EUROPEAN
COMMISSION

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COMMUNICATION FROM THE COMMISSION

Guidance note to Member States related to Commission implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorisation

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On 15 March 2020, as part of the response to the consequences of the outbreak of the epidemiological crisis caused by coronavirus, the Commission published Implementing Regulation (EU) 2020/402[1] making the exportation of certain personal protective equipment (PPE) subject to the production of an export authorisation.

As the Regulation implies new obligations on the competent authorities of the Member States as well as the economic operators, which are applicable from the day of publication, this Guidance is issued to assist them **in the implementation** process.

This Guidance is not legally binding and is for informative purposes only. It does not replace the Implementing Regulation. It is without prejudice to the interpretation of the Regulation by the Court of Justice.

1. Procedure

The Commission adopted this implementing Regulation under an urgency procedure, pursuant to Article 5 of Regulation (EU) 2015/479 of the European Parliament and of the Council on common rules for exports[2].

The Regulation is valid for a six-week period, during which Member States will be consulted in the Safeguard Committee to (i) confirm the approach and (ii) decide on the need to take appropriate measures for a subsequent period.

2. Objective of the measures

These measures have been adopted in the light of the increased need for PPE and the expectation that demand for these products will continue to increase significantly in the future, alongside developing shortages in several EU Member States.

Despite the fact that increased production has been encouraged, the current level of Union production and existing stocks will not be sufficient to meet the demand within the Union. This is particularly the case as PPE can be exported without restriction to other parts of the world, while some third countries have decided, officially or informally, to restrict exports of protective equipment. Some of these countries are also traditional suppliers to the Union market and this is further exerting pressure on the Union market.

PPE are an essential product to prevent the further spreading of the disease, and safeguard the health of medical staff treating infected patients.

Hence, the objective of these exceptional measures is to remedy and prevent a critical situation.

At the same time, 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. This is why Member States can and should grant export authorisations inter alia in the cases listed in Article 2(3) of the Implementing

[1] OJ L 077 I, 15.3. 2020, p. 1.
[2] OJ L 83, 27.3.2015, p. 34.

Regulation,, but also 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.

For any questions concerning the supply of PPE within the EU, the Member States may refer to the existing Emergency Response Coordination Centre (ERCC)[3].

3. Relation to Member States measures[4]

The shortages in the supply of PPE in recent days have lead some Member States to take certain measures at national level. At the same time, preserving the integrity of the single market is one of the objectives pursued by the Commission during the current crisis to enhance jointly the response to the challenge of health protection in the context of limited PPE supplies.

The Implementing Regulation was adopted with the understanding that Member States should revoke any restrictive national actions taken, formally or informally, concerning either exports to third countries or trade between the Member States within the Single Market, going beyond actions designed to ensure priority access to such material by those who need it most (e.g. hospitals, patients, healthcare workers, civil protection authorities)[5].

4. Practical guidance

4.1. Products concerned

The export authorisation requirement concerns **products listed in the "Description" in Annex I** to the Implementing Regulation.

This Annex details personal protective equipment for which there are vital needs within the Union with regard to **hospitals, patients, field workers, civil protection authorities**.

The Commission can review the **list** in the light of the developments both in terms of new evidence on scarcity of supplies or increased manufacturing capacities allowing to alleviate shortage concerns. In that case, it will amend the Implementing Regulation or adopt a new Regulation.

The information about the **latest state of play** of the Commission's response to coronavirus is provided on a dedicated web site: https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response_en#latest. The competent authorities in the Member States and economic operators are therefore invited to consult it on a daily basis.

The Implementing Regulation applies irrespective of whether the product concerned is **originating in the Union or not**.

4.2. Activity concerned

[3] ECHO-ERCC@ec.europa.eu

[4] On 16 March 2020, the Commission issued guidelines for Member States which set out a number of key principles for an integrated approach to an effective border management to protect health, while preserving the integrity of the Single Market, are set out in Commission guidelines, Guidelines for border management measures to protect health and ensure the availability of goods and essential services, COM(2020) 1753.

