Working procedure for minor change application of a Union authorisation

Version 1.2

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 a minor change to a Union authorisation. Participants include BPC members, Member State Competent Authorities (MSCAs), the European Chemicals Agency (ECHA) secretariat and applicants.

Document history

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Version	**Changes**	**Date**	**Date of applicability[1]**
1.0	First version	7 June 2023 at BPC-47	14 August 2023
1.1	Major changes in the document: • Addition of criteria for the request of data under step 5. • Clarifications on the applicant's role during commenting included. • Clarifications included when the discussion and agreement step is not carried out. • Clarifications on the vote by written agreement included to opinion forming. • Durations of steps 7 and 10 modified. • Transition from SPC Editor to dedicated configuration of SPC in IUCLID. • Update of flowchart.	22 November 2023 at BPC-49	5 December 2023
1.2	Minor clarifications in the document • Clarifications regarding deadlines • Information on the way forward concerning embedded files in disseminated redacted PARs • Editorial changes	26 February 2024 at BPC-50	22 March 2024

[1] This is the date when the document is published on the ECHA website

1. Purpose

This document establishes the working procedure of the BPC for the steps subsequent to the validation of applications for a minor change to a Union authorisation. According to Regulation (EU) 354/2013 ("Change Regulation"), the opinion on the minor change to a Union authorisation has to be submitted by ECHA to the Commission (COM) within 90 days after the validation of the application (Article 12(4)).

2. Scope

This document details the steps to be taken during the process of a minor change to a Union authorisation under the Change Regulation. The steps covered are those starting from the validation of the application by ECHA until the dissemination of the relevant information on the ECHA website. The steps are described for all the actors in the process including ECHA secretariat (SECR), applicant, MSCAs and BPC members.

3. Description

The individual steps and indicative timelines for the process are described in Table 1. The durations given in the table correspond to calendar days. These durations are indicative and the exact deadline to the applicant and MSCAs will be communicated with each request and should be followed. Should a time limit in accordance with Table 1 fall on a weekend, the deadline for the step will either be adjusted to the next Monday or preceding Friday. Similarly, should a time limit fall during the ECHA end-of-year closure (end of December – beginning of January), the deadline for the step will be be adjusted to ECHA's first working day of the year.

The actions and responsibilities of the applicant are included separately in Table 1 below each relevant step.

3.1 Communications

All formal communications will take place through R4BP 3.

3.2 Additional notes

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 applications for minor change of a Union authorisation.

Figure 1. *Flowchart of the evaluation phase of applications for a minor change to Union authorisation.*

