Note for agreement by Member States' Competent Authorities for biocidal products

This document is drafted in the interest of consistency of the implementation of Regulation (EU) No 528/2012 and with the aim of finding an agreement between Member States' Competent Authorities for biocidal products on a harmonised approach. Please note, however, it does not represent the official position of the Commission and that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Renewal of "same biocidal product" authorisations.

1. BACKGROUND AND PURPOSE OF THE DOCUMENT

(1) During the 92nd meeting of the Competent Authorities for biocidal products, a Member State raised questions on whether same biocidal product (SBP) authorisations in accordance with Commission Implementing Regulation (EU) No 414/2013[1] ('the SBP Regulation') can be subjected to renewal and, if so, what procedure should be followed.

(2) The questions of that Member State, as well as two suggested options, are reflected in the document *CA-June21-Doc.4.17-Renewal of same biocidal products*[2].

(3) With regard to the question whether renewal of SBP authorisations is possible, the Member State noted that the renewal of SBP authorisations is not mentioned in Regulation (EU) No 528/2012 ('the BPR') or in the SBP Regulation. According to the Member State, the procedure leading to the adoption of an SBP authorisation is a "mere administrative procedure". If changes were made to the related reference product, an application for renewal of an SBP authorisation would require an assessment of the SBP. According to the Member State, this contradicts the "administrative" nature of the SBP procedure. Moreover, the Member State underlines difficulties that may arise from the fact that the assessment of the application for renewal of the SBP authorisation would have to be carried out by the receiving competent authority, which might not have carried out the "original assessment".

(4) With regard to the questions concerning the procedure to be followed for the renewal of SBP authorisations, the Member State asked, first, whether the SBP authorisation should be treated like a national authorisation, also in the case where the authorisation for the related reference product was obtained through mutual recognition. Should the answer to this first question be in the negative, the Member

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0414

[2] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/f421b8e5-5b5a-40e6-bffd-d1604bad29f9/details

State asked what should be the renewal procedure for SBP authorisations that were subject to changes.

(5) The Member State proposed two options. The first option proposed would foresee that the renewal of an SBP authorisation is not possible. The second option would envisage that all applications for the renewal of SBP authorisations are handled like the renewal of a national authorisation. The Member State is of the opinion that in any case, a legal text addressing the renewal of SBPs is needed.

(6) The issue is partly addressed in ECHA's "Practical Guide on Biocidal Products Regulation", chapter on "Same biocidal product"[3]. The Guide states that "[t]he content of SBP authorisation shall be identical with that of the reference biocidal product (family), except for the administrative changes that have been applied for. [T]he authorisation of SBP will have a different authorisation number and may be changed, *renewed* or cancelled *independently of authorisation related to the reference product*. However, in some cases the appropriateness of cancelling or amending the authorisation of other products to which the product is linked in the R4BP 3 may be considered"[4] (emphasis added).

(7) The purpose of this document is to clarify whether SBP authorisations can be renewed and following which procedure.

2. RELEVANT PROVISIONS OF REGULATION (EU) NO 528/2012 AND COMMISSION IMPLEMENTING REGULATION (EU) NO 414/2013.

The relevant provisions are listed in the Annex to this document.

3. ANALYSIS AND AGREED WAY FORWARD

(8) Article 17(7) of the BPR (placed in Chapter IV "General principles concerning the authorisation of biocidal products") empowers the Commission to adopt an implementing act to "specify procedures for the authorisation of the same biocidal products by the same or different enterprises under the same terms and conditions".

(9) Article 3(1)(o) of the BPR provides that 'authorisation' means national authorisation, Union authorisation or authorisation in accordance with Article 26. Therefore, 'authorisation' of the same biocidal product as referred to in Article 17(7) is to be understood as referring to a national, Union or simplified authorisation within the meaning of the BPR.

(10) On the basis of that empowerment, the Commission has determined a lighter procedure for SBP authorisations in the SBP Regulation. In particular, that Regulation introduces derogations from the procedure for national, Union and simplified authorisations established in the BPR. For instance, Article 3 of the SBP Regulation, titled "Submission and validation of applications for national authorisation", provides that, where the authorisation of the related reference product is a national authorisation, "applications for authorisation of a same

[3] https://echa.europa.eu/documents/10162/1276600/pg_bpr_same_ch_15_en.pdf/500ba769-fedf-44e0-b722-8001ab14c3b9

[4] *Ibid.*, p. 112.

product shall be submitted in accordance with Article 29(1)" of the BPR, and introduces derogations from paragraphs 2 and 4 of said Article.

(11) Renewal is not addressed in the SBP Regulation. Therefore, the relevant BPR provisions apply: the renewal of a national SBP authorisation is governed by Article 31 of the BPR, and the renewal of a Union SBP authorisation is governed by Articles 45 and 46. Renewal of an SBP authorisation based on a reference product authorised through mutual recognition falls under the Regulation (EU) No 492/2014 on renewals of authorisations of BPs subject to mutual recognition ('the Renewal Regulation'), provided that the conditions of Article 1 thereof are satisfied.

