POSITION PAPER

Personal Protective Equipment during the coronavirus crisis and beyond

April 2020

Background

As the coronavirus hits Europe hard, the public **demand for facemasks is unprecedented.** Worldwide production of masks and other protective equipment cannot meet the demand of hospitals and clinics, which are struggling to keep their personnel safe. The European Commission is now turning to the continent's producers of protective equipment, many of which are SMEs, to strategize about how to deal with the situation at hand.

As it turns out, **there are several smart solutions to not only increase production, but also find better and more sustainable ways to use protective equipment.** These smart solutions would provide a viable answer to the current coronavirus crisis and would ensure **much stronger preparedness for similar crisis situations in Europe.**

Current situation: Limited capacity of Europe's safety equipment manufacturers

The demand for disposable masks has surged to an exponential level. Manufacturers estimate that the orders are at least 1000 times higher than the usual demand. No company in Europe and elsewhere is able to satisfy this exceptional demand, despite that all the personal protective equipment manufacturers are already running on maximum production capacity. Due to the exceptional circumstances, countries that have manufacturers of personal protective equipment have closed their borders and prohibited exporting safety equipment to meet the local demand.

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While they can rely on their own manufacturers, all the other countries will have severe shortages.

Importantly, epidemics similar to the current COVID-19 crisis, SARS or any other natural disaster such as flooding, and wildfires might happen in the future. There will be times like this, when Europe will find itself caught in the same problem of insufficient manufacturing capacity. In addition, it might be hard to import safety equipment from other regions because countries will give priority to their citizens and health workers. Therefore, **Europe should consider safety equipment manufacturers as a strategic asset to their countries, where they can meet national demand in times of crisis.**

Increasing production capacity of European producers

This crisis is triggering different responses in Europe and beyond. Currently, most countries concentrate their efforts on managing supplies of safety equipment. For example, France has announced that it will take control over masks' stock and redistribute them according to priority, where health workers and infected people have the highest priority.

However, the first step to ensure a stable supply of personal protective equipment should be the increase of its production capacity among European manufacturers. In the past, during the SARS epidemic crisis in France (early 2000s) and the national security threats in Israel because of regional military activity, **both states have introduced financial measures** to help their national manufacturers meet the market demand for respiratory protective devices. Similarly, as part of EU response, on 6 March 2020, Commissioners Kyriakides' proposed actions including a joint procurement plan to supply 20 participating member states with protective equipment.

While it is currently unclear what exact measures this joint procurement plan would entail, at this crucial point in time, **Europe must increase the production and usage of the appropriate type of face masks, and many SME producers are ready and willing to step up to the task.** On 10 March 2020, Commissioner Breton held a crisis meeting with safety equipment producers to discuss options to increase production of safety equipment. SBS encourages the follow up to explore options that lead to sufficient increase in production and **calls for European direct investments to expand the production lines of safety equipment manufacturers to build their capacity, not only for this crisis, but also future ones.**

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Increasing production and usage of Personal Protective Equipment

There are different types of masks in the market, and some of them are not effective against the coronavirus**. Standards can help to understand the different usage of these masks and choose not only the right mask but also the most sustainable solution.** For example, most commonly seen in public and on the media are disposable surgical masks. These masks are unfit to filter the virus, so they are not as effective protection against COVID-19. In fact, they are designed to protect patients from being contaminated by health workers during surgeries. Meanwhile, following the WHO Guidance on "Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected", filtering masks classified as FFP2 and FFP3 according to EN 149 are instead a good option for citizens and health workers to protect themselves.

However, these masks are disposable and typically need to be **changed every four hours**. Another type of masks that is effective against the virus, but is not yet under excessive demand, is the reusable half masks coupled with filters classified P2 and P3, respectively according to standards EN140 and EN143. Such combination offers the same filtering efficiency as FFP2 and FFP3 masks, while having the **additional benefit of being reusable up to one year,** provided the filter pieces are exchanged once a month.
Moreover, half masks with P2 or P3 filters have the advantage of a smoother adaptation to the face as they may come in different sizes and are adjustable to the facial features.
For cleaning and disinfection, half masks with P2 or P3 filters can be treated according to the WHO guidelines for coronavirus with the same procedures as other non-disposable devices used in hospitals (e.g. by using ethyl alcohol 70%).
As regards the price of half masks with P2 or P3 filters, these are approximately 4 or 5 times more expensive than FFP2 and FFP3 masks. However, the longer product lifetime more than compensates the higher price.

Read more about the different types of face masks here. The following table presents relevant standards for each product.

Mask Type	Standard	Classification	Filtering efficiency
Filtering Facepiece without valves	EN 149	FFP1	78%
		FFP2	92%

		FFP3	98%
Filtering Facepiece with valves	EN 149	FFP1	78%
		P2	92%
		P3	98%
Elastomer and techno-polymers filter ½ mask	EN 140 + EN 143	P2	92%
		P3	98%
Medical mask	EN 14683	N/A	N/A

The above-mentioned standards are normally available for purchase from the national standards bodies. Nevertheless, in view of the current COVID 19 emergency situation some of these standards (including EN 149 and 14683) can be downloaded for free from the online catalogues of the national standards bodies[1]. Also, SBS participates in technical bodies that work on standards for Respiratory Protective Devices (CEN TC 79) and Personal Protective Equipment (ISO TC 94 SC15).

Placing products faster on the market

Any manufacturer wishing to sell products in the EU must go through a conformity assessment procedure. The procedure ensures that the product's specifications are compliant with all the requirements specified by European legislation. European Harmonised Standards can be used by the manufacturer to ensure that products meet the essential requirements of applicable EU legislation. A successful conformity assessment means that the product can be placed on the EU market.

[1] https://www.cencenelec.eu/News/Press_Releases/Pages/PR-2020-003.aspx

The conformity assessment procedure can take time. Considering the current crisis, the recent EU recommendation on conformity assessment sets a mechanism to prioritise and quickly conduct conformity assessment activities for personal protective equipment[2] to ensure faster placement of masks and other safety equipment on the market. It also allows some flexibility of market surveillance procedures including the temporary placement on the market of personal protective equipment not bearing CE marking.

While quick placement on the market of the relevant PPEs is necessary under the current crisis, SBS stresses that **market surveillance authorities have an important responsibility:** they must ensure that Personal Protective Equipment not manufactured according to harmonised standards meet the essential safety and health requirements for the safety of health workers and citizens.

Recommendations: SBS calls on EU institutions and Member States to act rapidly in particular:

- To make investments in support of the up scaling of production capacity for masks and other PPEs necessary against COVID-19, and other possible future epidemics.
- To purchase masks that are effective against COVID-19 not limited to disposable masks FFP2 and FFP3, but also reusable half masks with filters P2 and P3.
- To make sure that market surveillance authorities prevent the placement on the market of products that are unsafe or not sufficiently effective against the virus**.**

Small Business Standards (SBS) is the European association representing and supporting small and medium-sized companies (SMEs) in the standardisation process, both at European and international levels.

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[2] The Commission has also published practical guidelines offering practical advice on the application of the Recommendation on conformity assessments of PPE, and certain types of medical devices, https://ec.europa.eu/commission/presscorner/detail/en/ip_20_558

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