[5] See also Guidance on national measures provided in Annex 2 to the Communication of 13 March 2020 on a Coordinated economic response to the COVID-19 outbreak, COM(2020) 112 final.

The Implementing Regulation applies to all **exports outside the Union**.

This implies all **non-EU countries**, including EFTA/EEA countries and preferential partners.

The Implementing Regulation does not apply to **trade between the EU Member States**. Pursuant to Article 127(3) of the Withdrawal Agreement, the UK is to be considered as a Member State, and not as a third country.

The Implementing Regulation does not apply to **imports** of PPE identified in Annex I to the Implementing Regulation into the Union. In the context of facilitating imports and avoiding delays, the Commission has put forward a Recommendation 2020/403 on the conformity assessment and market surveillance procedures within the context of the COVID-19[6].

4.3. Application obligation

The exporter makes an **application** for an export authorisation.

Member States define the content of the application form. The information required in the form should enable the Member State to establish an export authorisation in accordance with Annex II of the Implementing Regulation. With the aim to increase a co-ordinated approach, a possible **template** of an application form is provided as an example in the Annex I to this Guidance.

To the extent possible, the Member States should enable the submission of an application via electronic means.

5. Competent authorities in the Member States

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.

The Member States are **invited to notify to DG Trade**, at the latest by 19 March 2020 midnight, **the names and contact details of competent authorities** tasked with the issuance of the export authorisations. This information will be published on the website of DG Trade[7]. The notification must be done electronically using the functional mailbox indicated in paragraph 6.

5.1. Assessment of the application by the competent authorities

The system is not an export ban. However, all exports must be subject to an export authorisation.

In deciding whether to grant an export authorisation, the Member States must fulfil the objective of the implementing act, i.e. ensure the adequacy of supply in the Union in order to meet the vital demand for PPE.

[6] OJEU L 079I, 16.3. 2020 p. 1
[7] https://ec.europa.eu/trade/

In other words, export authorisations could be granted only where the shipment in question does not pose 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 the Regulation.

Within this overarching objective, the competent authorities enjoy a margin of discretion and exports of certain quantities of specific products, may be authorised under specific circumstances depending on the needs of Member States.

Article 2 (3) of the Implementing Regulation includes an illustrative list of considerations which are to be taken into account, where appropriate, in deciding whether an export authorisation could be issued.

These considerations concern, amongst others, the fulfilment of a supply obligation under joint procurement by the Union and the Member States, the support of the activities of the World Health Organisation (WHO), the support of EU-level coordinated responses to crisis situations or the request for assistance by third countries or international organisations, including the need for emergency supplies required by humanitarian non-governmental organisations or international organizations for their own operations to deliver humanitarian assistance in third countries.

The objective of the latter is to ensure, to the extent possible, the availability of PPE where needed outside the Union in third countries which may face an acute need for PPE at a particular moment. These are expressions of the principle of international solidarity both in general and in a situation of a global pandemic with impacts across the world and of the fact that international trade can contribute to the availability of products where needed and when needed.

The list in Article 2 (3) is not exhaustive and Member States may take other elements into account. However, they must comply with the general objective of the Implementing Regulation as recalled above.

In particular, the single market for medical and personal protective equipment is deeply integrated beyond the EU and so are its value chains and distribution networks – in particular, but not exclusively, with neighbouring countries such as the EEA/EFTA States and associated States. This should be taken into account in order to prevent undesirable trade effects.

Among other elements which the competent authorities could consider is whether the shipment in question serves to fulfil contractual obligations entered into before a reference period. To enhance a coordinated approach across the EU, Member States could use as reference the preceding calendar year (i.e. 2019). The Member States have the responsibility to ensure that these additional elements have to be subject to an overriding consideration of EU needs if those cannot otherwise be met.

5.2. Relevant deadlines

The Member States must process the export authorisation requests within 5 working days from the date on which all required information has been provided to the competent authorities.

The deadline can be extended for a further 5 working days in duly justified circumstances.

If the product is located in one or more Member States other than the one where the application for export authorisation has been made, the Member State to which the application has been made should immediately consult the competent authorities of the Member State or Member States in question and provide the relevant information.

