COUNCIL OF THE EUROPEAN UNION

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	10 March 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2014) 1420 final
Subject:	Commission Delegated Regulation (EU) No …/.. of 7.3.2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition

Delegations will find attached document C(2014) 1420 final.

Encl.: C(2014) 1420 final

EUROPEAN
COMMISSION

Brussels, 7.3.2014
C(2014) 1420 final

COMMISSION DELEGATED REGULATION (EU) No …/..

of 7.3.2014

supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

ARTICLE 17(4) OF REGULATION (EU) NO 528/2012 PROVIDES THAT AN AUTHORISATION OF A BIOCIDAL PRODUCT CAN BE GRANTED FOR A MAXIMUM PERIOD OF 10 YEARS. BEFORE THE END OF THE VALIDITY OF AN AUTHORISATION, THE AUTHORISATION HOLDER MAY SEEK RENEWAL BY SUBMITTING AN APPLICATION FOR THIS PURPOSE. THEREFORE, ARTICLE 31 OF THAT REGULATION ALREADY ADDRESSES THE RENEWAL OF A NATIONAL AUTHORISATION IN ONE MEMBER STATE (E.G. DEADLINES FOR APPLICATION, INFORMATION TO BE SUBMITTED BY THE AUTHORISATION HOLDER, THE DIFFERENT STEPS IN THE EVALUATION PROCESS, ETC.). IN ACCORDANCE WITH ARTICLE 40 OF REGULATION (EU) NO 528/2012, SUPPLEMENTARY RULES NEED TO BE LAID DOWN FOR THE RENEWAL OF AUTHORISATIONS SUBJECT TO MUTUAL RECOGNITION IN TWO OR MORE MEMBER STATES.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The delegated act has been the subject of consultations with 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 15-17 May 2013 and of 10-12 July 2013 and 25-27 September 2013. An updated draft of the delegated act was made public in advance of each of those meetings.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act lays down supplementary rules for the renewal of authorisations subject to mutual recognition procedures, both in the Member State having granted the first authorisation and in those Member States having granted an authorisation through mutual recognition of that first authorisation.

COMMISSION DELEGATED REGULATION (EU) No …/..

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supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition

(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 paragraph of Article 40 thereof,

Whereas:

(1) It is appropriate to lay down supplementary rules for the renewal of national authorisations having been subject to mutual recognition in accordance with Article 4 of Directive 98/8/EC of the European Parliament and of the Council[2] or with Articles 33 and 34 of Regulation (EU) No 528/2012, both in the Member States where the first authorisations were granted and in those Member States having granted authorisations through mutual recognition of the first authorisations.

(2) In order to avoid unnecessary duplication of work and to ensure consistency, renewal of authorisations having been subject to mutual recognition should in the first place be managed by the competent authority of one single reference Member State. In order to provide flexibility to applicants and competent authorities, the applicant should have the opportunity to choose the reference Member State subject to the latter's agreement.

(3) In order to facilitate the smooth running of the procedure and the tasks to be carried out by the competent authorities, the scope of this Regulation should be limited to those authorisations having, apart from limited exceptions, the same terms and conditions in all the Member States at the time of the application for renewal. For other national authorisations, an application for renewal should be submitted to the Member State in question in accordance with Article 31 of Regulation (EU) No 528/2012.

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

[2] 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).

(4) The content of an application for renewal of a national authorisation is specified under Article 31 of Regulation (EU) No 528/2012. However, for applications for renewal of national authorisations granted on the basis of mutual recognition, the content of the application should be further specified, in particular to facilitate the work of the Member States involved in the renewal of these authorisations.

(5) To take into account the workload associated with the evaluation, the time allowed for processing an application should depend on whether or not a full evaluation needs to be performed.

(6) In order to provide the same level of protection when an authorisation is renewed as when it is first granted, the maximum validity of the renewed authorisations should not exceed that of the initial authorisations. In addition, phasing-out provisions for the existing products on the market of Member States should be set for those authorisations for which an application for renewal is not submitted or is rejected.

(7) It is appropriate to refer any disagreement in the evaluation of renewal applications to the coordination group established under Regulation (EU) No 528/2012 for the purpose of examining disagreements relating to product authorisation, and to allow derogations from mutual recognition based on the general grounds for such derogations laid down in Article 37 of that Regulation.

(8) In order to bring further predictability, guidelines on the details related to the handling of renewals should be developed by the Agency and regularly updated on the basis of experience and scientific or technical progress,

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter and scope

1. This Regulation lays down rules for the renewal of a national authorisation of a biocidal product or a biocidal product family that has been subject to mutual recognition in accordance with Article 4 of Directive 98/8/EC or with Articles 33 and 34 of Regulation (EU) No 528/2012, or of a national authorisation granted through such mutual recognition (hereinafter referred to as an "authorisation").

