

COMMISSION IMPLEMENTING REGULATION (EU) 2020/568**of 23 April 2020****making the exportation of certain products subject to the production of an export authorisation**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports ⁽¹⁾, and in particular Article 6 thereof,

Whereas:

- (1) On 15 March 2020, the European Commission published Implementing Regulation (EU) 2020/402 ⁽²⁾ making the exportation of certain products subject to the production of an export authorisation, pursuant to Article 5 of Regulation (EU) 2015/479. That Regulation was amended by Commission Implementing Regulation (EU) 2020/426 of 19 March 2020 ⁽³⁾.
- (2) Regulation (EU) 2020/402, and its amendment, apply for a limited period of 6 weeks.
- (3) As the epidemiological crisis caused by the COVID-19 disease continues, the demand within the Union for personal protective equipment ('PPE'), which consists of protective masks (and surgical masks), gloves, goggles, face-shields, and overalls, remains very high and is even continuously increasing. The demand for certain types of PPE has especially led to shortages on the internal market. Given its nature 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.
- (4) Continuous efforts are being made to help ensuring urgent and adequate provision of protective equipment throughout the EU. The production capacities of personal protective equipment have been ramped-up. The Commission finalised a joint procurement for personal protective equipment, in which 25 Member States took part. These initiatives are proving successful, and equipment is planned to be made available 2 weeks after the Member States sign the contracts with the bidders.
- (5) Under the Union Civil Protection Mechanism (UCPM), the European Commission has decided to create a strategic resceEU stockpile of medical equipment such as ventilators and protective masks to help EU countries in the context of the COVID-19 pandemic. Entirely financed by the Commission via direct grants, this reserve will be hosted in one or several Member States.
- (6) The Commission also set up a Clearing House, including for PPE, with the objective to coordinate efforts to match supply and demand in the EU, and facilitate an adequate functioning of the internal market.
- (7) Despite these actions, and given increased needs for PPE in the Union, a gap between demand and supply within the Union still exists, in particular concerning certain types of PPE, which are vital to prevent the spreading of the disease and treat the patients.
- (8) In light of these efforts to overcome the critical situation of shortage of certain types of PPE in the Union, further measures are warranted to contribute to remedying and preventing shortages of PPE.
- (9) These measures, aimed at protecting health and impacting on trade, should be targeted, proportionate, transparent and temporary.

⁽¹⁾ OJ L 83, 27.3.2015, p. 34.

⁽²⁾ Commission Implementing Regulation (EU) 2020/402 of 14 March 2020 making the exportation of certain products subject to the production of an export authorisation (OJ L 77 I, 15.3.2020, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) 2020/426 of 19 March 2020 amending Implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorisation (OJ L 84 I, 20.3.2020, p. 1).

