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:

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 biocidal product or 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 registration or authorisation has been submitted (the 'related reference product'), with regards 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 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 [3].

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.

[1] OJ L 167, 27.6.2012, p. 1.

[2] OJ L 123, 24.4.1998, p. 1.

[3] OJ L 109, 19.4.2013, p. 4.

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.

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.

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, or, where applicable, from the subsequent date of adoption of the corresponding decision concerning the related reference product.

Article 6

Evaluation and decision on applications for Union authorisation

1. By way of derogation from Article 44(1), (2) and (3) of Regulation (EU) No 528/2012 the Agency shall prepare and submit to the Commission an opinion on the application within 30 days from the validation of the application in accordance with Article 4 of this Regulation, or, where applicable, on the subsequent date of submission of an opinion on the related reference product in accordance with Article 44(3) of Regulation (EU) No 528/2012.

2. If the Agency recommends the authorisation of the biocidal product, the opinion shall contain at least both the following elements:

(a) a statement on whether the conditions laid down in Article 19 of Regulation (EU) No 528/2012 are fulfilled, and a draft summary of biocidal products characteristics, as referred to in Article 22(2) of that Regulation;

(b) where relevant, details of any terms and conditions which should be imposed on the making available on the market and use of the biocidal product.

Article 7

Authorisations and changes of same products

1. A same product shall have a different authorisation number than that of the related reference product.

On all other aspects, the content of the authorisation of a same product shall be identical with that of the related reference product except in terms of the information in respect of which the products differ. The Register for Biocidal Products shall show a link between same products and related reference products.

2. Changes of a same product or of a related reference product shall be notified or applied for in accordance with Implementing Regulation (EU) No 354/2013 independently of each other.

Authorisations of a same product or of a related reference product may be changed or cancelled independently of each other.

However, in the evaluation of a proposed change of a same product or of a related reference product, the receiving competent authority or, where relevant, the Agency shall consider the appropriateness of cancelling or amending the authorisation of other products to which the product is linked in the Register for Biocidal Products as referred to in the second subparagraph of paragraph 1.

Article 8

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 September 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 May 2013.

For the Commission
The President
José Manuel BARROSO