Working procedure for Union authorisation applications

Version 6.3

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

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

Document history

Version	Changes	Date	Date of applicability
1.0	First edition (original unnumbered version)	10 October 2013 at BPC-3	10 December 2013
2.0	Main changes in the document: • R4BP 3 is included as the communication platform for submitting documents and for communicating with the applicants, the eCAs and COM; • The CIRCABC site is included for distributing any documents to MSCAs; • A step has been included of disagreeing to close a point for a WG discussion ("opinion-forming of closing a point"); • The approach is described for situations where an ad hoc follow-up does not reach an agreement; • The open issues document in preparation for the BPC meeting is now included; • The final stages of the BPC opinion processing are now described, including the most relevant steps related to the dissemination of the opinion, PAR and study results; • A new step was included to cover the 'other' documents for the WG and BPC meetings.	12 October 2016 at BPC-17	10 November 2016
3.0	Main changes in the document: • The section 3.1 "Submitting PARs and draft SPCs" has been revised to focus on the peer-review process; • Figure 1 has been updated; • The eCA will be in charge of the communication with the applicant; • More details are provided in the steps of the process to support the eCA and other MSCAs in their tasks; • Step 12 in version 2.0 has been moved under "2. Commenting phase"; steps 32 and 36 in version 2.0 have been merged; steps 3, 31-32, 42-46 have been added to version 3.0; • Two accordance check criteria have been added according to the current practice.	28 June 2018 at BPC-26	26 July 2018
4.0	Main changes in the document: • The commenting period in Step 6 is reduced	27 February 2019 at BPC-29	10 May 2019

	• The trilateral discussion and preparation and distribution of the RCOM are now merged and rephrased • The revised minutes of WG meeting can also be approved electronically/by email.		
5.0	Changes in the document: • Clarification that the eCA is responsible for communication with the applicant in the opinion-forming phase. Further clarification that the eCA should update the applicant on progress of ad hoc follow up discussions. • Footnote on commenting period for applicants vs commenting according to Article 44(1) • Clarification on applicants possibility to re-open closed points for discussion prior to the Working Groups • Information on how to handle comparative assessment reports.	6 October 2020 at BPC-36	10 November 2020
5.1	Changes in the document: • Link to the BPC opinion template • Update of the text in Step 3 how to close the evaluation task in R4BP3.	2 March 2021 at BPC-38	30 April 2021
6	Changes in the document: • The use of Interact Collaboration and Interact meetings is included • The use of RCOM and discussion table is clarified • Replacing the term "peer review" with "opinion forming".	9 June 2022 at BPC-43	12 June 2022
6.1	Changes in the document: • Based on the BPC-44 agreement in relation to the applicant involvement during the opinion forming process. • Clarification included about information redaction in the PAR provided for the dissemination. • Adding the table with the summary of the case relevant documents – mapping of the documents for the MSCAs	22 November 2022	Process flow 48[1]
6.2	Changes in the document: • Step 6 revised to reflect the long-established practice that SECR can submit comments during the commenting period	7 June 2023 at BPC-47	14 August 2023
6.3	Changes in the document:	NA	22 March

[1] The version 6.1 was published on ECHA website on 3 January 2023. The BPC agreed that this version of the procedure will be applicable for the UA applications submitted from the process flow 48 onwards.

	• 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	Subpoint 3 presented during the BPC-50 in February 2024	2024

1. Purpose

This document describes the working procedure of the Biocidal Products Committee (BPC) for the opinion-forming process of applications for Union authorisation (also referred to as peer-review process) according to the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012).

2. Scope

This document details the steps to be taken during the opinion-forming process of Union authorisation of biocidal products under the BPR. The process starts with the submission of the draft Product Assessment Report (PAR) and the draft Summary of Product Characteristics (SPC) until the dissemination of the relevant information on the opinion-forming (ECHA) website. The steps are described for all the actors in the process including the evaluating Competent Authority (eCA[2]), ECHA secretariat (SECR), European Commission (COM), applicant, Working Group (WG) members and BPC members.

3. Description

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

3.1 Submitting draft PAR and draft SPC

The PAR contains the Conclusion and Assessment Report. The eCA should submit the draft PAR and the draft SPC in i6z format *via* ad hoc communication in R4BP 3. The PAR should be in the format available on the ECHA website[5]. The PAR should also include a draft BPC opinion for the Union authorisation application as the conclusion.[6]

The SECR performs an accordance check on the submitted draft PAR and draft SPC to verify that they comply with the requirements for the opinion-forming (see 5.1 Accordance check). If the conclusion of the accordance check is positive, the opinion-forming phase will start on the predefined date given in *Timelines for the opinion-forming of Union authorisation applications*[4]. If the conclusion of the accordance check is negative, the evaluation phase will resume and the eCA will at a later stage submit the revised versions of the draft PAR and draft SPC (during a submission window).