- (10) In a Joint Statement of 26 March the members of the European Council underlined that the adoption of the decision on the authorisation for export of PPE should lead to the full and effective lifting of all forms of internal bans or restrictions.
- (11) It is not the intention of the Union to restrict exports any more than absolutely necessary, and the Union also wishes to uphold the principle of international solidarity in this situation of a global pandemic. Union measures should therefore be proportionate and ensure that exports remain possible, subject to a prior authorisation. To this effect, Member States should grant export authorisations under specific circumstances, where the shipment in question poses no threat to the actual need for PPE within the Union and serves to satisfy a legitimate need for official or professional medical use in a third country. In contrast, Member States should not authorise exports that would create speculative distortion and serve stockpiling and hoarding of essential equipment by those with little or no objective need.
- (12) An export authorisation system should remedy or prevent a situation of a shortage of essential products within the borders of the Union. The main objective of such system would be to protect public health within the Union.
- (13) The administrative modalities for these authorisations should be left to the discretion of the Member States during the time of this temporary system.
- (14) Based on the principle of international solidarity, Member States should authorise exports to enable the provisions of emergency supplies in the context of humanitarian aid.
- (15) Member States should positively consider granting authorisations when the exports are destined to State bodies, public bodies and other bodies governed by public law and in charge of distributing or making PPE available to the persons affected by or at risk from COVID-19 or involved in combating the COVID-19 outbreak.
- (16) Authorisations should be granted only to the extent that the volume of exports is not such that it poses a threat to the availability of PPE on the market of the Member State in question or elsewhere in the Union for the purpose of meeting the objective of this Regulation. For this purpose, Member States should contact the Clearing House established by the Commission before granting such an authorisation. Member States do however not have to contact the Clearing House in the case of authorisations for emergency supplies in the context of humanitarian aid.
- (17) In deciding whether to grant an export authorisation, the Member States should also take into consideration the fulfilment of a supply obligation under joint procurement or rescEU by the Union and the Member States, the support of the activities of the World Health Organization (WHO), the support of EU-level coordinated responses to crisis situations or the request for assistance by third countries or international organisations.
- (18) The degree of market integration for the products concerned between parts of the customs territory of the Union and other countries or territories, whether achieved under an arrangement establishing a free-trade area or for other reasons such as geographic proximity or historic ties, should also be considered. Likewise, it would be counterproductive to disrupt closely integrated value chains and distribution networks established on the basis of those arrangements or otherwise, in particular in the case of neighbouring countries and economies.
- (19) This Regulation should apply to certain types of PPE. In order to ensure coherence, the description of the types of PPE subject to this authorisation system laid down by this Regulation should be aligned with the corresponding specifications of the equipment subject to the Joint Procurement, which has identified the specific needs in the Union. The CN codes should be given for information only.
- (20) The objective of the Clearing House is to ensure adequacy of the supply to meet the demand for all types of PPE on the Union market. On that basis, a need may arise to review the scope of Annex I and products covered by this Regulation. A review of the scope should be based on a continuous assessment of needs of critical equipment related to the fight against COVID-19 and their potential shortages. Special attention should be given to the products covered by the Joint Procurement as well as requested under the Union Civil Protection Mechanism such as other types of PPE, ventilators and laboratory products (test kits).

- (21) The single market for medical and personal protective equipment is closely integrated beyond the boundaries of the Union, and so are its production value chains and distribution networks. This is particularly the case of the member States of the European Free Trade Association, and the Western Balkans which are engaged in a process of deep integration with the Union. Subjecting exports of certain personal protection equipment to these countries to an export authorisation requirement would be counterproductive, given the close integration of the production value chains and distribution networks, when such equipment is an essential product necessary to prevent the further spreading of the disease and safeguard the health of medical staff treating infected patients. It is therefore appropriate to exclude such countries from the scope of application of this Regulation.
- (22) It is likewise appropriate to exclude from the export authorisation requirement the overseas countries and territories listed in Annex II to the Treaty, as well as the Faeroe Islands, Andorra, San Marino, the Vatican City and Gibraltar, since they have a particular dependency on the metropolitan supply chains of the Member States to which they are attached or on the supply chains of neighbouring Member States, respectively.
- (23) This Regulation should apply to exports of Union goods from the customs territory of the Union. Therefore countries that form part of that customs territory need not be exempted in order to receive unrestricted shipments from within the Union. This is the case notably for the Principality of Monaco (*). Conversely, territories of Member States specifically excluded from the customs territory of the Union should not fall under the requirement of export authorisation and should therefore be exempted as well. This concerns the territories of Büsingen, Heligoland, Livigno, Ceuta and Melilla. Likewise, exports to the continental shelf of a Member State or the exclusive economic zone declared by a Member State pursuant to UNCLOS should be exempted from the application of this regulation.
- (24) The measures provided for in this Regulation should not apply to trade between the EU Member States. Pursuant to Article 127(3) of the Withdrawal Agreement, during the transition period, the United Kingdom of Great Britain and Northern Ireland is to be considered as a Member State, and not as a third country.
- (25) Some of the above-mentioned countries at present maintain export restrictions on personal protection equipment.
- (26) The authorities of the countries and territories excluded from the export authorisation system should offer adequate guarantees that they will control their own exports of the products concerned, in order to avoid undermining the objective pursued by Implementing Regulation (EU) 2020/402. The Commission should closely monitor this.
- (27) To avoid undermining the objective pursued by this Regulation, the authorities of the excluded countries and territories should make such exports to the Union available.
- (28) To assess the situation on a regular basis, and in order to ensure transparency and consistency Member States should report their decisions to grant or reject requests for export authorisations to the Commission. The Commission should make such information publicly available on a regular basis, due account being taken of their confidential nature.
- (29) Prior authorisation requirements are of an exceptional nature, should be targeted and of a limited duration. In order to ensure that the measures do not remain in place longer than is necessary, they should apply for a period of 30 days. Based on the development both in terms of the spreading of the COVID-19 disease and the adequacy between supply and demand, the Commission should review the situation on a regular basis and consider the need to shorten or extend the duration of the measures as needed.
- (30) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 3(1) of Regulation (EU) 2015/479,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purpose of this Regulation:

