Working procedure for major change application of a Union authorisation

Version 2.2

The purpose of this document is to establish principles to be applied by participants in the work of the Biocidal Products Committee (BPC) to develop opinions on applications for major change of a Union authorisation. Participants include BPC members, alternates, rapporteurs, the secretariat, applicants and accredited stakeholder organisations.

This working procedure will be reviewed in the light of experience.

Document history

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Version	**Changes**	**Date (of agreement)**	**Date of applicability**
1.0	First version	18 October 2018 at BPC-27	NA
1.1	Version updated based on BPC discussions	18 May 2021	20 May 2021
2.0	Version reviewed to simplify the process and, where relevant, to align with the Working procedure for Union authorisation application	7 June 2023 (BPC- 47)	14 August 2023
2.1	Changes in the document: • Change of the SPC format from xml to i6z • Inclusion of the date of applicability in the version history document • Information on the way forward concerning embedded files in disseminated redacted PARs • The 90-day timeline for opinion forming is clarified	NA Subpoints 3 and 4 presented during the BPC-50 in February 2024	22 March 2024
2.2	Changes in the document: • Further clarification on the SPC format used through the procedure	27 May 2024 at BPC-51	26 June 2024

1. Purpose

This document establishes the working procedures of the BPC for the opinion forming process of applications for major change of a Union authorisation. According to Regulation (EU) 354/2013 the opinion on the major change of a biocidal product has to be submitted by ECHA to the Commission (COM) within 90 days of the receipt of the conclusions of the evaluating Competent Authority (eCA[1]) (Article 13(7)).

2. Scope

This document details the steps to be taken during the process of a major change of a Union authorisation of biocidal products under the Regulation (EU) 354/2013. The steps covered are those starting from the eCA submitting the draft Product Assessment Report (PAR), the confidential annex to the draft PAR, the confidential annex for MSCA only (if applicable), the draft Summary of Product Characteristics (SPC)[2] and the draft BPC opinion until the dissemination of the relevant information on the ECHA website. The steps are described for all the actors in the process including evaluating Competent authority (eCA), ECHA secretariat (SECR), applicant and BPC members.

3. Description

The individual steps and indicative timelines for the process are described in Table 1[3]. The actions and responsibilities of the applicant are included separately in Table 1 below each relevant step. The actual dates for each step are given in the separate document ***Timelines for the opinion forming of Union authorisation major changes***[4].

3.1 Submitting draft PAR, confidential annex to draft PAR, confidential annex for MSCA only (if applicable), draft SPC and draft BPC opinion

The PAR contains the assessment report and the conclusions. The eCA should submit the draft PAR, the confidential annex to the draft PAR, the confidential annex for MSCA only (if applicable), the draft SPC in i6z format and the draft BPC opinion *via* ad hoc communication in R4BP 3. The PAR and its confidential annex should be in the format available on the ECHA website[5]. The eCA should clearly identify all the changes introduced to the draft PAR and its confidential annex, for example by highlighting them in yellow.

The 90-day timeline for opinion forming begins on the day when the commenting is initiated and the evaluation task in R4BP 3 is closed[6].

The eCA is responsible for assessing the confidentiality requests made by the applicant on the application dossier for major change and the draft PAR and deciding whether to accept them or not. The eCA should perform this assessment and implement its consequences in the IUCLID dossier and in the draft PAR and the confidential annex to the draft PAR during the evaluation phase.

The eCA should also check and ensure whether the names of authors of unpublished studies

[1] eCA in the working procedure refers to the rapporteur or other representative of the eCA.

[2] By referring to the draft Product Assessment Report (PAR), the confidential annex to the draft PAR, the draft Summary of Product Characteristics (SPC) – it should be read as the revised draft documents.

[3] The durations given in the Table 1 correspond to calendar days.

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

[5] https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities

[6] Timelines for the opinion forming of Union authorisation major changes applications.

are blanked (not limited to vertebrates) in the final redacted PAR[7] independently on whether this information was claimed as confidential by the applicant. This is based on the relevant provisions of the legislation concerning the protection of personal data (i.e., Article 66(2)(d) BPR, Article 6(1) of the General Data Protection Regulation (EU) 2016/679 and Article 5(1) of regulation (EU) 2018/1725). See also Annex 2 of the Guidelines for assessment the confidentiality of the information contained in the Competent Assessment report (CAR) and Product Assessment Report (PAR)[8].

3.2 Additional notes

The eCAs can request support/clarification from the applicant throughout the process[9].

The eCAs are encouraged to inform the applicants proactively about any developments, especially where it might adversely impact their authorisation. This is to ensure that the applicants are able to properly prepare for the BPC discussion.

