EUROPEAN
COMMISSION

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[…](2021) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Annex II to Delegated Regulation (EU) No 1062/2014 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

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

According 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, a work programme shall be carried out to review all active substances used in biocidal products, which were already on the market on 14 May 2000. This on-going work programme for the systematic examination of all existing active substances used in biocidal products is foreseen to run until 31 December 2024.

Commission Delegated Regulation (EU) No 1062/2014, the so-called "Review Regulation" lays down the detailed rules for the examination of these existing active substances. It also sets out in its Annex II the substance/product-type combinations included in this work programme on 6 November 2018.

Since the adoption of the Review Regulation, Annex II has been updated several times in light of the progress of the execution of the review programme, the last times by Commission Delegated Regulations (EU) 2019/157 and (EU) 2019/227. Since the adoption of those Delegated Regulations, some of the substance/product-type combinations included in this work programme are no longer supported. The Commission also adopted a number of approval and non-approval decisions pursuant to Article 89(1) of Regulation (EU) No 528/2012 approving or not approving certain active substances for use in biocidal products and a number of delegated acts pursuant to Article 28(1) of Regulation (EU) No 528/2012 including certain active substances in Annex I to that Regulation. Hence, these substance/product-type combinations should no longer be included in the work programme. In addition, the identity of several active substance was redefined pursuant to Article 13 of the Review Regulation and the active substance/product-type combination notified pursuant to Article 14(1)(b) and found compliant with Article 17(2) of the Review Regulation should be included in the work programme. Also, following the declarations received pursuant to Article 16(4) of the Review Regulation, an invitation was published where persons with an interest could notify active substances in product-type 19 that had benefitted from the derogation for food and feed provided for by Article 6 of Regulation (EC) No 1451/2007. Two active substance/product-type combinations for which the notification has been found compliant with Article 17(2) of the Review Regulation should be included in Annex II of this Regulation.

Consequently, Annex II of the Review Regulation needs to be updated.

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 in the meeting of 28-29 September 2021. A draft of the delegated act was made public in advance of the meeting.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends Annex II to Regulation (EU) No 1062/2014, and updates it in line with the actual state of the work programme.

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(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 the first subparagraph of Article 89(1) thereof,

Whereas:

(1) Annex II to Commission Delegated Regulation (EC) No 1062/2014[2] includes a list of active substance/product-type combinations included in the programme of review of existing active substances contained in biocidal products on 6 November 2018.

(2) The identities of certain active substances listed in Annex II to Delegated Regulation (EC) No 1062/2014 have been redefined pursuant to Article 13 of that Regulation in order to identify in a more precise manner those active substances and establish the corresponding new substance identity.

(3) Following the publication by the European Chemicals Agency ('the Agency') of an open invitation to take over the role of participant for certain active substance/product-type combinations covered by the existing substance identity but not by the new substance identity, substance/product-type combinations notified pursuant to Article 14(1), point (b), and found by the Agency to be compliant with Article 17(2) of Delegated Regulation (EC) No 1062/2014 should be included in Annex II to that Regulation pursuant to Article 18 of that Regulation.

(4) Following the declarations received pursuant to Article 16(4) of Delegated Regulation (EC) No 1062/2014, the Agency published an invitation so that any person with an interest could notify active substances in product-type 19 that benefitted from the derogation for food and feed provided for by Article 6 of Commission Regulation (EC) No 1451/2007[3]. Two notifications for peanut butter and brandy for use in product-type 19 were submitted pursuant to Article 16(5) and found by the Agency to be compliant with Article 17(2) of Delegated Regulation (EC) No 1062/2014. Those

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

[2] Commission Regulation (EC) 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 (OJ L 294, 10.10.2014, p. 1).

[3] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

active substances should therefore be included in Annex II to that Regulation pursuant to Article 18 of that Regulation.

(5) In the Annex to this Regulation, it is appropriate to state the Member States whose competent authorities should be the evaluating competent authorities for the active substance/product-type combinations to be added to Annex II to Delegated Regulation (EC) No 1062/2014.

(6) Active substances for which a decision of approval or non-approval has been adopted after 6 November 2018 for one or more product-types, or which were included in Annex I to Regulation (EU) No 528/2012 pursuant to Article 28(1) of that Regulation, are no longer in the review programme. Therefore, those active substances should no longer be included in Annex II to Delegated Regulation (EC) No 1062/2014 for the concerned product-types.

(7) In order to reflect the actual situation and for transparency, it is appropriate to provide a list of active substance/product-type combinations included in the programme of review of existing active substances contained in biocidal products on the day of adoption of this Regulation.

(8) Delegated Regulation (EC) No 1062/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Delegated Regulation (EC) No 1062/2014 is replaced by 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,

For the Commission
The President
Ursula VON DER LEYEN