- (1) 'export' means an export procedure within the meaning of Article 269 of Regulation (EU) No 952/2013;
- (2) 'customs territory of the European Union' means the territory within the meaning of Article 4 of Regulation (EU) No 952/2013.

(*) See Article 4(2)(a) of 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).

*Article 2***Export authorisation**

1. An export authorisation established in accordance with the form set out in Annex II shall be required for the export of certain types of PPE, listed in Annex I, whether or not originating in the Union. Such authorisation is limited to Union goods ^(*3*), and is not required for non-Union goods. It shall be granted by the competent authorities of the Member State where the exporter is established and shall be issued in writing or by electronic means.
2. An export authorisation is required for all exports and shall be provided when the goods are declared for export and no later than at the moment of the release of the goods.
3. Without the production of a valid export authorisation, the exportation of such goods is prohibited.
4. Exports to the Republic of Albania, Andorra, Bosnia and Herzegovina, the Faeroe Islands, Gibraltar, the Republic of Iceland, Kosovo ^(*4*), the Principality of Liechtenstein, Montenegro, the Kingdom of Norway, the Republic of North Macedonia, the Republic of San Marino, Serbia, the Swiss confederation, Vatican City State as well as the overseas countries and territories listed in Annex II to the Treaty shall not be subject to the measures set out in paragraphs 1 and 2. The same applies to exports to Büsingen, Heligoland, Livigno, Ceuta and Melilla.
5. Exports to facilities located on the continental shelf of a Member State or the exclusive economic zone declared by a Member State pursuant to UNCLOS shall not be subject to the measures set out in paragraphs 1 and 2.
6. Based on the principle of solidarity, Member States shall authorise exports for use in third countries to enable the provisions of emergency supplies in the context of humanitarian aid. Member States shall process applications for export authorisations in an expedite manner, as soon as possible, but no later than 2 working days from the date on which all required information has been provided to the competent authorities.
7. Member States should positively consider granting authorisations when the exports are destined to State bodies, public bodies and other bodies governed by public law and in charge of distributing or making PPE available to the persons affected by or at risk from COVID-19 or involved in combating the COVID-19 outbreak. These authorisations should be granted only to the extent that the volume of exports is not such that it poses a threat to the availability of the PPE listed in Annex I on the market of the Member State in question or elsewhere in the Union. For this purpose, Member States shall inform the Commission before granting such an authorisation, at the following email address SG-CCH@ec.europa.eu. The Commission shall issue an opinion within 48 hours after having been informed.

*Article 3***Procedural aspects**

1. Where the PPE listed in Annex I is located in one or more Member States other than the one where the application for export authorisation has been made, that fact shall be indicated in the application. The competent authorities of the Member State to which the application for export authorisation has been made shall immediately consult the competent authorities of the Member State or States where the good is located and provide the relevant information. The Member State or States consulted shall make known as soon as possible, but no later than within 5 working days any objections it or they may have to the granting of such an authorisation, which shall bind the Member State in which the application has been made.
2. Member States shall process applications for export authorisations as soon as possible, but shall issue a decision no later than 5 working days from the date on which all required information has been provided to the competent authorities. Under exceptional circumstances and for duly justified reasons, that period may be extended by a further period of 5 working days.

