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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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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 carbon dioxide generated from propane, butane or a mixture of both by combustion as an active substance in Annex I thereto

Delegations will find attached document C(2021) 1516 final.

Encl.: C(2021) 1516 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 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 products¹, and in particular Article 28(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014² establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list 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 2020³, having regard to the conclusions of the evaluating competent authority.

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.

- (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 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 Council⁴, 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*.

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).

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