Management of new information on an active substance submitted for a product authorisation application

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1. Introduction and scope

After the approval of an active substance (AS), new information on the AS (i.e., information not assessed at the AS approval) might be made available through different regulatory processes and/or can be submitted in applications for biocidal product (BP)/product family (BPF) authorisation. New information on the AS can be submitted by either the same legal entity/one of the legal entities that applied for AS approval (e.g., the applicant for the product authorisation application is the same legal entity as a company supporting the AS approval) or a different legal entity[1].

New information on the AS (i.e., information on the AS that were not assessed for the approval/renewal of that AS) can consist of:

- a complete alternative AS dossier,
- a Letter of Access (LoA) to a complete alternative AS dossier,
- new individual study/ies or data on a specific endpoint(s) or an LoA to these data, or
- a combination of new individual study/ies or data on a specific endpoint(s) and an LoA to some parts of an alternative AS dossier.

During the BP/BPF authorisation all information submitted by the applicant, including new information on the AS, should be taken into account (e.g., information relevant for a use which was not assessed during the AS approval or to refine the assessment). This document only addresses new information on an AS submitted in a BP/BPF authorisation application[2].

Discussion on the management of new information on the AS submitted in a product authorisation application took place in the past and resulted in the document CG-17-2016-13 *Evaluation of alternative dossiers during product authorisation* and the BPC-15 document *Procedure for the submission, evaluation and dissemination of data generated after active substance approval*. However, discussion was re-opened at CA level and a new approach was proposed by the COM and agreed at the CA-94 meeting (CA-Dec21-Doc.4.2 New active substance data submitted in applications for BP authorisation[3]). This new approach required the revision of the above mentioned CG and Biocidal Product Committee (BPC) documents.

The document CG-17-2016-13 *Evaluation of alternative dossiers during product authorisation* was revised and agreed at the CG-57 meeting by consensus. Upon publication of this CG-57 document and the BPC-47 document *Procedure for the submission, evaluation and dissemination of data generated after active substance approval*, the document CG-17-2016-13 *Evaluation of alternative dossiers during product authorisation* becomes obsolete. In addition, the `Overview of new information on active substances submitted in product authorisation applications' template for the list was agreed at the CG-57 meeting (CG-57-2023-02) and replaces the `List of alternative dossiers' document.

The objective of this document is to:

[1] New information on the AS submitted under the BPR by a legal entity different than the one having applied for AS approval is called an `alternative dossier'. If such data is submitted in a BP/BPF authorisation application, that alternative dossier is called a `third-party dossier'.

[2] Thus, new information generated under regulatory frameworks other than the BPR, but not submitted as part of the BP/BPF authorisation application (e.g., new harmonised classification of the AS) are not addressed in this document.

[3] The document is available at: https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/30657d7e-d58c-4382-b6dc-c0708fc53304/details

- revise the procedural steps for the consideration of additional information on the AS provided in applications for BP/BPF authorisation, identifying the role of MSs and ECHA in each process;
- suggest a coordinated approach to be followed when the same new information on the AS is submitted in support of several BP and/or BPF authorisation applications to several reference MSs[4] (rMSs)/evaluating Competent Authorities[5] (eCAs) in order to avoid work duplication, share the workload and avoid discrepancies between different assessments;
- clarify aspects that should be considered by the rMS/eCA for the assessment of the BP/BPF authorisation application or the MS in charge of assessing the new information on the AS, depending on the type of the information.

It should be noted that the main principles of this document are also recommended for UA process and are included here in order to align all product authorisation processes.

In addition, the procedural steps for the discussion and conclusion of the assessment of new information on active substances at BPC (and its Working Groups (WGs) level, handling of additional information on the reference source, the revision of the value of an endpoint already agreed for the AS (considering all the information already available for the AS for that endpoint), or the establishment of a value for a new endpoint which was not yet established in the list of endpoints (LoEP) are not addressed in this document, as they are in the remit of the BPC, and not the CG. The revised BPC-15 document addressing these was agreed at the BPC-47 meeting[6]. Nevertheless, when new information on the AS is submitted in a BP/BPF authorisation application, the CG and BPC documents should be considered and applied together.

