COMMISSION IMPLEMENTING DECISION (EU) 2021/713

of 29 April 2021

postponing the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) The active substance sulfuryl fluoride was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) for use in biocidal products of product-types 8 and 18, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) On 28 June 2017, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18.

(3) On 14 February 2018, the evaluating competent authority of Sweden informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) As the competent authority is carrying out a full evaluation of the application, in accordance with Article 14(3) of Regulation (EU) No 528/2012, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance within 270 days of receipt of the recommendation from the evaluating competent authority.

(5) Pursuant to Commission Implementing Decision (EU) 2018/1479 ([3]), the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-type 8 has been postponed to 30 June 2021, which corresponds to the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-type 18 under Commission Directive 2009/84/EC ([4]), in order to allow sufficient time for the examination of the application. However, the evaluating competent authority has not yet finalised the examination and has not yet submitted its assessment report and the conclusions of its evaluation to the Agency.

(6) On 18 February 2020, the evaluating competent authority requested the applicant to submit additional information to carry out the evaluation in accordance with Article 8(2) of Regulation (EU) No 528/2012 and has set the deadline of 31 March 2022 for submitting this information.

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

([2]) 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]) Commission Implementing Decision (EU) 2018/1479 of 3 October 2018 postponing the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-type 8 (OJ L 249, 4.10.2018, p. 16).

([4]) Commission Directive 2009/84/EC of 28 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (OJ L 197, 29.7.2009, p. 67).

(7) Consequently, the approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 for a period of time sufficient to enable the completion of the examination of the application.

(8) Considering the time necessary for the completion of the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 31 December 2023.

(9) Except for the expiry date of approval, sulfuryl fluoride remains approved for use in biocidal products of product-types 8 and 18 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 is postponed to 31 December 2023.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 29 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, 10.3.2021
C(2021) 1513 final

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 products[1], 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, referrred to in Article 89(1) of Regulation (EU) No 528/2012 and carried out in accordance with 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 4 December 2014 by the Biocidal Products Committee[3], 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 Council[4], 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.

(3) Potassium sorbate was therefore approved as an active substance for use in biocidal products of product-type 8 by Commission Implementing Regulation (EU) 2015/1729[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: 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).

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).

(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.

Done at Brussels, 10.3.2021

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, 10.3.2021
C(2021) 1516 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 10.3.2021

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

(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.

Carbon dioxide generated from propane, butane or a mixture of both by combustion 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°19 "repellents and attractants".

In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Product Committee of ECHA adopted its opinion on 16 June 2020 (ECHA/BPC/249/2020), concluding that biocidal products of product-type n°19 using carbon dioxide generated from propane, butane or a mixture of both by combustion may be expected to satisfy the requirements of Article 19(1)(b) of Regulation (EU) No 528/2012. The opinion of ECHA also concluded that this active substance does not give rise to concern and is eligible for inclusion in Annex I to Regulation (EU) No 528/2012. 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 June 2020 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 carbon dioxide generated from propane, butane or a mixture of both by combustion 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 from Member States' competent authorities for biocidal products, the European Chemicals Agency, the biocides industry and civil society during meetings on 25 September 2020 and 8 December 2020. During this consultation, one Member State suggested to add a restriction to limit the inclusion for use in biocidal products of product-type 19 only. In line with the general agreement reached on the management of Annex I inclusions during the 81st meeting of Member States' Competent Authorities on biocidal products in November 2018, it was concluded that no restriction was necessary, and that Member States receiving applications for product authorisation based on carbon dioxide generated from propane, butane or a mixture of both by combustion have in any case to decide case-by-case whether the concerned product is eligible for authorisation by the simplified authorisation procedure or requires one of the normal authorisation procedures.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated Regulation amends Annex I to Regulation (EU) No 528/2012.

COMMISSION DELEGATED REGULATION (EU) …/...

of 10.3.2021

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

(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) Commission Delegated Regulation (EU) No 1062/2014[2] establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That lists includes carbon dioxide generated from propane, butane or a mixture of both by combustion.

(2) Carbon dioxide generated from propane, butane or a mixture of both by combustion has been evaluated for use in biocidal products of product-type 19, repellents and attractants, as described in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 18 September 2019.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency on 16 June 2020[3], having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 19 using carbon dioxide generated from propane, butane or a mixture of both by combustion may be expected to satisfy the requirements of Article 19(1)(b) of Regulation (EU) No 528/2012. The opinion of the Agency also concluded that this active substance does not give rise to concern and is eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(6) Taking into account the opinion of the Agency, it is therefore appropriate to include carbon dioxide generated from propane, butane or a mixture of both by combustion in

[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: 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.

Annex I to Regulation (EU) No 528/2012. As carbon dioxide generated from propane, butane or a mixture of both by combustion has been assessed based on an active substance dossier complying with the requirements set out in Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[4], carbon dioxide generated from propane, butane or a mixture of both by combustion should be included in category 6 of Annex I to Regulation (EU) No 528/2012, "Substances for which a Member State has validated an active substance dossier in accordance with Article 7(3) of this Regulation or accepted such a dossier in accordance with Article 11(1) of Directive 98/8/EC".

(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 carbon dioxide generated from propane, butane or a mixture of both by combustion for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 July 2022, 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 carbon dioxide generated from propane, butane or a mixture of both by combustion for product-type 19 is 1 July 2022.

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.

Done at Brussels, 10.3.2021

For the Commission
The President
Ursula VON DER LEYEN

[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).