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 (Text with EEA relevance)

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(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 51 thereof,

Whereas:

(1) In order to ensure a harmonised approach, it is appropriate to adopt provisions for changes of biocidal products in respect of any of the information submitted in relation to the initial application for the authorisation or registration of biocidal products and biocidal product families authorised or registered in accordance with 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[(2)] and Regulation (EU) No 528/2012.

(2) Proposed changes of biocidal products should be classified in different categories, taking into account the extent to which they require a reassessment of the risk for human or animal health or the environment and of the efficacy of the biocidal product or biocidal product family. It is appropriate to establish the criteria to be used for classifying a change of a product in one of the categories referred to in Article 50(3) of Regulation (EU) No 528/2012.

(3) In order to bring further predictability, the European Chemicals Agency (hereinafter 'the Agency') should issue opinions on the classification of changes of products. The Agency should also issue guidelines on the details of the various categories of changes. Those guidelines should be regularly updated in the light of scientific and technical progress.

(4) It is necessary to clarify the procedure which will lead to a decision by the Commission in accordance with the first subparagraph of Article 50(2) of Regulation (EU) No 528/2012 and, where relevant, Article 44(5) thereof.

(5) In order to reduce the overall number of possible applications and to enable Member States, the Agency and the Commission to focus on those changes that have a genuine impact on the properties of biocidal products, an annual reporting system should

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 354/2013. 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*

be introduced for certain changes of an administrative nature. Such changes should not require any prior agreement and should be notified within 12 months following implementation. However, other types of changes of an administrative nature, whose immediate reporting and prior examination is necessary for the continuous supervision of the biocidal product concerned should not be subject to the annual reporting system.

(6) Each change should require a separate submission. Grouping of changes should nevertheless be allowed in certain cases, in order to facilitate the review of the changes and reduce the administrative burden.

(7) Provisions should be introduced regarding the role of the coordination group established under Regulation (EU) No 528/2012 to increase cooperation between Member States and allow for the settlement of disagreements in the evaluation of certain changes.

(8) This Regulation should clarify when the authorisation holder is allowed to implement a given change, as such clarification is essential for economic operators.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down provisions concerning changes of biocidal products sought in accordance with Article 50(2) of Regulation (EU) No 528/2012 with regard to any of the information submitted in relation to the initial application for the authorisation of biocidal products or biocidal product families in accordance with Directive 98/8/EC and Regulation (EU) No 528/2012 (hereinafter ‘changes of products’).

Article 2

Classification of changes of products

1 Changes of products are classified in accordance with the criteria laid down in the Annex to this Regulation. Certain categories of changes are listed in the tables of the Annex.

2 The holder of an authorisation may request the Agency to provide an opinion on the classification in accordance with the criteria laid down in the Annex to this Regulation of a change not listed in one of the tables of that Annex.

The opinion shall be delivered within 45 days following receipt of the request and payment of the fee referred to in Article 80(1)(a) of Regulation (EU) No 528/2012.

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The Agency shall publish the opinion after deletion of all information of commercial confidential nature.

Article 3

Guidelines on classification

1 The Agency shall, after consulting the Member States, the Commission and interested parties, draw up guidelines on the details of the various categories of changes of products.

2 Those guidelines shall be regularly updated, taking into account the opinions taken in accordance with Article 2(2), contributions from Member States as well as scientific and technical progress.

Article 4

Grouping of changes

1 Where several changes of products are sought, a separate notification or application shall be submitted in respect of each change sought.

2 By way of derogation from paragraph 1, the following rules shall apply:

a a single notification may cover a series of proposed administrative changes affecting different products in the same manner;

b a single notification may cover a series of proposed administrative changes affecting the same product;

c a single application may cover more than one proposed change of the same product in the following cases:

(1) one of the proposed changes in the group is a major change of the product; all other proposed changes in the group are a direct consequence of that change;

(2) one of the proposed changes in the group is a minor change; all other proposed changes in the group are a direct consequence of that change;

(3) all changes in the group are a direct consequence of a new classification of the active substance(s) or non-active substance(s) contained in the product or of the product itself;

(4) all changes in the group are a direct consequence of a specific condition of the authorisation;

d a single application may cover more than one proposed change if the Member State evaluating the application in accordance with Article 7(4) or 8(4), or, in the case of a change of a Union authorisation, the Agency, confirms that it is practically feasible to handle those changes in the same procedure.