During the CG-59 meeting, the CG agreed on the way forward concerning embedded files in disseminated redacted PARs to ensure that all information in the redacted PARs is accessible (CG-59-2023-01_AP_14.1_Way_forward_regarding_disseminated_redacted_PARs_final.pdf). The same approach should be followed for the UAs and applications for major change of a Union authorisation[10].

3.3 Communications

All formal communications will take place through R4BP 3.

The contact point between the eCA and SECR is the dossier manager (DM) appointed by SECR for each application. Depending on the topic of the e-mail communication, the following addresses should be used:

- for organisational issues of the BPC meetings: bpc@echa.europa.eu;
- for issues related to applications for major change of Union authorisation and the related process and procedures: biocides-union-authorisation@echa.europa.eu.

[7] See step 44 of the Working procedure for the Union authorisation.
[8] Guidelines for assessing the confidentiality of the information contained in the Competent Assessment Report (CAR) and Product Assessment Report (PAR).
9 This does not refer to the request of the new data.
10 Working Procedure for Union Authorisation applications: Biocidal Products Committee - ECHA (europa.eu)

Figure 1. *Flowchart of the opinion forming process for major change of Union authorisation applications.*

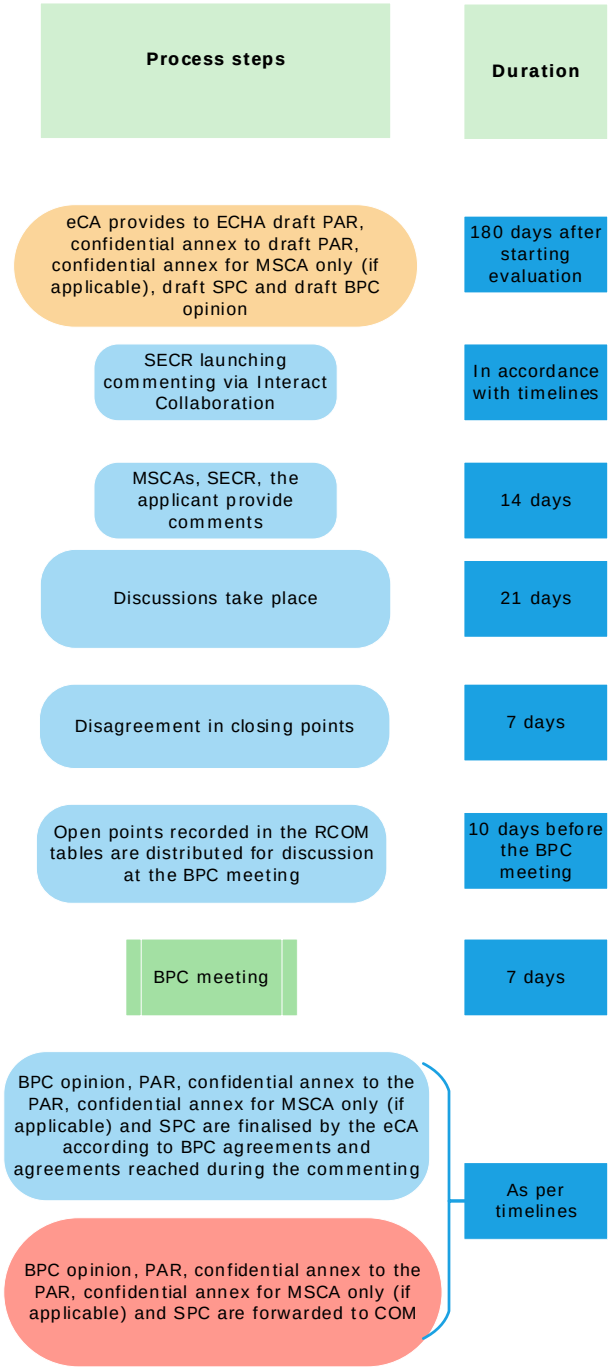

Table 1. *Description of the steps in the opinion forming process of applications for major change of a Union authorisation.*

1. Submission of the conclusions of the evaluation		**Responsible actor** (Indicative time limit)
1.	**Submission**. The eCA submits via ad-hoc communication in R4BP3 the following documents: - the results of evaluation in the form of the draft PAR, the confidential annex to the draft PAR, the confidential annex for MSCA only (if applicable) in word format. The eCA should clearly identify all the changes introduced to the draft PAR, for example by highlighting them in yellow; - the draft SPC in i6z format; - the draft BPC opinion; - a document used for 30 days commenting period (30dRCOM)[11] during the evaluation step that includes comments from the applicant and the eCA reply to the applicant's comments[12]. The access level of the documents in R4BP 3 should be "Restricted"[13]. The only exception would be the confidential annex for MSCA only, for which the access level in R4BP 3 should be "Restricted - Authority". The annotated IUCLID dossier is available in the IUCLID for BPR database. The eCA must not close the evaluation task in R4BP 3, as this should be done only when the commenting phase is initiated (see step 2).	eCA (180 days after starting evaluation)

