



2024/1290

6.5.2024

**COMMISSION DELEGATED REGULATION (EU) 2024/1290**

**of 29 February 2024**

**amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include nitrogen generated from ambient air as an active substance in Annex I thereto**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular Article 28(1) thereof,

Whereas:

- (1) On 4 April 2022, the European Chemicals Agency ('the Agency') received an application for inclusion of nitrogen generated from ambient air as an active substance in Annex I to Regulation (EU) No 528/2012, submitted to it in accordance with Article 3(1) of Commission Implementing Regulation (EU) No 88/2014 <sup>(2)</sup>. The application was evaluated by the competent authority of Germany.
- (2) The evaluating competent authority submitted the assessment report together with its conclusions to the Agency on 14 October 2022. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.
- (3) In accordance with Article 75(1), second subparagraph, point (c), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for inclusion in Annex I of active substances. In accordance with Article 4(4) of Regulation (EU) No 88/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency on 1 March 2023 <sup>(3)</sup>, having regard to the conclusions of the evaluating competent authority.
- (4) In its opinion, the Agency concluded that nitrogen generated from ambient air does not give rise to concern within the meaning of Article 28(2) of Regulation (EU) No 528/2012, and can thus be included in Annex I to that Regulation, provided that applications for product authorisations shall include evidence that exposure of the user and the general public to a hypoxic atmosphere is avoided and, where appropriate, the necessary measures are taken.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/2022-04-15>

<sup>(2)</sup> Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the amendment of Annex I to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 32, 1.2.2014, p. 3, ELI: [http://data.europa.eu/eli/reg\\_impl/2014/88/oj](http://data.europa.eu/eli/reg_impl/2014/88/oj)).

<sup>(3)</sup> Biocidal Products Committee Opinion on the application for inclusion into Annex I, Category 2 of the active substance nitrogen generated from ambient air; ECHA/BPC/372/2023; adopted on 1 March 2023.

- (5) Taking into account the opinion of the Agency, it is appropriate to include nitrogen generated from ambient air in Annex I to Regulation (EU) No 528/2012, subject to compliance with the condition set out by the Agency. As nitrogen is included in Annex IV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(4)</sup>, it should be included in category 2 'Substances included in Annex IV to Regulation (EC) No 1907/2006' of Annex I to Regulation (EU) No 528/2012.
- (6) Regulation (EU) No 528/2012 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 29 February 2024.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(4)</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/2014-04-10>).

## ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 2 of the List of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
—	Nitrogen generated from ambient air	Applications for product authorisations shall include evidence that exposure of the user and the general public to a hypoxic atmosphere is avoided and, where appropriate, the necessary measures are taken.	—