(12) As clarified in document *CA-September 21-Doc.4.6 - Mutual Recognition of same BP*, an SBP authorisation granted in accordance with the SBP Regulation can be the subject of a mutual recognition procedure pursuant to Chapter VII of the BPR. An SBP authorisation that has been subject to mutual recognition thus falls under the Renewal Regulation, provided that the requirements of Article 1 of said Regulation are fulfilled.

(13) The relevant provisions concerning fees are, depending on the applicable procedure, Article 31(4) of the BPR for national SBP authorisations; Article 45(3) and 46(2) for Union SBP authorisations; Article 3(3) of Regulation (EU) No 492/2014.

(14) With regard to the case where changes are introduced regarding the related reference product and/or the SBP, these aspects must be considered already at the time of introducing the changes (and prior to renewal). Article 7(2), third subparagraph, provides that "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". Article 7(2), second subparagraph, provides that "authorisations of a same product or of a related reference product *may* be changed or cancelled independently of each other" (emphasis added). In considering the appropriateness of cancelling or amending the linked authorisations, the competent authorities must have regard to Article 1 of the SBP Regulation, which provides that the procedural rules laid down therein apply to a product[5] which is *identical* to another 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 the Changes Regulation (emphasis added).

[5] More precisely, "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 (1) or Regulation (EU) No 528/2012, or for which an application for such authorisation has been submitted (the 'related reference product')".

Annex. Relevant provisions in the BPR and in the SBP regulation.

BPR:

Article 3

Definitions

1.

For the purposes of this Regulation, the following definitions shall apply:

[…]
(o)

‘authorisation’ means national authorisation, Union authorisation or authorisation in accordance with Article 26;

[…]

Article 17

Making available on the market and use of biocidal products

[…]
7.
The Commission shall, by means of an implementing act, specify procedures for the authorisation of the same biocidal products by the same or different enterprises under the same terms and conditions. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 31

Renewal of a national authorisation

1.
An application by or on behalf of an authorisation holder wishing to seek the renewal of a national authorisation for one or more product-types shall be submitted to the receiving competent authority at least 550 days before the expiry date of the authorisation. Where renewal is sought for more than one product-type, the application shall be submitted at least 550 days before the earliest expiry date.
2.
The receiving competent authority shall renew the national authorisation, provided that the conditions set out in Article 19 are still satisfied. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.
3.

When applying for renewal, the applicant shall submit:
(a)

without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and
(b)

its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

4.

The receiving competent authority shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fees payable under Article 80(2), the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

5.

On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, the receiving competent authority shall, within 90 days of accepting an application in accordance with paragraph 4, decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.

6.

Where the receiving competent authority decides that a full evaluation of the application is necessary, it shall decide on the renewal of the authorisation after carrying out an evaluation of the application in accordance with paragraphs 1, 2 and 3 of Article 30.

Where the receiving competent authority decides that a full evaluation of the application is not necessary, it shall decide on the renewal of the authorisation within 180 days of accepting the application in accordance with paragraph 4 of this Article.

7.

Where, for reasons beyond the control of the holder of a national authorisation, no decision is taken on the renewal of that authorisation before its expiry, the receiving competent authority shall grant a renewal for the period necessary to complete the evaluation.

Article 45

Submission and acceptance of applications

1.

An application by or on behalf of an authorisation holder wishing to seek the renewal of a Union authorisation shall be submitted to the Agency at least 550 days before the expiry date of the authorisation.

2.

When applying for renewal, the applicant shall submit:

(a)

without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and

(b)

its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

3.

The applicant shall also submit the name of the competent authority of the Member State that it proposes should evaluate the application for renewal and provide written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

The Agency shall inform the applicant of the fees payable to it under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable to it under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of acceptance.

4.

An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Article 46

Evaluation of applications for renewal

1.

On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for Union authorisation or, as appropriate, the previous renewal, the evaluating competent authority shall, within 30 days of the Agency accepting the application in accordance with Article 45(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary.

2.

Where the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 and 2 of Article 44.

Where the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application, prepare and submit to the Agency a recommendation on the renewal of the authorisation. It shall provide the applicant with a copy of its recommendation.

The evaluating competent authority shall, as soon as possible after the Agency has accepted the application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

3.

Within 180 days of receipt of a recommendation from the evaluating competent authority, the Agency shall prepare and submit to the Commission an opinion on the renewal of the Union authorisation.

4.

On receipt of the opinion of the Agency, the Commission shall adopt either an implementing Regulation to renew the Union authorisation or an implementing decision to refuse to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall renew a Union authorisation, provided that the conditions set out in Article 19 are still satisfied.
5.

Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

Commission Implementing Regulation 414/2013 (SBP 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 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 ([1]) 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 ([2]).

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.