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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the delegation conferred on the Commission pursuant 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 in accordance with Article 83(2) of that Regulation

1. INTRODUCTION AND LEGAL BASIS

The EU legal framework for biocidal products is intended to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market. The framework works on the principle that biocidal products can be placed on the market and used only if a marketing authorisation is granted by the competent authorities.

The requirements and procedures for authorising the marketing and use of biocidal products are laid down in Regulation (EU) No 528/2012[1] (hereinafter, "the BPR"). This report is to meet the obligation set for the Commission by Article 83(2) of the BPR. Article 83(2) requires the Commission to present to the European Parliament and to the Council a report on the exercise of the delegation conferred on the Commission by the BPR. The report shall be drawn up not later than nine months before the end of the five-year period of the delegation, running from 17 July 2012. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

The first report on the exercise of the delegation conferred on the Commission was adopted by the Commission on 11 October 2016 and covered the period from 17 July 2012 to 11 October 2016.[2]

The second report on the exercise of the delegation conferred on the Commission was adopted by the Commission on 27 May 2024 and covered the period from 12 October 2016 to 31 December 2023[3]. This second report should have been issued by 17 October 2021 and was thus delayed. In particular, during that period the Commission focused its attention on the submission of the first report from the Commission to the European Parliament and the Council on the implementation of the BPR (COM/2021/287 final), and the accompanying Staff Working Document[4]. The delegation of power to the Commission was tacitly extended by the European Parliament or the Council for the period from 17 July 2022 to 17 July 2027.

In order to comply with its obligations, the Commission now issues the third report on the exercise of the delegation conferred on the Commission. This third report covers the period from 1 January 2024 to 1 September 2026, in order to re-align with the time-periods foreseen in the BPR for the submission of the reports, and for its sending before 17 October 2026 to the European Parliament and the Council. The report provides an up-to-date comprehensive view of the actions taken by the Commission.

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[1] 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, OJ L 167, 27.6.2012, p. 1

[2] Report from the Commission to the European Parliament and the Council on the exercice of the delegation conferred in the Commission pursuant 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, COM/2016/0650 final

[3] Report from the Commission to the European Parliament and the Council on the exercise of the delegation conferred on the Commission pursuant 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 in accordance with Article 83(2) of that Regulation, COM/2024/214 final

[4] Report from the Commission to the European Parliament and the Council on the implementation of 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, COM/2021/287 final

Article 83(1) of the BPR empowers the Commission to adopt delegated acts subject to the conditions laid down in that Article, and in order to:

- adapt the definition of nanomaterial set out in the BPR in view of technical and scientific progress [Article 3(4)],
- specify scientific criteria for the determination of endocrine-disrupting properties [Article 5(3)],
- specify criteria for determining what constitutes adequate justification to adapt the data requirements for an application for approval of an active substance in case the data are not necessary owing to the exposure associated with the proposed use of the product [Article 6(4)],
- specify criteria for defining when the exposure associated with the proposed uses of the product would justify adapting the data requirements for applications for biocidal products authorisations [Article 21(3)],
- specify the criteria for determining when comparative assessments of biocidal products involve questions better addressed at Union level and the procedures for such comparative assessments [Article 23(5)],
- amend Annex I in order to include active substances that do not give rise to concern [Article 28(1)],
- amend Annex I in order to restrict or to remove the entry for an active substance if there is evidence that biocidal products containing that substance do give rise to concerns [Article 28(3)],
- adopt supplementary rules for the renewal of authorisations subject to mutual recognition [Article 40],
- adopt specific rules supplementing the BPR provisions on research and development [Article 56(4)],
- adopt acts supplementing the BPR rules for the use of the Register for Biocidal Products [Article 71(9)],
- adapt Annexes II, III and IV to scientific and technical progress [Article 85],
- establish the rules on the review programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC[5] and specification of the related rights and obligations of the competent authorities and the participants in the programme and extend the duration of the review programme for a determined period [Article 89(1)].

2. EXERCISE OF THE DELEGATION

During the period concerned by this report, the Commission adopted three delegated acts in order to fulfil obligations laid down in the BPR and supplement or amend certain non-essential elements of the BPR. The following acts were adopted between 1 January 2024 and 17 October 2026:

[5] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123, 24.4.1998, p. 13

2.1. Commission Delegated Regulation (EU) No 2024/1290[6]

This Delegated Regulation was adopted on the basis of Article 28(1) of the BPR, according to which "*The Commission shall be empowered to adopt delegated acts in accordance with Article 83 amending Annex I, after receiving the opinion of the Agency, in order to include active substances provided that there is evidence that they do not give rise to concern according to paragraph 2 of this Article*".

The Commission adopted Delegated Regulation (EU) No 2024/1290 to include nitrogen generated from ambient air in Annex I to the BPR. Since nitrogen is already listed in Annex IV to Regulation (EC) No 1907/2006[7], the substance has been included in Category 2 of Annex I to the BPR ("Substances included in Annex IV to Regulation (EC) No 1907/2006"). The inclusion is subject to the condition that applications for product authorisation provide evidence that exposure of users and the general public to hypoxic atmospheres is avoided and that appropriate measures are taken where necessary.

