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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	28 November 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2018) 7778 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 28.11.2018 amending Delegated Regulation (EU) No 1062/2014 as regards certain active susbtances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority

Delegations will find attached document C(2018) 7778 final.

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EUROPEAN
COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of 28.11.2018

amending Delegated Regulation (EU) No 1062/2014 as regards certain active susbtances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority

(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 be achieved by 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 active substance/product-type combinations included in this work programme.

The competent authority of the United Kingdom is the evaluating competent authority for several active substance/product-type combinations listed in Annex II to Commission Delegated Regulation (EU) No 1062/2014. On 29 March 2017, the United Kingdom of Great Britain and Northern Ireland (hereafter referred to as "the United Kingdom") notified the European Council of its intention to withdraw from the European Union, in accordance with Article 50 of the Treaty on European Union. This means that from 30 March 2019 onwards Union legislation will no longer apply to and in the United Kingdom. A withdrawal agreement is currently being negotiated between the European Union and the United Kingdom, which includes a "transition period". According to draft provisions of the Withdrawal Agreement as agreed between the EU and the United Kingdom at negotiator's level, during the transition period the United Kingdom can not act as leading authority for risk assessments, examinations, approvals and authorisations at the level of the Union. Moreover, there is no certainty whether the Withdrawal Agreement, once finalised, will be signed and ratified by both parties, and this before the 30 March 2019. It is therefore necessary to reallocate the role of the United Kingdom as evaluating competent authority for several active substance/product-type combinations to a competent authority of another Member State of the European Union, EEA Countries, or Switzerland, taking effect on 30 March 2019.

Notwithstanding the stage of evaluation of the application, the competent authority designated to replace that of the United Kingdom in accordance with this act should be allowed to request fees for the services they provide, taking into account the provisions of paragraphs 2 and 3 of Article 80 of Regulation (EU) No 528/2012.

Taking into account that the review programme has to be finalised by the target date indicated in Article 89(1) of Regulation (EU) No 528/2012, appropriate time limits should be established for finalising the evaluations of the reallocated applications for active substance/product-type combinations.

Consequently, the Review Regulation needs to be amended to designate new evaluating competent authorities for the concerned active substance/product-type combinations, additional rules need to be set up concerning the payment of fees and

the time limits to finalise the evaluations. All the other provisions set out in Regulation (EU) No 1062/2014 should remain applicable.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission has consulted the expert group "Competent Authorities for Biocidal Products (Regulation (EU) No 528/2012)" – Register Code E03125, consisting of representatives of Member States' competent authorities for biocidal products and of the European Chemicals Agency, as well as observers from industry and civil society, in meetings on 5-6 July 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 14 September to 12 October 2018 via the Better Regulation Portal. A total of two responses were received. One comment was editorial. The second comment related to fees, and the Commission has provided information to the submitter.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends Commission Delegated Regulation (EU) No 1062/2014.

COMMISSION DELEGATED REGULATION (EU) …/...

of 28.11.2018

amending Delegated Regulation (EU) No 1062/2014 as regards certain active susbtances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority

(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] 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 ("review programme").

(2) The competent authority of the United Kingdom of Great Britain and Northern Ireland ("the United Kingdom") is the evaluating competent authority for several active substance/product-type combinations listed in Annex II to Delegated Regulation (EU) No 1062/2014.

(3) The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. As a result, the United Kingdom will withdraw from the Union on 30 March 2019 and and the Union legislation will no longer apply to and in the United Kingdom. A withdrawal agreement is currently being negotiated between the European Union and the United Kingdom, which includes a "transition period". According to draft provisions of the Withdrawal Agreement as agreed between the EU and the United Kingdom at negotiator's level, during the transition period, a competent authority of the United Kingdom can not act as evaluating competent authority for any active substance/product-type combination included in the review programme. Moreover, there is no certainty whether the Withdrawal Agreement, once finalised, will be signed and ratified by both parties, and this before the 30 March 2019.

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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).

(4) Therefore, as regards the active substances/product-type combinations included in the review programme for which the competent authority of the United Kingdom has been designated as the evaluating competent authority, it is necessary to designate a new evaluating competent authority from among the competent authorities of the remaining 27 Member States of the European Union, EEA countries, or Switzerland, with effect from 30 March 2019.

(5) Notwithstanding the stage of evaluation of the application, the Member States whose competent authorities are designated to replace that of the United Kingdom should be allowed to request fees for the services provided, in accordance with Article 80 of Regulation (EU) No 528/2012.

(6) Taking into account that the review programme has to be finalised by the target date indicated in Article 89(1) of Regulation (EU) No 528/2012, appropriate time limits should be established for finalising the evaluations of the reallocated applications for active substance/product-type combinations.

(7) Delegated Regulation (EU) No 1062/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) the following Article is inserted:

"Article 6a
Applications for which the competent authority of the United Kingdom was the evaluating competent authority before 30 March 2019

1. This Article is applicable to applications for which the competent authority of the United Kingdom was the evaluating competent authority before 30 March 2019 for the entries 79, 85, 113, 171, 187, 188, 321, 345, 346, 458, 531, 554, 571, 599, 609, 1045, 1046 and 1047 of Annex II.

2. The evaluating competent authority of a Member State having replaced the competent authority of the United Kingdom in relation to an application that has been submitted before 30 March 2019, shall inform the participant of the fees payable under Article 80(2) of Regulation (EU) No 528/2012 at the latest by 30 April 2019, and shall reject the application if the participant fails to pay the fees within a period of time fixed by the evaluating competent authority. It shall inform the participant and the Agency accordingly.

3. By derogation from the time-limits laid down in Article 6(3), the assessment report and the conclusions shall be sent by the evaluating competent authority within either of the following time-limits, whichever is the later:

   (a) 31 December 2020;

(b) the time-limit for submitting the assessment report pursuant to Article 6(3)(b) set out in Annex III.";

(2) The table set out in Annex II is replaced by the table set out in 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*.

It shall apply from 30 March 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28.11.2018

For the Commission
The President
Jean-Claude JUNCKER