^(*3*) See for excluded transactions Article 269(2) 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.

^(*4*) This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

3. In deciding whether to grant an export authorisation under this Regulation, Member States shall take into account all relevant considerations including, where appropriate, whether the export serves, inter alia:

- to fulfil supply obligations under a joint procurement procedure in accordance with Article 5 of Decision No 1082/2013/EU of the European Parliament and of the Council ⁽⁶⁾;
- to support the rescEU stockpiling of medical countermeasures or personal protective equipment aimed at combatting serious cross-border threats to health, as referred to in Commission Implementing Decision (EU) 2019/570 ⁽⁷⁾;
- to respond to the request of assistance addressed to and handled by the UCPM (Union Civil Protection Mechanism) and to support concerted support actions coordinated by the Integrated Political Crisis Response Mechanism (IPCR), the Commission or other Union institutions;
- to support the statutory activities of aid organisations abroad that enjoy protection under the Geneva Convention, provided that they do not impair the ability to work as a national aid organisation;
- to support the activities of the World Health Organization's Global Outbreak Alert & Response Network (GOARN);
- to supply foreign operations of EU Member States including, military operations, international police missions and/or civilian international peacekeeping missions;
- for the supply of Union and Member State delegations abroad.

4. Member States may take into account other elements, such as the degree of market integration for the products concerned whether or not achieved under arrangements establishing a free-trade area with the intended country of export, as well as geographic proximity.

5. In deciding whether to grant an export authorisation, the Member States shall ensure the adequacy of supply in the Union in order to meet the demand for the PPE listed in Annex I. Export authorisations may therefore be granted only where the shipment in question does not pose a threat to the availability of these goods on the market of the Member State in question or elsewhere in the Union. In order to best assess the situation, Member States shall inform the Commission at the following email address: SG-CCH@ec.europa.eu, in particular when the volume of planned exports may cause a shortage.

6. The Commission shall issue an opinion within 48 hours from the receipt of the request.

7. Member States may decide to make use of electronic documents for the purpose of processing the applications for export authorisation.

Article 4

Notifications

1. Member States shall immediately notify the Commission the authorisations granted and those refused.
2. These notifications shall contain the following elements:
 - (a) Name and contact details of the competent Authority,
 - (b) identity of the Exporter,
 - (c) destination country,
 - (d) final recipient,
 - (e) acceptance or refusal to grant the export authorisation,
 - (f) commodity code,
 - (g) quantity,
 - (h) units and description of the goods.

⁽⁶⁾ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

⁽⁷⁾ Commission Implementing Decision (EU) 2019/570 of 8 April 2019 laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council as regards rescEU capacities and amending Commission Implementing Decision 2014/762/EU (OJ L 99, 10.4.2019, p. 41).

The notification shall be submitted electronically at the following address:
TRADE-EXPORTAUTHORISATIONPPE@ec.europa.eu

3. The Commission shall make this information on the authorisations granted and those refused publicly available, due account being taken of the confidentiality of the data submitted.

Article 5

Review clause

The Commission shall monitor the situation and, when necessary, review expeditiously the period of application of this Regulation, and its product scope, taking into account the evolution of the epidemiological crisis caused by the COVID-19 disease and the adequacy of supply and demand in the Union market.

Article 6

Final provisions

This Regulation shall enter into force on the 26 April 2020. It shall apply for a period of 30 days.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 April 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Protective Equipment

The equipment listed in this Annex is in conformity with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council ⁽¹⁾ or Council Directive 93/42/EEC ⁽²⁾, medical device class I.