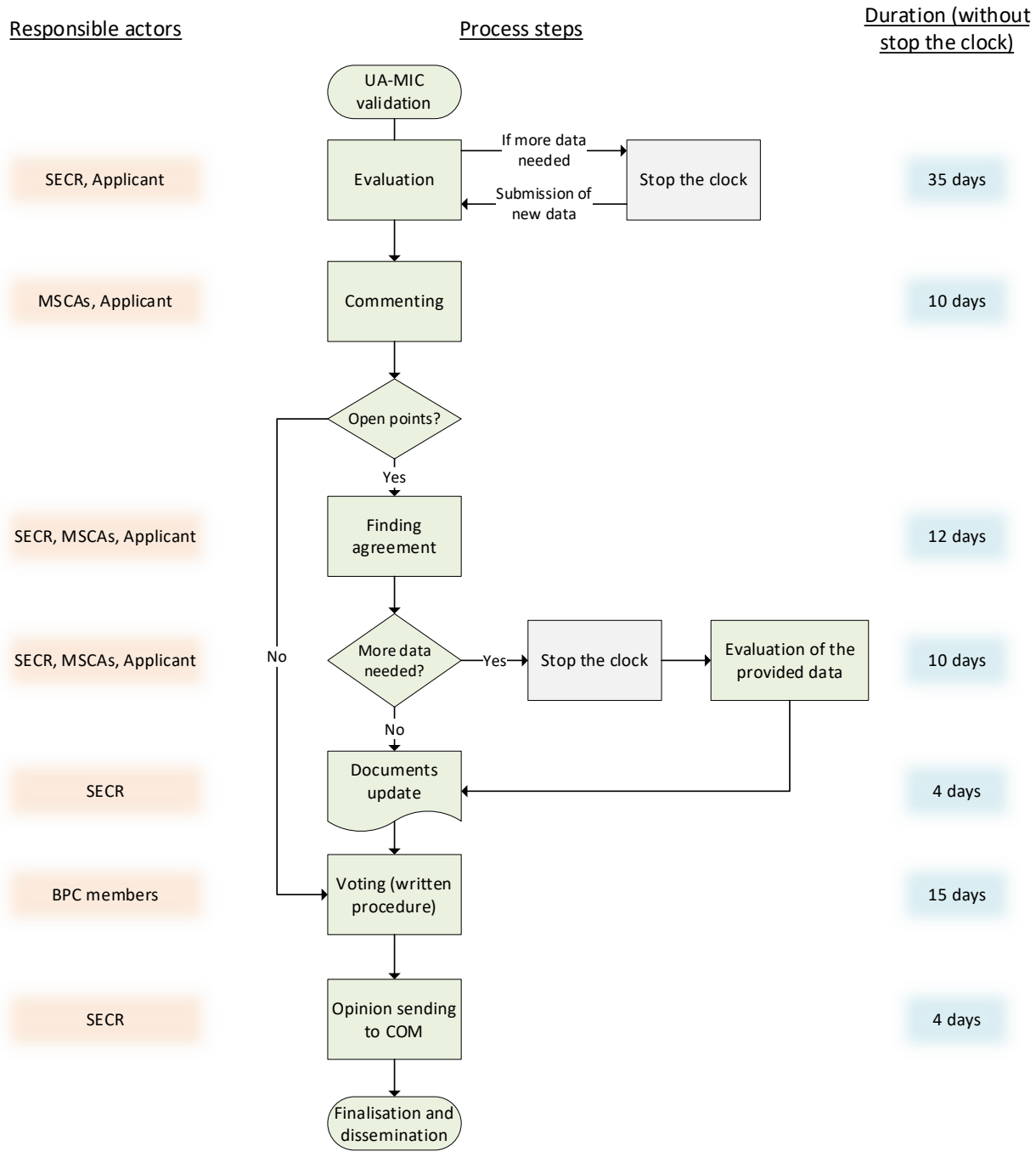

Table 1. *Description of the steps subsequent to the validation of applications for a minor change to Union authorisation. The durations are given in calendar days.*

1. Evaluation of the minor change		**Responsible actor** (Indicative time limit)
1.	**Evaluation**. The SECR evaluates the minor change and prepares the following documents for the commenting phase: - the results of the evaluation in the form of the draft revised Product Assessment Report (PAR) and its confidential annex and, where applicable, a confidential annex for MSCA only[2]. The SECR should clearly identify all changes introduced to the PAR (e.g. by highlighting them in yellow); - the draft revised Summary of Product Characteristics (SPC) in .i6z format prepared using the dedicated configuration of SPC in IUCLID; - the draft BPC opinion; **Request for additional information (optional).** In case additional information is necessary for the evaluation, the SECR requests the applicant to provide the additional information within a reasonable deadline. The deadline cannot exceed 45 days unless justified. The 90-day period referred to in Article 12(4) of the Change Regulation is suspended from the date of the issue of the request until the date the information is received ("stop the clock").	SECR (35 days)
	Applicant: The applicant must provide the requested additional information within the given deadline. Additional data can only be provided at the request of the SECR in case it is required for the evaluation. No additional time will be given to the applicant in case of failure to meet the given deadline, unless justified by the nature of the data requested or by exceptional circumstances. A justification for exceeding the given deadline should be provided by the applicant ahead of the deadline.	Applicant (Within the given deadline)

2. Commenting phase		**Responsible actor** (Indicative time limit)
2.	**Distribution of the relevant documents.** SECR distributes the draft PAR and its confidential annex, the confidential annex for MSCA only (if applicable), the draft SPC, the draft BPC opinion and a Response to Comments table (RCOM) template for commenting to MSCAs *via* the Interact Collaboration Tool. This marks the start of the commenting phase (see step below). SECR sends to the BPC members and Working Group (WG) members an e-mail notification to inform of the start of the commenting phase.	SECR (Without undue delay)

[2] Hereafter, by referring to the draft PAR including its confidential annex(es) and to the draft SPC – it should be read as the revised draft documents.

