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 II

CHANGES OF PRODUCTS AUTHORISED BY MEMBER STATES

Article 8

Procedure for major 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 validation 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 reference Member State 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 reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

4 Within 180 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report and shall send its assessment report and, where relevant, the revised summary of the biocidal product characteristics to the Member States concerned and to the applicant.

5 Where it appears that additional information is necessary to carry out the evaluation, the reference Member State shall ask the applicant to submit such information within a specified time limit. The period referred to in paragraph 4 shall be suspended from the date of the request until the date on which 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.

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

6 If, within 90 days of receipt of the assessment report and, where relevant, of the revised summary of the biocidal product characteristics, the Member States concerned express no disagreement in accordance with Article 10, those Member States shall be deemed to agree with the conclusions of the assessment report and, where appropriate, the revised summary of the biocidal product characteristics.

7 Within 30 days of reaching agreement, the reference Member State shall inform the applicant of the agreement, and the reference Member State and each of the Member States concerned shall, where relevant, amend the authorisations of the biocidal product in conformity with the agreed change.

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. 8 words substituted by S.I. 2019/720 Sch. 2 para. 186(2)
- Art. 8(1) words substituted by S.I. 2019/720 Sch. 2 para. 186(3)
- Art. 8(2) words omitted by S.I. 2019/720 Sch. 2 para. 186(4)(d)
- Art. 8(2) words substituted by S.I. 2019/720 Sch. 2 para. 186(4)(a)
- Art. 8(2) words substituted by S.I. 2019/720 Sch. 2 para. 186(4)(b)
- Art. 8(2) words substituted by S.I. 2019/720 Sch. 2 para. 186(4)(c)
- Art. 8(3) words omitted by S.I. 2019/720 Sch. 2 para. 186(5)
- Art. 8(4) words inserted by S.I. 2022/1291 reg. 3(3)(b)
- Art. 8(4) words omitted by S.I. 2019/720 Sch. 2 para. 186(6)
- Art. 8(5) words inserted by S.I. 2022/1291 reg. 3(3)(d)
- Art. 8(5) words omitted by S.I. 2019/720 Sch. 2 para. 186(7)
- Art. 8(6) omitted by S.I. 2019/720 Sch. 2 para. 186(8)
- Art. 8(7) substituted by S.I. 2019/720 Sch. 2 para. 186(9)

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)