingly, Articles 5 to 17 do not apply to agents in group 1. The main differences between agents in groups 3 and 4 are revealed in Annexes V and VI. The scope of Annex VI is quite limited in the case of SARSCoV2 (in practice, it would essentially affect the companies manufacturing the vaccines). Therefore, the main differences are found in Annex V. This contains a flexibility clause drafted in very broad terms. The wording in the 2000 Directive (which was not amended by the 2019 Directive) was as follows: "The measures contained in this Annex shall be applied according to the nature of the activities, the assessment of risk to workers, and the nature of the biological agent concerned." In this regard, the changes made to the Directive in 2019 are only of secondary importance. They are limited to explaining the meaning of the adjective "recommended" by specifying: "In the table, "Recommended" means that the measures should in principle be applied, unless the results of the assessment referred to in Article 3(2) indicate otherwise."

The use of the adjective "recommended" generally concerns only agents from group 3. The only exception is the recommendation to take a shower before leaving the contained area, for which the situation is identical for groups 3 and 4.

Other flexibility measures seem possible on the basis of the adoption of asterisks whose meaning is specified in the introductory notes to Annex III.

c) Prevention measures geared to the specifics of the actual work-related activity and based on the assessment in accordance with the principles of the Framework Directive

The Directive's general approach constitutes a solid and coherent basis for organising the prevention of biological risks. On the other hand, this text does not cover the specific characteristics of a pandemic situation. Understandably, back in the year 2000, the European institutions did not pay enough attention to this issue.

Any amendment to the Directive to bring it in line with the specific problems posed by a pandemic will necessarily take time, as it will have to go through the usual legislative process. Therefore, it would make sense for priority to be given to classification via an amendment procedure to take account of technical progress.

In violation of the basic principles of European legislation, it appears that classification often appears to be arbitrary and pragmatic, that the content of Article 2 of the Directive is interpreted with some degree of arbitrariness and that there are informal criteria that play a certain role in the decision-making process. As a result, delegated acts are of questionable legality and the transparent discussion of classification decisions is much more difficult than in the context of regulating chemical substances.

**2) Classification of SARS-CoV2**

We have limited the analysis to the criteria concerning group 3 and group 4 criteria since the *question* of the current debate is centred on this.

| Criteria | **Group 3** | **Group 4** |
|---|---|---|
| 1 | Can cause severe human disease | Causes severe human disease |
| 2 | Can present a serious hazard to workers | Is a serious hazard to workers |
| 3 | May present a risk of spreading to the community | May present a high risk of spreading to the community |
| 4 | There is usually effective prophylaxis or treatment available | There is usually not effective prophylaxis or treatment available |

The definition of the criteria is composite. A literal interpretation does not completely resolve the difficulty. The first criterion could lean towards classification in group 3 if the only

consideration were the ratio between people affected by the disease and people with severe symptoms up and including death.

However, consistency with public health measures adopted should rule out this approach. In the public health arena, there is a recognition of the mass nature of serious illnesses and mortality linked to COVID-19. The notion of causality, must include a probability factor. Nevertheless, criterion 1 is the main argument that appears in EC's expert decision, arguing thatin 80% of cases, the disease causes only mild symptoms. What is completely overlooked here, is the fact that 20% of numerous cases (that would definitely occur without accurate measures taken) would still amount to a large number of people falling seriously ill of this virus. For (frontline) workers being exposed much more than the general population, this is even more the case.

Criteria 2 and 3 are predominantly geared toward classification in group 4. The majority of businesses would not have been closed if there had definitely not been a serious threat to workers. Moreover, preliminary research shows that (categories of) workers are relatively more affected than the general population. The third criterion leaves no room for any doubt at all: the risk of spread is high. The EC's expert assertion that distancing and other barriers reduce the level of risk is highly questionable, becausefor many occupations these measures are impossible to be enforced due to the very nature of the work. The fourth criterion is also ambiguous due to the use of the adverb "usually". The EC expert's have affirmed that efforts to find a vaccine are under way, however, up to this date and most likely for the near future, we do not dispose of a vaccine or prophylaxis for COVID-19. Of course, if a treatment is made widely available, the SARSCoV2 classification could change over time. This is the very purpose of the process of amending directives to bring them in line with technical advances.

However, the fact that the wording used for composite criteria leaves room for doubt does not mean that the final decision can be purely arbitrary. Other legal principles tightly govern this decision-making process and make it possible to rule on its legality. In terms of occupational health and safety law, this question has already arisen with regard to the Working Time Directive. The definition of working time was also based on a composite wording of three factors. The Court of Justice of the European Union has ruled on this question and has provided the necessary legal certainty.

In addition, the TFEU requires that a high level of human health protection be ensured in all Union policies (Article 168). Likewise, Article 8 of the same Treaty requires the Union to aim for equality between men and women in all its activities. Even though we lack systematic figures at this stage, it is clear that among working age individuals, women are disproportionally affected by COVID-19 as an occupational hazard affects women more than men.

### 3) Flexibility measures and risk management

Since the start of the crisis, workers have shown a considerably greater sense of responsibility than employers and government authorities. Whether at nursing homes or hospitals, workers as a whole have taken enormous risks. This is not individual heroism. It is the result of a whole set of largely undervalued occupational qualifications, strong professional identities,

collective intelligence and solidarity. The many struggles waged against austerity policies and their impact on working conditions have certainly played an important role in the effectiveness of their response despite catastrophic policy decisions such as the failure to keep masks in stock.

From the start of the debate on classification, trade unions have served as relay points for this collective awareness. With a view to protecting public health, should it become clear that certain risk management conditions cannot be implemented, the trade union movement is fully prepared to discuss alternative measures which would offer an equivalent level of protection on the basis of the general principles set out in the framework Directive. Annex V to the Directive already contains a general flexibility clause. Should this prove to be insufficient, other solutions can be envisaged. On the other hand, what is acceptable for covering the public's essential needs ceases to be acceptable when it is a question of other interests, such as productivity or corporate profits.