Commission Delegated Regulation (EU) No 492/2014 of 7 March 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)

COMMISSION DELEGATED REGULATION (EU) No 492/2014

of 7 March 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)

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.

(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

Changes to legislation: *There are outstanding changes not yet made to Commission Delegated Regulation (EU) No 492/2014. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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)];

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.

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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).

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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.