Category	Description	CN Codes
Protective spectacles and visors	<ul style="list-style-type: none"> — 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, — Can seal the skin of the face. 	ex 9004 90 10 ex 9004 90 90
Mouth-nose-protection equipment	<ul style="list-style-type: none"> — Masks for the protection of the wearer against potentially infectious material or to prevent the wearer from spreading such material, — Reusable (can be cleaned and disinfected) or single-use items, — Can include a face shield, — Whether or not equipped with a replaceable filter. 	ex 6307 90 98 ex 9020 00 00
Protective garments	<ul style="list-style-type: none"> — Non-sterile garment (e.g. gown, suit) for the protection of the wearer against potentially infectious material or to prevent the wearer from spreading such material. — Reusable (can be clean and disinfected) or single-use items. 	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

⁽¹⁾ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

⁽²⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 69, 12.7.1993, p. 1).

ANNEX II

Export authorisation application as referred to in Article 2

When granting export authorisations, Member States will strive to ensure the visibility of the nature of the authorisation on the form issued. This is an export authorisation valid in all Member States of the European Union until its expiry date.

EUROPEAN UNION	Export of personal protective equipment (Regulation (EU) 2020/568)		
1. Exporter (EORI number if applicable)	2. Authorisation number		3. Expiry date
4. Issuing authority	5. Destination country	6. Final recipient	6a. Does the export contribute to one of the listed considerations in Article 3 or is the export meant to enable the provisions of emergency supplies in the context of humanitarian aid as set out in Article 2(6)?
7. Commodity code	8. Quantity	9. Unit	10. Description of the goods
11. Location			
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11. Location			
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11. Location			
7. Commodity code	8. Quantity	9. Unit	10. Description of the goods
11. Location			
12. Signature, place and date, stamp			

Explanatory notes to the export authorisation form

The completion of all the boxes is mandatory except when stated otherwise.

Boxes 7 to 11 are repeated 4 times to allow requesting an authorisation for 4 different products.

Box 1	Exporter	Full name and address of the exporter for whom the authorisation is issued + EORI number if applicable.
Box 2	Authorisation number	The authorisation number is completed by the authority issuing the export authorisation and has the following format: XXyyyy999999, where XX is the 2-letter geonomenclature code ⁽¹⁾ of the issuing Member State, yyyy is the 4-digit year of issuance of the authorisation, 999999 is a 6-digit number unique within XXyyyy and attributed by the issuing authority.
Box 3	Expiry date	The issuing authority can define an expiry date for the authorisation. This expiry date cannot be later than 30 days after the entry into force of this regulation. If no expiry date is defined by the issuing authority, the authorisation expires at the latest 30 days after the entry into force of this regulation.
Box 4	Issuing authority	Full name and address of the Member State authority that issued the export authorisation.
Box 5	Destination country	2-letter geonomenclature code of the country of destination of the goods for which the authorisation is issued.
Box 6	Final recipient	Full name and address of the final recipient of the goods, if known at the time of issuance + EORI number if applicable. If the final recipient is not known at the time of issuance, the field is left empty.
Box 6a	Does the export contribute to one of the listed considerations in Article 3 or is the export meant to enable the provisions of emergency supplies in the context of humanitarian aid as set out in Article 2(6)?	If the export serves one of the considerations listed in Article 3 or if the export is meant to enable the provisions of emergency supplies in the context of humanitarian aid as set out in Article 2(6), this should be indicated.
Box 7	Commodity code	The numerical code from the Harmonised System or the Combined Nomenclature ⁽²⁾ under which the goods to export are classified when the authorisation is issued.
Box 8	Quantity	The quantity of goods measured in the unit declared in box 9.
Box 9	Unit	The measurement unit in which the quantity declared in box 8 is expressed. The units to use are 'P/ST' for goods counted by number of pieces (e.g. masks).
Box 10	Description of the goods	Plain language description precise enough to allow identification the goods.
Box 11	Location	The geonomenclature code of the Member State where the goods are located. If the goods are located in the Member State of the issuing authority, this box must be left empty.
Box 12	Signature, stamp, place and date	The signature and stamp of the issuing authority. The place and the date of issuance of the authorisation.

⁽¹⁾ Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7).

⁽²⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).