



30 March 2021

EXPORT REQUIREMENTS FOR COVID-19 VACCINES

FREQUENTLY ASKED QUESTIONS

The authorisation requirement for exports of Covid-19 vaccines and their active substances including master and working cell banks has first been introduced, for a limited period of six weeks, by Commission Implementing Regulation (EU) 2021/111 of 29th January 2021. It was subsequently extended by Commission Implementing Regulation (EU) 2021/442 of 12th March 2021, until 30 June. The Commission implementing Regulation (EU) 2021/521 of 24th March 2021 has introduced additional arrangements for a period of six weeks.

The objective is to tackle the current lack of transparency of vaccine exports from the EU and to ensure timely access to COVID-19 vaccines for EU citizens in accordance with contractual agreements. This mechanism aims at preventing exports from companies with whom the EU has concluded Advance Purchased Agreements (APAs), where they threaten the execution of those APAs, as well as to preserve the security of the EU's supply chains.

All relevant documents can be consulted under the following links:

[Commission Implementing Regulation \(EU\) 2021/442](#)

[Commission Implementing Regulation \(EU\) 2021/521](#)

[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 Covid-19 vaccines and active substances including master and working cell banks ('the goods'), Member States customs authorities and competent authorities under the Regulation when implementing the Regulation.

1. **RELEVANT FACTORS FOR DECIDING TO ACCEPT/REJECT A REQUEST FOR EXPORT AUTHORISATION**

a. **On what grounds will Member States/the Commission decide to authorise/refuse export authorisation?**

1) **Threat to the execution of APAs concluded by the Union with vaccine manufacturers**

Vaccine manufacturers have been requested to provide information on the number of vaccine doses distributed in the Union since 1 December 2020 and data concerning their exports since 30 October 2020. This information, together with other elements as specified elsewhere in this Q & A, will be used in order to assess whether the exports threaten the execution of the APAs. It will also contribute to giving a picture as to how production delays, etc. are shared between the Union and export destinations. The assessment will be made on a case by case basis, taking into account the specificities of each APA in its specific context.

Member States may also decide to reject any request of export authorisation where the necessary information has not been supplied by the exporter. Member States may also verify the information submitted, even after authorising exports.

2) **Threat to the security of supply within the Union**

To determine whether the authorisation poses a threat to the security of supply within the Union, the Member States/ the Commission should take into consideration the following factors, considering the principles of reciprocity and proportionality:

- whether the country of destination of the export restricts its own exports of COVID-19 vaccines, their active substances, or of the raw materials from which they are made, either by law or by any other means, including through the conclusion of contractual arrangements with the manufacturers of those goods;
- the relevant conditions prevailing in the country of destination of the export, including the epidemiological situation, the vaccination rate and the existing availability of COVID-19 vaccines or their active substances.

b. **How will the Member States/the Commission ensure that supplies related to APAs concluded by third countries with vaccine suppliers in the EU will not be disturbed?**

The Commission is mindful of APAs contracted by third countries, and will endeavour that the expectations of these countries to obtain their deliveries will be met as much as possible. In case of shortages or delays in the production of vaccines, the Commission will endeavour to ensure that exports are authorised in an equitable manner so that APAs contracted by third countries are respected as much as possible. For that purpose, third country authorities are invited to work together with the Commission to ensure that the Commission has the necessary information at its disposal on the APAs they have concluded with vaccine producers, including, in case of requests for export authorisations to vaccine producing countries, to what extent they share their vaccines with third countries and whether or not

APAs concluded by these countries domestically and abroad contain clauses that should privilege domestic supply.

2. PRODUCT SUBJECT TO THE AUTHORISATION SCHEME

General remarks

The Regulation covers vaccines against SARS-related coronaviruses (SARS-CoV species) falling under CN code 3002 20 10, irrespective of their packaging. It also covers active substances including master and working cell banks used for the manufacture of such vaccines falling under CN codes ex 2933 99 80, ex 2934 99 90, ex 3002 90 90 and ex 3504 00 90.

The Regulation therefore concerns exports of either the finished vaccine in its final form or any product essential for its manufacturing.

This includes:

- The active substance (commonly called drug substances or bulk, intermediates, master and working cell banks)
- The vaccine in a bulk packaging
- The vaccine in its primary and/or secondary packaging

a. **Does the Regulation apply to exports of 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 threaten the execution of Union Advance Purchase Agreements (APAs) concluded with vaccines manufacturers may take into consideration the fact that the application concerns a limited quantity to be exported.

