



# Position paper : COVID-19 : use of FFP masks by general public

Date : 04/02/2021

To :

- EU Commission DG SANTE :
  - o Commissioner Kyriakides
  - o Director General Gallina
  - o cc Directors Rys and Ryan, Head of Unit Ampelas
- EU Commission DG GROW :
  - o Commissioner Breton
  - o Director General Jorna
  - o cc Director Cozigou, Head of Unit Bonvissuto
- ECDC :
  - o Director Ammon

ESF would like to bring to your attention that the obligation (or recommendation) to wear FFP2 masks for the general public might not result in the intended protection and could even be a step back, due to the created false sense of protection. We urge all involved authorities to carefully consider all aspects and make sure that a potential obligation (or recommendation) is accompanied by the necessary supporting measures.

## Background

There is no doubt that properly worn respiratory protective devices offers a higher level of protection against the COVID-19 virus for the wearer compared to medical masks or community face coverings. Originally FFP3 masks were recommended, but due to shortages, also FFP2 were deemed to be sufficient. In most cases, the masks used are disposable, even if reusable solutions e.g. face pieces with filters are available on the market and offer in some cases even better protection. Protective masks or other types of respiratory protection are designed to protect the wearer of the device. They are in the scope of the Regulation (EU)2016/425 for Personal Protective Equipment (PPE). Based on the type of risk they protect against, they are category III PPE and thus subject to the strictest conformity assessment procedures, including an EU type examination (module B) as well as follow-up of the production (module C2 or module D) by a Notified Body. Given the filtration and tight fit of the masks, they will also limit the spreading of the virus in the exhaled air, even if not tested as such. For this reason, valved FFP2 or FFP3 masks are not recommended when used in settings where the COVID-19 virus is potentially present.

Other types of masks are either designed to avoid, to some level, that the wearer spreads the virus, but not to protect the wearer of the mask. Medical masks are typically designed to avoid contamination with bacteria and viruses potentially spread by the wearer of the mask when sneezing or breathing. The filtration from inside to outside is tested. These masks are in the scope of the Directive 93/42/EEC for Medical Devices (to be repealed by Regulation (EU)2017/745). Given the functionality of these medical masks, they are class I Medical Device (unless sterile, which is usually not the case) and thus subject to conformity assessment procedures that do not include the involvement of a Notified Body. Community face coverings are neither PPE nor Medical Device and are designed to minimize the spreading of the virus by the wearer when sneezing or breathing, while no specific levels are set in harmonised standards as for the other types of masks. There is a big variation in the filtration effect of these face coverings. Different organisations have set up quality marks for this type of product to help the public in their choice.

Given the functionality masks are designed for, it is clear that only FFP3 or FFP2 masks are designed to protect the wearer (compared to community face coverings or disposable medical masks). The standard setting the requirements (EN 149) reflects this in the different tests performed on the masks. An important test is the inward leakage test (TIL) ensuring that the air inhaled by the wearer passes the filter. To achieve that, the mask must fit very well on the face of the wearer and a tight seal is necessary. To make that possible, often several sizes are made available by the manufacturers.

As the leakage is an essential factor, following the instructions given by the manufacturer is key. Currently, in occupational use, fit testing of each individual wearer is highly recommended (if not obliged by the Occupational Health and Safety legislation), this to make sure that the correct fit for each individual is guaranteed, but also that each wearer has been trained in the correct use.

For all types of disposable masks, it is important to replace them regularly, they are typically designed to be worn for a working shift. And even if studies have shown that the COVID-19 virus is no longer active on surfaces after a couple of days, other contamination (such as e.g. bacteria) does create hygienic challenges. Therefore, it is good practice to replace the masks and not keep it aside to reuse at a later time. For the same reason, timely and correct cleaning/washing of reusable masks (e.g. textile face coverings) is important.

### **Concerns when obliging FFP2 (or FFP3) masks for the general public.**

- Looking at how, in many cases, medical masks or community face coverings are currently used, it is doubtful that protective masks will be worn and used correctly by the general public. A simple example is the fact that in order to be able to have the necessary tight seal of a FFP mask, facial hair in the area where the mask seal touches the face is not allowed (see e.g. infographic from CDC/NIOSH<sup>1</sup>). Will everybody that is obliged to wear a FFP mask also be obliged to be clean shaven at all times ? If not, the potential protection will not be reached.