2. Commenting phase	**Responsible actor** (Indicative time limit)

[11] A harmonised template is proposed to be used during the 30 days commenting period and is available here: Formats and templates - ECHA (europa.eu)
[12] Regulation (EU) 354/2013 Article 13(5).
[13] For more details on the classification of documents in R4BP 3, please consult the latest version of the Biocides manual for authority users "How to run BPR processes with R4BP 3 in Member State competent authorities" available in S-CIRCABC at
Path: /CircaBC/echa/MSCA_IT_support/Library/User Manuals/User Manuals for End-Users/R4BP
Browse url: https://webgate.ec.europa.eu/s-circabc/w/browse/21143482-68ca-4a30-8b06-4bb8b33547f1

2.	**Distribution of the relevant documents.** SECR distributes the draft PAR, the confidential annex to the draft PAR, the confidential annex for MSCA only (if applicable), the draft SPC, 30dRCOM[14], the draft BPC opinion and a template for commenting to MSCAs (RCOM) *via* the Interact Collaboration Tool. This marks the start of the commenting phase (see step below). SECR sends to the BPC members and WG members an e-mail notification to inform of the start of the commenting phase.	SECR (in accordance with the timelines[15])
	Applicant: The applicant receives the draft PAR, the confidential annex to the draft PAR, the draft SPC, 30dRCOM and the draft BPC opinion and the template for commenting from the eCA *via* ad hoc communication in R4BP 3.	eCA (Without undue delay)
3.	**Closure of the evaluation task in R4BP 3**. On the first day of the commenting, the eCA without delay closes the evaluation task in R4BP 3 by choosing from the drop-down list "submit evaluation". The case is promoted and the "ECHA opinion" task is created.	eCA (without delay)
4.	**Commenting phase**. MSCAs and SECR should comment only on the sections of the draft PAR, the confidential annex to the draft PAR, the confidential annex for MSCA only (if applicable) and the draft SPC, which are affected by the change. MSCAs and SECR comment also on the draft BPC opinion. MSCAs and SECR include their comments directly to the appropriate comments table (RCOM) made available by SECR via the Interact Collaboration tool and indicated by the SECR in the launching message. The commenting MSCAs can express their agreement with the already provided comment by indicating their MSs name in the RCOM (i.e., column "Supporting MSCA"). If the comment cannot be shared with the applicant due to confidentiality reasons, the commenting MSCA is responsible for clearly noting in red in the RCOM that this comment is for "MSCA only".	MSCAs, SECR, eCA (14 days)
	Applicant: The applicant may provide comments on the sections affected by the change using the template for commenting. The applicant sends the comments to the eCA *via* ad hoc communication in R4BP 3. The eCA uploads these comments into the RCOMs available in Interact collaboration.	Applicant (14 days)
5.	**Discussions and finalisation of the response to the provided comments in the RCOM tables.**	eCA, MSCA, SECR, applicant

[14] During the commenting period MSs can use the 30dRCOM to identify whether the applicants comments have been sufficiently addressed, and whether any comments/issues should be further discussed during the opinion forming. If so, a MS has to include this (amended) comment in the case's relevant comments tables (RCOMs).
[15] Timelines for the opinion-forming of Union authorisation applications major changes applications available in Biocidal Products Committee - ECHA (europa.eu)

	Discussions As soon as MSCAs, applicant and SECR provide their comments, the eCA provides responses to the comments directly to MSCAs /applicant/SECR and continues discussing with the aim of reaching an agreement with the commenting body. In the first step, the eCA provides response on the comments. In order to allow a proper discussion, the eCA should provide the response to the comments approximately within the first 7 days of this step. Discussions with the MSCAs/SECR should take place directly in the RCOM tables available via Interact Collaboration. Discussions with the applicant should take place via R4BP 3. The eCA is responsible to include the comments received from the applicant in the relevant RCOM tables available in Interact Collaboration. An agreement to close point should be reached by the eCA with the commenting and supporting MSCA(s) and, where relevant, the SECR. In case of a lack of reply from the commenting/supporting MSCA(s) and, where relevant, the SECR, the eCA will make a proposal whether the point is closed. For each open point, the eCA together with the commenting MS, the SECR need to formulate a proposal for a question to be discussed at the BPC and include it in the RCOM. **The points related to classification[16] should not be closed by the MSs during this step, but kept open for the discussion at the BPC.** **Preparation of the consolidated RCOM** The eCA consolidates the RCOM (consolidated RCOM) by ensuring that the following is included: - all comments received, - all eCA responses, - the result of the discussions, e.g., the compromise wording that was agreed with the commenting body or an explanation why no such agreement could be reached, and - a clear indication marking each point as open or closed, - for each open point identification of the remaining open question for discussion at the BPC. The day following the end of this step, SECR downloads the RCOM tables. SECR locks those columns in the RCOM tables which were used for the commenting and discussions, uploads the consolidated RCOM tables back to the Interact Collaboration and informs the MSCAs by email on the start of the step - disagreement in closing a point (see step 5).	(21 days)

