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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	3 February 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2017) 477 final
Subject:	Commission Delegated Regulation (EU) …/... of 3.2.2017 amending 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 concerning the making available on the market and use of biocidal products

Delegations will find attached document C(2017) 477 final.

Encl.: C(2017) 477 final

EUROPEAN
COMMISSION

Brussels, 3.2.2017
C(2017) 477 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 3.2.2017

amending 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 concerning the making available on the market and use of biocidal products

(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", lays down the detailed rules for the examination of these existing active substances. It also lists in its Annex II the substance/product-type combinations that are included in this work programme. Since the adoption of that Regulation, some of the substance/product-type combinations originally 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 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, the Review Regulation needs to be updated. In addition further amendments are needed in the operative articles, as some references will no longer be valid.

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 meetings of 16-17 March 2016 and of 25-26 May 2016. An updated draft of the delegated act was made public in advance of each of those meetings.

A four-week public consultation was held. No comments were received by the deadline of 6 October 2016.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

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

COMMISSION DELEGATED REGULATION (EU) …/...

of 3.2.2017

amending 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 concerning the making available on the market and use of biocidal products

(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 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[2] sets out, in its Annex II, an exhaustive list of existing active substances/product-type combinations included in the programme of review of existing biocidal active substances on 4 August 2014.

(2) According to Article 14(3) of Regulation (EU) No 1062/2014, any person could have notified a substance/product-type combination included in part 2 of Annex II thereto within 12 months from the entry into force of that Regulation. Since that deadline has passed, part 2 of Annex II and Article 14(3) of that Regulation have become obsolete and Commission Implementing Decision (EU) No 2016/1950[3] has been taken not approving these substance/product type combinations.

(3) Substance/product-type combinations notified pursuant to Article 14(3) and found compliant with Article 17(2) of Regulation (EU) No 1062/2014 should be included in part 1 of Annex II to that Regulation and removed from part 2 of that Annex.

(4) According to Article 16(4) of Regulation (EU) No 1062/2014, an invitation was published where any person with an interest could notify the relevant active

[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 Implementing Decision (EU) 2016/1950 of 4 November 2016 on the non-approval of certain biocidal active substances pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 300, 8.11.2016, p. 14–18).

substance/product-type combination(s). One notification pursuant to Article 16(5) of Regulation (EU) No 1062/2014 and concerning dialuminium chloride pentahydroxide for use in product type 2, was made before the deadline and was found compliant with Article 17(2) of Regulation (EU) No 1062/2014. Therefore this substance/product-type combination has to be included in part 1 of Annex II to that Regulation.

(5) The Evaluating Competent Authority should be appointed pursuant to Article 81 of Regulation (EU) No 528/2012 for the active substance/product-type combinations mentioned in recital 3 and 4.

(6) Active substance/product-type combinations for which a decision of approval or non-approval has been adopted since 4 August 2014 are no longer in the review programme, and therefore shall no longer be referred to in part 1 of Annex II to Regulation (EU) No 1062/2014.

(7) The substance/product-type combinations listed in part 2 of Annex II to Regulation (EU) No 1062/2014 that were not notified pursuant to Article 14(3) of the Review Regulation should be removed from part 2 of that Annex. Part 2 of that Annex therefore becomes obsolete and should be removed.

(8) Consequently, part 1 of Annex II to Regulation (EU) No 1062/2014 should become Annex II as it is the only remaining part in Annex II and references to Article 14(3) and part 1 of Annex II need to be removed.

(9) Regulation (EU) No 1062/2014 should therefore be amended accordingly.

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1062/2014 is amended as follows:

(1) In Article 14, paragraph 3 is deleted.

(2) Article 17 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Notifications pursuant to Article 14(2) or Article 16(5) shall be made to the Agency through the Register."

(b) in paragraph 7, point (a) is replaced by the following:

"(a) where the notification has been submitted pursuant to Article 14(2), update the information in the Register with respect to the identity of the participant and, where relevant, of the substance;"

(3) In Article 20 points (b) and (c) are replaced by the following:

"(b) where no person has submitted a notification within the time limits provided for by Article 14(2) of this Regulation, or where such a notification has been submitted and rejected pursuant to Article 17(4) or Article 17(5) thereof;

(c) where a notification has been submitted within the time limits provided for by Article 14(2) of this Regulation and has been found compliant pursuant to Article 17(5) thereof, but the substance identity in the notification only covers part of the existing identity in Annex II to this Regulation."

(4) Annex II 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, 3.2.2017

For the Commission
The President
Jean-Claude JUNCKER