The Commission expert group 'Competent Authorities for Biocidal Products' (hereinafter, "Biocides CA Expert Group", E03125[8]) served as expert group in accordance with the applicable inter-institutional arrangements. In this setting, the draft Delegated Regulation was discussed in the Biocides CA Expert Group meetings of 28-29 September 2023 and of 7-8 December 2023. Updated drafts of the Delegated Regulation were made public in advance of each of those meetings. The Commission adopted the Delegated Regulation on 29 February 2024 and notified it to the European Parliament and the Council. Neither institution objected to the Delegated Regulation within the two-month period provided for in Article 83(5) of the BPR. Delegated Regulation (EU) No 2024/1290 was published in the Official Journal of 6 May 2024 and entered into force on 26 May 2024.

2.2. Commission Delegated Regulation (EU) No 2024/1398[9]

This Delegated Regulation was adopted in accordance with Article 89(1), second subparagraph, of the BPR, which provides that "*Depending upon the progress of the work programme, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the extension of the duration of the work programme for a determined period*".

The Commission adopted Delegated Regulation (EU) 2024/1398 to extend the duration of the work programme for the systematic examination of all existing active substances used in biocidal products. Regulation (EU) No 528/2012 provides for the continuation of the

[6] 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, OJ L, 2024/1290, 6.5.2024

[7] 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

[8] https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupId=3125&fromMembers=true&memberType=4&memberId=52888

[9] Commission Delegated Regulation (EU) 2024/1398 of 14 March 2024 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards a further extension of the duration of the work programme for the systematic examination of all existing biocidal active substances, OJ L, 2024/1398, 22.5.2024

review programme for existing biocidal active substances that commenced under Directive 98/8/EC and originally required its completion by 31 December 2024. However, substantial delays have affected the programme, as reported by the Commission in its implementation report on the BPR of 7 June 2021[10]. Due to these delays, the review programme could not be completed by the end of 2024. Delegated Regulation (EU) 2024/1398 therefore extended the duration of the work programme until 31 December 2030.

The Biocides CA Expert Group was consulted on the draft Delegated Regulation in meetings of 28-29 September 2023 and of 7-8 December 2023. The draft of the Delegated Regulation was made public in advance of the December 2023 meeting.

The Commission adopted the Delegated Regulation on 14 March 2024 and notified it to the European Parliament and the Council. Neither institution objected to the Delegated Regulation within the two-month period provided for in Article 83(5) of the BPR. Delegated Regulation (EU) No 2024/1398 was published in the Official Journal of 22 May 2024 and entered into force on 11 June 2024.

2.3 Commission Delegated Regulation 2026/447[11]

This Delegated Regulation was adopted on the basis of Article 28(1) of the BPR, according to which "*The Commission shall be empowered to adopt delegated acts in accordance with Article 83 amending Annex I, after receiving the opinion of the Agency, in order to include active substances provided that there is evidence that they do not give rise to concern according to paragraph 2 of this Article*".

The Commission adopted Delegated Regulation 2026/447 to amend the restriction concerning the use of the active substance carbon dioxide listed in Annex I, Category 6, to Regulation (EU) No 528/2012. Carbon dioxide was included in Annex I, Category 6, to the BPR with a restriction limiting its use to ready-for-use gas canisters functioning together with a trapping device. Following an application submitted in accordance with Article 3(1) of Regulation (EU) No 88/2014[12] to amend that restriction, the European Chemical Agency ("ECHA") delivered its opinion on 10 September 2025[13] concluding that the existing restriction should be revised. Accordingly, this Delegated Regulation amends Annex I to Regulation (EU) No 528/2012 as regards the restriction applicable to carbon dioxide.

The Biocides CA Expert Group was consulted on the draft Delegated Regulation in meetings of 11-12 December 2025 and 19-20 March 2026. Updated drafts of the Delegated Regulation were made public in advance of each of those meetings. The Commission

[10] Report from the Commission to the European Parliament and the Council on the implementation of 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, COM/2021/287 final

[11] Commission Delegated Regulation (EU) 2026/447 of 27 February 2026 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the restriction of the use for the active substance carbon dioxide in Annex I, Category 6, thereto, OJ L 30.7.2026

[12] 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

[13] Biocidal Products Committee Opinion on the amendment of inclusion in Annex I, Category 6 of the active substance: Carbon dioxide; ECHA/BPC/491/2025; adopted on 10 September 2025.

adopted the Delegated Regulation on 27 February 2026 and notified it to the European Parliament and the Council. Neither institution objected to the Delegated Regulation within the two-month period provided for in Article 83(5) of the BPR. Delegated Regulation (EU) No 2026/447 was published in the Official Journal of 30 July 2026 and entered into force on 19 August 2026.

3. Other delegations

The Commission has not yet exercised the delegated powers provided for in some of the areas referred in section I of this report (i.e. powers referred in Article 3(4), Article 6(4), Article 21(3), Article 23(5), Article 28(3), Article 56(4), Article 71(9) of the BPR), but may do so in the future if found necessary during the implementation of the BPR.

CONCLUSION

In the period covered by this report, the Commission has exercised the delegated powers provided for by the BPR on three occasions in compliance with the delegations conferred.

The implementation of the BPR is advancing and technical and scientific progress takes place. Therefore, the Commission may be required to adopt further delegated acts in the future in order to keep the legal framework up to date.