Similarly, samples labelled for the conduct of clinical trials are typically exported in small quantities and, in these cases, these exports should be swiftly authorised by Member States since they do not threaten the execution of APAs, unless there are indications that such labelling could be used to circumvent the regulation.

b. **Does the Regulation apply to active substances that are not used for the production of SARS-related coronavirus vaccines?**

Active substances are only covered when they are used for the manufacture of SARS-related coronavirus vaccines. In the event that there would be certain active substances that can be used both for SARS-related coronavirus vaccines and for other applications, these are only covered by the Regulation when they will actually be used in the manufacture of the vaccines concerned. In case an active substances that could theoretically be used in the manufacture of a SARS-related coronavirus vaccine is exported for a different use (unrelated to the production or sampling of SARS-related coronavirus vaccines), it is out of scope of the Regulation and additional TARIC code 4599 should be used, as explained in Annex II of Regulation (EU) 2021/442.

3. EXCLUSIONS FROM THE SCOPE OF THE REGULATION

a. Which countries, economies and/or territories are excluded from the scope of the Regulation?

The export authorisation mechanism concerns exports to all non-EU countries with the following exceptions:

- Overseas countries and territories listed in Annex II of the Treaty on the functioning of the European Union¹ [note that the territories having special relations with the United Kingdom listed in annex II of the TFEU are subject to the export authorisation²];
- Territories of Member States specifically excluded from the customs territory of the Union: Büsingen, Heligoland, Livigno, Ceuta and Melilla;
- Andorra, the Faroe Islands, Monaco, San Marino and the Vatican City;
- Low and middle income countries in the COVAX AMC list that can be found on the following website: <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc>, which are
 - Low income: Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Dem. Rep., Eritrea, Ethiopia, Gambia, The Guinea, Guinea-Bissau, Haiti, Korea, Dem. People's Rep., Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Togo, Uganda, Yemen
 - Lower-middle income: Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Rep. Côte d'Ivoire, Djibouti, Egypt, Arab Rep., El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyz Republic, Lao PDR, Lesotho, Mauritania, Micronesia, Fed. Sts., Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Príncipe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia, Zimbabwe
 - Additional International Development Association eligible: Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, Tuvalu.

b. Which exports are also excluded from scope of the Regulation based on the principle of solidarity?

- Exports of goods purchased/or delivered through COVAX, UNICEF and PAHO with destination to any other COVAX participating country

¹ OJ C 326, 26.10.2012, p. 336.

² Anguilla, Cayman Islands, Falkland Islands, South Georgia and the South Sandwich Islands, Montserrat, Pitcairn, Saint Helena and Dependencies, British Antarctic Territory, British Indian Ocean Territory, Turks and Caicos Islands, British Virgin Islands, Bermuda.

- exports of goods purchased by EU States under the EU APAs donated or resold to third countries
- exports in the context of a humanitarian emergency response.

Note that exports to countries that support COVAX, but which do not fall under any of the above exclusions, are not excluded.

c. Under which conditions are exports of goods purchased by EU States under EU APAs excluded?

According to Article 1.9(d) of Regulation EU 2021/442, exports of goods purchased by Member States under the APAs and donated or resold to a third country are exempted from the authorisation requirement. This would be the case even if the goods are directly shipped to the country of destination outside the EU customs territory.

d. Does the export authorisation requirement apply to exports which are parties to Agreement establishing the European Economic Area?

Exports to the countries which are parties to the Agreement establishing the European Economic Area (Iceland, Liechtenstein, Norway) are not excluded as such from the export authorisation requirement. However, exports to those countries are excluded from that requirement when they fall within the scope of one of the exemptions listed under Article 1(9) of Regulation EU 2021/442. In particular, in accordance with Article 1.9(d), exports to Iceland, Liechtenstein, Norway are excluded from the export authorisation requirement if they consist of goods procured by a Member State under a Union APA and donated or resold to one of those countries. This is the case even if the goods are directly shipped by the vaccine manufacturer to Iceland, Liechtenstein or Norway from a Member State other than the one which has procured the goods under the Union APA and resold it to those countries.

e. 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 principles³. It should, in principle, be guided by the 24 Principles and Good Practice of Humanitarian Donorship⁴ and fall under the OECD-DAC purpose codes used to report humanitarian aid activities.

In their assessment of the application, Member States competent authorities are encouraged to refer to existing registries and certifications for organisations providing humanitarian aid,

³ At EU level, the humanitarian principles are enshrined in the European Consensus on Humanitarian Aid: the principles of neutrality, humanity, independence and impartiality.

⁴ <https://www.ghdinitiative.org/ghd/gns/best-practices.html>

such as the list of organisations which are humanitarian partners of the European Commission⁵.

The Member States competent authorities are also encouraged 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>. The export to any organisation listed there should be automatically considered as an export in the context of a humanitarian emergency response. This list is however not exhaustive and Member States are welcome to consider other organisations under Article 1(9) of the Regulation.

f. 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 1(9) of Regulation (EU) 2021/442, 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.