The eCA is responsible for assessing the confidentiality requests made by the applicant on the application dossier and the PAR and deciding whether to accept them or not[7]. The eCA should perform this assessment and implement its consequences in the IUCLID dossier and in the draft PAR during the evaluation phase. The eCA should also check and ensure that the names of authors of unpublished studies are blanked (not limited to vertebrates) in the final redacted PAR[8] independently on whether this information was claimed confidential by the applicant.

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[2] eCA in the working procedure refers to the rapporteur or other representative of the eCA.
[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] http://echa.europa.eu/documents/10162/17169198/bpr_par_template_union_authorisation_en.doc
[6] Template for BPC opinion and instruction manual on preparing BPC opinions is available here: /CircaBC/echa/Biocidal Products Committee (BPC)/Library/Non Confidential Folder/01. Procedural Documents/04. Union Authorisation
[7] See also: Guidelines for assessing the confidentiality of the information contained in the Competent Assessment Report (CAR) and Product Assessment Report (PAR).
[8] See step 44.

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)[5].

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 Working Group and 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 UA applications, i.e,:

- for ongoing and future product and biocidal product families (BPF) authorisation applications, the eCA ensures that there are no embedded files in redacted PARs for dissemination, so all information will be accessible in the PAR. In addition, the redacted PARs for dissemination shall be in PDF-format.

- for already authorised products and BPFs, the eCA reviews the redacted PAR for dissemination with regard to the accessibility of embedded files (if any) at the latest when the authorisation is renewed, i.e., the PAR can be amended in regard to the accessibility of embedded files in the course of any application on a voluntary basis, and is mandatory to be amended in the course of the renewal application. Moreover, when this review is done, the redacted PAR shall be prepared in PDF-format.

- It is up to the eCA to decide what IT solution to use to include information in the PAR (e.g., adding attachments, copying text directly in the PAR) instead of embedding documents. However, the redacted PAR shall be a single document, i.e., no annexes of the redacted PAR should be created in the form of a separate document.

[9] The same approach applied for NA process.

3.3 Communications

The ECHA contact point for the eCA and the applicant is the dossier manager (DM) appointed by ECHA for each application. The SECR informs the eCA and the applicant of the DM *via* ad hoc communication in R4BP 3.

During the evaluation and the opinion-forming phases up to the BPC discussions, the eCA is responsible for all communication with the applicant: this means from the first step to step 24 in Table 1. This is indicated in detail in the individual steps in Table 1.

The tool specified in Table 1 (i.e. R4BP 3 or e-mail) should be used to contact the SECR for a given step.

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

Figure 1. *Flowchart of the opinion-forming process of Union authorisation applications.*

