EU Commission :
- Mrs. von der Leyen, President
- Mr. Hogan, Commissioner Trade
- Mr. Breton, Commissioner Internal market
- Mrs. Kyriakides, Commissioner Health and Food Safety
- Mr. Lenarčič, Commissioner Crisis Management

EU Council :
- Mr. Michel, President of the EU Council

Croatian Presidency of the EU Council :
- Mr. Plenković, Prime minister Croatia;
- Mrs. Andrassy, ambassador, permanent representative Croatia

3rd of April 2020

Dear Presidents, dear Commissioners, dear Prime Minister, dear Ambassador,

Subject : Market restrictions and Trade barriers impacting the Personal Protective Equipment (PPE) sector – indirect detrimental consequences for the health and safety of the EU citizens and for the PPE sector

First of all, we want to reaffirm the strong commitment of the European Safety Federation members (i.e. PPE manufacturers and suppliers) to provide the necessary protection, not only to the workers in or supporting the health care system, but also to all other professionals that are able to continue to operate - even under restrictions – during the COVID-19 crisis.

All ESF members are all working tirelessly to increase their production capacities and organise the supply chains to ensure the availability of PPE on the EU market, even when confronted with several hurdles at EU and global level.

Over the past weeks, ESF has constantly informed the European Commission services and your cabinets of practical concerns about several Commission and national initiatives that have created (certainly unintendedly) harmful consequences impacting the health and safety of the EU citizens and the PPE sector. These concerns were accompanied by proposals for guidance on the application of the initiatives. Also, several of our members have addressed on an individual basis similar concerns both on EU level as on national level.

The EU and national provisions (or their implementation) that have a detrimental impact on our sector are the following : Commission Implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorisation; existing national measures blocking exports or allowing for the confiscation of PPE (and medical devices); softening of EU rules for conformity assessment for PPE (Recommendation (EU) 2020/403) products.

You will find the earlier shared documents on these concerns in the annex. Unfortunately, we have to conclude today, that these concerns are apparently not all taken seriously enough to act on them.

We therefore call on your support to make sure that PPE manufacturers and suppliers will be able to ensure the necessary protection to citizens and workers both at EU and global level.

Below, we developed a brief summary illustrating the challenges our sector is facing an our suggested solutions.

Commission Implementing Regulation (EU) 2020/402 :

We recognise the intention of the EU Commission to make sure that essential PPE is available to the healthcare sector during this health crisis. We don't disagree with the principles.
However, in practice the list of products falling under the scope of the Regulation is not at all clear to the relevant actors that have to implement the Regulation (e.g. customs and competent authorities). Annex I of the Regulation lists the concerned PPE accompanied by a list of Combined Nomenclature (CN) Codes which are necessary for customs authorities to identify goods to be exported/imported.

As the custom officials on the field have neither the expertise, nor the time to check the goods descriptions accompanying every shipment, they base their decisions solely on the CN Codes. Unfortunately for the PPE and textile sector, these CN Codes are not exclusive for PPE and are certainly not restricted to the the specific products that are intended to be part of the export authorisation.

As a result, many products that are essential for critical industries, such as pharmaceuticals, are currently being blocked (e.g. cleanroom garments, cargo covers). In addition, PPE that are not at all suitable to protect against infectious diseases, like the COVID-19 virus, are unnecessarily being blocked at borders. Or alternatively, manufacturers of such products require an export authorisation to their national authorities to avoid blockage when exporting. To mention a few examples of products that have been blocked or for which export authorisation applications have been made : hearing protection; heavy duty chemical suits and gloves; and diving suits. In both cases, this results in unnecessary burdens for both the national authorities and the manufacturers.

Both the national authorities and the suppliers desperately need guidance to clarify the annex I and specify which products are intended to fall under the scope of the Regulation. ESF already provided a proposal to the Commission services, including references to EN standards and markings. The FAQ published on the 1st of April is a first step to remedy this concern, but is in our view in practice not yet enough.

