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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

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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 up to 11 October 2016.[2]

This is the second report on the exercise of the delegation conferred on the Commission. This second report should have been issued by 17 October 2021 and is thus significantly 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 Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of

[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

biocidal products (COM/2021/287 final), and the accompanying Staff Working Document[3].

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 2026. However, in order to comply with its obligation, the Commission now issues this second report, covering the period from 12 October 2016 up to 31 December 2023, in order to provide an up-to-date comprehensive view of the actions taken by the Commission.

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

[3] 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

98/8/EC[4] 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 sixteen 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 from 12 October 2016 until 31 December 2023:

2.1. Commission Delegated Regulation (EU) No 2017/698[5]

This Delegated Regulation was adopted on the basis of Article 89(1), first subparagraph, of the BPR, according to which "*The Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme*".

Commission Delegated Regulation (EU) No 1062/2014 sets out the review programme of existing active substance (the 'Review Programme Regulation')[6]. It had set out, in its Annex II, an exhaustive list of existing active substances/product-type combinations included in the programme of review of existing biocidal active substances on 4 August 2014. According to the Review Programme Regulation, any person could have notified to ECHA a substance/product-type combination included in Part 2 of Annex II within 12 months from the entry into force of that Review Programme Regulation. After the expiry of that deadline, Annex II and Article 14(3) of that Regulation needed to be updated. Consequently, Delegated Regulation (EU) No 2017/698 was adopted in order to remove from Part 2 of Annex II to Review Programme Regulation those substance/product type combinations which were not approved and include in Part 1 of Annex II to that Review Programme Regulation those notified and found compliant.

The Biocides CA Expert Group was consulted on the draft Delegated Regulation in the meetings of 16-17 March 2016 and of 25-26 May 2016. The Commission adopted the Delegated Regulation on 3 February 2017 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 2017/698 was published in the Official Journal of 19 April 2017 and entered into force on 9 May 2017.

[4] 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

[5] Commission Delegated Regulation (EU) 2017/698 of 3 February 2017 amending Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in 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 103, 19.4.2017, p. 1

[6] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 294, 10.10.2014, p. 1

2.2. Commission Delegated Regulation (EU) No 2017/2100[7]

This legal act was adopted on the basis of Article 5(3) of the BPR which provides that "*No later than 13 December 2013, the Commission shall adopt delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties*".

Delegated Regulation (EU) No 2017/2100 sets out the scientific criteria for the determination of endocrine-disrupting (ED) properties. These criteria reflect the current state of scientific and technical knowledge and allow identifying substances having such properties more accurately. This delegated act was under preparation when the first report of 11 October 2016 on the exercise of the delegation conferred on the Commission was submitted to the European Parliament and to the Council.

The Commission expert group 'Competent Authorities for Biocidal Products' (hereinafter, "Biocides CA Expert Group") 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 16-18 November 2016, 21 December 2016 and 28 February 2017. The Commission adopted the Delegated Regulation on 4 September 2017 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 2017/2100 was published in the Official Journal of 17 November 2017 and entered into force on 7 December 2017.

2.3 Commission Delegated Regulation (EU) No 2019/157[8]

This Delegated Regulation was adopted in accordance with Article 89(1), first subparagraph, of the BPR, on the basis of which *"The Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme".*

The Review Programme Regulation, as amended by the abovementioned Commission Delegated Regulation (EU) 2017/698, had set out in its Annex II a list of active substance/product-type combinations included in the programme of review of existing active substances contained in biocidal products on 3 February 2017. The identities of certain active substances listed in Annex II to the Review Programme Regulation, which could be generated *in situ*, were redefined in order to indicate in a more precise manner the active substances and their precursors presently covered in the review programme. Any person with an interest could notify a combination of an active substance and its precursors not yet covered by the new identity as well as active substances in product-type 19 which

[7] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council, OJ L 301, 17.11.2017, p. 1

[8] Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 31, 1.2.2019, p. 1

benefitted from the derogation for food and feed, provided for by Commission Regulation (EC) No 1451/2007[9].

The aim of Delegated Regulation (EU) No 2019/157 was to include in Annex II to the Review Programme Regulation substance/product-type combinations which were notified and found compliant by ECHA and to remove those for which a decision of approval or non-approval was taken after 3 February 2017.

The Biocides CA Expert Group was consulted on the draft Delegated Regulation in the meeting of 16-18 March 2018. The Commission adopted the Delegated Regulation on 6 November 2018 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 2019/157 was published in the Official Journal of 1 February 2019 and entered into force on 21 February 2019.

2.4 Commission Delegated Regulation (EU) No 2019/227[10]

This Delegated Regulation was adopted on the basis of Article 89(1), first subparagraph, of the BPR which empowers the Commission "*to adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme*".