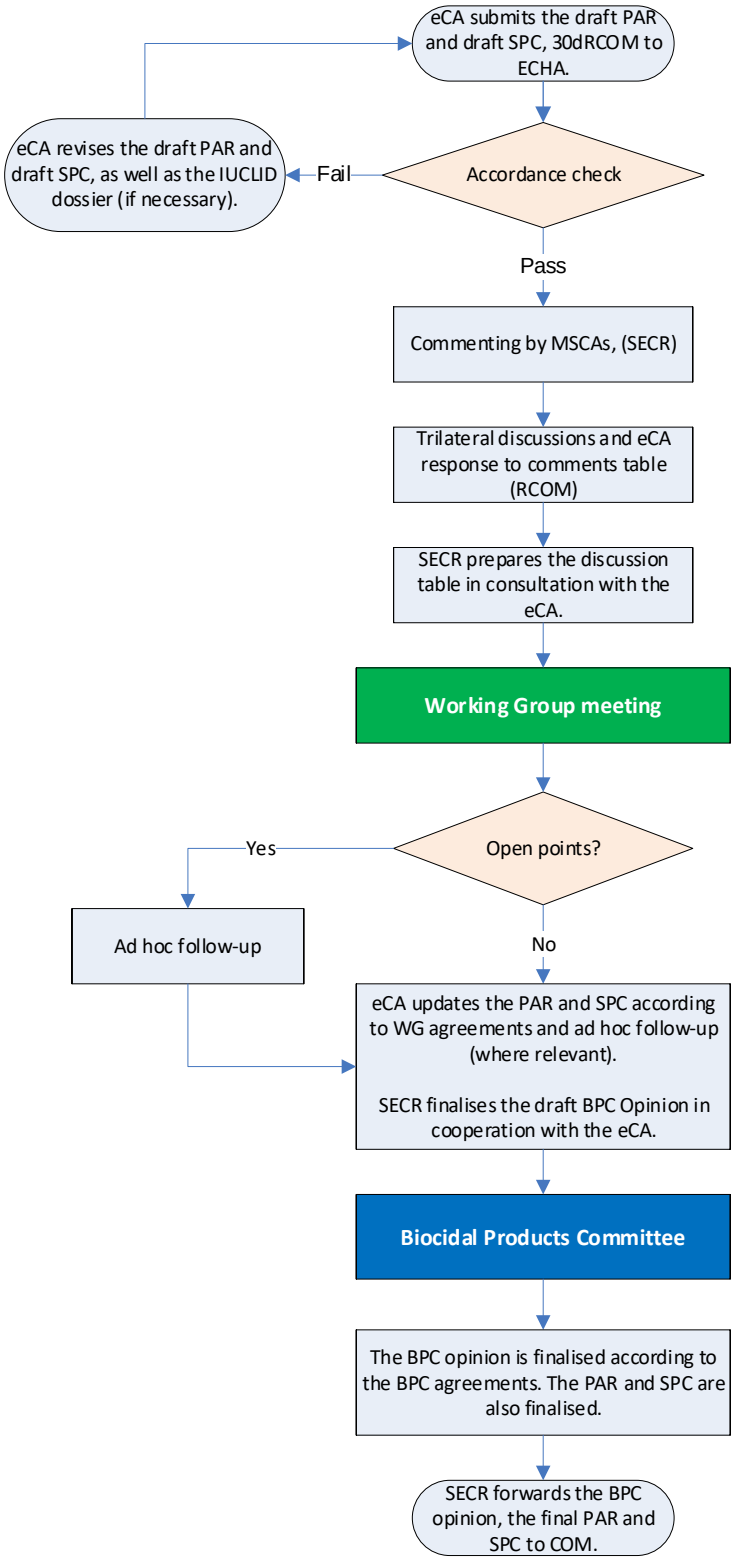

Table 1. *Description of the steps in the opinion-forming process of Union authorisation applications.*

1. Submission of the conclusions of the evaluation		**Responsible actor** (Indicative time limit)
1.	**Submission**. The eCA submits the following documents: • the results of the evaluation in the form of a draft PAR and a confidential annex to the draft PAR[10] in word format; a confidential annex for MSCA only (if applicable). • the draft SPC in i6z format. • 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]. • If applicable: also, the comparative assessment report is submitted in word format. The submission is done *via* ad hoc communication in R4BP 3. The access level of the documents in R4BP 3 should be "Restricted"[13]. The only exception would be a confidential annex for MSCA only, for which the access level in R4BP 3 should be "Restricted - Authority". The comparative assessment should also be uploaded in Circabc.[14] The eCA must not close the evaluation task in R4BP 3, as this will be done only following a positive result of the accordance check (see step 3).	eCA (365 days after validation of application)
2.	**Accordance check**. The SECR is mandated to perform a check to verify that the draft PAR and the draft SPC fulfil the opinion-forming requirements. Some criteria are indicated in Annex 5.1.. The SECR informs the eCA of the result of the accordance check *via* ad hoc communication in R4BP 3.	SECR (21 days after the end of a submission window)
	a) Accordance check: pass. The submission is accepted and the evaluation will proceed to the commenting phase (see section *2. Commenting phase*).	
	b) Accordance check: fail. The eCA will revise and resubmit the draft PAR and the draft SPC. The eCA will revise through annotations the IUCLID dossier as well, if necessary.	eCA
3.	**Closure of the evaluation task in R4BP 3**. Following a positive result of the accordance check, 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)

[10] The eCA shall assess the confidentiality requests in the application during the evaluation phase. After assessing the confidentiality requests, the eCA will implement its decisions on the confidentiality requests in the draft PAR and its confidential annex during the 30-day commenting period (Article 44(1) of BPR). The information contained in the confidential annex to the PAR will not be disseminated after the authorisation is granted.

[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] Article 44(1) of the BPR.

[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

[14] Path: /CircaBC/echa/Biocides Coordination Group (CG)/Library/Confidential folder/06. Comparative assessment reports
Browse url: https://webgate.ec.europa.eu/s-circabc/w/browse/8b62aec9-8271-4c23-9dfc-e49c391fad2f

4.	**Rapporteur**. The SECR appoints the BPC rapporteur according to Article 17(2) of the BPC Rules of Procedure (RoPs).	SECR

2. Commenting phase		**Responsible actor** (Indicative time limit)
5.	**Distribution of the relevant documents**. The SECR distributes the draft PAR, the confidential annex to the draft PAR, the confidential annex for MSCA only (if applicable), the draft SPC, 30dRCOM[15], the accordance check outcome, comparative assessment report (if applicable) and templates for commenting to the MSCAs *via* Interact Collaboration Tool.	SECR (in accordance with the timelines[16])
	Applicant: The applicant will receive the draft PAR, the confidential annex to the draft PAR, the draft SPC, 30 dRCOM for their information from the eCA *via* ad hoc communication in R4BP 3.	eCA (in accordance with the timelines)
6.	**Commenting phase**. The SECR launches the commenting phase by sending an e-mail to the BPC and WG members. The MSCAs and SECR[17] include their comments directly to the appropriate comments table made available by SECR via the Interact Collaboration tool (RCOM) 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 (after the step in disagreement in a closing point) due to confidentiality reasons, the commenting MSCA is responsible for clearly noting in red in the RCOM that this comment is for "MSCA only".	SECR (in accordance with the timelines) MSCAs, SECR (at least 14 days)

[15] 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 commenting tables (RCOMs).

