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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular Article 17(7) thereof,

Whereas:

(1) Regulation (EU) No 528/2012 specifies procedures for applying for and granting authorisation of biocidal products.

(2) Where applications are submitted to the same receiving competent authority or to the Agency for two or more authorisations of biocidal products with the same properties, the authorisations may be granted based on one single product evaluation and, as the case may be, comparative assessment. It is therefore appropriate to provide for an adapted authorisation procedure for such cases.

(3) The terms and conditions relating to the making available on the market and use of a biocidal product should be based on the evaluation made of the product. It is therefore appropriate to require that biocidal products authorised in accordance with this Regulation are authorised on the same terms and conditions as the evaluated biocidal products to which they refer, with the exception of the details on which the products differ.

(4) Since this Regulation specifies a procedure provided for by Regulation (EU) No 528/2012, which applies from 1 September 2013, this Regulation should also apply from that date.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

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. (See end of Document for details) View outstanding changes*

[F1 Article 1

Subject matter

This Regulation lays down the procedure applicable where an authorisation is sought for a product (the 'same product') which is identical to another single biocidal product, biocidal product family, or individual product of a biocidal product family which has been authorised or registered in accordance with Directive 98/8/EC of the European Parliament and of the Council[(2)] or Regulation (EU) No 528/2012, or for which an application for such authorisation has been submitted (the 'related reference product'), with regard to all the latest information submitted in relation to the authorisation or registration, except information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013[(3)].**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2016/1802 of 11 October 2016 amending Implementing Regulation (EU) No 414/2013 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 2

Content of applications

By way of derogation from Article 20(1) of Regulation (EU) No 528/2012 and the information requirements in Article 43(1) thereof, an application for authorisation of a same product shall contain the following information:

(a) the authorisation number or, for not yet approved related reference products, the application number in the Register for Biocidal Products of the related reference product;

(b) an indication of the proposed differences between the same product and the related reference product, and evidence that the products are identical on all other aspects;

(c) where required by Article 59(1) of Regulation (EU) No 528/2012, letters of access to all the data supporting the authorisation of the related reference product;

(d) a draft summary of the biocidal product characteristics for the same product.

Article 3

Submission and validation of applications for national authorisation

1 Where the related reference product has been authorised by national authorisation or is the subject of an application for such an authorisation, applications for authorisation of a same product shall be submitted in accordance with Article 29(1) of Regulation (EU) No 528/2012 to the competent authority that has granted or is requested to grant the national authorisation of the related reference product.

***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. (See end of Document for details) View outstanding changes*

[[F2]1a Where the related reference product has been authorised by Union authorisation or is the subject of an application for such an authorisation, applications for national authorisation of a same product shall be submitted in accordance with Article 29(1) of Regulation (EU) No 528/2012 to the competent authority of the Member State in which the national authorisation is sought.**]**

2 By way of derogation from paragraphs 2 and 4 of Article 29 of Regulation (EU) No 528/2012, the competent authority shall validate the application within 30 days of accepting it, provided that the information indicated in Article 2 has been submitted.

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.

Textual Amendments

F2 Inserted by Commission Implementing Regulation (EU) 2016/1802 of 11 October 2016 amending Implementing Regulation (EU) No 414/2013 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. (See end of Document for details) View outstanding changes*

[F2 Article 4a

Submission and acceptance of applications under the simplified procedure

1 Where the related reference product has been authorised in accordance with Article 26(3) of Regulation (EU) No 528/2012 or is the subject of an application for such an authorisation, applications for authorisation of a same product shall be submitted in accordance with Article 26(1) of that Regulation to the competent authority that has granted or is requested to grant the authorisation of the related reference product.

2 The competent authority shall accept the application in accordance with Article 26(2) of Regulation (EU) No 528/2012.

Textual Amendments

F2 Inserted by Commission Implementing Regulation (EU) 2016/1802 of 11 October 2016 amending Implementing Regulation (EU) No 414/2013 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 4b

Guidance on handling applications for authorisation of same products

1 The Agency shall, after consulting the Member States, the Commission and interested parties, draw up guidelines on the details related to the handling of applications covered by this Regulation.

2 Where necessary, those guidelines shall be updated taking into account the contributions from Member States and interested parties on its implementation as well as scientific and technical progress.**]**

Textual Amendments

F2 Inserted by Commission Implementing Regulation (EU) 2016/1802 of 11 October 2016 amending Implementing Regulation (EU) No 414/2013 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).

[F1 Article 5

Evaluation and decision on applications for national authorisation

By way of derogation from Article 30 of Regulation (EU) No 528/2012, the receiving competent authority shall decide whether to grant or refuse authorisation of a same product in accordance with Article 19 of that Regulation within 60 days from the validation of the application in accordance with Article 3 of this Regulation, or, where applicable, from the subsequent date of adoption of the corresponding decision concerning the related reference product.**]**