The consulted authorities have to make known in writing within 10 working days any objections they may have to the granting of such authorisation. These objections bind the Member State in which the application is made.

At the same time, 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.

5.3. Export authorisation

Without a production of an export authorisation, the exportation is prohibited.

To increase a co-ordinated approach across the EU, the template for the export authorisation is provided in Annex II of the Implementing Regulation.

6. Notification

The objective of these exceptional measures is to ensure an adequate level of supply in all Member States, depending on their needs for PPE.

In order to ensure a transparent process, Member States are requested to notify to the Commission electronically the authorisations granted and not granted, on the basis of the template in Annex II. This notification should be made without delay as soon as the decision on the authorisation is taken.

This information should be transmitted electronically, to the functional mailbox below:

TRADE-EXPORTAUTHORISATIONPPE@ec.europa.eu

The functional mailbox should also be used for any questions on the application of this system.

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This Guidance is a dynamic document and could be updated as the new issues and questions are flagged to the Commission.

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ANNEXES 1 to 2

ANNEXES

to the

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Annex I – Template for application of export authorisation

<table>
<tr><td colspan="2">EUROPEAN UNION</td><td colspan="2">Export of personal protective equipment (Regulation (EU) 2020/402)</td></tr>
<tr><td colspan="2">1. Exporter (EORI number if applicable)</td><td colspan="2"></td></tr>
<tr><td colspan="2">5. Destination country</td><td colspan="2">6. Final recipient</td></tr>
<tr><td>7. Commodity code</td><td>8. Quantity</td><td>9. Unit</td><td>10. Description of the goods</td></tr>
<tr><td>11. Location</td><td>12. Date of planned export</td><td></td><td></td></tr>
<tr><td colspan="4">13. Signature, place and date, stamp</td></tr>
</table>

Explanatory notes to the export authorisation form:

Box 1 Exporter: Full name and address of the exporter for whom the authorisation is issued + EORI number if applicable.

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 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), and "PA" for goods counted by pairs (e.g. gloves).

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 : Date at which the goods for which the authorisation is sought are to be exported

Box 13: Signature, stamp, place and date: The signature and stamp of the issuing authority. The place and the date of issuance of the authorisation.

Annex II

Template for Member States notifications

<table>
<tr><td colspan="2">EUROPEAN UNION</td><td colspan="2">Export of personal protective equipment (Regulation (EU) 2020/402)</td></tr>
<tr><td colspan="4">0. Name and contact details of the competent Authority</td></tr>
<tr><td colspan="2">1. Exporter (EORI number if applicable)</td><td colspan="2"></td></tr>
<tr><td colspan="2">2. Destination country</td><td colspan="2">3. Final recipient</td></tr>
<tr><td>4. Commodity code</td><td>5. Quantity</td><td>6. Unit</td><td>7. Description of the goods</td></tr>
<tr><td>8. Location</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Authorisation to export granted? (Yes/No)</td></tr>
<tr><td colspan="4">Reasons for acceptance/refusal:</td></tr>
<tr><td colspan="4">Any pertinent information concerning the consultation of other Member States pursuant to Article 2(2) of the implementing Regulation:</td></tr>
</table>

Box 0: Full name and address of the Member State authority that issued the export authorisation.

Box **1 Exporter:** Full name and address of the exporter for whom the authorisation is issued + EORI number if applicable.

Box 2: Destination country: 2-letter geonomenclature code of the country of destination of the goods for which the authorisation is issued.

Box 3 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 4 Commodity code: The numerical code from the Harmonised System or the Combined Nomenclature under which the goods to export are classified when the authorisation is issued.

Box 5 Quantity: The quantity of goods measured in the unit declared in box 6.

Box 6 Unit: The measurement unit in which the quantity declared in box 5 is expressed. The units to use are "P/ST" for goods counted by number of pieces (e.g. masks), and "PA" for goods counted by pairs (e.g. gloves).

Box 7 Description of the goods: Plain language description precise enough to allow identification the goods.

Box 8 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.