4. AUTHORISATION PROCEDURE

a. Where do exporters have to make the request for the export authorisation?

The request for export authorisation shall be made to the competent authorities of the Member States where products subject to the Regulation (working cells, active substances, primary packaging, secondary packaging, finished products) are physically manufactured.

b. Where is a product considered to be manufactured?

If a vaccine for which authorisation is sought is already filled and finished, the manufacturer is the entity that filled and finished the products. If the authorisation request concerns the vaccines in bulk, the manufacturer is the entity that produced substance in bulk. If the authorisation request concerns an active substance, the manufacturer is the entity that produced the active substance. Manufacturing includes filling and packaging of vaccines.

If the vaccine or active substance is being re-exported, the manufacturer conducting the manufacturing operation in the EU shall ask the export authorisation. If the manufacturing of the active substance is taking place in one Member State and the packaging is taking place in another Member State, the entity that has done the final manufacturing operation to the product exported, i.e. the packaging, shall request the export authorisation.

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

⁵ <https://ec.europa.eu/echo/sites/echo-site/files/weblistpartners.pdf>

The list of competent authorities is published at the following link:

[List of competent authorities in Member States](#)

d. What information needs to be submitted by the exporter?

- The request for export authorisation shall contain the information set out in Annex I and the applicable TARIC additional codes in Annex II to Regulation 2021/442. This information will be necessary for the Member State to issue the export authorisation. The exporter should use the application form issued by the Member State competent authority or, if not available, may use the template attached in Annex I to this FAQs.
- Each request shall also contain information on the number of vaccine doses of goods covered by this Regulation distributed since 1 December 2020 broken down as indicated in Article 2(1) of the Regulation (EU) 2021/442.
- At the latest together with the first request for an export authorisation request, the vaccine manufacturers that have concluded APAs shall provide electronically to the Member State competent authorities and to the Commission [email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu] the relevant data concerning their exports since 30 October 2020. This information shall include the volume of exports of COVID-19 vaccines, the final destination and final recipients and a precise description of the products under the form of a table containing the number of doses per destination and recipient (row) and exported per week (column) in Excel or Word format that will be made available by the Commission. The absence of such information may lead to refusal of export authorisations.
- In order to ensure that export authorisations are considered on the basis of all relevant data and to allow the Commission to evaluate any potential impact of exports on the relevant Advanced Purchasing Agreements with the Union, exporters are also encouraged to supply Member States and the Commission [email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu] with estimated production forecasts. The applicants are invited to present this information in a table with the number of estimated doses per Member State (row) and the expected week of delivery (column) in excel format.

e. How is the authorisation request processed and how long will the procedure take?

In line with Article 2(2) and (4) of the Regulation (EU) 2021/442, within two working days from the receipt of a duly completed request for an export authorisation, the Member State competent authority will issue a draft decision. In case of disagreement with the draft decision, the Commission will issue an opinion on the draft decision within one working day.

In exceptional and duly justified cases, the competent authority may extend the time needed for the draft decision by an additional two working days.

f. Who will decide in the end?

The Member State competent authority will decide about the request for an export authorisation in accordance with the Commission's opinion. The Commission will however only give an opinion in cases it disagrees with the Member States' draft decision.

g. 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 goods were manufactured (i.e. where the last step in the manufacturing process took place). If goods to be exported are 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.

h. Member States shall process applications for export authorisations as soon as possible, but shall issue a draft decision no later than two working days from the date on which all required information has been provided to the competent authorities. How is this deadline of two 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 two working days deadline⁶. 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 draft decision should be taken by the end of the Wednesday.]

Within the 2-day deadline, the Member States must notify the Commission (SANTE-PHARMACEUTICALS-B4@ec.europa.eu) of the draft decision. This means that consulting the Commission does not extend the deadline beyond two days for the Member State to prepare its draft decision. The Commission is bound to issue an opinion within one day from the receipt of the notification of the draft decision of the Member State.

i. 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.

j. 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 remedy the critical situation concerning the supply of Covid-19 vaccines. 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.

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.

⁶ 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.

- k. **If the exporter exports multiple consignments in one shipment, is it allowed to request only one export authorisation?**

If the exporter wants to export multiple consignments to different final recipients, it is allowed to request a single authorisation for all of them, provided that all consignments are part of one single shipment destined to the same destination country and released by the same customs office of export.

- l. **Why should the office of export be indicated in the authorisation?**

The office of export is indicated in the authorisation to help customs monitoring that each authorisation is used only once.

- m. **Can an operator change the office of export after it received the authorisation from the competent authorities?**

Yes, it may happen that the customs office of export changes after the authorisation has been approved. Lodging the customs declaration in a customs office of export other than the one mentioned in the authorisation does not invalidate the authorisation, as the customs authorities can still monitor that the same authorisation is not used multiple times by contacting the customs office mentioned in the authorisation as customs office of export.

