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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of 2.9.2024

laying down rules for the application of Regulation (EU) 2024/573 of the European Parliament and of the Council as regards the format of the labels for certain products and equipment containing fluorinated greenhouse gases and repealing Commission Implementing Regulation (EU) 2015/2068

(Text with EEA relevance)

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(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 517/2014¹, and in particular Article 12(17) thereof,

Whereas:

- (1) Regulation (EU) 2024/573 contains labelling requirements for certain products and equipment that contain, or whose functioning relies upon, fluorinated greenhouse gases.
- (2) Regulation (EU) 2024/573 replaced Regulation (EU) No 517/2014 of the European Parliament and of the Council² and changed some rules on labelling for products and equipment containing fluorinated greenhouse gases. As Commission Implementing Regulation (EU) 2015/2068³ established the format of the labels for products and equipment containing fluorinated greenhouse gases pursuant to Regulation (EU) No 517/2014, that Implementing Regulation should also be replaced.
- (3) For the sake of clarity, it is appropriate to establish the wording of the information to be indicated on the labels referred to in Article 12(1) and (5) of Regulation (EU) 2024/573 and to set out requirements ensuring the visibility and readability of such labels regarding their layout and placement, taking into account space constraints on certain types of products.
- (4) To ensure that a single label is used for products containing fluorinated greenhouse gases which are also subject to Regulation (EC) No 1272/2008 of the European

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

² Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195, ELI: <http://data.europa.eu/eli/reg/2014/517/oj>).

³ Commission Implementing Regulation (EU) 2015/2068 of 17 November 2015 establishing, pursuant to Regulation (EU) No 517/2014 of the European Parliament and of the Council, the format of labels for products and equipment containing fluorinated greenhouse gases (OJ L 301, 18.11.2015, p. 39, ELI: http://data.europa.eu/eli/reg_impl/2015/2068/oj).

Parliament and of the Council⁴, in particular for the labelling of containers such as cylinders, drums and road and rail tankers, the labelling information laid down in Regulation (EU) 2024/573 should be indicated in the section for supplemental information on the label referred to in Regulation (EC) No 1272/2008.

- (5) For small products falling within the scope of points (f) to (h) of Article 12(1) of Regulation (EU) 2024/573, it is necessary to provide for practicable ways to convey the required information to the users, including by using digitally readable links to the information referred to in Article 12(3), points (b) and (c). In order to take into account the specific requirements of labelling of products and equipment for medical uses in the scope of Directive 2001/83/EC of the European Parliament and of the Council⁵ and Regulations (EC) No 726/2004⁶, (EU) 2019/6⁷ and (EU) 2017/745⁸ of the European Parliament and of the Council and laid down in those legal acts, additional methods to present the required information to users should be provided for as regards those products and equipment.
- (6) The application of this Regulation should be deferred in line with the date of application of Article 12 of Regulation (EU) 2024/573.
- (7) The enforcement of the provisions set out in this Regulation should take into consideration the regulatory processes for changing existing labelling requirements or the process of re-labelling equipment or products already placed on the EU market.
- (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 of Regulation (EU) 2024/573,

HAS ADOPTED THIS REGULATION:

Article 1

Format of labels

1. The information on a label shall stand out clearly from the background of the label and shall be of such size and spacing as to be clearly readable. Where the information required by this Regulation is added to an existing label, the font size shall not be smaller than the minimum size of other information on that label or, as relevant, on existing nameplates, on other product information labels or package leaflets.

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

⁵ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.

⁶ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.

⁷ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 7.1.2019, p. 43.

⁸ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1.

2. The entire label and its contents shall be designed so as to ensure that it remains securely in place on the product or equipment and shall be legible under normal operational conditions, at the time of the placing on the market and throughout the entire period during which the product or equipment is containing or its functioning relies upon fluorinated greenhouse gases.
3. The label shall include the following text: ‘contains fluorinated greenhouse gases’.
4. Information on the weight of the fluorinated greenhouse gases, where required, shall be expressed in kilogram or gram and the CO₂ equivalent shall be expressed in tonne, using the global warming potential values of the fluorinated greenhouse gases as listed in the column ‘GWP’ in Annexes I, II and III to Regulation (EU) 2024/573.
5. When equipment is pre-charged with, or when its functioning relies upon, fluorinated greenhouse gases and such gases may be added outside the manufacturing site and the resulting total quantity is not indicated by the manufacturer, the label shall contain the quantity charged at the manufacturing site, or the quantity for which the equipment is designed, and shall provide space for the quantity added outside the manufacturing site, as well as for the resulting total quantity of fluorinated greenhouse gases to be inserted by the supplier or, where applicable, the installer of the equipment prior to putting the equipment into operation.
6. When a product, including a container, containing fluorinated greenhouse gases or a pre-blended polyol, is also to be labelled pursuant to Regulation (EC) No 1272/2008, the information referred to in Article 12(3), (5) and (7) to (15) of Regulation (EU) 2024/573, as applicable, shall be indicated in the section for supplemental information on the label referred to in Article 25 of Regulation (EC) No 1272/2008.
7. Where the fluorinated greenhouse gases are either reclaimed or recycled or intended to serve for certain uses in accordance with Article 12(7) to (13) of Regulation (EU) 2024/573, the following text shall be included in the label on the container, as relevant:
 - (a) ‘100 % Recycled’ for recycled fluorinated greenhouse gases listed in Annexes I and II to Regulation (EU) 2024/573 that do not contain any virgin substances;
 - (b) ‘100 % Reclaimed’ for reclaimed fluorinated greenhouse gases listed in Annexes I and II to Regulation (EU) 2024/573 that do not contain any virgin substances, or, in the case of mixtures, that the addition of virgin substances, to adjust the mixture composition, does not exceed 10% of the mass of the mixture;
 - (c) ‘For destruction only’: for fluorinated greenhouse gases listed in Annex I to Regulation (EU) 2024/573 and placed on the market, made available or supplied for destruction;
 - (d) ‘For direct export out of the EU only’: for fluorinated greenhouse gases listed in Annex I to Regulation (EU) 2024/573 and supplied by a producer or importer to an undertaking for direct export in bulk out of the Union;
 - (e) ‘For use in military equipment only’: for fluorinated greenhouse gases listed in Annex I to Regulation (EU) 2024/573 and placed on the market, made available or supplied for use in military equipment;
 - (f) ‘For etching/cleaning in the semiconductor industry only’: for fluorinated greenhouse gases listed in Annexes I and II to Regulation (EU) 2024/573 and