The Commission adopted Delegated Regulation (EU) No 2019/227 to amend the Review Programme Regulation, in order to designate new evaluating competent authorities in charge of carrying out the assessment of certain active substances in the EU biocides review programme, following the withdrawal of the UK from the EU. Given that the UK was the evaluating competent authority for several active substance/product-type combinations, it was considered necessary to designate new evaluating competent authorities from the remaining 27 Member States of the EU, EEA countries, or Switzerland[11], with effect from 30 March 2019.

The Biocides CA Expert Group was consulted on the draft Delegated Regulation in meetings of 5-6 July 2018 and 27-28 September 2018. Updated drafts of the Delegated Regulation were made public in advance of each of those meetings. The Commission adopted the Delegated Regulation on 28 November 2018 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

[9] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, OJ L 325, 11.12.2007, p. 3.

[10] Commission Delegated Regulation (EU) 2019/227 of 28 November 2018 amending Delegated Regulation (EU) No 1062/2014 as regards certain active substances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority, OJ L 37, 8.2.2019, p. 1

[11] Switzerland can act as an evaluating competent authority in accordance with Decision No 1/2015 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 14 April 2015 on the amendment of Chapter 16 on construction products, Chapter 18 on biocidal products and the update of legal references listed in Annex 1, OJ L 171, 2.7.2015, p. 25

Regulation (EU) No 2019/227 was published in the Official Journal of 8 February 2019 and entered into force on 28 February 2019.

2.5 Commission Delegated Regulation (EU) No 2021/525[12]

This Delegated Regulation was adopted in accordance with Article 85 of the BPR which provides "*In order to allow the provisions of this Regulation to be adapted to scientific and technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the adaptation of Annexes II, III and IV to such scientific and technical progress*".

Annexes II and III to the BPR set out the information requirements for active substances and biocidal products. It was considered necessary to modify the information requirements on active substances and biocidal products in order to take into account new methods for generating better information on toxicological properties, new testing strategies favouring *in vitro* tests instead of *in vivo* tests in order to reduce testing on vertebrate animals and a testing strategy and methods for the determination of endocrine disrupting properties of substances.

The Biocides CA Expert Group was consulted on the draft Delegated Regulation from its 80th to 88th meetings (from September 2018 to May 2020). Updated drafts of the Delegated Regulation were made public in advance of each of those meetings. The Commission adopted the Delegated Regulation on 19 October 2020 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 2021/525 was published in the Official Journal of 26 March 2021 and entered into force on 15 April 2021.

2.6 Commission Delegated Regulation (EU) No 2022/825[13]

This Delegated Regulation was adopted in accordance with Article 89(1), first subparagraph, of the BPR, which empowers the Commission to "*adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme*".

Annex II to the Review Programme Regulation contained a list of active substance/product-type combinations included in the programme of review of existing active substances contained in biocidal products on 6 November 2018. Through Delegated Regulation (EU) No 2022/825, substance/product-type combinations whose notifications were found compliant by ECHA, namely peanut butter and brandy for use in product-type 19, were therefore included in Annex II to the Review Programme Regulation. Active substances for which a decision of approval or non-approval was adopted after 6 November

[12] Commission Delegated Regulation (EU) 2021/525 of 19 October 2020 amending Annexes II and III 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 106, 26.3.2021, p. 3

[13] Commission Delegated Regulation (EU) 2022/825 of 17 March 2022 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 147, 30.5.2022, p. 3

2018, or which were included in Annex I to the BPR, were removed from Annex II for the concerned product-types.

The Biocides CA Expert Group was consulted on the draft Delegated Regulation in the meeting of 28-29 September 2021. The Commission adopted the Delegated Regulation on 17 March 2022 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 2022/825 was published in the Official Journal of 30 May 2022 and entered into force on 19 June 2022.

2.7 Commission Delegated Regulations on the inclusion of active substances in Annex I to Regulation (EU) No 528/2012

Article 28(1) of the BPR empowers the Commission 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*".

Annex I to the BPR lists active substances which do not give rise to concern in accordance with the criteria established in Article 28(2) of the BPR. Products that contain only those active substances and comply with the requirements established in Article 25 of the BPR, are eligible for a simplified authorisation procedure.

The Commission has adopted several delegated acts on the basis of Article 28(1) in the period from 2019 to 2021 as set out in the following three subsections.