	Applicant: The applicant receives the draft PAR and its confidential annex, the draft SPC, the draft BPC opinion and a template for commenting from the SECR *via* ad hoc communication in R4BP 3.	SECR (Without undue delay)
3.	**Commenting**. MSCAs should comment only on the sections of the draft PAR and its confidential annex, the confidential annex for MSCA only (if applicable) and the draft SPC, which are affected by the change. MSCAs should also comment on the draft BPC opinion. MSCAs include their comments directly to the appropriate RCOM table made available by SECR via the Interact Collaboration tool and indicated by the SECR in the launching message. 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". Should there be no open points at the end of the "Commenting" step, the "Discussion and finding agreement" step will be skipped and the application will proceed directly into opinion forming (step 7 - Preparation of the updated documents).	MSCAs (10 days)
	Applicant: The applicant may provide comments using the template for commenting and send it to the SECR via ad hoc communication in R4BP 3 within the given deadline. The SECR will include these comments into the RCOM available in Interact Collaboration.	Applicant, SECR (10 days)
4.	**Discussions and finding agreement.** As soon as MSCAs provide their comments, the SECR provides responses to the comments and continues discussing with the aim of reaching an agreement with the commenting body. Every effort shall be made by all concerned parties to come to an agreement. Discussions with the MSCAs should take place in the RCOM table available via Interact Collaboration. An agreement to close a point should be reached by the SECR with the commenting and any supporting MSCA(s). In case of a lack of reply from the commenting/supporting MSCA(s), the SECR will consider the point closed. For each point indicated as open by the MSCA, the SECR together with the commenting MSCA and any supporting MSCA(s), will discuss on the best way forward e.g. requesting additional data from the applicant or organising an ad hoc teleconference. **Preparation of the consolidated RCOM.** The SECR consolidates the RCOM (consolidated RCOM) by ensuring that the following is included: - all comments received, - all SECR 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	SECR, MSCAs (12 days)

	- a clear indication marking each point as open or closed. - for each open point, identification of the remaining issue and the agreed follow-up action. **Note:** Any consolidated RCOM table shared with the applicant should not contain information of confidential nature, e.g. explicit reference to Union authorisation applications previously discussed[3] or data on the representative product for active substance approval.	
	Applicant: After step 3 (commenting) has ended, the applicant receives the RCOM table including the MSCA's comments (except for the comments marked as "MSCA only") from the SECR via R4BP 3. SECR will discuss bilaterally with the applicant on the applicant's comments. The applicant may also provide replies to MSCA's comments however, the applicant cannot re-open issues raised by MSCA's that have been closed. The SECR sends via R4BP 3 the consolidated RCOM table to the applicant after the finalisation of step 4 for their information.	SECR, applicant (12 days)

3. Request for additional data (optional)		**Responsible actor** (Indicative time limit)
This phase is optional and is triggered by a need for additional data identified following the commenting phase. Otherwise, the process jumps to phase 4 (Opinion making).		
5.	**Request for additional data.** If a need for additional data for the purpose of the evaluation was identified following commenting, the applicant is requested to provide this data to the SECR within a reasonable deadline. The deadline cannot exceed 45 days unless justified. In case a request for additional information has already been made during step 1 (evaluation), the deadline for the new request cannot exceed 45 days when combined with the already allocated days during step 1, unless justified by the nature of the data requested or by exceptional circumstances. The data request indicated above can only concern information that: • Has not been formally requested previously by ECHA to be provided by the applicant during the validation or evaluation phase; • Has the potential to change the outcome of ECHA's evaluation from a recommendation to not approve the change(s) to a recommendation to approve the changes, Additional data can only be provided at the request of the SECR in case it is required for the evaluation. The 90-day period referred to in Article 12(4) of the Change Regulation is suspended from the date of the issue of the request until the date the information is received ("stop the clock")	SECR (Max. 45 days)

