Procedure for the submission, evaluation and dissemination of data generated after active substance approval

Date: 5 June 2023	**Agreed at BPC – 47**

1 Background

Members were requested to establish a procedure from submission to dissemination of data received after the approval of an active substance.

Some cases of after-approval data were already discussed at BPC-8 ("Process and procedure of submission and evaluation of data generated after active substance approval"; document No. BPC-8-2014-03). The BPC agreed on the cases for additional data, their evaluation and reporting except on the handling of additional information from alternative dossiers during product authorisation, which was forwarded to the Coordination Group (CG).

Discussion on the management of new information on an active substance submitted at product authorisation stage was re-opened at CA level, followed by a proposal by the COM, agreed at the CA-94 meeting[1]. This approach required the revision of the BPC-15 document[2] and of the CG document[3].

This document is a revision of the document agreed at BPC-15 (document BPC-15-2016-09) and aims to lay down the procedure for the revision of the list of endpoints (LoEP) when required as a consequence of new data generated on an active substance. The intention is to focus on the procedural aspects[4], in particular related to the amendment of the LoEP and its dissemination. This amendment might lead to modifying the value of an existing endpoint or establishing the value of a new endpoint not yet included the LoEP. Depending on the nature of the amendment, it can also require updating the assessment. This document was presented and discussed at BPC-46. The current version has been updated with the comments received and is presented at BPC-47 for agreement.

The document CA-Dec21-Doc.4.2 indicates that in case the new data on an active substance submitted during product authorisation is considered by the reference Member State (rMS)/ evaluating competent authority (eCA) as reliable and would lead to modify the value of an endpoint or establish the value of a new endpoint not yet in the LoEP, ECHA will organise a discussion with the experts of Member States.

The revision of the former procedure includes the steps for handling these new data by the rMS/ eCA and the BPC.

[1] CA-Dec21-Doc.4.2 New active substance data submitted in applications for BP authorisation.
[2] Procedure for the submission, evaluation and dissemination of data generated after active substance approval.
[3] CG-17-2016-13 Evaluation of alternative dossiers during product authorisation.
[4] Data ownership and sharing are not within the scope of this document.

2 Cases for submission, evaluation and dissemination of data generated after active substance approval

The following cases where submission, evaluation and dissemination of data generated after active substance approval which could lead to a need to update the LoEP in the Assessment Report (AR) were identified. The detailed description and timelines for each case are provided in section 3a.

Case 1. New data is submitted due to an outcome of the approval process, where such additional data requirements are described in section 2.5 of the BPC Opinion. Following the submission of the data by the applicant and evaluation by the eCA, the new data are peer-reviewed by the BPC (if needed, in consultation with the BPC WGs). The revised LoEP, and revised AR, when applicable, will be adopted at the BPC meeting.

Case 2. New data is submitted and assessed during any of the possible product authorisation processes (NA, UA or SA[5] for a biocidal product or a biocidal family product, and their renewals), hereafter referred as product authorisation, unless the specific process is indicated. Normally, this will be data for an endpoint not covered by the assessment carried out for the active substance approval or to revise the value of an endpoint already agreed for the active substance (considering all the information already available for the active substance for that endpoint)[6].

When new information on a certain active substance is submitted in one or several applications for product authorisation, duplication of work should be avoided and a consistent and coordinated approach is needed by the involved MSCAs. BPC members are invited to liaise and align views with the CG members. The reference MSs[7] (rMSs)/evaluating CAs[8] (eCAs) for which a product application was submitted containing these new AS data will record these data in a list (hereby referred to as 'list of new data on active substances submitted at product authorisation'). This list is used to identify the MS responsible for assessment of the data, i.e. the MS in charge. It will be available via the Interact Portal and managed by the MSs. Member State must follow the same process when they act as eCA for applications for Union authorisation. The details of this procedure are established in the Coordination Group document[9].

Assessment of new information on an AS submitted in a product authorisation application and, if necessary, discussion at the WG/BPC level should take place in parallel to the evaluation of the 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 an 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, below the maximum time per step is provided that should shortened as the case may be. To maintain due process the authorisation deadlines

[5] National, Union and Simplified authorisations respectively.
[6] This can happen, for example when an applicant for product authorisation submits data relevant for a use not assessed during the active substance approval or to refine the assessment.
[7] In case of National authorisation applications.
[8] In case of Simplified and Union authorisation applications.
[9] The document is available at: https://webgate.ec.europa.eu/s-circabc/w/browse/a23c47a9-638c-427a-9b22-5b7733bf0b01.

need to be met.