2.7.1 Commission Delegated Regulations adopted in 2019

On 8 August 2019, in accordance with the opinion of the European Chemicals Agency[14], the Commission adopted a series of delegated acts, namely Delegated Regulations (EU) 2019/1819[15], 2019/1820[16], 2019/1821[17], 2019/1822[18], 2019/1823[19], 2019/1824[20] and

[14] Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017

[15] Commission Delegated Regulation (EU) 2019/1819 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include vinegar as an active substance in Annex I thereto, OJ L 279, 31.10.2019, p. 1

[16] Commission Delegated Regulation (EU) 2019/1820 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include Saccharomyces cerevisiae as an active substance in Annex I thereto, OJ L 279, 31.10.2019, p. 4

[17] Commission Delegated Regulation 2019/1821 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include powdered egg as an active substance in Annex I thereto, OJ L 279, 31.10.2019, p. 7

[18] Commission Delegated Regulation (EU) 2019/1822 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include honey as an active substance in Annex I thereto, OJ L 279, 31.10.2019, p. 10–12

[19] Commission Delegated Regulation (EU) 2019/1823 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include D-fructose as an active substance in Annex I thereto, OJ L 279, 31.10.2019, p. 13

[20] Commission Delegated Regulation (EU) 2019/1824 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include cheese as an active substance in Annex I thereto, OJ L 279, 31.10.2019, p. 16

2019/1825[21] with the objective of respectively including in Annex I to the BPR the following food and feed active substances: vinegar, saccharomyces cerevisiae, powdered egg, honey, D-fructose, cheese and concentrated apple juice.

The Biocides CA Expert Group was consulted on the draft Delegated Regulations in meetings of 27-28 September 2018, 13-15 March 2019 and 16-17 May 2019. Successive updated drafts of the Delegated Regulations were made public in advance of those meetings. The Commission adopted the Delegated Regulations on 8 August 2019 and notified them to the European Parliament and the Council. Neither institution objected to the Delegated Regulations within the two-month period provided for in Article 83(5) of the BPR. These were published in the Official Journal of 31 October 2019 and entered into force on 20 November 2019.

2.7.2 Commission Delegated Regulation adopted in 2020

On 3 November 2020, in accordance with the opinion of the European Chemicals Agency[22], the Commission adopted Delegated Regulation (EU) 2021/407[23] which included in Annex I to the BPR the active substance citric acid. The Biocides CA Expert Group was consulted on the draft Delegated Regulation in the meeting of 25 September 2020. The Commission adopted the Delegated Regulation on 3 November 2020 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 2021/407 was published in the Official Journal of 9 March 2021 and entered into force on 29 March 2021.

2.7.3 Commission Delegated Regulations adopted in 2021

On 10 March 2021, in accordance with the opinions of the European Chemicals Agency[24] [25], the Commission adopted Delegated Regulations (EU) 2021/806[26] and 2021/807[27], which incorporated in Annex I to the BPR carbon dioxide and potassium sorbate, respectively. The Biocides CA Expert Group was consulted on the draft Commission Delegated Regulations in the meeting of 8-9 December 2020. The Commission adopted

[21] Commission Delegated Regulation (EU) 2019/1825 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include concentrated apple juice as an active substance in Annex I thereto, OJ L 279, 31.10.2019, p. 19

[22] Biocidal Products Committee Opinion on the application for approval of the active substance: Citric acid, Product type: 2, ECHA/BPC/088/2016, adopted on 16 February 2016

[23] Commission Delegated Regulation (EU) 2021/407 of 3 November 2020 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include citric acid as an active substance in Annex I thereto, OJ L 81, 9.3.2021, p. 15

[24] Biocidal Products Committee Opinion on the application for approval of the active substance: Carbon dioxide generated from propane, butane or a mixture of both by combustion, Product type: 19, ECHA/BPC/249/2020, adopted on 16 June 2020

[25] Biocidal Products Committee Opinion on the application for approval of the active substance: Potassium sorbate, Product type: 8, ECHA/BPC/37/2014, adopted on 4 December 2014

[26] Commission Delegated Regulation (EU) 2021/806 of 10 March 2021 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include carbon dioxide generated from propane, butane or a mixture of both by combustion as an active substance in Annex I thereto, OJ L 180, 21.5.2021, p. 78

[27] Commission Delegated Regulation (EU) 2021/807 of 10 March 2021 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include potassium sorbate as an active substance in Annex I thereto, OJ L 180, 21.5.2021,p. 81

the Delegated Regulations on 10 March 2021 and notified them to the European Parliament and the Council. Neither institution objected to the Delegated Regulations within the two-month period provided for in Article 83(5) of the BPR. Commission Delegated Regulation (EU) No 2021/806 and Commission Delegated Regulation (EU) No 2021/807 were published in the Official Journal of 21 May 2021 and entered into force on 10 June 2021.

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 sixteen 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.