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

(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]).

(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.

([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).

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 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 6 of the List of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
'201-069-1	Citric acid	Minimum degree of purity of the active substance (*): 995 g/kg	CAS No 77-92-9

(*) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.'.