Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant 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)

COMMISSION IMPLEMENTING REGULATION (EU) No 564/2013

of 18 June 2013

on the fees and charges payable to the European Chemicals Agency pursuant 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 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products[(1)], and in particular Article 80(1) thereof,

Whereas:

(1) The structure and amount of the fees payable to the European Chemicals Agency, (hereinafter referred to as 'the Agency'), as well as the conditions for payment should be established.

(2) The structure and amount of the fees should take account of the work required by Regulation (EU) No 528/2012 to be carried out by the Agency. Fees should be set at such a level as to ensure that the revenue derived from them, when combined with other sources of the Agency's revenue, is sufficient to cover the cost of the services delivered.

(3) It follows from Article 80(3)(d) of Regulation (EU) No 528/2012 that the structure and amount of fees is to take into account whether information has been submitted jointly or separately. In order to reflect the actual work load of the Agency and to promote joint submission of information, it is appropriate to only levy one fee per application, in case several persons apply jointly for the approval of an active substance or the renewal of an approval of an active substance.

(4) To take into account the specific needs of small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium sized enterprises[(2)] (hereinafter 'SMEs') established in the Union, reduced fees for active substance approval, renewal of approval or inclusion in Annex I to Regulation (EU) No 528/2012 and biocidal product authorisation or renewal should apply to such companies. The levels of the reductions should take into account the significant proportion of SMEs in the biocides sector combined with the interest of avoiding excessive fees for other enterprises while

ensuring that the Agency's work is fully financed. For the purpose of discouraging applications for products containing active substances fulfilling one of the substitution criteria listed in Article 10(1) of Regulation (EU) No 528/2012, as well as of such active substances, reductions should not apply to applications for such biocidal products or active substances.

(5) Taking into account the Agency's work required to handle an appeal lodged in accordance with Article 77 of Regulation (EU) No 528/2012, it is appropriate to levy a fee for such appeals in accordance with the third subparagraph of Article 77(1) of that Regulation. However, to avoid penalising persons launching justified appeals, it is appropriate to refund such fees where the appeal is well founded.

(6) Taking into account the reduced work required by the Agency in cases where applications are rejected before or during validation, or withdrawn during their assessment, it is appropriate to provide for partial refund of fees in such cases.

(7) For the purpose of encouraging applications for approval of active substances that are suitable alternatives to approved active substances fulfilling one of the exclusion criteria listed in Article 5(1) of Regulation (EU) No 528/2012, it is appropriate to provide for reimbursement of the fee for such applications.

(8) The fee for applications for inclusion in Annex I to Regulation (EU) No 528/2012 of active substances that do not give rise to concern should take into account the estimated work required by the Agency to handle such applications, as well as the public interest in allowing products containing such substances to be authorised.

(9) For the purpose of discouraging applications for approval or renewal of approval of active substances fulfilling one of the substitution criteria listed in Article 10(1) of Regulation (EU) No 528/2012 as well as applications for authorisation or renewal of products requiring a comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012, and of contributing to financing the waivers and reductions provided for by this Regulation, it is appropriate to provide for increased fees for such applications.

(10) In view of the Agency's work required to handle a request for an opinion on the classification of a 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)], it is appropriate to levy a fee for such requests. However, to avoid, to the extent possible, penalising applicants whose requests to have a change classified as minor or administrative are justified, it is appropriate to grant a fee reduction to the subsequent application for a change, where the request leads to a recommendation to classify the change as an administrative or minor change.

(11) Given the Agency's work required to treat submissions for inclusion in the list of relevant persons referred to in Article 95 of Regulation (EU) No 528/2012, it is appropriate to levy a fee for such submissions. The amount of work required for such submission will vary significantly depending on whether the relevant person submits a letter of access or a new dossier, since, in the latter case, the Agency will have to

check that the dossier complies with Annex II to Regulation (EU) No 528/2012 or, where appropriate, Annex IIA to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing on the market of biocidal products[(4)]. It is appropriate to differentiate the fee accordingly.

(12) Given the Agency's work required to handle a request for confidentiality in accordance with Article 66(4) of Regulation (EU) No 528/2012, it is appropriate to levy a fee for such requests.

(13) Since the Agency's budget is drawn up and implemented in euro, and its accounts are also presented in euro in accordance with Article 19 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002[(5)], with Article 17 of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities[(6)] and with Article 17 of the Financial Regulation of the European Chemicals Agency of 24 September 2008[(7)], it is appropriate to levy fees only in euro.

(14) It follows from Article 80(3)(f) of Regulation (EU) No 528/2012 that the deadlines for the payment of fees should be fixed taking due account of the deadlines of the procedures provided for in that Regulation.

