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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, 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 6.11.2018 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

Delegations will find attached document C(2018) 7151 final.

Encl.: C(2018) 7151 final

EUROPEAN
COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of 6.11.2018

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)

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", amended by Commission Delegated Regulation (EU) 2017/698, 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 3 February 2017.

Since the adoption of the Review Regulation the identities of certain active substance/product-type combinations in Annex II which can be generated in situ have been redefined pursuant to Article 13 of the same Regulation.

At the same time, 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. The substance/product-type combinations for which notifications have been found compliant with Article 17(2) of the Review Regulation should be included in Annex II of this Regulation.

In addition, some of the substance/product-type combinations originally included in this work programme are no longer supported and the Commission also adopted a number of approval and non-approval decisions pursuant to Article 89(1) of Regulation (EU) No 528/2012 with a view to approve or not approve certain active substances for use in biocidal products. Hence, these substance/product-type combinations should no longer be included in the work programme.

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 meetings of 14-16 March 2018 and 27-28 September 2018. A draft of the delegated act was made public in advance of the meetings.

A four-week public consultation was held from 1st to 29 June 2018. One contribution was received from a consultancy on behalf of a French company, requesting clarifications regarding one entry of Annex II of the Review Regulation. This

contribution was taken into account in the version presented for discussion after the public consultation.

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.

COMMISSION DELEGATED REGULATION (EU) …/...

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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)

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) Commission Delegated Regulation (EU) No 1062/2014[2], as amended by Commission Delegated Regulation (EU) 2017/698[3], sets out in its Annex II a list of active substance/product-type combinations included in the programme of review of existing active substances contained in biocidal products on 3 February 2017.

(2) The identities of certain active substances listed in Annex II which can be generated in situ have been redefined pursuant to Article 13 of Delegated Regulation (EU) No 1062/2014 in order to indicate in a more precise manner the active substances and their precursors presently covered in the work programme for systematic examination.

(3) Any person with an interest could notify a combination of an active substance and its precursors not yet covered by the new identity. Substance/product-type combinations notified pursuant to Article 14(1)(b) and found compliant by the European Chemicals Agency (the Agency) with Article 17(2) of the Delegated Regulation (EU) No 1062/2014 should be included in Annex II to that Regulation pursuant to its Article 18.

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1 OJ L 167, 27.6.2012, p. 1.

2 Commission 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 (OJ L 294, 10.10.2014, p. 1).

3 Commission Delegated Regulation (EU) 2017/698 of 3 February 2017 amending 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 concerning the making available on the market and use of biocidal products (OJ L 103, 19.4.2017, p 1).

(4) Following the declarations received pursuant to Article 16(4) of Delegated Regulation (EU) No 1062/2014, an invitation was published by the Agency where 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[4]. The substance/product-type combinations notified pursuant to Article 16(5) and found compliant by the Agency with Article 17(2) of the Delegated Regulation (EU) No 1062/2014 should be included in Annex II to that Regulation pursuant to its Article 18.

(5) It is appropriate to indicate the Member States the competent authorities of which shall be the evaluating competent authorities for the active substance/product-type combinations to be added to Annex II to Delegated Regulation (EU) No 1062/2014.

(6) Active substance/product-type combinations for which a decision of approval or non-approval has been taken after 3 February 2017 should no longer be included in Annex II to Delegated Regulation (EU) No 1062/2014.

(7) In order to reflect the actual situation and for reasons of legal certainty 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 (EU) No 1062/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Delegated Regulation (EU) 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, 6.11.2018

For the Commission
The President
Jean-Claude JUNCKER

[4] 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).