



STATUTORY INSTRUMENTS.

S.I. No. 49 of 2021

EUROPEAN UNION (COVID-19 VACCINES EXPORT
AUTHORISATION) REGULATIONS 2021

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I, LEO VARADKAR, Minister for Enterprise, Trade and Employment, in exercise of the powers conferred on me by Section 3 of the European Communities Act (No. 27 of 1972) and for the purpose of giving full effect to Commission Implementing Regulation (EU) 2021/111 of 29 January 2021¹, hereby make the following regulations:

1. These Regulations may be cited as the European Union (COVID-19 Vaccines Export Authorisation) Regulations 2021.

2.

(1) In these Regulations –

- (a) “applicant” means an individual or entity that has applied for an authorisation.
- (b) “Commission Implementing Regulation” means Commission Implementing Regulation (EU) 2021/111 of 29 January 2021¹ making the exportation of certain products subject to the production of an export authorisation.
- (c) “Minister” means the Minister for Enterprise, Trade and Employment.

(2) A word or expression used in these Regulations and which is also used in the Commission Implementing Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Commission Implementing Regulation.

3.

(1) The Minister is the competent authority in the State for the purposes of the Commission Implementing Regulation.

(2) The Minister is responsible for the notification obligations provided for in Articles 2(3) and 3(1) of the Commission Implementing Regulation.

4.

(1) Where the Minister is satisfied that the requirements of these Regulations and the Commission Implementing Regulation will be complied with, he or she may, subject to these Regulations, grant an authorisation to a person for the purposes of Article 1 of the Commission Implementing Regulation.

¹ OJ No. L 31 I, 30.01.2021, p.1

(2) A person applying for an authorisation shall furnish the Minister with such information as the Minister may reasonably require to ensure that the Commission Implementing Regulation will be complied with and to decide whether or not to grant the authorisation.

(3) An application for an authorisation must be made in accordance with the form specified in Schedule 1.

(4) An authorisation is valid for such period and for such exports as the Minister may determine and the period shall be specified in the authorisation.

(5) The holder of an authorisation shall inform the Minister if significant changes are made in the operation or organisation of the activities to which the authorisation relates.

5.

(1) The Minister may appoint such and so many persons as he or she thinks fit to be authorised officers for the purposes of ensuring compliance with the Commission Implementing Regulation and these Regulations.

(2) The Minister shall furnish an authorised officer with a warrant of her or her appointment and when exercising a power conferred by these Regulations, the authorised officer shall, if requested by a person affected, produce the warrant or a copy of it to that person for inspection.

(3) The Minister may terminate the appointment of an authorised officer whether or not the appointment was for a fixed period.

(4) The appointment of an authorised officer ceases –

- (a) If it is terminated under paragraph (3)
- (b) If it is for a fixed period, on the expiry of that period, or
- (c) If the person appointed as an officer of the Minister, upon the person ceasing to be such an officer.

(5) An authorised officer may, for the purposes of ensuring compliance with the Commission Implementing Regulation and these Regulations, do one or more of the following:

- (a) Subject to paragraph (6), enter at all reasonable times any place at which the authorised officer has reasonable grounds for believing that books, records or other documents relating to the Commission Implementing Regulation are kept;
- (b) at such place, inspect and take copies of any books, records or other documents (including books, records or documents stored in non-legible form) that the authorised officer finds in the course of his or her inspection;
- (c) remove any such books, records or other documents from such place and return them for such period as he or she reasonable considers to be necessary for the purposes of this Regulation;

- (d) require any person at the place concerned to give the authorised officer such information and assistance as the authorised officer may reasonably require for the purposes of this Regulation;
- (e) require any person at the place concerned to produce to the authorised officer such books, records or other documents (and in the case of books, records or documents stored in non-legible form, a legible reproduction thereof) that are in that person's possession or procurement, or under that person's control, as the authorised officer may reasonably require for the purposes of this Regulation.

(6) An authorised officer shall not, other than with the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court under paragraph (8) authorising such entry.

(7) Where an authorised officer in the exercise of his or her powers under this Regulation is prevented from entering any place, an application may be made to the District Court under paragraph (8) for a warrant authorising such entry.

(8) If a judge of the District Court is satisfied on the sworn information of an authorised officer that there are reasonable grounds for suspecting that books, records or other documents required by an authorised officer for inspection under this Regulation are held in any place and that such inspection is likely to disclose evidence of a contravention of the Commission Implementing Regulation or these Regulations, the judge may issue a warrant authorising the authorised officer, accompanied by such other authorised officers or members of the Garda Síochána as may be necessary, at any time or times within one month from the date of issue of the warrant, on production of the warrant, if requested, to enter (if necessary by the use of reasonable force) the place concerned and perform the functions conferred on an authorised officer under this Regulation.

(9) In this Regulation, "place" includes -

- (a) a dwelling or a part thereof,
- (b) a building or a part thereof, and
- (c) any other premises or part thereof.

6. A person who –

(1) Contravenes Article 1(3) of the Commission Implementing Regulation shall be guilty of an offence.

