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

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Finalised at BPC - 15

1 Introduction

Members requested to establish a procedure from submission to dissemination of data received following a decision taken on the approval of an active substance. At BPC-8 the process and procedure of submission and evaluation of additional data generated after active substance approval (see document No. BPC-8-2014-03) was proposed for discussion. 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). The CG has recently finalised the document (latest version discussed at the CG Document No. AP 13.1-CG-17-2016-13).

This document is the revision of the document prepared for BPC-15 (see document No. BPC-15-2016-09) and aims to lay down the procedure for the dissemination of the revised list of endpoints (LoEP) when required as a consequence of new data generated. The intention is not to revise the original document prepared for BPC-8, nor to incorporate the draft CG paper, but to focus on the procedural aspects, in particular related to the amendment of the LoEP and its dissemination. The handling of alternative dossiers is not in the scope of this document; only the procedural aspects related to dissemination are relevant.

2 Cases for dissemination of updated List of Endpoints

The following cases were identified where an updated LoEP in the Assessment Report (AR) needs to be made available:

1. As an outcome of the peer review process, where such additional data requirements are described in section 2.5 of the opinion. Following the evaluation of the data submitted the eCA will send it to the SECR. SECR will upload the evaluation to a post-approval folder of the active substance on CIRCA BC and will launch a commenting phase. If an endpoint changes significantly,, the eCA in consultation with SECR may decide to consult with the relevant BPC Working Group on a case by case basis. A proposal on the need for further consultation will be given when launching the commenting phase. Based on the nature of the comments, if required, a WG consultation may still be launched even if it was initially not foreseen.

2. New data is assessed during product authorisation. This can be when an applicant for product authorisation submits data, for example relevant for a use which was not assessed during the active substance approval or to refine the assessment. Normally, this will be data for an endpoint not covered by the assessment carried out for the active substance approval.

   In the case described in the document of the CG on alternative dossiers either the

LoEP of the active substance will not need to be amended or, if it is considered necessary to revise some conclusions of the assessment, the data will be reviewed under an Article 75(1)(g) procedure. In the latter case, the possible revision of the LoEP or even the assessment depends on the content of the request. In exceptional cases, when well justified significant concerns exist (i.e. there are either significant indications that the conditions supporting the approval of the active substance are not met any more or well justified reasons to believe that the use of the biocidal product(s) raises significant concern about the safety of such biocidal product(s)) the data will be reviewed under Article 15 and dissemination of data will follow a similar route as for the active substance approval process. The detailed procedure for the review of approval of an active substance under Article 15 is not in the scope of this document and will be prepared by COM.

Another possibility is when new information from other sources (e.g. assessment by other regulatory frameworks or bodies; scientific literature) is included in the evaluation by a MSCA (refCA or eCA in case of Union authorisation), provided the data is relevant for the reference source. In most cases, this case could also be initiated via an Article 75(1)(g) procedure.

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 normal procedure of the active substance approval process. This case is not further detailed in this document.

4. If an editorial mistake or calculation 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.

3 Reporting and dissemination

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

Reporting
Ad 1): the data will be reported using the relevant section(s) of the old study summary format (Doc III) or IUCLID. The LoEP will be updated and clear reference added indicating that the additional data was not considered during the evaluation. The evaluation in the Assessment Report will not need to be updated.

Ad 2): the data will be reported in the Product Assessment Report (PAR). In case the LoEP for the active substance is disseminated separately in the future, it will be updated by the rMS in case of national or the eCA in case of Union Authorisation.

Ad 3): the data will be reported in the Assessment Report (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.

In general, when the amendment of the LoEP has no consequence on the risk assessment, e.g. amended with confirmatory data, no formal mechanism is needed as these cases are part of a "normal" regulatory process under the BPR. However, in case the new information has an impact on a reference value the BPC may refer the issue to the relevant Working Group and advise whether the LoEP of an approved active substance PT combination needs to be amended.

Dissemination
In all cases the MSCA carrying out the evaluation updates the List of Endpoints (LoEP) in the Assessment Report and submits this to the SECR with a cover note informing on the changes. The SECR will then table the revised Assessment Report as an information item for the BPC and make it available via CIRCABC and the dissemination web-page of the ECHA web-site.

Table 1. *Description of the steps for dissemination of new data generated after active substance approval*

1. Dissemination of data requested during a.s. approval		**Responsible actor** (Approximate time limit)
1.	**Submission of data**. The Applicant(s) submits 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 a IUCLID dossier.[1]	Applicant(s) during active substance approval No later than 6 months before PA (existing substances) No later than active substance approval (new active)
2.	**Evaluation of new data and submission to SECR**. The eCA evaluates the new data and submits 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. Pending 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. The submission is done via CIRCABC in the following folder: - Path: /CircaBC/echa/BPC-WG/Library/Confidential/05. Submissions - https://webgate.ec.europa.eu/echa-scircabc/w/browse/a080e867-292f-4cf4-9383-2a6282f2dcec	eCA
3.	**Commenting and BPC**: SECR will table the revised LoEP as an information item for the BPC and will launch a commenting phase via CIRCA BC Newsgroups.	SECR, all MSCA (28 days before the BPC meeting) BPC and BPC WG
4.	**Dissemination of updated LoEP**. eCA will revise the LoEP based on the comments made during the commenting phase. SECR will make the updated documents available via CIRCA BC and the dissemination web-page of the ECHA web-site.	eCA and SECR

[1] via R4BP in the future, when the function will be available

2. Dissemination of data submitted by the applicant for product authorisation		Responsible actor (Approximate time limit)
1.	**Submission of data**. The data are submitted by the applicant for product authorisation to the reference Member State (rMS) under national authorisation or the eCA under Union authorisation. The submission of data is done in a IUCLID dossier.	Applicant
2.	**Evaluation of new data and review**. Peer review will take place for Union authorisation and consultation will take place for national authorisation during the mutual recognition process. As the timelines for the process for mutual recognition are short, in case the reference MS considers it necessary, peer review is organised via the CG contacts by e-consultation as early as possible after the rMS has finalised its evaluation of the new data.	rMS/eCA cMS/BPC and BPC WG
3.	**Submission to SECR.** Following product authorisation the rMS/eCA submits the updated LoEP and a cover note introducing the amendments. The additional study summaries will be distributed in the PAR. The submission is done via CIRCABC in the following folder: - Path: /CircaBC/echa/BPC-WG/Library/Confidential/05. Submissions - https://webgate.ec.europa.eu/echa-scircabc/w/browse/a080e867-292f-4cf4-9383-2a6282f2dcec	rMS/eCA
4.	**Dissemination of updated LoEP**. SECR will table the updated LoEP as an information item for the BPC and make it available via CIRCA BC and the dissemination web-page of the ECHA web-site. Depending on the nature of the data submitted for national product authorisation the BPC and/or a relevant BPC Working Group may be consulted prior to the revision.	SECR

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 (see "Consideration of cut-off dates for the implementation of paragraph 8(a) of Annex VI of the BPR"; CA-March16-Doc.4.15).

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