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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 10.3.2021 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

Delegations will find attached document C(2021) 1513 final.

Encl.: C(2021) 1513 final



Brussels, 10.3.2021
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COMMISSION DELEGATED REGULATION (EU) .../...

of 10.3.2021

**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**

(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.

Potassium sorbate 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 8 “wood preservatives”.

In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Product Committee of ECHA adopted its opinion on 4 December 2014 (ECHA/BPC/37/2014), concluding that biocidal products of product-type 8 containing potassium sorbate 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 potassium sorbate in accordance with Article 90(2) of Regulation (EU) No 528/2012. Potassium sorbate was therefore approved as an active substance for use in biocidal products of product-type 8 by Commission Implementing Regulation (EU) 2015/1729 of 28 September 2015.

The opinion of ECHA also concluded that potassium sorbate 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) 2015/1729 of 28 September 2015. 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 4 December 2014 is considered as an opinion of the Agency pursuant to Article 28(1) of Regulation (EU) No 528/2012.

This draft Delegated Regulation therefore proposes to include potassium sorbate 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 8 December 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) .../...

of 10.3.2021

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

(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) Potassium (E,E)-hexa-2,4-dienoate (potassium sorbate) has been assessed as an existing active substance included in the work programme for the systematic examination of all existing active substances, referred to in Article 89(1) of Regulation (EU) No 528/2012 and carried out in accordance with Commission Delegated Regulation (EU) No 1062/2014².
- (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 4 December 2014 by the Biocidal Products Committee³, having regard to the conclusions of the evaluating competent authority. As the evaluation of the competent authority was completed on 20 October 2010, the application for approval of potassium sorbate was examined in accordance with Directive 98/8/EC of the European Parliament and of the Council⁴, as provided for in Article 90(2) of Regulation (EU) No 528/2012, and the Agency concluded in its opinion that biocidal products of product-type 8 containing potassium sorbate may be expected to fulfill the requirements of Article 5 of Directive 98/8/EC.

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: Potassium sorbate, Product type: 8, ECHA/BPC/37/2014, adopted on 4 December 2014.

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).

- (3) Potassium sorbate was therefore approved as an active substance for use in biocidal products of product-type 8 by Commission Implementing Regulation (EU) 2015/1729⁵.
- (4) Potassium sorbate is still included in the work programme for the systematic examination of all existing active substances for its use in biocidal products of product-type 6.
- (5) In the opinion of 4 December 2014, the Agency also concluded that potassium sorbate fulfils the criteria for inclusion in Annex I to Regulation (EU) No 528/2012.
- (6) Taking into account the opinion of the Agency, it is appropriate to include potassium sorbate in Annex I to Regulation (EU) No 528/2012. As potassium sorbate has been assessed on the basis of an active substance dossier that has been accepted in accordance with Article 11(1) of Directive 98/8/EC, potassium sorbate should be included in category 6 of Annex I to Regulation (EU) No 528/2012.
- (7) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to potassium sorbate for product-type 6, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 February 2023, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of 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

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of potassium sorbate for product-type 6 is 1 February 2023.

Article 3

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.

⁵ Commission Implementing Regulation (EU) 2015/1729 of 28 September 2015 approving potassium sorbate as an existing active substance for use in biocidal products of product-type 8 (OJ L 252, 29.9.2015, p. 24).

Done at Brussels, 10.3.2021

For the Commission
The President
Ursula VON DER LEYEN