



2024/3122

17.12.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/3122

of 16 December 2024

authorising an exemption pursuant to Regulation (EU) 2024/573 of the European Parliament and of the Council, with regard to the use of fluorinated greenhouse gases with a GWP of 150 or more in blood transport boxes and blood plasma contact shock freezers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2024/573 of the European Parliament and of the Council of 7 February 2024 on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 ⁽¹⁾, and in particular Article 11(5) thereof,

Whereas:

- (1) Point 4 of Annex IV to Regulation (EU) 2024/573, prohibits from 1 January 2025 the placing on the market of self-contained refrigeration equipment, except chillers, that contains fluorinated greenhouse gases with a GWP of 150 or more, except if required to meet safety requirements at the site of operation.
- (2) Pursuant to Article 11(5) of Regulation (EU) 2024/573, on 14 October 2024, the Luxemburg competent authorities submitted to the Commission a request for the authorisation of an exemption allowing the placing on the Union market of blood transport boxes and blood plasma contact shock freezers, that fall within the scope of Annex IV, point 4, to Regulation (EU) 2024/573.
- (3) Blood transport boxes are single systems for blood collection, storage and delivery. They keep blood or blood components at a protective and stable temperature between 2 °C to 6 °C, or platelet components between 20 °C to 24 °C until they are ready for use. Blood plasma contact shock freezers are devices used for the rapid freezing of blood plasma to a core temperature of -30 °C.
- (4) The exemption request states that, at present, blood transport boxes and blood plasma contact shock freezers heavily rely on fluorinated greenhouse gases with a GWP of more than 150 and that there are many technical challenges involved in developing an equipment that can use alternative substances without compromising safety. In order to ensure that alternatives will be used safely, make the necessary changes to design and to keep costs at a proportionate level, time is needed to facilitate the switch to refrigerants with a GWP value below 150. Moreover, there is also a risk to the availability of products on the market, in case manufacturers of such equipment can no longer supply equipment. In the absence of an exemption, such equipment will also not be allowed for export as from 12 March 2025 in accordance with Article 22(3) of Regulation (EU) 2024/573.
- (5) The exemption request asks for a two-year extension from the placing on the market prohibition to allow finalising the development and testing of new compliant machines and ensure the continuity of supply of critical blood products essential for many urgent and vital medical interventions.
- (6) The Commission has assessed the exemption request and considers that the conditions set out in Article 11(5), points (a) and (b), of Regulation (EU) 2024/573 are fulfilled. The Commission also considers that under such exceptional circumstances, sufficient time should be granted to avoid market disruption in the supply of such essential equipment. The Commission considers that a period of 2 years would be justified in this exceptional case.

⁽¹⁾ OJ L, 2024/573, 20.2.2024, ELI: <http://data.europa.eu/eli/reg/2024/573/oj>.

- (7) Considering that the prohibition for the placing on the Union market of the type of equipment referred in the exemption applies from 1 January 2025 this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee on fluorinated greenhouse gases, established by Article 34(1) of Regulation (EU) 2024/573,

HAS ADOPTED THIS REGULATION:

Article 1

By way of derogation from Annex IV, point 4, to Regulation (EU) 2024/573, the placing on the market of blood transport boxes and blood plasma contact shock freezers containing fluorinated greenhouse gases with a GWP of 150 or more is authorised from 1 January 2025 to 31 December 2026, provided they are labelled pursuant to Article 12(2) of Regulation (EU) 2024/573.

Article 2

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 from 1 January 2025.

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

Done at Brussels, 16 December 2024.

For the Commission
The President
Ursula VON DER LEYEN