[16] Timelines for the opinion-forming of Union authorisation applications.

[17] If SECR considers this necessary.

7.	**Trilateral discussions and finalisation of the response to the provided comments in the RCOM table**. **Trilaterals** Upon receipt of a comment, the eCA immediately initiates trilateral discussions with the MSCAs and the SECR, to reach an agreement. 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 the trilateral`s step. Trilaterals with the MSCAs/the SECR should take place directly in the RCOM tables available via Interact Collaboration. An agreement on closing point should be reached by the eCA with the commenting and supporting MSCA(s) and the SECR. In case of a lack of reply from the commenting/supporting MSCA(s) and 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 during the WG and include it in the RCOM. **The points, which lead to non-authorisation (product, metaSPC, use), should not be closed by the MSs during the trilaterals, but kept open for the discussion in the Working Group.** **Finalisation of the consolidated RCOM:** The eCA consolidates the RCOM by ensuring that the following is included: - all comments received, - the eCA responses, - the result of the trilateral discussions, e.g. the compromise wording that was agreed with the commenting body or an explanation why no such agreement could be reached, - a clear indication marking each point as open (i.e., for discussion in the WG) or closed, - for each open point identification of the remaining open question for discussion at the WG. Length of the trilaterals depends on the process flow. The next day following trilaterals, the SECR downloads the RCOM tables. The SECR locks those columns in the RCOM tables which were used for the commenting and trilaterals, 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 8).	eCA, MSCA, SECR (approx. 21 days)

8.	**Disagreement in closing a point**. When the email is received from the SECR (see step 7) the other MSCAs can request re-opening a closed point for discussion at the WG directly noting the disagreement in the RCOM tables available in Interact Collaboration tool. It is important to note that the timeline for this must be strict because of the preparation of the discussion tables (see step 13). 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 included in the discussion table as provisionally closed. 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[18] or data on the representative product for active substance approval.	MSCAs (5 days)
	Applicant: The eCA sends the consolidated RCOM tables after the disagreement in closing a point to the applicant for their information.	eCA (without undue delay)

3. Working Group meeting and preparations		**Responsible actor** (Indicative time limit)
9.	**Draft agenda**. The draft agenda for the WG meeting is published on the ECHA webpage https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups and in S in Interact meetings.	SECR (21 days[19] before the WG)
	Applicant: The eCA informs the applicant that their application is on the draft agenda.	eCA (without undue delay)
10.	**Invitations for the WG meeting**. The SECR will send invitations to WG members and representatives of Accredited Stakeholder Organisation (ASO).	SECR (21 days[16] before the WG)
	Applicant: The eCA informs the applicant when the agenda item is confirmed. The SECR provides the applicant with the link to register for the meeting via R4BP 3. In the invitation, the applicant is asked, among other instructions, to provide, if appropriate, a written justified objection to the presence of the representatives of ASOs on the grounds of confidential business information.	eCA (without undue delay) SECR (no later than 15 days before the WG)

[18] The RCOM tables may contain information on other UA applications where this information is already published, such as the publicly available BPC opinion.
[19] This is according to the BPC RoPs. The agenda and invitations will be sent as early as possible, usually at least 30 days before the WG.

11.	**Registration.** Registration is opened for members, applicants and stakeholders. All core members are expected to register. Registration is possible only until the specified timeline, and late registrations without justification will not be handled. If there are no open points for discussion, the eCA informs the applicant that their application is not going to be discussed and the application is listed in the WG agenda under items for which there are no open points and no discussion.	SECR (21 days[16] before the WG)
	Applicant: The applicants, their representatives and their accompanying experts should register for the meeting by the deadline provided in the invitation. Registration is possible only until the specified timeline, and late registrations without justification will not be handled. They may nominate one representative for each WG meeting in which they wish to participate. According to the Code of conduct for the applicants, one accompanying expert may be permitted for each WG when a justified case is made.	
12.	**Discussion tables**. The SECR prepares the discussion tables. All points that are marked as open in the consolidated RCOM tables will be included in the discussion tables. Irrespective of a possible bilateral/trilateral agreement, the SECR may additionally include any issues that are of special relevance for the assessment (e.g. additional studies required) where the relevant WG should reach conclusions. The discussion table will contain all the issues to be discussed at the WG meeting (i.e. no other issues will be discussed). It is distributed to MSCAs via Interact meeting tool. The eCA should notify the SECR immediately if they consider that some of the information in the discussion table cannot be shared with the applicant.	SECR in collaboration with eCA (10 days before the WG)
	Applicant: The eCA provides the discussion tables for each WG to the applicant, for information, via ad hoc communication in R4BP 3.	eCA
13.	**Other documents**. Any documents intended for discussion at the WG meeting have to be provided to the SECR no later than 11 days before the meeting. The SECR will make these documents available, if relevant, to the MSCAs via Interact meeting tool no later than 10 days before the meeting.	eCA; MSCAs (11 days before the WG) SECR (10 days before the WG)
	Applicant: If the applicant wishes to provide e.g. position papers on the points included in the discussion table, these have to be provided to the SECR via ad hoc communication in R4BP 3 no later than 11 days before the meeting. The applicant will receive all documents for the WG from the eCA via ad hoc communication in R4BP 3.	Applicant (11 days before the WG) eCA (without undue delay)