(15) The fees set out in this Regulation should be reviewed at appropriate intervals, with a view to aligning the fees with the inflation rate and with the actual costs to the Agency of the services provided. These reviews should take into account the Agency's increased experience in dealing with applications under the Regulation and the efficiencies thereby gained.

(16) The Standing Committee on Biocidal Products referred to in Article 82(1) of Regulation (EU) No 528/2012 did not deliver an opinion on the measures provided for in this Regulation. Since an implementing act was deemed to be necessary, the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 564/2013. (See end of Document for details)*

CHAPTER I

FEES

Article 1

Fees for work in relation to active substances

The Agency shall levy the fees provided for in Table 1 of Annex I for work required by Regulation (EU) No 528/2012 to be carried out in relation to approval and renewal of approval of active substances, as well as inclusion in Annex I to that Regulation.

Article 2

Fees for work in relation to Union authorisation of biocidal products

The Agency shall levy the fees provided for in Table 1 of Annex II for work required by Regulation (EU) No 528/2012 to be carried out in relation to Union authorisation of biocidal products.

Article 3

Other fees

1 The Agency shall levy the fees provided for in Annex III for work required by Regulation (EU) No 528/2012 to be carried out in relation to establishment of technical equivalence, applications for mutual recognition, requests for inclusion in the list of relevant persons, and requests for confidential treatment of information submitted to the Agency.

2 The Agency shall levy the annual fees provided for in Annex III for every biocidal product or biocidal product family authorised by the Union. The annual fee shall be due on the first and each subsequent anniversary of the entry into force of the authorisation. It shall relate to the preceding year.

Article 4

Fees for appeals against a decision of the Agency under Article 77 of Regulation (EU) No 528/2012

1 For any appeal against a decision of the Agency under Article 77 of Regulation (EU) No 528/2012, the Agency shall levy a fee as set out in Annex III.

2 An appeal shall not be considered to be received by the Board of Appeal until the relevant fee has been received by the Agency.

3 If the appeal is considered inadmissible by the Board of Appeal, the fee shall not be refunded.

4 The Agency shall refund the fee levied in accordance with paragraph 1 if the Executive Director of the Agency rectifies a decision in accordance with Article 93(1) of Regulation (EU) No 1907/2006 of the European Parliament and of the Council[8], or if the appeal is decided in favour of the appellant.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 564/2013. (See end of Document for details)*

Article 5

Reimbursement possibility for alternatives to approved active substances fulfilling one of the exclusion criteria

1 Upon submission of an application to the Agency for the approval of an active substance, which may be a suitable alternative, within the meaning of the second subparagraph of Article 5(2) of Regulation (EU) No 528/2012, to an approved active substance fulfilling one of the exclusion criteria pursuant to Article 5(1) of that Regulation, an applicant may request reimbursement of the fee to be paid to the Agency.

2 Upon receipt of the opinion from the Agency in accordance with Article 8(4) of Regulation (EU) No 528/2012, which shall also include a recommendation on whether the active substance is a suitable alternative within the meaning of the second subparagraph of Article 5(2) of Regulation (EU) No 528/2012, the Commission shall decide on the request.

3 Where the Commission decides that the active substance is a suitable alternative, the Agency shall inform the applicant thereof and fully reimburse the fee referred to in paragraph 1.

CHAPTER II

SUPPORT FOR SMEs

Article 6

Recognition of SME status

1 Before submission of an application to the Agency for approval, renewal or inclusion in Annex I to Regulation (EU) No 528/2012 of an active substance or for Union authorisation of a biocidal product or biocidal product family, submitted in accordance with Articles 7(1), 13(1), 28(4), 43(1) or 45(1) of that Regulation respectively, containing a claim for SME reduction, the prospective applicant shall submit to the Agency the relevant elements proving entitlement to such reduction by virtue of the status of SME in the meaning of Recommendation 2003/361/EC.

2 In the case of an application for approval, renewal or inclusion of an active substance in Annex I to Regulation (EU) No 528/2012, the question shall be determined by reference to the active substance manufacturer that is represented by the prospective applicant. In case of an application for product authorisation or renewal of product authorisation, the question shall be determined by reference to the prospective authorisation holder.

3 The Agency shall publish a list of the relevant elements to be submitted in accordance with paragraph 1.

4 Within 45 days of receipt of all the relevant elements referred to in paragraph 1, the Agency shall decide what SME status, if any, can be recognised.

5 A recognition of an enterprise as an SME shall be valid for applications submitted under Regulation (EU) No 528/2012 for two years.

6 An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012 against a decision taken by the Agency under paragraph 4.