2. This Regulation shall apply to authorisations having the same terms and conditions at the time of the application for renewal in all the Member States where the renewal is sought.

3. This Regulation shall also apply to authorisations having different terms and conditions on one or more of the following aspects:

   (a) concerning merely information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013[3];

[3] Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

(b) derived from an adjustment of the initial authorisation based on the second and third subparagraphs of Article 4(1) of Directive 98/8/EC;

(c) established by a Commission Decision adopted either in accordance with Article 4(4) of Directive 98/8/EC or in accordance with Article 37(2)(b) of Regulation (EU) No 528/2012;

(d) derived from an agreement with the applicant under the first subparagraph of Article 37(2) of Regulation (EU) No 528/2012, or from equivalent agreements reached when implementing the provisions of Article 4 of Directive 98/8/EC.

Article 2
Content of the application

1. An application for renewal of an authorisation shall be made by using the application form available from the Register for Biocidal Products and shall contain the following:

(a) the name of the Member State which evaluated the initial application for authorisation or, where relevant, the Member State having been chosen by the applicant together with written confirmation that the Member State agrees to be responsible for the evaluation of the application for renewal (hereinafter referred to as the 'reference Member State');

(b) a list of all other Member States where the renewal of an authorisation is sought (hereinafter the 'Member States concerned'), which shall also include the numbers of the authorisations granted by the reference Member State and the Member States concerned;

(c) confirmation from the applicant that those authorisations fall within the scope of this Regulation as provided for by Article 1(2) and (3);

(d) all relevant data required under Article 31(3)(a) of Regulation (EU) No 528/2012 that the applicant has generated since the initial authorisation or, as appropriate, previous renewal, unless those data have already been submitted to the Agency in the required format;

(e) a draft summary of the biocidal product characteristics containing the information required under Article 22(2) of Regulation (EU) No 528/2012, in the official languages of the reference Member State and of the Member States concerned which, where relevant, may differ between Member States in accordance with Article 1(3) of this Regulation;

(f) the applicant's assessment of whether the conclusions of the initial or previous assessment of the biocidal product or biocidal product family remain valid, including a critical review of any information notified in accordance with Article 47 of Regulation (EU) No 528/2012, including any supporting information to that assessment where it is not already available on the Register for Biocidal Products.

2. For the purposes of paragraph 1(d), where applicable, the application for renewal of an authorisation shall also contain:

(a) a list of the actions to be completed by the authorisation holder according to the conditions for the validity of the authorisation in any Member State and confirmation that these actions have been completed;

(b) a list of the decisions on changes agreed by any Member State before 1 September 2013;

(c) a list of the decisions on changes agreed by any Member State in accordance with Implementing Regulation (EU) No 354/2013;

(d) a list of the notifications or applications for changes submitted to any Member State in accordance with Implementing Regulation (EU) No 354/2013, which are pending at the time of the submission of the application for renewal.

The competent authority of the reference Member State may, for the purposes of the evaluation of the application, request the submission of a copy of the decisions referred to in points (b) and (c).

Article 3
Submission and validation of the application

1. An applicant wishing to seek the renewal of an authorisation by or on behalf of an authorisation holder (hereinafter "the applicant") shall submit an application to the competent authority of the reference Member State at least 550 days before the expiry date of the authorisation.

2. The applicant shall, at the same time when submitting the application to the reference Member State, submit to the competent authorities of the Member States concerned an application for renewal of the authorisations granted in those Member States.

3. The competent authorities of the reference Member State and of the Member States concerned shall inform the applicant of the fees payable under Article 80 of Regulation (EU) No 528/2012 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly.

4. Upon receipt of those fees, the competent authorities of the reference Member State and of the Member States concerned shall accept the application and inform the applicant indicating the dates of acceptance.

5. Within 30 days of the acceptance in the reference Member State, that Member State shall validate the application if it contains all the relevant information referred to in Article 2. The reference Member State shall inform the applicant and the Member States concerned accordingly.

When validating the application, the reference Member State shall not make an assessment of the quality or adequacy of the data or justifications submitted.

6. Within 30 days of acceptance by a Member State concerned, that Member State shall verify whether the authorisation falls within the scope of this Regulation as provided for by Article 1(2) and (3).

Where the authorisation does not fall within the scope of this Regulation, the competent authority in the Member State concerned shall process the application as an application submitted in accordance with Article 31(1) of Regulation (EU) No 528/2012 and it shall inform the applicant and the competent authorities in other Member States accordingly.

7. Where the competent authority of the reference Member State considers that the application is incomplete, it shall require additional information for the validation of the application from the applicant and shall set a reasonable time limit for the submission of that information. The time limit shall not normally exceed 90 days.