14.	**Identification of further discussion items**. If an MSCA wishes to discuss an issue that is not in the discussion table, they should immediately contact the SECR using the functional mailbox biocides-union-authorisation@echa.europa.eu and copying the Chair(s) of the respective WG(s). The SECR will include such issues in the discussion table only when they are considered critical in deciding on the (non)authorisation of the biocidal product/uses. The eCA is consulted before new items are added to the discussion table and the discussion table is updated. The SECR distributes the updated discussion table to MSCAs via Interact meeting tool.	MSCAs; SECR; eCA (before the WG)
	Applicant: The applicant can contact SECR using ad hoc communication in R4BP 3 to request including issues in the discussion table. The SECR will include such issues in the discussion table before the WG only when they are considered critical in deciding on the authorisation of the biocidal product and were already raised by the applicant in step 6 of this working procedure. The eCA is consulted before items are added to the discussion table and the discussion table is updated. The eCA provides the updated discussion table to the applicant via ad hoc communication in R4BP 3.	Applicant; SECR (before the WG) eCA (before the WG)
15.	**Working Group meeting**. The issues identified in the discussion table are discussed with the aim of finding an agreement. The representatives of ASOs can be present unless the applicant has sent a written justified objection on the grounds of confidential business information and the SECR has accepted the objection (see RoPs and step 11). The representatives of ASOs do not have access to documents concerning the biocidal products.	n.a.
	• **WG: closed issues.** The conclusions, action points and deadlines are finalised at the WG meeting and included in the discussion table.	n.a.
	• **WG: open issues**. Where an agreement cannot be reached during the WG meeting, this is marked as an open point in the discussion table. An ad hoc follow-up group will be coordinated by the SECR (see section *4*. Ad hoc follow-up).	n.a.
16.	**Distribution of conclusions and action points**. The discussion table with conclusions, action points and deadlines is distributed to MSCAs *via* Interact meetings after the WG meeting. Please note that these are not the minutes of the WG meeting.	SECR (without undue delay)
	Applicant: The eCA provides the conclusions and action points to the applicant via ad hoc communication in R4BP 3.	eCA (without undue delay)

4. Ad hoc follow-up	**Responsible actor** (Indicative time limit)
These steps are followed only if there are open points after the WG meeting. ***An ad hoc follow-up will not be used for 'early' WG discussions, i.e. those taking place before the eCA has submitted the draft PAR and the draft SPC.***	

17.	**Ad hoc follow-up discussion**. Immediately following the WG meeting, the SECR will initiate discussions with the relevant participants. The intention is to reach an agreement for all remaining open points from the WG meeting.	SECR, eCA, MSCAs, applicant (n.a.)
	Applicant: The applicant can normally participate as an observer in the ad hoc follow up discussion unless confidential information of other applicants is disclosed. The eCA will ensure that the applicant remains informed on the progress of the ad hoc follow up.	
18.	**Ad hoc follow-up arrangement**. The ad hoc follow-up is initiated by the SECR indicating the arrangement and timelines. The deadline for providing the outcome is established on a case-by-case basis, taking into account the need of the eCA to update the PAR and the SPC for the following BPC meeting. There is no predefined format for the discussions. Any means of communication may be used as long as the reporting is agreed on. It is normally, but not exclusively, the task of the eCA representative to prepare the documents detailing the proposed solutions to the open questions. If the discussion is relevant for another WG, the SECR will contact the Chair of that WG to agree on the appropriate procedure.	SECR, eCA
19.	**Reporting: points closed**. The SECR, in cooperation with the eCA, will draft the text that, once agreed by the ad hoc follow-up participants, is considered as finalised and will be included in the minutes as the result of the ad hoc follow-up. Note that this will take place after providing the draft minutes (see section *5. Minutes of the Working Group meeting*).	SECR, eCA
20.	**Reporting: open points**. Where no agreement is reached and there is no majority, the eCA will decide the approach to be presented to the BPC, clearly indicating that there was no agreement at the WG. This will also be included in the draft minutes of the WG.	eCA

