

## Export requirements for personal protective equipment

### Frequently Asked Questions

Commission Implementing Regulation (EU) 2020/402 of 14 March 2020, as amended by Commission Implementing Regulation (EU) 2020/426, ('the Regulation') has made the exportation of certain products subject to the production of an export authorisation. The Commission has also issued a Guidance note to Member States on these Regulations and published a list of Member States authorities responsible for export authorisations (including contact details of those authorities).

All relevant documents can be consulted under the following links:

- [Regulation 2020/402 \(original\)](#)
- [Regulation 2020/426 \(amendment\)](#)
- [Guidance note to Member States](#)
- [List of competent authorities in Member States](#)
- [Press release of 20 March 2020](#)
- [Press release of 15 March 2020](#)

The clarifications provided below are not legally binding, they are for informative purposes only and should serve as a guidance for exporters of personal protection equipment ('PPE'), Member States customs authorities and competent authorities under the Regulation when implementing the Regulation.

#### 1. Authorisation procedure

##### a. How long will the measure last?

The current measures were adopted in accordance with Article 5(5) of Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports and will be applicable until 25 April 2020. Before that day, the Commission must decide whether further measures should be adopted pursuant to Article 6 of Regulation (EU) 2015/479.

##### b. When assessing an application for an export authorisation, should the competent authority make any specific considerations regarding emergency supplies to third countries and humanitarian operations, carried out at the Union level or organised by the Member States or by the humanitarian organisations?

Article 2(3) of the Regulation provides a list of situations, including a number of humanitarian causes, in which the competent authorities shall consider an export authorisation as justified.

It follows that export of emergency supplies to third countries and of supplies to humanitarian operations should also be considered in the same spirit and in line with the commitment of the Union to a global collective response, to international cooperation and to assisting the most vulnerable countries around the world.

- c. In cases where the competent authorities of another Member State(s) have to be consulted (Article 2(1) of the Regulation), it may not be possible for the competent authority issuing the export authorisation to meet the 5+5 days deadline (Article 2(2) of the Regulation).**

The Regulation specifies deadlines for Member States to process applications for export authorisations. Given the urgent needs arising from the outbreak of coronavirus, Member States are invited to process the applications as soon as possible and ahead of the indicated deadlines of 5 or 10 working days respectively. This is in particular necessary when different Member States are involved in the process, speedy and adequate communication between the relevant Member States authorities are therefore encouraged.

- d. How does the Commission facilitate the communication among the Member States authorities?**

The list of the Member States competent authorities responsible for issuing the export authorisation, available on the DG Trade's website, should facilitate the communication among them. To access the list, click [here](#).

Moreover, the Commission services are available to help in individual cases where such facilitation is necessary. Member States in need of assistance may contact the Commission services at the following e-mail address: [trade-exportauthorisationppe@ec.europa.eu](mailto:trade-exportauthorisationppe@ec.europa.eu).

- e. When rejecting a request for an export authorisation, should the competent authority issue a formal rejection, which can be appealed by the exporter, or only a simple reply?**

In cases where the competent authority decides to reject an application for an export authorisation, the competent authority should follow the national law and practice concerning the form, in which the rejection will be communicated to the exporter.

Based on the Guidance note, in order to ensure a transparent process, Member States are requested to notify to the Commission electronically all export authorisations (granted or not granted), on the basis of the template in Annex II of the Guidance note. This notification should be made without delay as soon as the decision on the export authorisation is taken.

- f. Can a competent authority issue an export authorisation for a global quantity (e.g. the applicant submitted an invoice for 10 000 pcs but applied for an export authorisation for 500 000 pcs)?**

No, issuing an export authorisation for a global quantity would circumvent the objectives of the Regulation as it would fail to ensure that certain exports can be prohibited in a situation of shortage of the particular PPE.

## **2. Customs procedures**

### **General remarks**

Regulation (EU) 2020/402 is now<sup>1</sup> integrated in the TARIC with measures 709 (export control). The list of products is also<sup>2</sup> inserted in the TARIC.

Regulation (EU) 2020/426 was published on Friday 20 March 2020. It removes the bans on some destinations. It was sent in the TARIC with a retroactive<sup>3</sup>, and accurate, date of entry into force of Saturday 21 March 2020

- a. Which export transactions are concerned by the Regulation?**

The Regulation applies when Union goods are exported, i.e. when they undergo export customs procedures.

In this context, the following transactions are excluded<sup>4</sup>:

- (a) goods placed under the outward processing procedure;
- (b) goods taken out of the customs territory of the Union after having been placed under the end-use procedure;
- (c) goods delivered, VAT or excise duty exempted, as aircraft or ship supplies, regardless of the destination of the aircraft or ship, for which a proof of such supply is required;
- (d) goods placed under the internal transit procedure;
- (e) goods moved temporarily out of the customs territory of the Union in accordance with Article 155.

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<sup>1</sup> Since it is an export restriction, the validity start date cannot be retroactive in the TARIC and is therefore two days after the validity start date published in the OJ.