placed on the market, made available or supplied for etching and cleaning purposes in the semiconductor industry;

- (g) 'For feedstock use only': for fluorinated greenhouse gases listed in Annex I to Regulation (EU) 2024/573 and placed on the market, made available or supplied for use as feedstock;
- (h) 'For MDI production only': for fluorinated greenhouse gases listed in Section 1 of Annex I to Regulation (EU) 2024/573 and placed on the market, made available or supplied for manufacturing MDI.

Where the containers contain fluorinated greenhouse gases referred to in the first subparagraph, points (c) to (g), and listed in Section 1 of Annex I to Regulation (EU) 2024/573, the text to be indicated in the labels as provided for in those points shall be complemented by the following statement: 'Exempted from quota under Regulation (EU) 2024/573 of the European Parliament and of the Council'.

- 8. The equipment referred to in Article 12(1), points (a), (b) and (c), of Regulation (EU) 2024/573, which are insulated with foam blown with fluorinated greenhouse gases, shall be marked with a label containing the following text: 'Foam contains fluorinated greenhouse gases'.
- 9. The labels shall be placed in accordance with Article 12(4) of Regulation (EU) 2024/573 and, where possible, adjacent to existing nameplates or product information labels of the product or equipment that contains the fluorinated greenhouse gas.
- 10. Where the size of a product referred to in point (f) to (h) of Article 12(1) of Regulation (EU) 2024/573 does not allow for the legibility of the full information referred to in Article 12(3) in accordance with Article 12(4), second subparagraph, of that Regulation, the text 'Contains fluorinated greenhouse gases' in the languages already used on the product may be complemented by a digitally readable link to the information referred to in Article 12(3), points (b) and (c), of Regulation (EU) 2024/573.
- 11. In addition or alternatively to the method of providing information laid down in paragraph 10, for metered dose inhalers referred to in Article 12(1), point (f), of Regulation (EU) 2024/573, the indication 'Contains fluorinated greenhouse gases' may be placed on the outer packaging as defined in Article 1, point (24), of Directive 2001/83/EC, or in Article 4, point (26), of Regulation (EU) 2019/6 or on a sale packaging of a medical device referred to in Article 1(9) of Regulation 2017/745, as applicable, and written at least in the languages used for labelling other information on the outer packaging or, as applicable, sale packaging, provided that the package leaflet or the instructions for use contains all the information referred to in Article 12(3) of Regulation (EU) 2024/573.
- 12. The label of the products and equipment referred to in Article 12(15) of Regulation (EU) 2024/573 shall, from the dates of prohibition specified in Annex IV to that Regulation, include the following text:
 - (a) for equipment referred to in points 2(b), 4, 5(c), 7(b), (c) and (d), 8(b) to (e), 9(b) to (f) and 11(c) of Annex IV to Regulation (EU) 2024/573: 'Prohibited to be operated, unless required by safety requirements that have to be applied at the site of operation', complemented by a reference to the applicable safety requirement that would make its use necessary, or, where it is not feasible to specify prior to placing on the market the safety requirement for the specific

site of operation, providing space on the label for this specification to be inserted by the supplier or, where applicable, the installer or operator of the equipment prior to putting the equipment into operation;

- (b) for the foams referred to in points 16 and 17(a) and (b) of Annex IV to Regulation (EU) 2024/573: ‘Prohibited to be used unless required by national safety standard(s)’, specifying the national safety standard(s), with a short description of the conditions that would make their use necessary;
- (c) for the foams referred to in point 17(c) of Annex IV to Regulation (EU) 2024/573: ‘Prohibited to be used unless required by safety requirement(s)’, specifying the safety requirement(s), with a short description of the conditions that would make their use necessary;
- (d) for the technical aerosols referred to in point 19(a) of Annex IV to Regulation (EU) 2024/573: ‘Prohibited to be used unless required by national safety standard(s)’, specifying the national safety standard(s), with a short description of the conditions that would make their use necessary; or, when used for medical applications: ‘For medical use only’;
- (e) for the technical aerosols referred to in point 19(b) of Annex IV to Regulation (EU) 2024/573: ‘Prohibited to be used unless required by safety requirement(s)’, specifying the safety requirement(s), with a short description of the conditions that would make their use necessary; or, when used for medical applications: ‘For medical use only’;
- (f) for the equipment used for cooling the skin referred to in point 21 of Annex IV to Regulation (EU) 2024/573: ‘For medical use only’.

Article 2

Repeal

Implementing Regulation (EU) 2015/2068 is repealed.

References to Implementing Regulation (EU) 2015/2068 shall be construed as references to this Regulation and shall be read in accordance with the correlation table in the Annex.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth 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, 2.9.2024

For the Commission
The President
Ursula VON DER LEYEN