2. Management of new information on active substances submitted in product authorisation applications

2.1 Establishment of a list of new information on active substances

To avoid duplication of work and to ensure a consistent approach is applied by the MSCAs involved when new information on an AS is submitted in an application for BP/BPF authorisation, a list `Overview of new information on active substances submitted in product authorisation applications' which is a list of new information on active substances submitted in BP/BPF authorisation application (hereby `list') will be established for the purpose of recording the submission of new data on active substances at BP/BPF authorisation. The list will be made available in the form of a collaboration via Interact Portal and be managed by the MSs.

2.2 Procedural steps concerning management of new information on an active substance submitted at the product authorisation

2.2.1 Identification of new information on an active substance submitted within a product or product family authorisation application

When a BP/BPF authorisation application including new information on an AS is submitted, the applicant has to indicate for the rMS/eCA that such information is included in the dossier. Indication should be done in the IUCLID dossier (and the new information on AS should be included in it under the AS data set section) and in the supporting document. In case new

[4] In case of National authorisation (NA) applications.
[5] In case of Simplified (SA) and Union authorisation (UA) applications.
[6] The document is available at: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

information on the AS submitted in a BP/BPF authorisation application is the same as information submitted on that particular AS in:

- a successful technical equivalence (TE) application (i.e., TE was established) for which the applicant was the same, and/or
- an Article 95 inclusion application closed with the decision of inclusion on the Article 95 list (hereby `successful Article 95 list inclusion application')[7] for which the applicant was the same, and/or
- a successful TE application and/or successful Article 95 list inclusion application for which the applicant was not the same, but for which access is granted with an LoA, and/or
- another BP/BPF authorisation application for which the applicant was the same, and/or
- another BP/BPF authorisation application for which the applicant was not the same, but for which access is granted with an LoA

clear reference to the exact application(s) (i.e., R4BP 3 asset number) where the same new information on the AS was submitted should be indicated by the applicant[8].

In addition, the applicant should include in the submitted BP/BPF authorisation application (in section 13 of the AS data set of the IUCLID dossier) in accordance with the BPR an assessment of the consequence/impact of the provided new information on the AS on the BP/BPF (e.g., highlighting any difference in results with the approved AS and proposing an assessment of the difference).

When processing the BP/BPF authorisation application, the rMS/eCA checks whether there is any indication from the applicant that new information on the AS is submitted. If such information is identified during a BP/BPF authorisation procedure, the list should be checked in order to determine the way forward.

2.2.2 Checking and updating the list

Before processing of the new information on an AS, the rMS/eCA of the BP/BPF authorisation application shall check in the list whether this information have already been submitted to another MS in support of an application for BP/BPF authorisation. The possible four scenarios and how the rMS/eCA of the BP/BPF authorisation application should proceed are described below.

In cases 1,2 and 4, the rMS/eCA of the BP/BPF authorisation application in which the new information on the AS was submitted records the details concerning the new information on the AS in the form of a new entry in the list in accordance with the instructions descibed in the list, while for case 3 a new entry in the list does not need to be made. The update has to be done within the first 2 weeks of the evaluation step, at the latest. When the list is updated later on during the process it should be done so without undue delay.

Case 1: an entry for the new information on the AS received is not included in the list. The rMS/eCA proceeds with the assessment of the new information on the AS and informs the CG at the next regular CG meeting of being the MS in charge of assessing the new information on the AS. The MS in charge of assessing the new information (hereby `MS in charge')

[7] An Article 95 list inclusion application can consist of a complete active substance dossier, an LoA to a complete substance dossier, a reference to a complete substance dossier where data protection has expired, or a combination of these.