Irrespective of the type of product application, upon assessment of the new data on the active substance, the MS in charge of assessing the new information on the active substance initiates the scientific/technical discussion of the new data on the active substance at the relevant WG(s), if:

- there is uncertainty regarding the reliability and/or the acceptability of the new active substance data, and/or whether it modifies the value of an endpoint already agreed, the conclusions of the hazard of the active substance, or
- it is considered that the new data on the active substance modifies the value of an endpoint already agreed, the conclusions of the hazard in the active substance, 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 other MS disagrees with the assessment conclusion reached by the MS in charge and recorded in the list, by a deadline indicated by the MS in charge of assessing the information.

If the WG considers the revision of some conclusions of the assessment of the active substance necessary, the data will be reviewed under an Article 75(1)(g) BPR procedure, upon request of the MS in charge of assessing the new information (within 30 days of the WG discussion). The BPC will be consulted and will adopt a BPC opinion including an amended AR and updated LoEP which shall be used by MSCAs for the evaluation of biocidal product applications.

The MS in charge of assessing the new data shall keep the list of new data on active substances submitted at product authorisation up-to-date (e.g., regarding the outcome of their assessment, the outcome of the WG(s) and the BPC).

Case 3. Additional or new data may be generated during the approval process of the active substance for another Product Type (PT) or at renewal stage. The evaluation and dissemination of the updated LoEP will follow the procedure including timelines of the active substance approval process for the new PT under evaluation. This case is not further detailed in this document.

Case 4. If an error is detected, the eCA will amend the AR including the revised LoEP and this case will follow the same process as described under case 1.

Note: For the four cases, and similar to the approval and authorisation processes, the applicant is to be involved by the MS in charge of the evaluation/eCA as required during their evaluation of the data. The applicant involvement in the potential BPC and WG meetings will be done as per the BPC Rules of Procedure[10]. Applicants are informed of changes via their R4BP 3 cases (where the updated documents are provided), and also via ECHA website where the list of endpoints and AR are published.

3 Reporting and dissemination

Additional data generated in the above mentioned cases is proposed to be reported and disseminated as follows:

[10] https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

Reporting

Case 1: the new data will be reported by the eCA using the relevant section(s) of the old study summary format (Doc III) or, preferably, reported via resubmission of an updated IUCLID file in R4BP 3. The LoEP will be updated and a clear reference added indicating that the additional data was not considered during the evaluation. The evaluation in the AR will need to be updated to reflect the changes performed in the LoEP.

Case 2: the new data will be reported in the Product Assessment Report (PAR) by the rMS/eCA of the product authorisation application for which the new information on the active substance was submitted. Furthermore, the updated LoEP and the updated AR[11] for the active substance, including the new data in an addendum, will be provided by the MS in charge of assessing the new information or the eCA for original active substance approval, if agreed. Changes in the LoEP should be flagged when the new information covers an endpoint which was not addressed at the approval stage.

Case 3: the data will be reported in the LoEP and AR for the evaluated PT. If the data has a significant impact on the LoEP compared to previously approved PT(s) a case by case decision is needed whether the change should be applied for other approved active substance/PT combinations.

Case 4: the eCA will amend the AR including the revised LoEP and this case will follow the same process as described under case 1.

Dissemination

In all cases the MSCA carrying out the evaluation of the new information, or the eCA for the original active substance approval if agreed, updates the LoEP and the corresponding sections of the AR and submits it to the SECR with a cover note informing on the changes via R4BP 3. This will allow dissemination in ECHA's website. The SECR will then table the revised AR as an information item for the BPC and make the confidential version available via S-CIRCABC.

a. Steps description

Case 1. Description of the steps for handling new data requested in Section 2.5 of the BPC opinion

	Handling data requested in Section 2.5 of the BPC opinion	**Responsible actor** Maximum time limit/step
1.	**Submission of data** The Applicant(s) submit(s) the additional data requested during the active substance approval process to the eCA. The submission of data is done in an electronic format, including the study summary using the old format (study summaries in Doc III) or preferable a IUCLID dossier via R4BP 3. A specific case type in R4BP 3 (AS-UPD) is designated for this purpose.	AS asset owner(s) No later than 6 months before approval (existing substances) No later than active substance approval (new active)

[11] The hazard part of the AR should be updated in line with the new information, but the risk assessment does not need to be amended.

2.	**Evaluation of new data and submission to SECR** The eCA evaluates the new data and submits to ECHA (applicant in copy) the results of the evaluation in the form of the updated AR containing the updated LoEP, together with the additional study summaries and a cover note introducing the amendments. Depending on the nature of the new data and its potential impact on the risk assessment the SECR will decide in consultation with the eCA whether a discussion at one or more Working Groups is necessary before the revision of the LoEP and proceeding to the BPC. A proposal on having further discussion or not will be included in the cover note to the BPC. The submission is done via R4BP 3 in the relevant AS-UPD case.	eCA Within 3 months of receipt of the data
3.	**Commenting and BPC** SECR tables the revised LoEP and the revised AR for the active substance for adoption at the BPC meeting and launches a commenting phase via Interact collaboration.	SECR, BPC member 28 days before the relevant BPC meeting
4.	**Dissemination of updated LoEP** The eCA revises the LoEP and the AR based on the comments made during the commenting phase and submits them to ECHA via R4BP 3, with applicant in copy. This allows the dissemination in ECHA's website. SECR makes the updated confidential documents available via S-CIRCA BC.	eCA and SECR Within 3 months

