



Proposal for guidance on annex I of Commission implementing Regulation (EU) 2020/402

Date : 26/03/2020 – update of 20/03/2020 document

We receive practical questions concerning the implementation of the Regulation (EU)2020/402. The wording of the Regulation (and particularly the Annex I) is in practice causing blockage of PPE that have no function in the protection against the COVID-19 virus (e.g. hearing protection) and therefore are not intended in the export limitations set in the implementing Regulation.

It must also be noted that this EU Export Ban is now leaving industries, but also hospitals and first responders in non-EU member states without supply, putting the life of patients and healthcare workers at risk and endangering the stability of their healthcare systems.

The EU Export Ban, risks in our view, achieving exactly the opposite effect than intended as Global economic operators in some case have now no alternative but to ship to non-EU destinations directly, leading to less product arriving in the EU.

Therefore, ESF proposes the following guidance to help authorities and economic operators identify the products that are intended and thus allow movement as usual for all other PPE :

Which products fall under the export authorization?

Products covered by Regulation (EU) 2020/402 are products compliant to the PPE Regulation 2016/425 (and thus CE marked) and listed in Annex I of Regulation 2020/402. The PPE protect against potentially infectious materials.

The list in the annex contains custom codes. As several of these codes are not unique for PPE or for PPE as intended in this Regulation, there is confusion with authorities and economic operators. We have been informed about products being blocked at the EU borders based solely on the custom codes.

To help the customs and economic operators on how to apply this Regulation and avoid an overload of work or avoid products being unduly blocked at the borders, guidance is proposed per category of products mentioned in the attached table.

We added the applicable (harmonised) EN standards and where, foreseen in the standard, also the pictogram that is used on the marking of the products. Pictures of typical products are included. Products compliant with other EN standards than those mentioned are not covered by this Regulation and can be critical for the protection of other groups of workers (e.g. firefighters, welders, employees in chemical plants, ...). For these other PPE there is no shortage on the global market. To complete the proposed guidance, the most common types of products that, in our view, are not included in Regulation (EU)2020/402 are also included in the attached table.

NOTE : Products not compliant with the PPE legislation (and thus not CE marked) or products in compliance with other legislation (e.g. Medical Device legislation) are not covered by this Regulation.

(text in italic is the text as in Annex I of the Regulation)

Protective spectacles and visors :

- *Protection against potentially infectious material,*
- *Encircling the eyes and surroundings,*
- *Compatible with different models of filtering facepiece (FFP) masks and facial masks,*
- *Transparent lens,*
- *Reusable (can be cleaned and disinfected) or single-use items*

ex 9004 90 10 / ex 9004 90 90

further clarification :

- Splash Protection against potentially infectious material,
- Encircling the eyes and surroundings with goggles which seal against the user's facial features

Applicable standard : EN 166 – clear lens marked with “3”

Face shields :

- *Equipment for the protection of the facial area and associated mucous membranes (ex: eyes, nose, mouth) against potentially infectious material,*
- *Includes a visor of transparent material,*
- *Usually includes fixations to secure over the face (e.g.: bands, temples)*
- *Can include a mouth-nose protection equipment as described below,*
- *Reusable (can be cleaned and disinfected) or disposable*

ex 3926 90 97 / ex 9020 00 00

further clarification :

- Includes solid, clear, not coloured, plastic faceshields (EN 166)

Applicable standard : EN 166 – clear lens marked with “3”

Mouth-nose-protection equipment :

- *Masks for the protection of the wearer against potentially infectious material and for the protection of the environment against potentially infectious material spread by the wearer,*
- *Can include a face shield as described above,*
- *Whether or not equipped with a replaceable filter*

ex 6307 90 98 / ex 9020 00 00

further clarification as the description in the Regulation would cover basically all types of respiratory protective equipment :

- Tight fitting masks for the protection of the wearer against potentially infectious material and for the protection of the environment against potentially infectious material spread by the wearer: respiratory protection – PPE legislation, type FFP2 and FFP3 of standard: EN149

- Note : masks only designed for the protection of the environment against potentially infectious material spread by the wearer (medical face mask - medical device legislation) – standard EN 14683 type II or IIR are not covered by this Regulation.

Protective garments :

Garment (e.g. gown, suit) for the protection of the wearer against potentially infectious material and for the protection of the environment against potentially infectious material spread by the wearer

ex 3926 20 00 / ex 4015 90 00 / ex 6113 00 / ex 6114 / ex 6210 10 10 / 6210 10 92 / ex 6210 10 98 / ex 6210 20 00 / ex 6210 30 00 / ex 6210 40 00 / ex 6210 50 00 / ex 6211 32 10 / ex 6211 32 90 / ex 6211 33 10 / ex 6211 33 90 / ex 6211 39 00 / ex 6211 42 10 / ex 6211 42 90 / ex 6211 43 10 / ex 6211 43 90 / ex 6211 49 00 / ex 9020 00 00

This means only garments that are certified to the product standard EN 14126 and are marked with the following pictogram :

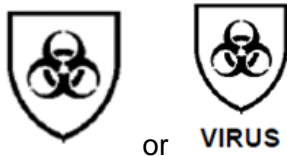


Gloves :

Gloves for the protection of the wearer against potentially infectious material and for the protection of the environment against potentially infectious material spread by the wearer

ex 3926 20 00 / 4015 11 00 / ex 4015 19 00 / ex 6116 10 20 / ex 6116 10 80 / ex 6216 00 00

This means only thin single use disposable gloves (< 0,3 mm) that are certified to the product standard EN ISO 374-5 or EN ISO 374-5 with the marking “VIRUS” and marked with the following symbols



Annex : EU 2020-402 table