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 9a

Procedure for changes already agreed by other Member States

1 Where an administrative change has already been agreed in one or more Member States and the authorisation holder seeks the same administrative change in an additional Member State concerned, the authorisation holder or its representative shall submit a notification in accordance with Article 6(1) to the additional Member State concerned.

2 Where a minor or a major change has already been agreed in one or more Member States and the authorisation holder seeks the same minor or major change in an additional Member State concerned, the authorisation holder, or its representative, shall submit an application complying with Article 5 to the additional Member State concerned.

3 The 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.

4 If within 45 days in the case of a minor change, or 90 days in the case of a major change, of the date of acceptance, the Member State concerned express no disagreement in accordance with Article 10, it shall be deemed to agree with the conclusions of the assessment report and, where appropriate, the revised summary of the biocidal product characteristics.

5 Within 30 days of the agreement referred to in paragraph 4, the Member State concerned shall inform the applicant of the agreement, and, where relevant, amend the authorisation 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 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)