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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	3 November 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2020) 7402 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 3.11.2020 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

Delegations will find attached document C(2020) 7402 final.

Encl.: C(2020) 7402 final

EUROPEAN
COMMISSION

Brussels, 3.11.2020
C(2020) 7402 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 3.11.2020

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

(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 (ECHA), provided that there is evidence that the active substance do 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.

Citric acid has been assessed as an existing active substance within the review programme set out in Article 89(1) of the BPR established by Commission Delegated Regulation (EU) No 1062/2014 (the Review Regulation) for use in biocidal products of product-type n°2 "disinfectants and algaecides not intended for direct application to humans or animals".

In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Product Committee of ECHA adopted its opinion on 16 February 2016 (ECHA/BPC/088/2016), concluding that biocidal products of product-type n°2 containing citric acid may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC which were the requirements applicable to the examination of the application for approval of citric acid in accordance with Article 90(2) of Regulation (EU) No 528/2012. Citric acid was therefore approved as an active substance for use in biocidal products of product-type n°2 by Commission Implementing Regulation (EU) 2016/1938 of 4 November 2016.

The opinion of ECHA also concluded that citric acid does not give rise to concern and is eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

During the 81st meeting of Member States' Competent Authorities on biocidal products in November 2018, Member States' Competent Authorities agreed that this active substance could be included into Annex I to the BPR, with the view to replace in the long term its previous approval made by Commission Implementing Regulation (EU) No 2016/1938 of 4 November 2016. Such inclusion would in particular reduce the administrative burden, facilitate the placing on the EU market of biocidal products presenting lower concerns for human health, animal health and the environment, and promote innovation for such biocidal products.

The opinion of ECHA of 16 February 2016 is considered as an opinion of the Agency pursuant to Article 28(1) of Regulation (EU) No 528/2012.

This Delegated Regulation therefore proposes to include citric acid 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 meeting of 25 September 2020. During this consultation, no concerns were raised.

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) …/...

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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

(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[1], and in particular Article 28(1) thereof,

Whereas:

(1) Citric acid has been assessed as an existing active substance within the review programme set out in Article 89(1) of Regulation (EU) No 528/2012 established by Commission Delegated Regulation (EU) No 1062/2014[2].

(2) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency ("the Agency") was adopted on 16 February 2016 by the Biocidal Products Committee[3], having regard to the conclusions of the evaluating competent authority. That opinion concluded that biocidal products of product-type 2 containing citric acid may be expected to fulfill the requirements of Article 5 of Directive 98/8/EC of the European Parliament and of the Council[4] which were the requirements applicable to the examination of the application for approval of citric acid in accordance with Article 90(2) of Regulation (EU) No 528/2012.

(3) Citric acid was therefore approved as an active substance for use in biocidal products of product-type 2 by Commission Implementing Regulation (EU) 2016/1938[5].

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1 OJ L 167, 27.6.2012, p. 1.

2 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).

3 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.

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. 1).

5 Commission Implementing Regulation (EU) 2016/1938 of 4 November 2016 approving citric acid as an existing active substance for use in biocidal products of product-type 2 (OJ L 299, 5.11.2016, p. 54).

(4) The opinion of the Agency also concluded that citric acid does not give rise to concern and is eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(5) Taking into account the opinion of the Agency, it is therefore appropriate to include citric acid in Annex I to Regulation (EU) No 528/2012. As citric acid has been assessed based on an active substance dossier satisfying the requirements laid down in Article 11(1) of Directive 98/8/EC, citric acid should be included in category 6 of Annex I to that Regulation,

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, 3.11.2020

For the Commission
The President
Ursula VON DER LEYEN