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)

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.

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.

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.

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.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 4(2)(d) words substituted by S.I. 2019/720 Sch. 2 para. 181(2)
- Art. 5(1) words omitted by S.I. 2019/720 Sch. 2 para. 182(2)(a)
- Art. 5(1)(b)-(d) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(b)
- Art. 5(1)(e)(1) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(ii)
- Art. 5(1)(e)(2) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(ii)
- Art. 5(1)(e) words omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(i)
- Art. 5(4) words inserted by S.I. 2019/720 Sch. 2 para. 182(3)
- Art. 5(5) omitted by S.I. 2019/720 Sch. 2 para. 182(4)
- Art. 7(2A) inserted by S.I. 2022/1291 reg. 3(2)(a)
- Art. 7(4A) inserted by S.I. 2022/1291 reg. 3(2)(c)
- Art. 7(5A) inserted by S.I. 2022/1291 reg. 3(2)(e)
- Art. 8(2A) inserted by S.I. 2022/1291 reg. 3(3)(a)
- Art. 8(4A) inserted by S.I. 2022/1291 reg. 3(3)(c)
- Art. 8(5A) inserted by S.I. 2022/1291 reg. 3(3)(e)