



29 April 2020

EXPORT REQUIREMENTS FOR CERTAIN PERSONAL PROTECTIVE EQUIPMENT

FREQUENTLY ASKED QUESTIONS

Commission Implementing Regulation (EU) 2020/568 of 24 April 2020 ('the Regulation') has replaced Commission Implementing Regulation (EU) 2020/402 of 14 March 2020, as amended by Commission Implementing Regulation (EU) 2020/426 ('the old Regulation'). The Regulation continued the production of an export authorisation for the exportation of certain products.

All relevant documents can be consulted under the following links:

- [Regulation 2020/568](#)
- [List of competent authorities in Member States](#)

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

1. Product scope of the Regulation and product definition

General remarks

The Regulation covers certain medical and personal protective equipment designed for protection against infectious material. It consists of three main categories, i.e. protective spectacles and visors, mouth-nose protection equipment, and protective garments.

The products falling within the scope of the Regulation are listed in Annex I to the Regulation. The scope of the measures is limited to the products described in Annex 1 falling within the CN codes described. Products under CN codes not listed in Annex I are not included.

Since in some cases, the CN codes listed in Annex I 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 goods not specifically designed for healthcare or health protection use?

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 the goods in Annex I of the Regulation 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 the requirements provided in the description. This means that only goods falling under the indicated CN codes are in the scope of the Regulation but not all goods falling under the indicated CN codes require an export authorisation. The CN codes should be read in combination with the description of the goods in Annex I of the Regulation.

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

The authorities should follow the description of the goods, provided in Annex I of the Regulation. They may take into account the following further guidance with regard to the specific standards of those goods. However, this information is only illustrative. If the good falls under the description of Annex I, but complies to a different standard than indicated below, it should still fall within the product scope.

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. Thus, goods produced in line with comparable foreign standards are also covered by the Regulation.

Mouth-nose-protection equipment: all equipment manufactured in accordance with standards EN149, EN 140, EN 143, EN 14683, ISO 22609 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. Thus, goods produced in line with comparable foreign standards are also covered by the Regulation.

This category covers face masks classified under FFP1, FFP2 and FFP3, and medical/surgical masks.

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. Thus, goods produced in line with comparable foreign standards are also covered by the Regulation.

This category only covers non-sterile garments that cover (parts of) the body, i.e. it does not include sterile garments. Similarly, garments (e.g. gowns, coveralls, aprons) that are designed and used for other purposes (e.g. in industrial applications) **and** are not suitable for the protection of the wearer against potentially infectious material or to prevent the wearer from spreading such material are not included in this category.

d. Does the Regulation apply to exports of small quantities, e.g. face masks included in first aid kits?

First aid kits are classified under HS subheading 3006 50, which is not included in Annex I of the Regulation. They are, therefore, not subject to the export authorisation regime.

With regard to small quantities, the Regulation does not define any *de minimis* thresholds, which would enable exports of small quantities without an export authorisation. Nevertheless, the competent authorities when assessing whether certain exports could cause shortage on the Union market may take into consideration the fact that the application concerns a limited quantity to be exported.

e. Does the Regulation apply to parts of goods covered by the Regulation (e.g. replaceable filters for face masks)?

The product scope of the Regulation is limited to the goods listed in Annex I of the Regulation. The goods are specifically defined by the description and the CN code. Goods that are not listed in Annex I are not subject to the export authorisation scheme.

f. The Regulation has limited the product scope to protective spectacles and visors, mouth-nose-protection equipment, and protective garments (as compared to five product categories covered by the previous export authorisation scheme). What will happen should there be a shortage of other medical and personal protective equipment on the Union market in the future?

The Regulation contains a review clause in Article 5 of the Regulation. The review clause requires the Commission to propose a review of the export authorisation scheme and thus, to extend the product scope of the scheme should the situation on the Union market call for it. If the Commission has received adequate evidence justifying the change of the products scope, it will proceed expeditiously with a new proposal.

