17.12.2024

2024/3120

COMMISSION IMPLEMENTING REGULATION (EU) 2024/3120

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 mechanical cryogenic freezers (– 150 °C)

(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:

- Point 4 of Annex IV to Regulation (EU) 2024/573, prohibits from 1 January 2025 the placing on the market of selfcontained 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.
- Pursuant to Article 11(5) of Regulation (EU) 2024/573, on 15 May 2024, the Dutch competent authorities (2) submitted to the Commission a request for the authorisation of an exemption allowing the placing on the Union market of mechanical cryogenic freezers (- 150° C), that fall within the scope of Annex IV, point 4, to Regulation (EU) 2024/573.
- Mechanical cryogenic freezers (- 150 °C) are used for cryopreservation, namely the storage of living organisms, cells and tissues at ultra-low temperatures, and are intended for critical applications mostly in the fields of science and healthcare.
- (4)The exemption request states that, at present, mechanical cryogenic freezers (- 150 °C) heavily rely on fluorinated greenhouse gases with a GWP of more than 150 and that there are many technical challenges involved in identifying an alternative substance for equipment with such low temperature without compromising safety, energy efficiency and reliable performance of the equipment. Full reliability of such equipment is essential for the preservation. The development of the equipment that can use alternative substances requires more time, due to the changes in design needed to accommodate refrigerants with a GWP below 150 while also addressing safety concerns in relation to flammable refrigerants and safeguarding reliability. In order to ensure that alternatives are going to be used safely and to retain 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.
- The exemption request asks for the maximum period of time authorised under Article 11(5) of Regulation (5) (EU) 2024/573, namely 4 years, due the complexity of the transition to alternative refrigerants for such types of equipment.
- The Commission has assessed the request submitted by the Dutch competent authority and considers that the conditions set out in points (a) and (b) of Article 11(5) 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 4 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.

EN OJ L, 17.12.2024

(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 mechanical cryogenic freezers (– 150 °C) containing fluorinated greenhouse gases with a GWP of 150 or more is authorised from 1 January 2025 to 31 December 2028, 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