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

	Applicant: The applicant must provide the requested information within the given deadline. No additional time will be given to the applicant in case of failure to meet the given deadline, unless justified by the nature of the data requested or by exceptional circumstances. A justification for exceeding the given deadline should be provided by the applicant ahead of the deadline.	Applicant (Within the given deadline)
6.	**Evaluation of the provided data.** The SECR evaluates the new data provided by the applicant and provides its conclusions to the MSCAs. The SECR initiates dialogue with the MSCA that proposed the request during commenting and any supporting MSCA(s). The aim of the dialogue is to find an agreement on the remaining open issue(s) from commenting.	SECR, MSCAs (10 days)

4. Opinion forming		**Responsible actor** (Indicative time limit)
7.	**Preparation of the updated documents (optional).** If needed, the SECR updates the PAR and its confidential annex, the confidential annex for MSCA only (if applicable), the SPC and the BPC opinion.	SECR (Max. 4 days)
8.	**Launch of the voting.** The SECR launches the voting (written procedure) via Interact Collaboration and informs the BPC members and COM. The updated PAR and its confidential annex, the updated confidential annex for MSCA only (if applicable), the updated SPC and the updated BPC opinion are made available to MSCAs via Interact Collaboration. The SECR provides the updated PAR and its confidential annex and the SPC to the applicant via ad hoc communication in R4BP 3 for information.	SECR (Without undue delay)
9.	**Adoption of the opinion.** As per the rules of procedure[4] of the BPC: • At least 60 % of the members having the right to vote have to respond for the written procedure to be considered valid. • Minority positions have to be submitted to the SECR by the involved member within 7 days of the completion of the written procedure • Under exceptional circumstances, such as when majority is not achieved, the BPC Chair may decide to terminate the written procedure and postpone the agreement of the decision to the next BPC meeting.	BPC members (15 days)
10.	**Transmission of the BPC opinion to COM.** The SECR closes the "ECHA evaluation" task in R4BP 3 by uploading the BPC opinion and its annex (i.e. the draft SPC), the final PAR and its confidential annex, the confidential annex for MSCA only (if applicable) and informs COM by email.	SECR (Without undue delay but no later than 4 days after the end of the vote)

[4] Rules of procedure for the Biocidal Products Committee

5. Finalisation and dissemination steps		Responsible actor (Indicative time limit)
11.	**Combined request: i) SPC translations ii) confidentiality requests for the PAR.** The SECR sends a combined request to the applicant via an ad hoc communication R4BP 3 for: **i) The SPC translations.** The SECR requests the draft SPC translations from the applicant and informs the applicant whether a linguistic review or a linguistic check is required. The SECR assesses whether a linguistic review of the SPC translations performed by MSCAs is required. It is considered required, if the minor change results in the addition/modification of text to the SPC, which: - is required to be translated; - is not automatically translated in the dedicated configuration of SPC in IUCLID; Else, a linguistic check will be performed by the SECR (see step 12). **ii) Confidentiality requests by the applicant on the sections of the PAR affected by the minor change.** The SECR asks the applicant to provide the confidentiality requests on the sections of the PAR affected by the minor change.	SECR (Without undue delay)
	Applicant: By replying to the ad hoc communication in R4BP 3, the applicant provides within the given deadline: • The SPC translations and, if a linguistic review is required, the completed LRUA-F1 form (Section 1) • The confidentiality requests on the updated sections of the PAR.	Applicant (Within 7 days)