2. Geographical scope of the Regulation

a. Which countries, economies and/or territories 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;
- Western Balkans: Albania, Bosnia and Herzegovina, Kosovo¹, Montenegro, North Macedonia, Serbia;
- Overseas countries and territories listed in Annex II of the Treaty on the functioning of the European Union²;
- Countries that form part of the customs territory of the Union: notably Monaco;

¹ 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.

² OJ C 326, 26.10.2012, p 336.

- Territories of Member States specifically excluded from the customs territory of the Union: Büsingen, Heligoland, Livigno, Ceuta and Melilla;
- Andorra, the Faeroe Islands, territory of Gibraltar, 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. Does the Regulation apply to goods supplied to the continental shelf or exclusive economic zones of the Member States (e.g. to oil rigs)?

Continental shelf and exclusive economic zones are not part of the customs territory of the Union. Nevertheless, under Article 2(5) of the Regulation, supplies to facilities located in the continental shelf or the exclusive economic zone of a Member State are exempted from the requirement to submit a valid export authorisation when lodging the customs declaration.

c. Should the competent authority consider more favourably applications for an export authorisation for supplies to preferential trade partners, candidate countries (other than those already excluded from the scope of the Regulation), neighbouring countries or countries with close historic ties?

The Regulation (recital 18 and Article 3 (4) of the Regulation) invites the competent authorities to take into account the integration of certain countries or territories (in particular candidate countries³, neighbouring countries, preferential trade partners, countries with close historic ties) into the internal market of the Union. The export authorisation scheme should not disrupt established closely integrated value chains and distribution networks.

Nevertheless, issuing an export authorisation for exports to all the countries, economies and/or territories mentioned above should not be automatic. The competent authorities need to consider the situation on the Union market as required by the Regulation.

3. Authorisation procedure

a. How long will the measures last?

The current measures were adopted for a duration of 30 days from the day of their entry into force, that is 26 April 2020

Article 5 of the Regulation provides, however, for a review clause that requires the Commission to propose an extension of the Regulation should the situation call for it.

b. Where to find the list of competent authorities in each Member State?

The list of competent authorities is published on the following website (see the box dedicated to the export authorisation scheme):

<https://ec.europa.eu/trade/import-and-export-rules/>

³ E.g. Turkey

c. Can an exporter apply for an export authorisation in any Member State?

No. The application is made to the competent authority in the Member State where the exporter is established. If protective equipment is located in one or more Member States other than the one where the application for export authorisation has been made, that fact is to be indicated in the application. In case of multiple locations, all locations should be indicated.

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 email address: trade-exportauthorisationppe@ec.europa.eu.

e. Member States shall process applications for export authorisations as soon as possible, but shall issue a decision no later than five working days from the date on which all required information has been provided to the competent authorities. How is this deadline of 5 days calculated?

The day, on which a complete export authorisation form is submitted to a competent authority, is not considered as falling within the period of the five working days deadline⁴. This means that the deadlines start counting the first working day after the receipt of the authorisation request. [For a form submitted on a Monday, a decision should have been taken by the end of the next Monday.]

If another Member State has to be consulted, the Member State where the application for export authorisation has been made still only has five working days to decide whether to grant an authorisation. However, this might be a valid exceptional circumstance under Article 3(2) of the Regulation to extend the deadline for a further period of five working days, only if duly justified.

Within the 5-day deadline, the Commission (Clearing House) needs to be informed. This means that informing the Clearing House does not extend the deadline beyond 5 days. The Clearing House is bound to issue opinions within 48 hours. This should be factored in by the Member States authorities when contacting the Commission, in order not to exceed the 5 working days deadline.

f. 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.

⁴ Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits, OJ L 124, 8.6.1971, p. 1.

- g. 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 could be prohibited in a situation of shortage of the particular medical and personal protective equipment. It is a case-by-case assessment by the requested Member State in the light of the circumstances at the moment the application for export is assessed.