Case 2. Description of the steps for handling new data submitted by the applicant during product authorisation

Evaluation and dissemination of new data submitted by the applicant in applications for product authorisation[12]		**Responsible actor** Maximum time limit/step
1.	**Identification of new data for the AS** The rMS/eCA identifies new AS data in the product authorisation dossier submitted by the applicant [13]. The submission of data is done in a IUCLID dossier and as described in section 2.2.1 of the CG document.	rMS/eCA Within the first two weeks of the evaluation step (in line with the CG document)
2.	**List update** The MS in charge of assessing the new data is assigned and updates the "list of new data on active substances submitted at product authorisation".	rMS/eCA Without undue delay

[12] This procedure should be read together with the CG document.

[13] To allow sufficient time for the rMS/eCA to process this new data, these studies should only be provided at the time of submission of the application and not at a later stage during the validation or evaluation of the product.

	Evaluation and dissemination of new data submitted by the applicant in applications for product authorisation[12]	Responsible actor Maximum time limit/step
3.	**Evaluation of new data and review** The MS in charge will assesses the information and provides, via R4BP 3, its conclusion to ECHA whether the new information is reliable and leads a revision of the value of an endpoint already agreed for the AS or to the establishment of a value for a new endpoint not yet established in the LoEP. If the MS in charge of assessing the new information considers that a scientific/technical discussion of the new information on the AS is not necessary, it notes this in the list and any other MS should indicate its disagreement with concerns about the assessment, together with a justification. If a (scientific) discussion is necessary or a MS disagrees with the assessment of the MS in charge, (a) BPC WG meeting(s) will be organised to discuss the scientific/technical evaluation of the data. If a WG considers it necessary to revise some conclusions of the initial assessment made for the AS approval, the data will be reviewed under an Article 75(1)(g) BPR procedure, upon request of the MS. The timeline of the Article 75(1)(g) procedure take into account the scope of task, actors involved and sets a reasonable timeline for the BPR opinion. The MS in charge updates the list of new data on active substances submitted at product authorisation in regards of the outcome of their assessment and the outcome of that WG discussion.	MS in charge of assessing the new data Within 3 months of the evaluation step Any other MS As early as possible after the MS in charge of assessing the new data has finalised its evaluation of the new data, by the deadline set by the MS in charge. MS in charge in consultation with ECHA MS in charge of assessing the new data Timelines for the Article 75(1)(g) BPR request MS in charge of assessing the new data Without undue delay
4.	**Commenting and agreement by the BPC** The MS in charge of assessing the new data, or the eCA for the AS approval if agrees, prepares the results of the review in the form of an opinion, an amended AR and an updated LoEP, including the new data in an addendum to the AR; and submits them to ECHA via R4BP 3. ECHA SECR tables the revised LoEP for the BPC and launches a commenting phase via Interact Collaboration. The MS in charge updates the list of new data on active substances submitted at product authorisation in regards of the outcome of the BPC.	MS in charge of assessing the new data/eCA for the AS approval Depending on the amount and complexity of the new information BPC SECR 28 days before the BPC meeting MS in charge of assessing the new data Within 15 days of the BPC meeting
5.	**Submission to SECR** Following agreement by the BPC, the MS in charge of assessing the new data provides the final updated AR containing the LoEP to ECHA SECR via R4BP 3 (both confidential and non-confidential version of the AR should be provided). The additional study summaries will be distributed in the PAR of all products and product families for the authorisation of which the new data on the active substance was submitted.	MS in charge of assessing the new data/eCA for the approval Within 15 days of the BPC meeting All rMSs/eCAs for cases where the new data was submitted

Evaluation and dissemination of new data submitted by the applicant in applications for product authorisation[12]		Responsible actor Maximum time limit/step
6.	**Dissemination of updated LoEP** Upon submission, the final updated AR and updated LoEP, are made available via S-CIRCA BC (confidential version) and the dissemination webpage of the ECHA website (non-confidential version).	SECR Without undue delay

4 Applicability of updated LoEP

The most recent, published LoEP needs to be used by the MSCAs in the evaluation of the active substance at product authorisation.

In case the LoEP of an active substance is revised in an adverse way, the rMS[14]/eCA[15]/the COM[16] that authorised a product/product family containing that particular active substance has to review that authorisation and consider whether it needs to be amended or cancelled in accordance with Article 48 of the BPR.

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[14] In case of National authorisation applications.

[15] In case of Simplified authorisation applications.

[16] In case of Union authorisation applications.