5. Minutes of the Working Group meeting		**Responsible actor** (Indicative time limit)
21.	**Minutes in the form of discussion table.** The SECR distributes the draft minutes to MSCAs via Interact Collaboration for commenting.	SECR (14 days after the WG)
	Applicant: The eCA provides the draft minutes to the applicant via ad hoc communication in R4BP 3 for information only.	eCA (without undue delay)
22.	**Commenting minutes**. MSCAs include their comments to the appropriate document provided via Interact Collaboration. Comments should concern only the WG meeting unless a clear error is identified in the conclusions agreed during the WG meeting.	MSCAs (21 days)
23.	**Update of the minutes**. The SECR will revise the minutes and distribute them to MSCAs *via* Interact meetings.	SECR (7 days)
	Applicant: The eCA provides the updated minutes to the applicant via ad hoc communication in R4BP 3.	eCA (without delay)

24.	**Finalisation of the minutes**. The revised minutes are uploaded in Interact meetings. They are agreed at the following WG meeting(s) or by email / electronically and uploaded to Interact meetings as "final minutes". If the results of the ad hoc follow-up are not yet available/included, the minutes will be called "agreed minutes" and thereafter finalised by including the ad hoc follow-up. Links to the public version of the final minutes will be available at the ECHA webpage https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups.	SECR (without undue delay)
	Applicant: The eCA provides the final minutes to the applicant via ad hoc communication in R4BP 3.	eCA (without undue delay)

If there is a need to provide updated IUCLID dossier (e.g., new studies were made available based on the WG request), the eCA informs the applicant on the necessary updates of the IUCLID dossier and asks the SECR to open a task via R4BP 3.

6. Biocidal Products Committee and preparations		**Responsible actor** (Indicative time limit)
25.	**Draft agenda**. The draft agenda for the BPC meeting is published on the ECHA webpage https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee.	SECR (21 days before the BPC)
26.	**Invitation & Registration**. An invitation, containing a link to register, is sent to the BPC members, representatives of ASOs and applicants.	SECR (21 days before the BPC)
	Applicant: If applicants wish to participate for their agenda item, they should contact the BPC Secretariat (BPC@echa.europa.eu) and in particular follow the approach described in section 3 of the Code of Conduct for applicants.	
27.	**Registration deadline for the BPC meeting**. The participants shall register for the meeting by the deadline.	Members (14 days[20] before the BPC)
	Applicant: The applicant shall register for the meeting by the same deadline.	Applicant (14 days before the BPC)
28.	**SECR-eCA dialogue**. Immediately following the WG meeting, the SECR and the eCA will start preparations for the BPC meeting. The aim of the dialogue is to find an agreement on issues related to the BPC opinion.	eCA (35 days before the BPC meeting)
29.	**Update of the PAR and the SPC**. The eCA will begin modifying the PAR and the SPC immediately after the WG discussion, based on the agreements in the RCOM tables, WG meeting and ad hoc follow-up where relevant. The eCA may consult the SECR, the commenting MSs and the applicant as relevant. All changes should be introduced in the updated PAR and confidential Annex of the updated PAR by using the function - track changes.	eCA (without undue delay)

[20] When the agenda and invitations are sent more than 4 weeks before the meeting, the registration deadline is two weeks after sending the invitations.

30.	**Confidentiality requests by the applicant on the sections of the PAR updated after the WG meeting**. The eCA asks the applicant to provide *via* ad hoc communication in R4BP 3 the confidentiality requests on the sections of the PAR, updated on the basis of the agreements in the RCOM tables, WG meeting and ad hoc follow-up (where relevant). **Applicant:** the applicant provides the confidentiality requests on the updated sections of the PAR by replying to the ad hoc communication in R4BP 3 sent by the eCA.	eCA, applicant (without undue delay)
31.	**Submission of the updated PAR, the confidential annex to the updated PAR, the confidential annex for MSCA only (if applicable), the updated SPC and the draft BPC opinion**. The eCA assesses the confidentiality requests provided by the applicant on the updated sections of the PAR, decides and implement its decisions in the final PAR and in the confidential annex to the PAR, where relevant. The eCA submits to the SECR the updated PAR[21], the confidential annex to the updated PAR, the confidential annex for MSCA only (if applicable), the updated SPC (in i6z format) and the draft BPC opinion (see also the template and instruction manual on preparing the BPC opinion[4]) *via* ad hoc communication in R4BP 3.	eCA (35 days before the BPC meeting)
32.	**Finalisation of the BPC opinion**. The SECR finalises the draft BPC opinion in cooperation with the eCA.	SECR; eCA (21 days before the BPC meeting)
33.	**Distribution of the updated PAR, the confidential annex to the updated PAR, the confidential annex for MSCA only (if applicable), the updated SPC and the draft BPC opinion**. The SECR distributes the updated PAR, the confidential annex to the updated PAR, the confidential annex for MSCA only (if applicable), the updated SPC and the draft BPC opinion to MSCAs for commenting via Interact meetings and open issue table via Interact Collaboration. **Applicant**: The SECR provides the updated PAR, the confidential annex to the updated PAR, the updated SPC and the draft BPC opinion to the applicant via ad hoc communication in R4BP 3.	SECR (Without undue delay)
34.	**Other documents**. Any documents intended for discussion at the BPC meeting have to be provided no later than 10 days before the meeting. The SECR will make these documents available to the MSCAs via Interact meetings and to the applicant via R4BP 3.	eCA; MSCAs; SECR (10 days before the BPC meeting)
35.	**Commenting period**. The MSCAs and the SECR may provide written comments on the updated PAR, the confidential annex to the updated PAR, the updated SPC and the draft BPC opinion, especially where agreements in the RCOM tables and discussion table have not been included. The SECR will launch a collaboration via Interact Collaboration for each Union authorisation application. The eCA includes the comments from the applicant, if any, in the open issue document provided by the SECR via Interact Collaboration.	MSCAs, SECR, applicant (14 days)