- h. Can the competent authority issue a general authorisation to a humanitarian organisation (e.g. Doctors Without Borders) or any other general authorisation (e.g. for small quantities)?**

Article 2(6) of the Regulation obliges the competent authorities to automatically issue an export authorisation to supplies in the context of humanitarian aid within two working days. Such authorisation should be obtained for each export transaction and issuing a general authorisation is not possible. The automaticity of the authorisation in a short deadline should ensure a swift handling of exports in case of urgency, while at the same time allowing the Commission to monitor these transactions, which need to be reported by the relevant Member States. This also implies that such exports – for transparency purposes - are not exempted from the obligation to file an authorisation request but the authorisations are issued in any case.

- i. Competent authorities should refrain from issuing a general authorisation for any types of exports. In the case of small quantities, a general authorisation for exports of small quantities could enable circumvention of the measures (big quantities artificially and only on paper split into several shipments) and could potentially lead to unequal treatment of the exporters where Member States would individually determine the definition of a small quantity.**
- j. Where can the competent authority find the information necessary to check the destinations covered in Article 2(7) or the considerations mentioned under Article 3(3)?**

It is for the exporter requesting the export authorisation to indicate if any of the relevant considered stated under Article 3(3) of the Regulation are met or if the exports are destined to any of the parties under Article 2(7), and provide the necessary evidence, potentially with some information provided by the final recipient.

The competent authority should conduct any relevant checks in line with their national law and practice.

- k. If the competent authority fails to issue a decision about an application for an export authorisation within the statutory deadlines, can it be interpreted as tacit approval of the application?**

No, the Regulation does not provide for the option of an export authorisation issued by tacit approval.

- l. How often should a competent authority notify the Commission of granted and rejected export authorisations?**

Article 4 of the Regulation requires that the competent authorities notify the Commission of a granted or rejected export authorisation **immediately**.

In order for the Commission to have the best overview of the situation and to be able to advise the Member States in a most accurate way possible, the up-to-date and reliable data on the supply/demand side are needed. Therefore, in the spirit of co-operation, the competent authorities are invited to submit one notification of all export authorisations issued/rejected in one day in the format described under point 3l of these FAQ and submit it to the Commission at the end of the respective business day or at the latest, before noon of the following working day.

m. What format should a competent authority use when notifying the Commission of granted and rejected export authorisations under Article 4 of the Regulation?

The type of information to be submitted is specified in Article 4 of the Regulation. This information is asked to enhance transparency and to warrant an equal treatment of economic operators throughout the Union. The notification should be sent electronically to the email address: trade-exportauthorisationppe@ec.europa.eu.

The notification should be provided in the form of a table, preferably in a spreadsheet, with the following columns:

Name and contact details of the competent authority:									
1	2	3	4	5	6	7	8	9	10
Notifying Member State	Authorisation number	Identity of the Exporter	Country of destination	Identity of the final recipient	Decision on the application (granted/rejected)	CN code	Quantity	Units	Description of goods

- Column 1: 2-letter geonomenclature code of the Member State notifying a decision about an application for an export authorisation
- Column 2: from Box 2 of the export authorisation form
- Column 3: from Box 1 of the export authorisation form
- Column 4: from Box 5 of the export authorisation form
- Column 5: from Box 6 of the export authorisation form
- Column 6: GRANTED for accepted applications; REJECTED for rejected applications
- Column 7: from Box 7 of the export authorisation form
- Column 8: from Box 8 of the export authorisation form
- Column 9: from Box 9 of the export authorisation form
- Column 10: from Box 10 of the export authorisation form

n. How will the Commission ensure the protection of confidential data submitted in the notifications, in particular when making the information on granted/rejected export authorisations publicly available?

When making the information publicly available, the Commission will delete the information provided in columns 2, 3 and 5 of the notification to respect the confidentiality of the data submitted, as set out in Article 4(3).

4. Humanitarian supplies

General remarks

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.

Following Article 2(6), Member States shall process the applications for export authorisations for such emergency supplies 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. According to the Regulation, in this case, there is no requirement to consult the Commission for an opinion.

a. What counts as provisions of emergency supplies in the context of humanitarian aid?