<sup>2</sup> The regulation 2020/420 entered into force on Sunday 15.3.2020 and TAXUD was able to make it available to the Member States on Tuesday 17.3.2020. This is because the regulation entered into force on a Sunday and TARIC updates may be sent only on Commission working days. So, it could be sent at the earliest on Monday 16 and restriction measures (ex: bans) cannot be sent with a retroactive date of entry into force, simply because the goods have already been cleared. Therefore, the earliest date of entry into force in the TARIC was Tuesday 17.3.2020.

<sup>3</sup> Retroactive cancellations of bans are entered retroactively in the TARIC to free blocked goods.

<sup>4</sup> See Article 269(2)(c) Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269 10.10.2013, p. 1) as amended

**b. Do ship operators need to apply for an export authorisation to carry on board of the ship PPE that will be exclusively used by the personnel or the passengers?**

Ship supplies are goods and equipment for use on board the ship by the crew, and not for export.

According to Article 269(2)(c) of the Union Customs Code ('UCC')<sup>5</sup>, the export procedure does not apply to ship supplies. Ships leaving the Union ports are considered leaving the Union (even if this is a voyage between two Union ports – maritime law). Therefore, PPE on board is subject to export formalities, even if it is not formally placed under the export procedure.

Ships must have on-board pharmacies (Council Directive 92/29/EEC of 31 March 1992 on the minimum safety and health requirements for improved medical treatment on board vessels). Therefore, they should be allowed to leave the Union ports carrying protective gear and medication for the on-board pharmacies catering for their ship's crews.

This specific type of "ship supplies" are accordingly exempted from the export restrictions on personal protective equipment implemented by the Regulation.

**c. Goods in the scope of the Regulation were imported from a third country to the Union but were not intended for the Union market. On the contrary, they were intended for re-export to another third country. Does the Regulation apply to such goods? Is the exporter obliged to apply for an export authorisation?**

The Regulation applies to exports of Union goods. It does not apply to re-exports of non-Union goods. According to Article 5(23) of UCC, **Union goods** are:

- (a) goods wholly obtained in the customs territory of the Union and not incorporating goods imported from countries or territories outside the customs territory of the Union;
- (b) **goods brought into the customs territory of the Union from countries or territories outside that territory and released for free circulation;**
- (c) goods obtained or produced in the customs territory of the Union, either solely from goods referred to in point (b) or from goods referred to in points (a) and (b).

Therefore, in the above described situation, it is decisive whether the goods originating in third country were released for free circulation in the customs territory of the Union before being again exported to a third country or not.

If they were released for free circulation, they are considered Union goods and therefore subject to export authorisation. If they were not released for free circulation, they are considered non-Union goods (Article 5(24) of UCC) and their re-export is not subject to export authorisation.

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<sup>5</sup> Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269 10.10.2013, p. 1) as amended.

**d. Does the Regulation apply to goods in a customs warehouse?**

According to Article 240(1) of UCC, only non-Union goods can be placed under the customs warehousing procedure. Sales of non-Union goods to third countries are not considered exports but re-exports. As explained under point 1b, the Regulation does not apply to re-exports of non-Union goods.

**e. Does the Regulation apply to goods in temporary storage?**

The situation of goods in temporary storage is similar to the one of goods in a customs Warehouse. According to Article 144 of UCC, “non-Union goods shall be in temporary storage from the moment they are presented to customs”. Moreover, according to Article 149 UCC, “non-Union goods in temporary storage shall be placed under a customs procedure or re-exported within 90 days”. However, these goods cannot be placed under the export procedure, as this procedure is only applicable to Union goods.

Thus, an export authorisation for goods placed in a temporary storage is not required.

**f. Does the Regulation apply to exports of PPE of non-commercial nature, e.g. a Ministry of Defence in a Member States intends to supply its armed forces stationed outside of the Union?**

Export of non-commercial goods is **not exempted** from the Regulation. This follows from the UCC Delegated Act ('UCC DA')<sup>6</sup>:

- Article 137 of UCC DA allows that for goods of non-commercial nature, the export declaration can be done orally;
- According to Article 142(c) UCC DA, the above (Article 137 of the UCC DA) does not apply to goods that are subject to a prohibition or restriction.

A valid export authorisation is required when a written export declaration is lodged. Nevertheless, Article 2(3) of the Regulation, refers to specific situation which may justify the granting of an export authorisation, and this list indeed includes military operations. The decision on an application for an export authorisation in the listed situations is left at the discretion of the Member States, following the Guidance note.

**g. Does Regulation 2020/402 apply to passenger travel or personal post?**

Export of non-commercial goods is **not exempted** from the Regulation. This follows from the UCC Delegated Act ('UCC DA')<sup>7</sup>:

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<sup>6</sup> Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code (OJ L 343 29.12.2015, p. 1) as amended.

<sup>7</sup> Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code (OJ L 343 29.12.2015, p. 1) as amended.