[21] Note that section *1 Conclusion*, corresponding to the draft BPC opinion, should be removed from the updated PAR.

	Applicant: The applicant may provide written comments by replying to the ad hoc communication in R4BP 3 sent by the SECR.	
36.	**Preparation of the open issues document**. The SECR downloads the open issues document prepared by the eCA from the Interact Collaboration tool. This is the discussion document for the BPC meeting. The SECR distributes the document to MSCAs via Interact meetings.	SECR, eCA (approx. 5 days before the BPC meeting)
	Applicant: The SECR provides the open issues document to the applicant *via* ad hoc communication in R4BP 3.	
37.	**BPC meeting**. BPC adopts the opinion unless written procedure is requested (see RoPs). 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[22].	

7. Finalisation and dissemination steps		**Responsible actor** (Indicative time limit)
38.	**Finalisation of the open issues document**. The SECR finalises the open issues document according to the agreements at the BPC and distributes the document to MSCAs *via* Interact meetings.	SECR (without undue delay)
39.	**Finalisation of the BPC opinion**. The SECR, in consultation with the eCA, finalises the BPC opinion according to the agreements at the BPC. Minority positions will have to be submitted to the SECR by the involved member within 7 days after the BPC meeting.	SECR, eCA (in accordance with the timelines)
40.	**Preparation of the final PAR, the confidential annex to the final PAR, the confidential annex for MSCA only (if applicable), and SPC and update of the IUCLID dossier**. The eCA prepares the final PAR, the confidential annex to the final PAR, the confidential annex for MSCA only (if applicable), and the SPC, updated on the basis of the discussions and agreements at the BPC. The IUCLID dossier is also updated through annotations based on the discussions and agreements at the BPC[23].	eCA (without delay after the BPC meeting)
41.	**Confidentiality requests by the applicant on the sections of the PAR updated after the BPC meeting**. The eCA asks the applicant to provide *via* ad hoc communication in R4BP 3 the confidentiality requests on the sections of the PAR, updated on the basis of the discussions and agreements at the BPC.	eCA, applicant (without delay after the BPC meeting)
	Applicant: The applicant provides the confidentiality requests on the updated sections of the PAR by replying to the ad hoc communication in R4BP 3 sent by the eCA.	

[22] Code of Conduct for the applicants

[23] The IUCLID dossier does not have to be provided to SECR, as it can be retrieved based on the dossier UUID displayed in R4BP 3.

42.	**Submission of the final PAR, the confidential annex to the final PAR, the confidential annex for MSCA only (if applicable), and the SPC**. The eCA assesses the confidentiality requests provided by the applicant on the updated sections of the PAR, decides and implement its decisions in the final PAR and in the confidential annex to the final PAR, where relevant[24]. The eCA submits to the SECR the final PAR, the confidential annex to the final PAR, the confidential annex for MSCA only (if applicable), and the SPC (in i6z format) *via* ad hoc communication in R4BP 3.	eCA (as in accordance with the timelines)
43.	**Closure of the "ECHA opinion" task in R4BP 3**. The SECR closes the task "ECHA opinion" in R4BP 3 by uploading the BPC opinion and its annex (i.e. SPC), the final PAR, the confidential annex to the final PAR, the confidential annex for MSCA only (if applicable), and the SPC in i6z format and informs the COM by email. The SECR informs the applicant to submit the SPC in all official languages of the Union[25]. **Applicant**: The SECR provides the BPC opinion and its annex, the final PAR and the confidential annex to the final PAR and SPC in i6z format to the applicant via R4BP 3.	SECR (Without undue delay)
44.	**Sending the redacted final PAR to the SECR for dissemination**. The eCA prepares the redacted final PAR in pdf format and provides it to the SECR via ad hoc communication in R4BP 3.	eCA (at the latest 60 days after the BPC meeting)
45.	**Informing the COM on the available redacted final PAR**. The SECR informs the COM about available redacted final PAR via ad hoc communication in R4BP 3.	SECR (without undue delay)
46.	**The BPC opinion dissemination.** Once the draft agenda of the Standing Committee of the Biocidal Products (SCBP) meeting is published, ECHA disseminates the BPC opinion on the ECHA website. [26]	SECR (without undue delay)
47.	**Dissemination**. Once the asset is generated by the COM in R4BP 3, ECHA disseminates the relevant information on the ECHA webpage https://echa.europa.eu/information-on-chemicals/biocidal-products.	ECHA (without undue delay)