Humanitarian aid shall comprise assistance, relief and protection operations on a non-discriminatory basis to help people in third countries, including delivering or facilitating the delivery of assistance, providing medical supplies and food, the transfer of humanitarian workers and related assistance or evacuations in accordance with the humanitarian principles⁵. It should, in principle, be guided by the 24 Principles and Good Practice of Humanitarian Donorship⁶ and fall under the OECD-DAC purpose codes used to report humanitarian aid activities.

b. How can humanitarian non-governmental organisations or international organisations prove the provision of emergency supplies in the context of humanitarian aid?

Question 6a in the Export authorisation application provided in Annex II of the Regulation should be filled in if the organisation intends to export the equipment for emergency supplies in the context of humanitarian aid.

In their assessment of the application, Member States are encouraged to refer to existing registries and certifications for organisations providing humanitarian aid, such as the list of organisations which are humanitarian partners of the European Commission⁷.

To facilitate a quick implementation of the automatic authorisation, Member States are encouraged, once the first authorisation is provided for export of emergency supplies in the context of humanitarian aid, to keep an internal list of such organisations in order to facilitate the process in subsequent requests.

A list of humanitarian aid partners of the Commission established by DG ECHO and can be consulted here: <https://ec.europa.eu/echo/sites/echo-site/files/weblistpartners.pdf>. Any organisation listed there should be automatically granted an export authorisation within the

⁵ At EU level, the humanitarian principles are enshrined in the European Consensus on Humanitarian Aid: the principles of neutrality, humanity, independence and impartiality.

⁶ <https://www.ghdinitiative.org/ghd/gns/best-practices.html>

⁷ <https://ec.europa.eu/echo/sites/echo-site/files/weblistpartners.pdf>

given deadlines. This list is however not exhaustive and Member States are welcome to consider other organisations under Article 2(6).

c. Relevant deadlines

The Member States must process the export authorisation requests for emergency supplies in the context of humanitarian aid within 2 working days from the date on which all required information has been provided to the competent authorities.

To enable the provisions of emergency supplies in the context of humanitarian aid, Member States do not need, prior to granting the authorisation for exports for use in third countries, to inform the Commission (Clearing House) and wait for its opinion, as laid down under Articles 2(7) and 3(5) of the Regulation.

d. Does an intention to import the products listed in the regulation have to be transmitted through the Union Civil Protection Mechanism (UCPM) as a request for assistance?

There is no obligation to pass through the UCPM. The request of a third country for in-kind assistance under the UCPM may be a consideration that Member State's competent authority will take into account when deciding on granting the authorisation

e. How should exports to government agencies be treated? How should exports to government agencies in vulnerable developing countries be treated?

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 the goods as listed in Annex I to the Regulation available to the persons affected by or at risk from COVID-19 or involved in combating the COVID-19 outbreak. This notably includes exports to government agencies in vulnerable developing countries, unless they are meant to enable the provisions of emergency supplies in the context of humanitarian aid and would thus need to be granted automatically.

5. Customs procedures

General remarks

The Regulation is integrated in the TARIC with measures 709 (export control)⁸. The list of goods is also inserted in the TARIC. The goods are described in footnotes linked to the measures. These footnotes are numbered PE001, PE002, PE003.

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, i.e. customs procedures under codes 10/00 and 11/00.

In this context, the following transactions, i.e. customs procedures under all other codes, are excluded⁹:

⁸ 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.

- (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.

b. Do ship operators need to apply for an export authorisation to carry on board of the ship the goods in the scope of the Regulation 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')¹⁰, 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, goods 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.

In case that a ship is docked in a port outside of the Union, supplies leaving the customs territory of the Union to be delivered to such ship are considered exports and therefore, require an export authorisation notwithstanding their end use.

c. Does the Regulation apply to supplies carried on board of an aircraft?

Like for ship supplies, the same applies to aircraft supplies under Article 269(2)(c) of UCC.

d. 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:

⁹ 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

¹⁰ 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.