(2) In making an application for an authorisation wilfully makes a false or misleading statement is guilty of an offence.

(3) Without reasonable excuse, fails to comply with any requirement made by an authorised officer under Regulation 5 or in purported compliance with such a requirement gives the authorised officer information which is false or misleading in a material respect is guilty of an offence.

(4) Obstructs or interferes with an authorised officer in the exercise of his or her powers under Regulation 5 is guilty of an offence.

7. A person who is guilty of an offence under Regulation 6 shall be liable

- (a) on summary conviction, to a class A fine or to imprisonment for a term not exceeding 12 months or both, or
- (b) on conviction on indictment, to a fine not exceeding €500,000 or to imprisonment for a term not exceeding 3 years or both.

8. A summary offence under Regulation 6 may be prosecuted by the Minister.

GIVEN under my Official Seal,
4 February, 2021.

LEO VARADKAR,
Minister for Enterprise, Trade and Employment.



Schedule 1*Export authorisation application form*

 An Roinn Fiontar, Trádála agus Fostaíochta Department of Enterprise, Trade and Employment	Application for Export Authorisation COVID-19 Vaccines Pursuant to Commission Implementing Regulation (EU) 2021/111
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1. Exporter <i>Name, Address, EORI number, TARIC additional code of manufacturer</i>	2. Final Recipient <i>Name, Address, EORI number (if applicable)</i>		
3. Destination Country			
4. Commodity Code	5. Description of the goods	6. Quantity	7. Unit
8. Location			
4. Commodity Code	5. Description of the goods	6. Quantity	7. Unit
8. Location			
4. Commodity Code	5. Description of the goods	6. Quantity	7. Unit
8. Location			

1. Doses Distributed in the EU to Date

Information on the number of vaccine doses of goods covered by Commission Implementing Regulation (EU) 2021/111 distributed in the Union since 1st December 2020, broken down by Member States as well as information on the number of vaccine doses of goods covered by this Regulation distributed in Northern Ireland since the entry into force of the Regulation.

Vaccine manufacturers that have concluded an Advance Purchased Agreement with the EU are required to submit the following information with their first application for an authorisation:

Relevant data concerning their exports in the three months prior to the entry into force of the Regulation. 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.

Manufacturers shall provide this information electronically to the European Commission at

SANTE-PHARMACEUTICALS-B4@ec.europa.eu

and the Department of Enterprise, Trade and Employment at

exportcontrol@enterprise.gov.ie

Failure to provide this information may result in the refusal of export authorisations.

2. Declaration

I, the undersigned, certify that the information provided in this application is true and given in good faith.

Name of applicant (block capitals)	
Signature	
Date	
Position in the Company	
Telephone Number	
Email Address	

Please type the required information and return a scanned copy of the signed form to the

Department of Enterprise, Trade and Employment at

exportcontrol@enterprise.gov.ie

Explanatory note to the export authorisation application form

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

Box 1	Exporter details	Full name and address of the exporter for whom the authorisation is issued and EORI number if applicable. TARIC additional code of manufacturer as defined in Annex II to the Commission Implementing Regulation.
Box 2	Final recipient	Full name and address of the final recipient of the goods, if known at the time of issuance and EORI number or equivalent, if applicable. If the final recipient is not known at the time of issuance, the field is left empty.
Box 3	Destination Country	2-letter geonomenclature code of the country of destination of the goods for which the authorisation is issued.
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	Description of goods	Plain language description precise enough to allow identification the goods.
Box 6	Quantity	The quantity of goods measured in the unit declared in box 7.
Box 7	Unit	The measurement unit in which the quantity declared in box 8 is expressed. The units to use are the number of vaccine doses.
Box 8	Location	If the goods are located in one or more Member States other than Ireland, please indicate that fact by including the geonomenclature code of the Member State where the goods are located. If the goods are located in Ireland, this box must be left empty.
Box 9	Doses Distributed in the EU to Date	Information on the number of vaccine doses of goods covered by Commission Implementing Regulation (EU) 2021/111 distributed in the Union since 1st December 2020, broken down by Member States as well as information on the number of vaccine doses of goods covered by this

		Regulation distributed in Northern Ireland since 30th January 2021.
Box 10	Declaration	Declaration that the information provided in the form is true and given in good faith.

EXPLANATORY NOTE

(This note is not part of the instrument and does not purport to be a legal interpretation.)

These Regulations give full effect to the transparency and authorisation mechanism for COVID-19 vaccines contained in Commission Implementing Regulation (EU) No 2021/111 regarding making the exportation of certain products subject to the production of an export authorisation.

The Regulations provide that an export authorisation shall be required for the export of vaccines against SARS-related coronaviruses falling under CN code 3002 20 10, as well as active substances including master and working cell banks used for the manufacture of such vaccines.

The Regulations create offences for breach of the Commission Implementing Regulations or for failure to comply with the directions of competent authorities of the State with regard to implementation of the export authorisation and provides for appropriate penalties.

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