12.	**Option A: linguistic review conducted by the MSCAs.** Without undue delay, the SECR distributes the draft translations to MSCAs for linguistic review together with the LRUA-F1 form via ad hoc communication in R4BP 3[5]. **Translation quality check:** MSCAs perform the detailed linguistic review of the translations of the information affected by the minor change and assess whether the remaining information is identical to the previous relevant SPC. *If translations are considered unacceptable or of poor quality:* Each translation considered unacceptable will be returned **to the applicant** by the concerned MSCA at the latest 5 days after receiving the translation. The translation and the LRUA-F1 form with an appropriate explanation in section 2 of the document are sent to the applicant via ad hoc communication in R4BP 3 by selecting the click box "reply required". The MSCA should set the deadline for the applicant, and ECHA should be in cc of the message as this may result in delaying the finalisation of the translation check. *If translations are considered acceptable:* In case a translation is provided by the applicant where the MSCA has no comments, the MSCA will send the completed, definitive LRUA-F1 form (Section 2) to ECHA via ad hoc communication in R4BP 3. **Resubmission of SPC translations (when applicable):** The applicant will reply by submitting the amended translation within 7 days to the MSCA who has initiated the ad hoc communication in R4BP 3. **Detailed review of translation:** MSCAs review the translations and correct the SPC file using the dedicated configuration of SPC in IUCLID. MSCA should make sure that the the correct market area (European Union) has been indicated and that all fields have been filled in correctly. Within 20 days after receiving the draft SPC translations from the SECR, the MSCA will send the final SPC file and the completed, definitive LRUA-F1 form to the applicant and ECHA via ad hoc communication in R4BP 3. **Transmission of the revised translations:** Without undue delay, the SECR transmits the final translations to the COM via ad hoc communication in R4BP 3 and uploads the completed form LRUA-F2 in R4BP 3.[6] If an MSCA does not provide a revised translation or written confirmation that the translation as provided by the applicant is correct, ECHA informs the COM and transmits the translations as provided by the applicant.	MSCAs, applicant (23 days)

[5] The applicant will be in cc of this communication in R4BP 3.

	Option B: linguistic check conducted by the SECR. If a linguistic review is not needed, a linguistic check is conducted by the SECR on the SPC translations. For sections not affected by the changes, the SECR assesses whether the translations are identical to the previous relevant SPC. If any of the translations is not acceptable for any reasons, the SECR returns **all SPC translations** to the applicant and requests correction of the translations via ad hoc communication in R4BP 3 at the latest 10 days after the SECR has received the SPC translations. **Resubmission of SPC translations (when applicable).** The applicant amends the SPC translations and replies by submitting **all SPC translations** within 7 days to the SECR via an ad hoc communication in R4BP 3. The SECR reinitiates the check of the SPC translations. **Transmission of the revised SPC translations.** Without undue delay, the SECR transmits the final SPC translations to COM via an ad hoc communication in R4BP 3[6].	SECR, applicant (23 days)
13.	*This step may be conducted in parallel with step 12.* **Assessment of confidentiality requests.** The SECR assesses the confidentiality requests provided by the applicant on the updated sections of the PAR, decides and implements its decisions in the final PAR and in its confidential annex, where relevant. **Submission of redacted PAR.** The SECR prepares the redacted final PAR in PDF-format and provides it to the COM via ad hoc communication in R4BP 3.	SECR (23 days)
14.	**BPC opinion dissemination.** The SECR disseminates the BPC opinion on the ECHA website.	SECR (according to internal schedule)
15.	**Dissemination.** Once the case is approved by the COM in R4BP 3, ECHA disseminates the relevant information on the ECHA website.	ECHA (without undue delay)

4. Definitions and acronyms

Abbreviation	Definition
BPC	Biocidal Products Committee
COM	European Commission
ECHA	European Chemicals Agency

[6] The SECR will not send the Norwegian and Icelandic translations to COM. These translations will be used directly by the relevant MSCA (Norway or Iceland).

MSCA	Member State Competent Authority
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

2. Code of conduct for applicants participating in the Biocidal Products Committee and its Working Groups

6. Links

1. Templates for PAR and confidential annex
2. Website of the Biocidal Products Committee

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