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Export restrictions outside the EU of certain Medical and Personal Protective Equipment (PPE) (Implementing Regulation (EU) 2020/402)

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Since the outbreak of the epidemiological crisis caused by the new coronavirus, the disease associated with it, Covid-19, has been spreading fast across the world, reaching the territory of the EU. According to the Commission, the virus might have an enormous public health impact with substantial fatal outcomes in high-risk groups and significant economic and societal disruptions. Due to the current situation the Commission has on 15 March 2020, introduced export restrictions outside the EU of certain medical and personal protective equipment inter alia mouth protection masks, protective visors, and gloves with the intended use of combating or preventing the spread of the coronavirus. Export authorizations may however be granted. Exports without authorizations are prohibited. The prohibition will be in force during six weeks.

Background to the export restriction

According to Article 207.2 of the Treaty on the Functioning of the European Union (the Treaty) the European Parliament shall adopt the measures defining the framework of implementing the common commercial policy. As part of this, Regulation (EU) 2015/479 of the European Parliament and of the Council on common rules for exports was adopted on 11 March 2015.

The demand for medical protective equipment has exploded in the last few days and is expected to continue increasing significantly in the imminent future with accompanying shortages developing in several Member States. Given the nature of the equipment and the prevailing circumstances, such type of equipment is an essential product since it is necessary to prevent the further spreading of the disease and safeguard the health of medical staff treating infected patients. According to the Commission, constraints exist throughout the EU single market to meet customers demand for the relevant Personal Protective Equipment, in particular mouth protection masks.

With respect to the prevailing situation and in accordance with article 291 of the Treaty¹ and Regulation (EU) 2015/479 on common rules for exports, the Commission adopted Implementing Regulation (EU) 2020/402 of 14 March 2020 making the exportation of certain products subject to an export authorisation. In order to prevent speculative depletion of stocks the restrictions entered into force on the day of its publication, i.e. 15 March 2020.² The restrictions apply for a period of six weeks, through 26 April 2020.³

1. Authorising the Commission to adopt implementing regulations.
2. See article 3 in the Commissions Implementing Regulation (EU) 2020/402.
3. See article 3 in the Commissions Implementing Regulation (EU) 2020/402.

What products are covered by the Regulation?

The equipment covered by the export restrictions are divided into categories with description.

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

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

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

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

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

In total approximately 30 product descriptions are covered by the restriction

For which countries is an export authorisation required?

An export authorisation is required when exporting to countries outside the EU. Since the Commission uses the term "Union" without mention of the EEA, export without authorization is permitted only to the EU Member States. Pursuant to Article 127(3) of the Withdrawal Agreement, the Regulation is also to be implemented by the UK and the UK is to be considered as a Member State, and not as a third country. All other countries, including members of the EEA and EFTA e.g. Norway and Iceland should therefore be considered as third country and thus, exports to these countries requires authorization.⁴ The restrictions apply whether or not the products are of EU-origin.

How can an authorisation be obtained?

An authorisation can be issued by the competent authorities of the Member State where the exporter is established. The competent authority in Sweden is the National Board of Trade Sweden (Sw: "Kommerskollegium").⁵

Authorisations can be issued in writing or by electronic means. Member States shall process applications for export authorisations within a period of time to be determined by national law or practice, which shall not exceed 5 working days from the date on which all required information has been provided to the competent authorities. Under exceptional circumstances that period may be extended by a further period of 5 working days.⁶

4. See information provided by the National Board of Trade Sweden, <https://www.kommerskollegium.se/om-oss/nyheter/2020/exporttillstand-for-medicinsk-skyddsutrustning/>.

5. See the Swedish Decree (1997:969) on import and export regulation,
6. See article 2.2 in the Commissions Implementing Regulation (EU) 2020/402.

In deciding whether to grant an export authorisation, Member States shall take into account all relevant considerations including, where appropriate, whether the export serves, inter alia: to support concerted support actions coordinated by the EU, to support the activities of the World Health Organisation's (WHO) Global Outbreak Alert & Response Network or to supply foreign operations of EU Member States including, military operations, international police missions and/or civilian international peacekeeping missions.

Future development?

Lena Hallengren, Minister for Health and Social Affairs, stated on 18 March 2020 that there is a shortage of supplies and that hospitals and regions (local government) do everything in their power to obtain supplies.⁷ Some Member States have implemented internal restrictions on export to other EU-countries. The ambitions of the Swedish Government are according to Minister Hallengren to pursue a removal of internal restrictions on export and instead establish common procedures for export on an EU level. At this moment in time, there are on-going efforts to increase manufacturing capabilities within the EU. This may also feed into review of the measure as necessary and as the situation evolves. It should also be mentioned that a procurement procedure has been launched under the Joint Procurement Agreement which, according to the timeline and depending on the market situations, might be finalized as of the beginning of April 2020.

7. See press conference with Lena Hallengren, Minister for Health and Social Affairs, March 18 2020, <https://www.regeringen.se/pressmeddelanden/2020/03/presstraff-med-socialminister-lena-hallengren/>.

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