[8] If this cannot be provided by the applicant when the same data had been submitted in another BP/BPF authorisation application for which access is granted with an LoA, at least the identity of the rMS/eCA and the type (NA, SA or UA) of that BP/BPF authorisation application should be indicated. If this cannot be provided by the applicant when the same data had been submitted in a successful TE application or successful Article 95 list inclusion application for which access is granted with an LoA, at least the identity of applicant for that application should be indicated.

updates the list according to the progress of the assessment.

Case 2: an entry for the new information on the AS received is already on the list and a MS is indicated in charge of assessing the new information. The rMS/eCA of the BP/BPF authorisation application in which the same new information on the AS was submitted does not assess the new information on the AS and in case of any questions contacts the MS in charge via R4BP 3.

Case 3: an entry for the new information on the AS received is already on the list stated as already evaluated by another MS, and i) scientific/technical discussion is indicated as not necessary and the deadline established for MSs to indicate their disagreement with the assessment made by the MS in charge passed, or ii) scientific/technical discussion is indicated as necessary (see section 2.2.3 of this document for more details) and the BPC (or its relevant WG(s)) concluded on the assessment. The rMS/eCA of the BP/BPF authorisation application in which the same new information on the AS was submitted does not assess the new information on the AS and in case of any questions contacts the MS that already evaluated the information (preferably via R4BP 3).

Case 4: an entry for the new information on the AS received is already on the list and indicated as submitted in several MSs, but no MS is indicated in charge of assessing the new information[9]. The rMS/eCA of the BP/BPF authorisation application should contact all other MSs who recorded submission of the same new information on the AS for different BP/BPF applications in order to determine which MS will be in charge of assessing the new information. The matter should be reported at the next regular CG meeting by the MS in charge, if agreement has been reached; and by one of the MSs where the rMS/eCA of the BP/BPF authorisation application was submitted in case there has been no agreement on the MS in charge prior to the regular CG meeting. Upon finalisation of these discussions, the new MS in charge updates the list, proceeds with the assessment of the new information on the AS and informs the CG about it at the next regular CG meeting. The MS in charge updates the list according to the progress of the assessment.

MSs in charge will inform other MSs about relevant updates regarding the status of the process at regular CG meetings. This includes a notification to all MSs (including MSs where the same new information on the AS was not submitted) via R4BP 3 once the assessment is finalised[10] together with the final assessment and recorded in the list. In addition, the MS in charge should indicate and record in the list whether discussion at the WG(s) is considered necessary and establish a deadline by which any other MS can indicate its disagreement with that assessment. If the MS in charge indicates that scientific/technical discussion of the new information on the AS at the relevant WG(s) is considered not necessary, discussion at the WG(s) will not take place. However, if any of the other MSs (independent whether the same new information on the AS was submitted in that particular MS for a BP/BPF authorisation application) disagrees with the outcome of that assessment, it should indicate it in the list within the deadline set by the MS in charge, together with a justification. In the latter case, the MS in charge should initiate scientific/technical discussion at the relevant WG(s).

2.2.3 Assessment of the new information on the active substance submitted in a product or product family authorisation application

Assessment of new information on an AS submitted in a BP/BPF authorisation application and,

[9] Such a situation should only happen if the same new data on the AS were submitted in several MSs, but the BP/BPF authorisation application in the MS that was in charge of assessing that particular new data on the AS has been withdrawn/rejected. In these cases the withdrawal of the application should be recorded in the list by the MS that was in charge of assessing that particular new data on the AS, and that MS should inform all other concerned MSs (i.e., the MSs where the same new data on the AS has been submitted) based on the list, so discussion of a new MS to be in charge could be initiated as soon as possible by these concerned MSs.

[10] Generally the assessment of the new information of the AS should be finalised by the MS in charge within the first 3 months of the evaluation step, at the latest.

if necessary, discussion at the WG/BPC level should take place in parallel to the evaluation of the BP/BPF authorisation application. For the timelines of the assessment of that new information on an AS (including the possible need of WG/BPC level discussion) the MS in charge should always consider the different steps of the authorisation process and their deadlines set in the BPR. Due to the fact that the quantity and complexity of the new information on an AS submitted in a BP/BPF authorisation application is not predictable and can vary significantly case-by-case (e.g., complete alternative AS dossier, or a new individual study on a specific endpoint), establishing definitive timelines for the assessment of the information is not purposeful. It would in fact lead to either too generous, or too short timelines for assessment of the information. Therefore, this document only includes indicative timelines per step and these should be adjusted, if necessary and justified. To maintain due process the authorisation deadlines need to be met.