Also, we would like to bring to your attention the fact that, as a result of this unclear situation, global PPE suppliers avoid shipping their products, including those that are clearly not intended to protect against the COVID-19 virus and/or PPE that are not compliant with the EU legislation as they are destined to non-EU markets, to the warehouses located in the EU. This has led to a complete reorganisation of supply chains towards non-EU regions. This could therefore undermine – in the short and medium term – the availability of PPE stocks in the EU. In the long term, production and distribution of those products presently in the EU might be moved permanently to other regions.

Short term this means unnecessary efforts for the suppliers, efforts that they then cannot allocate to working on solutions for the supply of necessary PPE. Longer term, once the

supply chains and production locations changed, there will be an impact on the employment in the sector in the EU.

Moreover, ESF stresses the fact that its members are committed to protect citizens and workers not only within the EU, but also in other regions. The COVID-19 crisis is having dramatic impacts at global level, and ESF members strongly believe that it is crucial to provide a global response. We therefore call on the Commission to ensure that PPE production or storage in the EU of products destined for (and fulfilling the legal requirements for) other markets, can continue.

Within this extremely challenging context, we should not deny PPE to all the workers in other sectors than healthcare. The normal functioning of the market for PPE is essential to protect the health and safety of these workers, who are already confronted with shortages of certain products they are used to wear (e.g. FFP2/FFP3 masks are typically used in the construction sector to protect workers against dangerous dusts such as silica or quartz).

Also, we observe that in the current situation, customs authorities are devoting excessive resources to (often inefficiently) verify PPE exports or applications for export authorisations and cannot pay the necessary attention to the much-needed market surveillance activities on the imports of PPE.

In view of the above, an extension beyond the originally foreseen period of 6 weeks would only worsen the situation and should, in our view, certainly not be considered.

We cannot believe that the European Commission prefers to allow imports of non-compliant, non-protecting PPE from outside the EU over supporting the correct functioning of the existing PPE sector in the EU.

Existing national measures blocking exports or allowing for confiscation of PPE (and medical devices) :

As of today, there are several EU Member States maintaining (or even recently introducing) national measures to completely block exports from their country or to allow national (health) authorities to confiscate certain types of PPE (and medical devices).

These measures create enormous uncertainties in the market. Shipments destined for distributors who sold their PPE to hospitals or other healthcare organisations in the destination country are confiscated at the national border by the national authorities of the same country for distribution to the healthcare sector… This sounds absurd, but unfortunately it is the reality.

With these measures, it is impossible for serious specialised suppliers to participate to public tenders for or to sell PPE and medical devices directly to the healthcare sector as there is no guarantee that the PPE they offer (and signed a contract for) can actually be delivered.

It also means that those companies that produce or have their warehouses in countries where the risk of confiscation exist have no incentive to make any effort to increase the production or stock to make the PPE available for the entire EU market as they might be confronted with national protectionist measures. Again, a need to reorganise the supply chains, creating unnecessary burdens and potential disastrous consequences on their level of employment in the EU, too.

There is certainly no need to repeat that those national measures are completely against all solidarity principles as well as against the proper functioning of the EU Single Market.

We therefore ask the European Commission to show leadership during this crisis by ensuring that any harming national measure allowing export ban or product confiscation is withdrawn in the shortest delay possible.

Softening of EU rules for conformity assessment for PPE (Recommendation (EU) 2020/403).

Apart from the above mentioned challenges, there are other threats to the EU PPE sector as a result of measures taken with the best intentions.

The Recommendation (EU) 2020/403 on conformity assessment and market surveillance certainly has positive effects on the speed with which new products can be made ready for the market as well as for ensuring an effective market surveillance.

However, in practice we see that many operators try to use this Recommendation to place products on the market that are not at all in conformity with EU legislation. This is obviously is not in line with the rationale behind this Recommendation. Also, this means that the role of the market surveillance authorities is even more important than ever in this moment.

