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 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)