As new information on the AS submitted in a BP/BPF authorisation application might be identical to information submitted for different regulatory processes under the BPR, the following different aspects should be considered by the MSs for the assessment of the BP/BPF authorisation application:

- The objective of the TE assessment is to determine whether the alternative source of the AS is similar (equivalent) to the reference source of the approved AS regarding the chemical composition and hazard profile. The TE assessment is carried out according to Guidance on the Biocidal Products Regulation Volume V, Guidance on applications for technical equivalence[11]. If the applicant of the BP/BPF authorisation application does not use the reference source presented for the approval of the AS for the manufacturing of the BP(s), TE of the AS of this alternative source has to be established. The TE decision has to be included in section 13 of the AS data set of the IUCLID dossier (i.e., the TE application has to be finalised by ECHA before the BP/BPF authorisation application is submitted)[12].

  Thus, if an alternative source not technically equivalent to the reference source of the approved AS is indicated to be used for the manufacture of the BP(s), but no TE is established for it, that alternative source cannot be considered for the BP/BPF, even if the alternative source is included in the Article 95 list. If at least one reference source of the approved AS, or an alternative source technically equivalent to it is not indicated for the manufacture of the BP(s), it means that the requirements of Article 20(1)(a)(i) of the BPR (i.e., point 2.5 of Title 1 of Annex III to the BPR) are not fulfilled, and the BP(s)/BPF authorisation application shall be rejected[13], or the BP/BPF shall not be authorised[14].

- If new information on the AS is submitted in a BP/BPF authorisation application and that new information uses an alternative source not technically equivalent to the reference source of the approved AS, the MS in charge should consider and decide on a case by case basis whether it can be taken into account for the authorisation of the BP/BPF, and (if applicable) the revision of the value of an endpoint already agreed for

[11] The document is available at: https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

[12] The TE decisions are available in R4BP 3 to all MSs, as well as all the documentation related to the cases assessed (e.g., request of additional information during the evaluation process) and the TE assessment reports. The TE assessment process does not include a validation of the dossier according to the information requirements of Annex II to the BPR, nor an assessment of that information (compliance check). Article 54 of the BPR and the guidance on TE do not require the submission of a complete AS dossier, although it is possible for ECHA to request additional data if deemed necessary.

[13] In case this happens in the context of the validation or evaluation of an NA application, the application shall be rejected in accordance with Article 29(3) or 30(2) of the BPR, as applicable. In case this happens in the context of the evaluation of an SA application, the application shall be rejected in accordance with Article 26(4) of the BPR. In case this happens in the context of the validation of a UA application, the application shall be rejected in accordance with Article 43(4) of the BPR.

[14] In case this happens in the context of the evaluation of a UA application, the failure to provide core data should result in the BP(s)/BPF not being authorised.

the AS, or the establishment of a value for a new endpoint which was not yet established in the LoEP.

- If the new information on the AS submitted in a BP/BPF authorisation application is identical to the information submitted in a successful Article 95 list inclusion application, it means that ECHA has already confirmed in that procedure that this information is in accordance with Article 95 of the BPR (i.e., it complies with the requirements of relevant Annexes of the BPR or the BPD) by including the applicant on the Article 95 list[15]. Therefore, for such new information on the AS submitted in a BP/BPF authorisation application, the MS in charge should only carry out the evaluation of the submitted data or justifications.

  In case a complete alternative AS dossier is submitted for product authorisation that is not identical to information submitted in any successful Article 95 application, the MS in charge needs to both validate and evaluate the information or justifications submitted.