As an example: the number of suspicious certificates and test reports in circulation is very high. From our side, together with the national PPE organisations that are effective member of ESF, we relentlessly inform the market as much as possible (through explanatory webpages including examples, ad-hoc LinkedIn messages, …). The result is that we receive requests from all sides (including national authorities) to check if the presented documents for the PPE are valid (or not). A job that we do without complaining as it helps to make sure that the PPE delivered are actually protecting as promised. This should of course also be accompanied by proper testing of PPE (or medical devices) entering the EU, unfortunately we don't have the resources to do this.

We are aware that in some Member States the market surveillance authorities are making efforts to test products and first results are already obtained. But this is not the case in all Member States.

We therefore call on the EU Commission to support those market surveillance efforts and to simultaneously organise an awareness campaign to provide the necessary information to (new) importers and distributors in the EU, to buyers of the products in the EU but also to authorities in third countries clarifying the rules to place products on the EU market.

Ongoing campaign on the manufacturing of 'artisanal' masks and their potential negative consequences.

Last but not least, we are witnessing an increased number of campaigns and appeals explaining how to produce masks. At least in the meantime, contrary to 2-3 weeks ago, it is usually made clear in those campaigns, what the function of such masks is, compared to medical or PPE masks. But still the perception of the public (and unfortunately also of professionals in the healthcare sector) is that a mask protects, no matter what type of mask it is. There is very little understanding of the differences between the PPE, the medical and the 'artisanal' masks. This combined with efforts made to convert companies from other sectors into mask producers gives the impression that masks are simple products that everybody can manufacture.

We therefore remind you that protective masks are PPE of category III, meaning protecting against mortal or irreversible risks. This categorisation was made decades ago for a very good reason.

Also, manufacturers continuously spend resources on R&D to make sure that the masks are continuously improved both in terms of protection and comfort. Completely opposite to the current perception on masks.

Clear communication from the European Commission on this subject will support the existing specialists, clearly explaining the need for proper protective masks.

In conclusion, you will understand that the existing specialised companies in the PPE sector are confronted with the above-mentioned challenges. The bigger global companies are considering their involvement in the EU market under these contra-productive conditions. For the many SMEs in the sector it means unexplainable burdens, potentially leading to the disappearance of a number of those SMEs.

We would certainly suggest, next to keeping the PPE sector committed during the crisis, to have a conversation about the role of the PPE sector in the future. There are certainly lessons to be learned from the experiences we all live now.

ESF members continue to believe in the positive intentions of the European Commission, but we call on a swift action on the above-listed concerns. Initiatives to support the entrance of new producers of PPE are understandable and even welcome in an attempt to increase the PPE production in the EU. However, we believe that those efforts are far less efficient than allowing existing companies - with proven and existing technology, expertise and products - to continue to function in the single market and increase their output for the benefit of all EU citizens.

The ESF team and members stand with the European Commission and we are eager to collaborate and provide additional information on how to work through these challenging times.

We thank you for your commitment and support.

Sincerely,

On behalf of the ESF members (*) :

Alan Murray, President ESF, CEO BSIF UK
Renaud Derbin, Past-President ESF, President Synamap France
Guido Van Duren, President-Elect ESF, President Febelsafe Belgium
Claudio Galbiati, Treasurer ESF, President Assosistema Safety Italy

Henk Vanhoutte, Secretary General ESF

Annexes :

1. ESF Paper : COVID-19 : availability of PPE in the EU : national trade limitations up to confiscation (dated 26/03/2020)
2. ESF Proposal for guidance on annex I of Commission Implementing Regulation (EU) 2020/402 (dated 26/03/2020 as update of original proposal dated 20/03/2020) – including its annex.

(*) The ESF members are :

Effective members : national organisations of PPE suppliers : Belgium - Febelsafe / Finland – STYL / France – Synamap / Germany – IVPS / Italy – Assosistema / Netherlands – VVGW /
Russia - ASIZ / Sweden, Norway, Denmark and Iceland – NSA / Turkey – TIGIAD / UK - BSIF

Affiliated members : ETSA / VTH

Cooperative members : 3M / Ansell Healthcare Europe / Alsico / Dupont / Ejendals / Granberg / Honeywell Safety / Intersafe / Moldex / Peter Greven / Portwest / SC Johnson Professional / Sioen / Skincare /
Vostok Service