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 III

CHANGES OF PRODUCTS AUTHORISED BY THE COMMISSION

Article 13

Procedure for major changes of products

1 The authorisation holder, or its representative, shall submit to the Agency an application complying with Article 5.

2 The Agency shall inform the applicant of the fee payable under Article 80(1)(a) of Regulation (EU) No 528/2012, and shall reject the application if the applicant fails to pay the fee within 30 days. It shall inform the applicant and the competent authority of the Member State referred to in Article 5(1)(d) (hereinafter referred to as the 'evaluating competent authority') accordingly.

Upon receipt of the fee, the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against decisions of the Agency under this paragraph.

3 Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if it complies with the requirements laid down in Article 5.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

The evaluating competent authority shall, within 15 days from the Agency's acceptance of an application, inform the applicant of the fee payable under Article 80(2) of Regulation (EU) No 528/2012 and shall reject the application if the applicant fails to pay the fee within 30 days.

4 Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the completeness of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and

the Agency accordingly. In such cases, part of the fee paid in accordance with paragraph 2 shall be reimbursed.

5 The evaluating competent authority shall, within 180 days of the validation of an application, evaluate it and send an assessment report and the conclusions of its evaluation, including, where relevant, a draft revised summary of the product characteristics, to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide written comments on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

6 Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. The period referred to in paragraph 5 shall be suspended from the date of the request until the date the information is received. The time limit given to the applicant shall not exceed 90 days in total unless justified by the nature of the data requested or by exceptional circumstances.

7 Within 90 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the proposed change. In case of a favourable opinion, the Agency shall indicate whether the proposed change would require an amendment of the authorisation.

The Agency shall inform the applicant of its opinion and shall, where relevant, request the applicant to submit, in all the official languages of the Union, a draft revised summary of the biocidal product characteristics.

8 Within 30 days of the submission of its opinion to the Commission, the Agency shall, where relevant, transmit to the Commission, in all the official languages of the Union, the draft revised summary of the biocidal product characteristics, as referred to in Article 22(2) of Regulation (EU) No 528/2012.

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 :

- Art. 9-13 omitted by S.I. 2019/720 Sch. 2 para. 187

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)