The LoEP of the AS is a key reference since it contains a summary of the conclusions and parameters evaluated in the assessment and it is included as an annex to the assessment report agreed by the BPC following its peer-review by all MSs. As part of the assessment of the new information on the AS submitted in a BP/BPF authorisation application, it has to be considered whether the new information is reliable, acceptable, and whether it leads to the revision of a value for an endpoint already agreed for the AS (considering all the information already available for the AS for that endpoint), or to the establishment of a value for a new endpoint which was not yet established in the LoEP.

The MS in charge informs other MSs at regular CG meetings about relevant updates regarding the status of the assessment of new information on the AS submitted in a BP/BPF authorisation application. However, scientific/technical discussion on the new information on the AS, if any, will not take place at CG level.

Upon finalization of the assessment of the new information on the AS, the MS in charge should initiate the scientific/technical discussion of it at the relevant WG(s)[16], if:

- it has concerns regarding the reliability and/or the acceptability of the new AS data, and/or whether it modifies the conclusions of the hazard assessment of the AS, or
- it considers that the new data on the AS modifies the conclusions of the hazard assessment of the AS, or
- following the notification of the finalisation of the assessment to all MSs (including MSs where the same new information on the AS was not submitted), including recording it in the list with an indication whether discussion at the WG(s) is considered necessary, any MS disagreed with the assessment made by the MS in charge and recorded this in the list in accordance with the instructions in section 2.2.2 of this document.

If the rMS/eCA authorizes a BP/BPF authorisation application (NA or SA) in context of which the new information on an AS was submitted taking into consideration the assessment of the MS in charge, while discussions at the BPC or its relevant WG(s) are still ongoing[17] and afterwards the BPC concludes on the assessment of the new information on the AS with the modification of the LoEP in an adverse way that differs from the assessment taken into consideration by the rMS/eCA for the authorisation of the BP/BPF, the rMS/eCA has to review that authorisation and consider whether the authorisation needs to be amended or cancelled

[15] This assessment is not intended to establish (or modify) the LoEP for the AS, as an evaluation of the data is not carried out. Furthermore, the alternative dossier submitted for the inclusion on the Article 95 list is not compared with the dossier of the reference source and thus this process does not support the identification of discrepancies between the two dossiers.
[16] It is independent whether the new data on the AS was submitted within a UA, NA or SA application, as it is AS related and therefore in the remit of the BPC.
[17] This should be avoided, especially in case of an authorisation application subject to mutual recognition.

in accordance with Art. 48 of the BPR[18].

The additional study summaries should be included in the PAR of all BPs/BPFs for which the new data on the AS was submitted, even in case of those authorisation applications where the rMS/eCA of the BP/BPF authorisation application was not the same as the MS assessing the new information on the AS.

The procedural steps concerning the steps for scientific/technical discussion and modification of the LoEP (agreement on the revision of the value of an endpoint already agreed for the AS, or the establishment of a value for a new endpoint which was not yet established in the LoEP), are addressed in the revised BPC-15 document agreed at the BPC-47 meeting. Nevertheless, when new information on the AS is submitted in a product authorisation application, this CG document should be considered and applied together with the BPC-47 document.

However, it should be noted that if it is agreed that either the revision of the value of an endpoint already agreed for the AS[19], or the establishment of a value for a new endpoint which was not yet established in the LoEP, is necessary, the new LoEP resulting from the new information on the AS submitted in a BP/BPF authorisation application needs to be taken into consideration for the BP/BPF authorisation process (by all rMS/eCA of BP/BPF authorisation applications where the new information on the AS was submitted).

[18] If the LoEP of an AS is revised, but not in an adverse way, the authorisation holder of an already authorised BP/BPF containing that particular AS for which the new information on the AS had not been submitted could request the amendment of their authorisation in accordance with Art. 50 of the BPR, if appropriate.

[19] In case the value of an endpoint in question is such that can be affected by e.g., the non-active substances contained in the product (e.g., dermal absorption value), the LoEP does not need to be revised/modified for the AS, but should be used for the BP/BPF authorisation.