The single applications referred to in points (c) and (d) of the first subparagraph shall be made in accordance with Article 7 or 12 where at least one of the proposed changes is a minor change of the product and none of the proposed changes is a major change of the product, and with Article 8 or 13 where at least one of the proposed changes is a major change of the product.

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Article 5

Information requirements

An application submitted in accordance with Article 50(2) of Regulation (EU) No 528/2012 shall contain the following:

(1) the relevant filled application form as available from the Register for Biocidal Products, which shall contain:

- (a) a list of all the authorisations affected by the proposed change(s);
- (b) a list indicating all the Member States in which the product is authorised and the changes are sought (hereinafter the 'Member States concerned');
- (c) for products authorised by national authorisation, the Member State which evaluated the initial application for authorisation of the biocidal product or, if the changes are not sought in that Member State, the Member State having been chosen by the applicant together with written confirmation that that Member State agrees to be reference Member State (hereinafter referred to as the 'reference Member State');
- (d) for major changes of products authorised by Union authorisation, the Member State who evaluated the initial application for authorisation of the biocidal product or, if the changes are not sought in that Member State, the Member State having been chosen by the applicant together with written confirmation that that Member State agrees to evaluate the application of the change;
- (e) where relevant, a draft revised summary of the biocidal product characteristics in, as appropriate,
  - (1) for products authorised by national authorisation, the official language(s) of all the Member States concerned;
  - (2) for products authorised by Union authorisation, one of the official languages of the Union, which in case of major changes must be a language accepted by the Member State referred to in point (c) at the time of application;

(2) a description of all the changes sought;

(3) where a change leads to or is the consequence of other changes of the terms of the same authorisation, a description of the relation between these changes;

(4) all relevant supporting documents to demonstrate that the proposed change would not adversely affect the conclusions previously reached concerning the compliance with the conditions set out in Article 19 or 25 of Regulation (EU) No 528/2012;

(5) where relevant, the opinion issued by the Agency in accordance with Article 3 of this Regulation.

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CHAPTER II

CHANGES OF PRODUCTS AUTHORISED BY MEMBER STATES

Article 6

Notification procedure for administrative changes of products

1 The authorisation holder, or its representative, shall submit simultaneously to all Member States concerned a notification complying with Article 5 and, in each of those Member States, pay the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012.

2 Without prejudice to the second subparagraph, the notification shall be submitted within 12 months following the implementation of the change.

In case of a change referred to in Section 1 of Title 1 of the Annex to this Regulation, the notification shall be submitted before the implementation of the change.

3 Within 30 days following receipt of the notification, where one of the Member States concerned disagrees with the change or the relevant fee has not been paid, that Member State shall inform the authorisation holder, or its representative, and the other Member States concerned that the change is rejected and the grounds for the rejection.

If, within 30 days following receipt of the notification, a Member State concerned has not expressed its disagreement, that Member State shall be deemed to have agreed with the change.

4 Each of the Member States concerned which has not rejected the change in accordance with paragraph 3 shall, where relevant, amend the authorisation of the biocidal product in conformity with the agreed change.

Article 7

Procedure for minor changes of products

1 The authorisation holder, or its representative, shall submit simultaneously to all Member States concerned an application complying with Article 5.

2 Each Member State concerned shall inform the applicant of the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012. If the applicant fails to pay the fee within 30 days, the Member State concerned shall reject the application and inform the applicant and the other Member States concerned accordingly. Upon receipt of the fee, the Member State concerned shall accept the application and inform the applicant accordingly indicating the date of acceptance.

3 The reference Member State shall validate the application within 30 days of its acceptance, if it complies with the requirements laid down in Article 5 and inform the applicant and the Member States concerned accordingly.

In the context of the validation referred to in the first subparagraph, the reference Member State shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

Where the reference Member State considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the application to