

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 11

Notification procedure for administrative changes of products

1 The authorisation holder, or its representative, shall submit to the Agency a notification complying with Article 5 and pay the fee referred to in Article 80(1)(a) of Regulation (EU) No 528/2012.

2 Without prejudice to the second subparagraph, that notification shall be submitted within 12 months following 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 and subject to the payment of the relevant fee, the Agency shall prepare and submit to the Commission an opinion on the proposed change.

4 If, within 30 days following receipt of the notification, the relevant fee has not been paid, the Agency shall reject the application and inform the applicant accordingly.

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

5 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.

6 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 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\(3\)\(e\)](#)