REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 88/2014

of 31 January 2014

specifying a procedure for the amendment of Annex I to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

(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 28(5) thereof,

Whereas:

(1) Categories 1, 2, 3, 4 and 5 of Annex I to Regulation (EU) No 528/2012 are well defined so as to allow certain presumptions as regards the properties of the substances falling therein. The inclusion in category 6 of that Annex requires the submission of a data package allowing a full risk assessment for the intended use. The procedure for amending one of those categories upon request in order to include therein active substances, or modifying the restrictions therein, should be transparent and equal for all applicants. It is therefore appropriate to further specify it.

(2) The data required for inclusion of an active substance in Annex I to Regulation (EU) No 528/2012 should be sufficient to evidence that the substance does not give rise to concern within the meaning of Article 28(2) of Regulation (EU) No 528/2012.

(3) In order to be consistent, the procedure for submission and validation of an application for inclusion of an active substance in Annex I to Regulation (EU) No 528/2012 should be identical to that for submission and validation of an application for approval of an active substance. However, where the former may require less data to be submitted, the evaluation procedure should be adapted accordingly.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products referred to in Article 82(1) of Regulation (EU) No 528/2012,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down the procedures to be followed for the purpose of amending, at the request of an applicant, Annex I to Regulation (EU) No 528/2012 in order to:

(a) include active substances in category 1, 2, 3, 4, 5 or 6 of that Annex in accordance with Article 28(1) of that Regulation; or

(b) make amendments of the relevant restrictions in those categories.

Article 2

Data requirements for an application

An application for an inclusion or an amendment referred to in Article 1 shall include the information specified in the Annex to this Regulation.

Article 3

Submission and validation of applications

1. The procedure laid down in Article 7(1) and (2), the third subparagraph of Article 7(3), and Article 7(6) of Regulation (EU) No 528/2012 shall apply for the submission of applications for inclusions or amendments referred to in Article 1 of this Regulation.

2. Where the application concerns category 6 of Annex I to Regulation (EU) No 528/2012, the first and second subparagraphs of Article 7(3) and Article 7(4) and (5) of that Regulation shall apply for the validation of the application.

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

Article 4

Evaluation of applications

1. The evaluating competent authority shall evaluate whether there is evidence that the substance does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and, where relevant, to which restrictions its use should be subject. It shall send an assessment report and the conclusions of its evaluation to the European Chemicals Agency set up under Regulation (EC) No 1907/2006 of the European Parliament and of the Council [1] ('the Agency'). Where the application concerns inclusion in category 1, 2, 3, 4 or 5 of Annex I to Regulation (EU) No 528/2012, the assessment report and the conclusions shall be submitted within 180 days of the payment of the fees referred to in the third subparagraph of Article 7(3) of that Regulation. Where the application concerns inclusion in category 6 of Annex I to Regulation (EU) No 528/2012, the assessment report and the conclusions shall be submitted within 365 days of validation of that application.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall give the applicant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2. Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall request that the applicant submit such information within a specified time limit, and shall inform the Agency accordingly. The periods referred to in paragraph 1 of this Article shall be suspended from the date of issue of that request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

3. An application concerning inclusion of an active substance in category 1, 2, 3, 4 or 5 of Annex I to Regulation (EU) No 528/2012, which, following a request for additional data pursuant to paragraph 2, complies fully with Article 6 of Regulation (EU) No 528/2012 shall, where the applicant so requests,

(a) be considered as an application for inclusion in category 6 of Annex I to that Regulation; and

(b) be subject to validation pursuant to Article 3(2).

4. The Agency shall, having regard to the conclusions of the evaluating competent authority, prepare and submit to the Commission the opinion referred to in Article 28 of Regulation (EU) No 528/2012 within 270 days of receipt of the conclusions of the evaluation in the case of an application for inclusion in category 6 of Annex I to Regulation (EU) No 528/2012, and within 180 days of that receipt in the case of an application for inclusion in category 1, 2, 3, 4 or 5 of Annex I to that Regulation.

Article 5

Agency opinions eligible to form the basis for a Commission decision

Provided that there is evidence that an active substance does not give rise to concern within the meaning of Article 28(1) of Regulation (EU) No 528/2012, the Commission may adopt a decision pursuant to that Article amending Annex I to that Regulation in the sense referred to in Article 1 of this Regulation where the Agency has submitted an opinion pursuant to:

(a) Article 4(4) of this Regulation;

(b) Article 8(4) of Regulation (EU) No 528/2012; or

(c) one of the acts provided for by Article 89(1) of Regulation (EU) No 528/2012.

Article 6

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, 31 January 2014.

For the Commission
The President
José Manuel BARROSO

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

ANNEX

Data requirements for the inclusion of an active substance in Annex I to Regulation (EU) No 528/2012

SECTION A

Data for inclusion in category 1, 2, 3, 4 or 5

1. An application for inclusion of an active substance in category 1, 2, 3, 4 or 5 of Annex I to Regulation (EU) No 528/2012 shall specify the relevant category, the identity of the substance and the intended uses of the products for which authorisation will be sought, and contain conclusive evidence to demonstrate the following:

   (a) that the substance complies with the description of the relevant category; and

   (b) that there is a robust consensus of expert opinion that the substance does not give rise to concern in accordance with Article 28(2) of that Regulation.

   The evidence referred to in point (b) shall include all relevant published literature data regarding the substance in question and all relevant data on the substance generated by the applicant. It may also include read-across from chemical analogues/homologues, (Q)SAR predictions, data from existing studies, *in vitro* studies, historical human data, or conclusions from other regulatory authorities or frameworks.

2. By way of derogation from paragraph 1(b), where there is no conclusive evidence of a robust consensus of expert of opinion regarding one or more endpoints, an application shall contain all additional data necessary to show that the substance does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012.

SECTION B

Data for inclusion in category 6

An application for inclusion of an active substance in category 6 of Annex I to Regulation (EU) No 528/2012 shall contain the data referred to in Article 6 of that Regulation to allow a state-of-the-art risk assessment.