- n. **Where can the competent authority find the information necessary to check the destinations or purposes covered by Article 1(9) of Regulation (EU) 2021/442?**

It is for the exporter requesting the export authorisation to indicate if any of the relevant exemptions considered under Article 1(9) of Regulation (EU) 2021/442 apply or if the exports are destined to any of the parties listed in that article, 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.

- o. **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.

5. **WHAT SHOULD MEMBER STATES NOTIFY TO THE COMMISSION AND WHEN?**

Member States should notify the following information at the following email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu:

- a. Any application received, immediately;

- b. Draft decision, as soon as possible and within two working days;
- c. Granted or rejected export authorisation immediately, and including the reason for rejection.

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

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 above information should be submitted in the form of a table, in a spreadsheet, based on templates that the Commission will make available.

6. RELATION TO MEMBER STATES MEASURES

The Implementing Regulation was adopted with the understanding that Member States should avoid any restrictive national actions taken, formally or informally, concerning either exports to third countries or trade between the Member States within the Single Market of the products subject to the Regulation.

7. DURATION OF THE EXPORT AUTHORISATION SCHEME

The current measures are in place until 30 June 2021.

8. CUSTOMS PROCEDURES

General remarks

The Regulation is integrated in the TARIC with measures 709 (export control). The list of goods is also inserted in the TARIC, as well as the TARIC additional codes identifying the manufacturers and the document type for the export authorisation (code C089).

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 or when non-Union goods are re-exported, i.e. customs procedures under code 31.

In this context, the following transactions, i.e. customs procedures under all other codes, are excluded⁷:

- (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. **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 and to re-exports of non-Union goods after such goods have been subject to manufacturing operations including filling and packaging within the customs territory of the Union. This means that also in case goods are imported into the Union to be re-exported, the Regulation applies and an export authorisation must be requested.

⁷ 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

c. 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”. According to Article 270(3)(c) UCC, if the goods in temporary storage are directly re-exported from a temporary storage facility, a re-export declaration is not needed.

Thus, an export authorisation for goods placed in a temporary storage is generally required, if such goods have been subject to manufacturing operations including filling and packaging within the customs territory of the Union, unless the transaction is covered by Article 270(3)(c) UCC.

d. 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.

e. 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.

f. Should the exporter for customs purposes (box 2 on the export declaration) correspond to the “authorisation holder” mentioned on the authorisation (box 1 export authorisation form)? Or can the export declaration be lodged by another exporter?

The Regulation leaves to the discretion of the Member States the modalities for administering the export authorisation system, requiring only for customs that the goods are not released for export if there is no export authorisation. Therefore, if the Member States customs authorities put in place systems to verify that the export is covered by an authorisation, there is no need to require the same exporter in the customs declaration and in the authorisation. The system could identify the relevant export declarations through the CN code of the product (specific for vaccines) and/or the additional TARIC code (Box 33), for instance. Please contact the customs authorities of the Member State where the export declaration of the vaccines is to be lodged.

g. Where should the export authorisation be mentioned in the export declaration?

Box 44 (or data element 2/3) allows to state the authorisation number (document type = C089 + authorisation number). The declaration must also contain the specific CN code for vaccines or active substances, and the additional TARIC code for the producer.

h. Is the additional TARIC code of Annex II of Regulation 2021/442 a mandatory element for the exporter?

Yes, it is mandatory. The export declaration must contain the export authorisation number and the additional TARIC code. If the company is not individually specified in Annex II of the

regulation, the additional TARIC code for other manufacturers should be used. In case the export declaration concerns active substances that are not going to be used in the manufacture Covid-19 vaccines, TARIC additional code 4599 must be declared, regardless of the identity of the authorisation holder.

* *

*

ANNEX I

Template for application of an export authorisation

EUROPEAN UNION			
Export of COVID-19 vaccines and active substances including master and working cell banks (Regulation EU 2021/442)			
1. Exporter <i>(EORI number if applicable) and TARIC additional code</i>			
2. Destination country		3. Expiry date	
4. Issuing authority	5. Customs office of export	6. Destination country	
7. Commodity code	8. Quantity	9. Unit (vaccine doses)	10. Description of the goods
11. Location			
7. Commodity code	8. Quantity	9. Unit (vaccine doses)	10. Description of the goods
11. Location			
7. Commodity code	8. Quantity	9. Unit (vaccine doses)	10. Description of the goods
11. Location			
7. Commodity code	8. Quantity	9. Unit (vaccine doses)	10. Description of the goods
11. Location			
7. Commodity code	8. Quantity	9. Unit (vaccine doses)	10. Description of the goods
11. Location			
12. Signature, place and date, stamp			