- Article 137 of UCC DA allows that for goods of non-commercial nature, the export declaration can be done orally;
- According to Article 142(c) UCC DA, the above does not apply to goods that are subject to a prohibition or restriction.

As a valid export authorisation is required when a written export declaration is lodged, it suggests that an export authorisation is also necessary for goods exported as personal items, e.g. in passenger's luggage or in postal consignments.

Notwithstanding the above, a **pragmatic approach** should be taken for the goods contained in travellers' personal luggage where they are of an occasional nature and consist exclusively of goods for the personal use of the travellers or their families. The nature and quantities of such goods should indicate that they are exported for non-commercial reasons.

**h. Does the Regulation apply to goods that were declared for export before the Regulation entered into force but are leaving the customs territory of the Union after the entry into force of the Regulation?**

No, a valid export authorisation is required when the export declaration is lodged. Therefore, the Regulation does not apply to goods that were declared for exports before the Regulation entered into force.

**3. Geographical scope of the Regulation**

**a. Which countries are excluded from the scope of the Regulation?**

The Regulation concerns exports to all non-EU countries with the following exceptions:

- European Free Trade Association (EFTA) countries: Iceland, Liechtenstein, Norway, Switzerland;
- Overseas countries and territories listed in Annex II of the Treaty on the functioning of the EU<sup>8</sup>;
- The Faeroe Islands, Andorra, San Marino and the Vatican City.

Pursuant to Article 127(3) of the Withdrawal Agreement, the United Kingdom of Great Britain and Northern Ireland is to be considered as a Member State, and not as a third country.

**b. Is Monaco in the scope of Regulation 2020/402?**

According to Article 4(2)(a) of UCC, Monaco is considered to be part of the customs territory of the Union. Thus, sales of PPE to Monaco do not require an export authorisation.

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<sup>8</sup> OJ C 326, 26.10.2012, p 336.

#### 4. Product scope of the Regulation and product definition

##### General remarks

The Regulation covers PPE designed for protection against infectious material. It consists of five main categories, i.e. protective spectacles and visors, face shields, mouth-nose protection equipment, protective garments, and gloves.

These products are listed in Annex I to the Regulation.

Since in some cases, the CN codes listed in Annex cover a variety of goods wider than those targeted by the Regulation (CN codes marked as “ex”), the CN codes should be considered in combination with the description provided in the Annex when deciding whether certain goods fall within the scope of the Regulation.

**a. Does the product scope of the Regulation cover protective equipment not designed for healthcare use?**

No, Annex I to the Regulation clearly defines all covered goods as being used for the protection against potentially infectious material and/or for the protection of the environment against potentially infectious material spread by the wearer.

**b. Should the description of PPE in Annex I be read cumulatively?**

Yes, for an individual item to fall within the scope of the Regulation, it must fall under the indicated CN code and meet all the requirements provided in the description.

**c. Is there any other guidance the competent authorities and the customs authorities of the Member States might follow when assessing whether certain products fall under the Regulation?**

The authorities may take into account the following guidance:

**Protective spectacles and visors:** all equipment manufactured in accordance with standards EN 166; EN ISO 16321-1 or any other standard, which was assessed by a national market surveillance authority in the implementation of points 7 and 8 of Recommendation (EU) 2020/403 and was found to provide an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425.

**Face shields:** all equipment manufactured in accordance with standards EN 166; EN ISO 16321-1 or any other standard, which was assessed by a national market surveillance authority in the implementation of points 7 and 8 of Recommendation (EU) 2020/403 and was found to provide an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425.

**Mouth-nose-protection equipment:** all equipment manufactured in accordance with standards EN149, EN 140, EN 143 or any other standard, which was assessed by a national

market surveillance authority in the implementation of points 7 and 8 of Recommendation (EU) 2020/403 and was found to provide an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425. It should be taken into account that under a situation of shortage, medical masks (manufactured in accordance with standard EN 14683 or any other standard providing adequate level of health and safety) can be considered a substitute product.

**Protective garments:** all equipment manufactured in accordance with standards EN 14126; EN 13982, EN 14605, EN 1073 or any other standard, which was assessed by a national market surveillance authority in the implementation of points 7 and 8 of Recommendation (EU) 2020/403 and was found to provide an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425.

**Gloves:** all equipment manufactured in accordance with standards EN 374, EN 420 or any other standard, which was assessed by a national market surveillance authority in the implementation of points 7 and 8 of Recommendation (EU) 2020/403 and was found to provide an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425.

## **5. Availability of PPE in the European Union**

### **a. How to get information about PPE availability in other Member States? How to assess whether sufficient or not?**

Member States are responsible for the issuance of authorisations. However, for any questions concerning the supply of PPE within the EU, the Member States may refer to the existing Emergency Response Coordination Centre (ERCC) by email: [ECHO-ERCC@ec.europa.eu](mailto:ECHO-ERCC@ec.europa.eu).