EUROPEAN
COMMISSION

Brussels, 24.3.2021
C(2021) 2081 final

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of 24.3.2021

making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorisation

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports [1], and in particular Article 5 thereof,

Whereas:

(1) On 30 January 2021, the Commission adopted Implementing Regulation (EU) 2021/111[2] making the exportation of COVID-19 vaccines as well as active substances, including master and working cell banks, used to manufacture these vaccines, subject to the production of an export authorisation, pursuant to Article 5 of Regulation (EU) 2015/479. At the end of the six weeks period following the date of entry into force of these measures, the Commission adopted Implementing Regulation (EU) 2021/442[3] making the exportation of the same products subject to an export authorisation until 30 June 2021, pursuant to Article 6 of Regulation (EU) 2015/479.

(2) The global shortage of supply of COVID-19 vaccine persists and is even increasing in view of the delays of production.

(3) In accordance with Regulation (EU) 2021/442, export authorisations are to be refused by the Member States where the exports concerned pose a threat to the execution of the Advanced Purchase Agreements (APAs) between the Union and vaccine manufacturers in view of their volume or other relevant circumstances, such as the volume of vaccines delivered to the Union at the time of the request.

(4) There is still a lack of transparency as well as persisting constraints on production of COVID 19 vaccines and delays in their delivery in the Union, which may pose a threat to the security of supply within the Union of the goods covered by Regulation (EU) 2021/442. Additional elements should therefore also be considered in the decision to grant or refuse an export authorisation.

(5) The information collected by the Commission through the export authorisation mechanism put in place by Regulation (EU) 2021/111 and continued by Regulation (EU) 2021/442 and through customs data has shown that exports which are subject to the authorisation mechanism may be channelled via countries so far exempted from the export authorisation requirement, thereby not allowing for the required level of transparency. These exemptions should therefore be temporarily suspended.

(6) The exemption should be maintained for some of the countries and territories mentioned Article 1(9) (a) of Regulation (EU) 2021/442, namely those which have a

[1] OJ L 83, 27.3.2015, p. 34.
[2] OJ L 31 I, 30.1.2021, p. 1.
[3] OJ L 85, 12.3.2021, p. 190.

particular dependency on the metropolitan supply chains of the Member States to which they are attached or on the supply chains of neighbouring Member States, respectively.

(7) The information mentioned in recital (5) has also shown that Union manufacturers have exported large quantities of goods covered by the export authorisation mechanism to countries which have a large production capacity of their own, while those countries restrict their own exports to the Union, either by law or through contractual or other arrangements concluded with vaccine manufacturers established in their territory. This imbalance leads to shortages of supply within the Union.

(8) Furthermore, the same information has shown that Union manufacturers have exported large quantities of goods covered by the export authorisation mechanism to certain countries without production capacity, but which have a higher vaccination rate than the Union or where the current epidemiological situation is less serious than in the Union. Exports to those countries may thus threaten the security of supply within the Union.

(9) Member States should refuse export authorisations accordingly.

(10) The Commission should take the same additional elements into consideration when conducting its assessment of the draft decision notified by the competent authority of the Member State pursuant to Article 2(4) of Regulation (EU) 2021/442.

(11) Due to the urgency of the situation, the measures provided for in this Regulation should be taken in accordance with Article 3(3) of Regulation (EU) 2015/479.

(12) This Regulation should enter into force immediately. Having regard to Article 5(5) of Regulation (EU) 2015/479, the measures provided for in this Regulation should apply for six weeks,

HAS ADOPTED THIS REGULATION:

Article 1

The application of point (a) of Article 1(9) of Regulation (EU) 2021/442 is suspended.

However the suspension shall not apply to the following countries and territories:

– Andorra,

– the Faroe Islands,

– San Marino,

– Vatican City,

– the overseas countries and territories listed in Annex II to the Treaty on the Functioning of the European Union,

– Büsingen,

– Helgoland,

– Livigno,

– Ceuta and Melilla.

Article 2

1. The competent authority of a Member State shall grant an export authorisation requested pursuant to Regulation (EU) 2021/442 provided that:

(a) the export authorisation fulfils the condition of Article 1(7) of Regulation (EU) 2021/442;

(b) the authorisation does not otherwise pose a threat to the security of supply within the Union of the goods covered by Regulation (EU) 2021/442.

2. To determine whether the condition in point (b) of paragraph 1 is fulfilled, the competent authority of the Member State shall assess the following factors:

(a) whether the country of destination of the export restricts its own exports to the Union of goods covered by Regulation (EU) 2021/442, 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;

(b) the relevant conditions prevailing in the country of destination of the export, including the epidemiological situation, the vaccination rate and the existing availability of goods covered by Regulation (EU) 2021/442.

3. When the Commission assesses the draft decision notified by the competent authority of the Member State pursuant to Article 2(4) of Regulation (EU) 2021/442, it shall also evaluate whether the condition in point (b) of paragraph 1 of this Article is fulfilled, having regard to the factors listed in its paragraph 2.

Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply until six weeks from its entry into force.

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

Done at Brussels, 24.3.2021

For the Commission
The President
Ursula VON DER LEYEN