The competent authority of the reference Member State shall, within 30 days of receipt of the additional information, validate the application if the additional information is sufficient for the application to comply with the requirements laid down in Article 2.

The competent authority of the reference Member State shall reject the application if the applicant fails to submit the required information within the deadline and shall inform the applicant and the Member States concerned accordingly.

Article 4
Evaluation of the application

1. On the basis of an assessment of the available information and in the light of current scientific knowledge, the competent authority of the reference Member State shall, within 90 days of validating the application, decide whether a full evaluation of the application for renewal is necessary.

2. Where a full evaluation is necessary, the competent authority of the reference Member State shall draft an assessment report, following the procedure and timelines set out in Article 30 of Regulation (EU) No 528/2012. The assessment report shall conclude on whether the conditions for granting the authorisation set out in Article 19 of that Regulation are still satisfied, and take into account the results of the comparative assessment carried out in accordance with Article 23 of that Regulation, where appropriate.

Without prejudice to the first subparagraph of Article 30(2) of Regulation (EU) No 528/2012, the assessment report and the draft summary of biocidal product characteristics shall be sent to the Member States concerned and to the applicant within 365 days of validating the application.

3. Where a full evaluation is not necessary, the reference Member State shall draft an assessment report, following the procedure laid down in points (a), (b) and (c) of Article 30(3) of Regulation (EU) No 528/2012. This report shall conclude on

whether the conditions for granting the authorisation set out in Article 19 of that Regulation are met, and take into account the results of the comparative assessment carried out in accordance with Article 23 of that Regulation, where appropriate.

The assessment report and the draft summary of biocidal product characteristics shall be sent to the Member States concerned and to the applicant within 180 days of validating the application.

Article 5
Decision on renewal

1. Within 90 days of receipt of the assessment report and the draft summary of biocidal product characteristics, and subject to Article 6, the Member States concerned shall agree on the summary of biocidal product characteristics, with the exception, where relevant, of the differences referred to in Article 1(3)(a), and shall record their agreement in the Register for Biocidal Products.

   The reference Member State shall enter the agreed summary of biocidal product characteristics and the final assessment report in the Register for Biocidal Products, together with any agreed terms or conditions imposed on the making available on the market or use of the biocidal product or biocidal product family.

2. Within 30 days of reaching agreement, the reference Member State and each of the Member States concerned shall renew the authorisations in conformity with the agreed summary of biocidal product characteristics.

   Without prejudice to the provisions of Article 23(6) of Regulation (EU) No 528/2012, the authorisation shall be renewed for a maximum period of 10 years.

3. Without prejudice to Article 7, where no agreement is reached within 90 days, each Member State that agrees to the summary of biocidal product characteristics referred to in paragraph 1 may renew the authorisation accordingly.

4. Where, for reasons beyond the control of the holder of an authorisation, no decision is taken on the renewal of that authorisation before its expiry, the respective competent authority shall grant a renewal for the period necessary to complete the evaluation.

Article 6
Period of grace

Article 52 of Regulation (EU) No 528/2012 shall apply to existing stocks of the biocidal product made available on the following markets:

(a) on the market of a Member State to which no application for renewal has been submitted or which has rejected an application pursuant to Article 3(3) of this Regulation;

(b) on the market of the reference Member State and of the Member States concerned, where the reference Member State rejects the application for renewal in accordance with Article 3(3) or the third subparagraph of Article 3(7) of this Regulation.

Article 7
Coordination group, arbitration and derogation from mutual recognition

1. A Member State concerned may propose to refuse to renew an authorisation or to adjust the terms and conditions of the authorisation in accordance with Article 37 of Regulation (EU) No 528/2012.

2. Where, regarding matters other than those referred to in paragraph 1, the Member States concerned do not reach an agreement on the conclusions of the assessment report or, where relevant, on the summary of the biocidal product characteristics proposed by the reference Member State in accordance with Article 5(1), the reference Member State shall refer the matter to the coordination group established under Article 35 of Regulation (EU) No 528/2012.

Where a Member State concerned is in disagreement with the reference Member State, the former shall give a detailed statement of the reasons for its position to all Member States concerned and to the applicant.

3. Articles 35 and 36 of Regulation (EU) No 528/2012 shall apply to matters of disagreement referred to in paragraph 2.

Article 8
Guidance on handling renewals in the mutual recognition procedures

1. The Agency shall, after consulting the Member States, the Commission and interested parties, draw up guidelines on the details related to the handling of renewals of authorisations covered by this Regulation.

2. Those guidelines shall be regularly updated, taking into account the contributions from Member States and stakeholders on its implementation as well as scientific and technical progress.

Article 9

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, 7.3.2014

For the Commission
The President
José Manuel BARROSO