[16] The Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008).

	Note: Any RCOM tables shared with the applicant should not contain information of confidential nature, including, for example, explicit reference to Union authorisation applications previously discussed[17] or data on the representative product for active substance approval.	
	Applicant: After the commenting the applicant receives the RCOM tables from the eCA via R4BP 3 and discusses bilaterally with the eCA on the responses.	eCA, applicant
6.	**Disagreement in closing a point**. When the email is received from SECR (see step 5) the other MSCAs can request re-opening a closed point for discussion at the BPC directly noting the disagreement in the consolidated RCOM tables available in Interact Collaboration tool. It is important to note that the timeline for this must be strict because of the preparation for BPC meeting. If disagreement to closing a point is not communicated within the time limit, this will be considered as tacit agreement to close it. If during this step the eCA finds an agreement with the commenting body and point is proposed to be closed, this point still should be marked by the eCA as provisionally closed. **Note:** Any consolidated RCOM tables shared with the applicant should not contain information of confidential nature, including, for example, explicit reference to Union authorisation applications previously discussed[18] or data on the representative product for active substance approval.	eCA, MSCA, SECR, applicants (7 days)
	Applicant: The eCA send the consolidated RCOM tables after the discussion step (step 4) to the applicant for their information.	eCA, (without undue delay)

3. Biocidal Products Committee and preparations		**Responsible actor** (Indicative time limit)
6.	**Distribution of the documents for BPC.** The RCOM tables used for commenting/discussion and disagreement in closing points are used as the open issue documents for discussion at the BPC meeting. The SECR distributes the RCOM tables, the draft PAR, the confidential annex to the draft PAR, the confidential annex for MSCA only (if applicable), the draft SPC, the draft BPC opinion via the Interact meetings.	SECR (10 days before the BPC meeting)

[17] The RCOM tables may contain information on other UA applications where this information is already published, such as the publicly available BPC opinion.
[18] The RCOM tables may contain information on other UA applications where this information is already published, such as the publicly available BPC opinion.

	Applicant: SECR provides the RCOM tables, the draft PAR, the confidential annex to the draft PAR, the draft SPC, the draft BPC opinion to the applicant *via* ad hoc communication in R4BP 3.	
7.	**Other documents**. Any documents intended for discussion at the BPC meeting have to be provided no later than 10 days before the meeting. SECR makes these documents available to MSCAs via Interact meetings and to the applicant *via* ad hoc communication in R4BP 3.	eCA; MSCAs; SECR (10 days before the BPC meeting)
8.	**BPC meeting**. BPC adopts the opinion, unless written procedure is requested (see RoPs). Minority positions have to be submitted to SECR by the involved member within 7 days after the BPC meeting. Subject to the agreement of the applicant, the representatives of ASOs may be present.	n.a.
	Applicant: The applicant may participate in the discussion at the BPC meeting.	

4. Finalisation and dissemination steps	**Responsible actor** (Indicative time limit)
The steps of finalisation and dissemination, as well as the responsible actors and indicative time limits, are the same as in the "Working procedure for Union authorisation applications" and therefore are not repeated in this document. The reader is kindly invited to consult directly the "Working procedure for Union authorisation applications".	

4. Definitions and acronyms

Abbreviation	Definition
ASO	Accredited Stakeholder Organisations
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
COM	European Commission
DM	(ECHA) Dossier Manager
eCA	Evaluating Competent Authority
ECHA	European Chemicals Agency
MSCA	Member State Competent Authority
n.a.	Not applicable
PAR	Product Assessment Report
R4BP 3	Register for Biocidal Products

RCOM	Response to Comments table
SECR	ECHA Secretariat
SPC	Summary of Product Characteristics
WG	Working Group

5. References

1. Rules of procedure for the Biocidal Products Committee: LINK
2. Code of conduct for applicants participating in the Biocidal Products Committee and its Working Groups: LINK

6. Links

1. Templates for PAR and confidential annex

   https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities

2. Website of the Biocidal Products Committee

   http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

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