

Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (Text with EEA relevance)

Article 4

Submission and validation of applications for Union authorisation

1 Where the related reference product has been authorised by Union authorisation or is the subject of an application for such an authorisation, applications for authorisation of a same product shall be submitted to the Agency in accordance with Article 43(1) of Regulation (EU) No 528/2012.

2 However, the application shall not include a confirmation that the biocidal product would have similar conditions of use across the Union or a reference to an evaluating competent authority.

3 For the purposes of the application of this Article, Article 43(2) of Regulation (EU) No 528/2012 shall be read as requiring the Agency to inform the applicant only.

4 By way of derogation from the first and second subparagraphs of Article 43(3) of Regulation (EU) No 528/2012, the Agency shall validate the application within 30 days of accepting it provided that the information indicated in Article 2 has been submitted.

5 The validation shall include a check that the proposed differences between the same product and the related reference product concern merely information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

6 For the purposes of the application of this Article, all references to the evaluating competent authority in the third subparagraph of Article 43(3) and in Article 43(4) and (5) of Regulation (EU) No 528/2012 shall be read as referring to the Agency.

Changes to legislation:

There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 414/2013. 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. 4 omitted by [S.I. 2019/720 Sch. 2 para. 198](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 2(a) words substituted by [S.I. 2019/720 Sch. 2 para. 196\(b\)](#)
- Art. 5(1) Art. 5 renumbered as Art. 5(1) by [S.I. 2022/1291 reg. 4\(2\)\(a\)](#)
- Art. 5(1) words inserted by [S.I. 2022/1291 reg. 4\(2\)\(b\)](#)
- Art. 5(2) inserted by [S.I. 2022/1291 reg. 4\(2\)\(c\)](#)
- Art. 6a(1A) inserted by [S.I. 2022/1291 reg. 4\(3\)\(b\)](#)