- (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.

e. 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. The Regulation does not apply to re-exports of non-Union goods.

f. 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.

g. Does the Regulation apply to exports of goods of non-commercial nature, e.g. 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')¹¹:

- 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.

¹¹ 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.

A valid export authorisation is required when a written export declaration is lodged. Nevertheless, Article 3(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.

h. Does the Regulation 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')¹²:

- 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.

i. 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.

The fact that a certain delivery was already agreed between a Union exporter and an importer in a third country is not decisive. Contractual obligations of an exporter cannot be interpreted as the goods being declared for export.

j. Does the Regulation apply to intracompany sales of goods covered by the Regulation?

If the subsidiary/related company of an exporter is located in one of the countries falling under the geographical scope of the Regulation, such exports require an export authorisation. The competent authorities may, however, take into consideration whether such intracompany sales represent closely integrated value chains and distribution networks that should not be disrupted by the measures as mentioned in recital 18 of the Regulation.

¹² 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.

k. Can the customs authorities block exports of goods not covered by the Regulation?

Under Article 46(1) of UCC, customs authorities have the right to detain goods to perform controls.

6. Availability of the goods covered by the product scope of the Regulation in the European Union and the role of the European Commission (Clearing House)

a. What is the objective of the Clearing House?

The objective of the Clearing House is to facilitate matching supply and demand for all types of PPE on the Union market and maintain the correct functioning of the internal market.

Member States should inform the Commission (Clearing House) before granting or rejecting an authorisation for exports to ensure it does not create a threat to the availability of the goods as listed in Annex I to the Regulation on the market of the Member State in question or elsewhere in the Union.

b. When should the Clearing House be contacted?

According to Article 3(5) of the Regulation, Member States are requested to only grant export authorisations where the shipment in question does not pose a threat to the availability of the goods as listed in Annex I to the Regulation 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 Clearing House, in particular when the volume of planned exports may cause a shortage (Article 3 (5) last sentence). If Member States do not intend to grant an export authorisation, they may decide not to contact the Clearing House. To get the opinion of the Clearing House within the relevant 5-days deadline, it is nevertheless advisable for a Member State to immediately inform the Clearing House.

Furthermore, according to Article 2(7) of the Regulation, Member States shall inform the Commission's Clearing House when it positively considers to grant an authorisation for the exports 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.

This means that when a Member State intends to grant an authorisation, the Member State must inform the Clearing House at the following email address SG-CCH@ec.europa.eu.

The Clearing House shall issue an opinion about the availability and the possible threat of availability of the goods as listed in Annex I to the Regulation on the market of the Member State in question or elsewhere in the Union. The Clearing House may indicate where there is a need for relevant goods.

The Clearing House shall issue an opinion within 48 hours after having been informed (Article 3 (6)).

A Member State does not have to contact the Clearing House in case of an export:

- As no export authorisation is required, to one of the countries, economies and territories, listed in Article 2(4), that are excluded from the scope of the Regulation;

- As no export authorisation is required, to facilities located on the continental shelf of a Member State or the exclusive economic zone declared by a Member State pursuant to UNCLOS, as set out in Article 2(5);
- For use in third countries to enable the provisions of emergency supplies in the context of humanitarian aid, pursuant to Article 2(6);
- If the volume of the planned exports is so small that it won't cause a threat to the EU market.

c. In what format should the Commission be consulted? Is there a template?

No specific format is needed, as long as the email/document clearly identifies the description of the product, its volume and destination and the contact details from the reporting Member State.

d. What if the Clearing House does not send an opinion within 48 hours?

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

If the Clearing House does not send a reply within the deadline provided in Articles 2(7) and 3(6) of the Regulation, the Member State can proceed with informing the exporter with its intention to grant or deny the export authorisation.

e. Is the opinion of the CCH binding or only informative?

The Commission's Clearing House provides an informed opinion, being part of its efforts to match supply and demand in the EU and facilitate an adequate functioning of the internal market. Therefore, it is advisable that the Member State follows up the opinion of the Clearing House.