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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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)

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(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) In Commission Implementing Regulation (EU) No 414/2013[2] it is necessary to clarify that an individual product covered under a biocidal product family authorisation is also eligible as a related reference product with a view to obtain an authorisation for a same product.

(2) References to applications for registration are now obsolete as this procedure is no longer applicable since the repeal of Directive 98/8/EC of the European Parliament and of the Council[3] and should therefore be deleted.

(3) To respond to the needs of economic operators, in particular small and medium-sized enterprises, Article 3 of Implementing Regulation (EU) No 414/2013 should provide for the possibility to apply for national authorisation of same products in cases where the related reference product has been authorised by Union authorisation or is the subject of an application for such an authorisation.

(4) It is necessary to clearly identify and to further specify the procedure for the submission of applications for authorisation of a same product and for acceptance of such applications where the related reference product has been authorised under the simplified authorisation procedure set out in Article 26 of Regulation (EU) No 528/12 or is the subject of an application for such an authorisation.

(5) In order to bring further predictability, guidelines on the details related to the handling of the applications covered by Implementing Regulation (EU) No 414/2013 should be developed by the European Chemicals Agency ('the Agency') and regularly updated on the basis of experience and scientific or technical progress.

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1 OJ L 167, 27.6.2012, p. 1.

2 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 (OJ L 125, 7.5.2013, p. 4).

3 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

(6) To make the text clearer and unambiguous, the wording of Articles 5 and 6 should be amended.

(7) Implementing Regulation (EU) No 414/2013 should therefore be amended accordingly.

(8) 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

Implementing Regulation (EU) No 414/2013 is amended as follows:

(1) Article 1 is replaced by the following:

'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* 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**.

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* Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

** 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 (OJ L 109, 9.4.2013, p.4).'

(2) In Article 3, the following paragraph 1a is inserted.

'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.'.

(3) The following Article 4a is inserted:

'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 Regulation (EU) No 528/2012 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 that Regulation.'.

(4) The following Article 4b is inserted:

'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 [*Please specify*], 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.'.

(5) Article 5 is replaced by the following:

'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.*'*.

(6) In Article 6, paragraph 2 is replaced by the following:

'2. If the Agency recommends the authorisation of the same 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 same product.'.

(7) The following Article 6a is inserted:

'Article 6a
Evaluation and decision on applications under the simplified procedure

1. By way of derogation from Article 26(3) and (4) 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 25 of that Regulation within 60 days from the acceptance of the application in accordance with Article

4a(2), or, where applicable, from the subsequent date of adoption of the corresponding decision concerning the related reference product.

2. The evaluation shall include a check that the information indicated in Article 2 has been submitted and 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.

3. Where the product authorised through this procedure is intended to be made available on the market of other Member States, Article 27 of Regulation (EU) No 528/2012 shall apply.'.

Article 2

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

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

Done at Brussels,

For the Commission
The President
Jean-Claude Juncker