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<sup>1</sup> Facial Hairstyles and Filtering Facepiece Respirators :  
<https://www.cdc.gov/niosh/npptl/pdfs/FacialHairWmask11282017-508.pdf>

- In practice, (disposable) masks are often not replaced when they should be. This will most likely also be the case with FFP masks (theoretically an FFP mask marked NR is designed for maximum 8 hours of use), and thus not lead to the effect that is envisaged with an obligation.
- With the reasoning for the obligation being that FFP2 masks offer the best possible protection against the virus, without the necessary supporting measures, the general public will get a false sense of safety and thus the risk of not following other essential rules (e.g. keep distance) will be felt as less needed.
- FFP2 masks (and FFP3 even more) are more expensive than other types of masks. Unless those masks are made available free of charge in sufficient quantities, the obligation to wear them will have a substantial impact on the budget of the general population. Because of the cost, at least for a part of the population, it will be tempting to use the mask for longer period, with all risks related to not timely replacing the mask, including loose fitting, and thus loss of the expected protection.
- The use of Recommendation (EU)2020/403 made it possible to place products on the market for which the full conformity assessment procedure is (not) yet finished. This under strict conditions and in principle destined for the healthcare sector only. Several member states have already stopped applying this Recommendation and others are planning so in the near future. In any case, masks destined to industry or general public are not covered by this Recommendation, and thus must be fully compliant with the PPE Regulation.
- It is clear that in the previous period, a huge amount of non-compliant masks have been made available on the EU market, and this not only in the healthcare sector.
- Sustainability aspects<sup>2</sup> are not at all taken into consideration when issuing obligations to wear disposable FFP2 masks.
- An obligation to wear FFP2 masks by the general public will drastically increase the demand for those masks. This will inevitably lead to :
  - o Increase of attempts to place non-compliant masks on the market
  - o Increase of sales prices (a matter of demand and offer in a free market)
  - o Potential shortages : even with the very substantial increase of production capacity for these masks organised in the previous period, shortages for healthcare and industrial sectors that need those masks to be able to provide the necessary protection of the employees (based on legally obligatory risk assessment of workplaces), cannot be excluded. Trade limitations or confiscation, as experienced in the beginning of the current health crisis, must be avoided.

## Conclusions

When recommending the use of FFP2 masks or making it compulsory for the general public in the fight against the COVID-19 virus, the above mentioned concerns need to be taken into account, which must lead to :

- An information / training campaign destined for the general public to make sure that the masks are worn and used correctly at all times. A simple information will

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<sup>2</sup> See e.g. ESF reflection paper PPE-20-1-10 submitted to the PPE expert group : <https://circabc.europa.eu/ui/group/e34f47d0-f6b1-422a-ba5c-4da1f56d4ddc/library/d0669f67-ec8d-43d9-99b3-7a977e2a2788/details>

not be sufficient, an extensive and repeated multimedia campaign is certainly necessary. And ideally, fit testing will be available at easily accessible locations (e.g. in railway stations, in shopping centres, ...) this to educate the general public.

- Financial support must be organised in order to avoid that budgetary limitations create discrimination between parts of the population when it comes to availability of the masks.
- Increased market surveillance activities to avoid that non-compliant masks enter the EU market.
- Guaranteed availability of the masks for the healthcare and industrial sectors that need the masks to protect their employees.

Unless the above is realised, the obligation (or recommendation) to wear FFP2 masks for the general public will not result in the intended protection and could even be a step back, due to the created false sense of protection.

We urge all involved authorities to carefully consider all aspects and make sure that a potential obligation (or recommendation) is accompanied by the necessary supporting measures. The European Safety Federation is available to cooperate and support any action (e.g. training/information) to improve the protection of all citizens, be it in a professional or private setting.

Henk Vanhoutte  
Secretary General, on behalf of the members

About ESF:

The European Safety Federation (ESF) was founded in 1991. National organisations each representing the manufacturers and suppliers of PPE (Personal Protective Equipment) in their country decided to group and unite the European manufacturers, importers, distributors and service providers of PPE and to represent them at government level of the European Union and other European institutions and instances.

Today, ESF represents over 600 companies, of which at least 70% are SMEs. The effective and cooperative members of ESF and the enterprises that affiliated to the national federations are dedicated and committed to provide compliant CE certified and high-quality PPE. Moreover, they link quality and service by giving expert advice and assistance in the process of risk assessment and analysis as well as training and advice in all aspects related to PPE. Supporting a safety conscious way of life is a common interest to all of us.

As all citizens (be it as employee, as self-employed or in his/her free time) use PPE to protect him/her against risks for his/her health or safety, the ESF members have an essential role in the protection of the population.