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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	29 February 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 29.2.2024 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

Delegations will find attached document C(2024) 1235 final.

Encl.: C(2024) 1235 final



EUROPEAN
COMMISSION

Brussels, 29.2.2024
C(2024) 1235 final

COMMISSION DELEGATED REGULATION (EU) .../...

of 29.2.2024

**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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 28(1) of Regulation (EU) No 528/2012 (the BPR) empowers the Commission to adopt delegated acts in order to include an active substance into Annex I to the BPR after receiving the opinion of the European Chemicals Agency (the Agency), provided that there is evidence that the active substance does not give rise to concern according to the conditions set out in Article 28(2) of that Regulation. A simplified authorisation procedure is provided in Chapter V of the BPR for biocidal products containing active substances listed in Annex I to the BPR and fulfilling other conditions set out in Article 25 of that Regulation.

Nitrogen generated in-situ is currently not approved for use in the Union and it is neither listed in Annex I to the BPR, nor included in the review programme of existing active substances in biocidal products. Between 2020 and 2022, following applications from ten Member States, the Commission granted derogations pursuant to Article 55(3) to those Member States, allowing them to authorise the making available on the market and use of biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage until 31 December 2024. These derogations were granted as the use of in-situ generated nitrogen appeared to be the only effective technique for the control of harmful organisms that can be used for all types of materials and combinations of materials present in cultural institutions without damaging them. The respective Commission Decisions indicate that the inclusion of in-situ generated nitrogen in Annex I to the BPR would allow Member States to authorise products consisting of in-situ generated nitrogen without the need for a derogation.

On 4 April 2022, the Agency received an application for inclusion of nitrogen generated from ambient air as an active substance in Annex I, category 2, of Regulation (EU) No 528/2012, in accordance with Article 3 of Implementing Regulation (EU) 88/2014. This application was evaluated by the competent authority of Germany. The evaluating competent authority of Germany 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.

The opinion of the Agency of 1 March 2023, considered as an opinion of the Agency pursuant to Article 28(1) of Regulation (EU) No 528/2012, concluded that nitrogen generated from ambient air does not give rise to concern and is eligible for inclusion in Annex I to BPR.

This draft Delegated Regulation therefore proposes to include nitrogen generated from ambient air in Annex I to Regulation (EU) No 528/2012.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission has consulted an expert group (the 'Biocides CA meeting') consisting of representatives of Member States' competent authorities for biocidal products, of the European Chemicals Agency, of the biocides industry and of the civil society during the 101st and 102nd CA meetings in September 2023 and December 2023 respectively.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated Regulation amends Annex I to Regulation (EU) No 528/2012. The legal basis is Article 28(1) of that Regulation.

COMMISSION DELEGATED REGULATION (EU) .../...

of 29.2.2024

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 products¹, 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 88/2014². 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 2023³, 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.

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

² 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).

³ 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 Council⁴, 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, 29.2.2024

For the Commission

The President

Ursula VON DER LEYEN

⁴ 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>).