[24] Please note that the final PAR should not contain any information assessed as confidential by the eCA, as it will be disseminated in its redacted form. All confidential information should be contained in the confidential annex to the final PAR, except for parts of the final PAR that can be redacted directly in the document, such as names and addresses of persons (including the name of the laboratory) involved in testing on vertebrate animals. The redaction of the final PAR will take place at a later stage in the process (see step 45). The redacted final PAR will be disseminated.

[25] The document "Linguistic review of the translations of the summary of product characteristics (SPC) for Union authorisation applications" is available at https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee.

[26] The BPC Chair will inform the SECR when the involved application is on the agenda of the SCBP meeting.

4. Definitions and acronyms

Abbreviation	Definition
ASO	Accredited Stakeholder Organisation
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
COM	European Commission
DM	(ECHA) Dossier Manager
eCA	Evaluating Competent Authority
ECHA	European Chemicals Agency
IG	S-CIRCABC Interest Group
MSCA	Member State Competent Authority
n.a.	Not applicable
PAR	Product Assessment Report
R4BP 3	Register for Biocidal Products
RCOM	Response to Comments table
RoPs	BPC Rules of Procedure
S-CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
SECR	ECHA Secretariat
SPC	Summary of Product Characteristics
WG	Working Group

5. Annexes

5.1 Accordance check

A list of some criteria to "pass" the accordance check performed on the draft PAR and the draft SPC submitted by the eCA. Please note that this is not exhaustive list. However, if one of the conditions is not fulfilled, it is possible that accordance check would result is "fail".

1) The draft PAR and draft SPC are provided in the correct format and are complete.

   Using the PAR template, all sections must be included and filled. The SPC is prepared using the SPC in IUCLID and is in i6z format.

2) The PAR unambiguously specifies the proposed conclusion on the authorisation of the biocidal product (family) and any conditions for the authorisation.

3) Comparative assessment has been performed, where relevant.

   A check will be carried out to verify whether comparative assessment has been performed when an active substance is a candidate for substitution.

4) There are no obvious inconsistencies in reporting.

   The conclusions need to reflect the assessment of the data. No scientific evaluation is made in the accordance check but any obvious inconsistencies would constitute a fail.

5) For a biocidal product family, the accordance check will verify if the eCA included[27] a justification demonstrating the similarity of the products in the product family in line with the definition in Article 3(1)(s).

6) For a biocidal product (family), the complete composition of biocidal product(s) is(are) specified.

7) The active substance(s) is (are) supplied from a reference source(s) or is proven as technically equivalent.

[27] ECHA will not check scientific/technical validity of provided justification.

5.2 Summary of the case relevant documents - mapping for MSs

Section	Step	Type of documents	Location of the documents
1. Submission of the conclusions of the assessment by the eCA	Submission (1[28])	• The draft PAR • The confidential annex to the draft PAR, • The confidential annex for MSCA only (if applicable) • The draft SPC • The comparative assessment report (if applicable) • 30dRCOM	R4BP3 under the relevant case
	Accordance check (2)	• Outcome of the accordance check	R4BP3 under the relevant case
2. Commenting phase	Distribution of the relevant documents (5) Trilateral discussions and finalisation of the response to the provided comments in the RCOM table (7) Disagreement in closing a point (8)	• The draft PAR • A confidential annex to the draft PAR, • A confidential annex for MSCA only (if applicable) • The draft SPC • The comparative assessment report (if applicable) • 30dRCOM • The outcome of the accordance check • Template for commenting	Interact collaboration
3. Working Group meeting and preparation	Discussion tables (12, 13)	• Discussion tables for WGs • Other WG documents	Interact meetings
	Distribution of conclusions and action points (16)	• Discussion table with conclusions, action points and deadlines	Interact meetings
4. Ad hoc follow-up (if applicable)	Reporting point closed/opened (19/20)	• In the draft minutes of the WG (See section 5. Minutes of the Working Group)	
5. Minutes of the Working group meeting	Minutes in the form of discussion table (21)	• The draft minutes in the form of discussion table	Interact collaboration
	Finalisation of the minutes (24)	• The revised minutes • The final/agreed minutes	Interact meetings
6. Biocidal Products Committee and preparation	Submission of the updated PAR, the confidential annex to the updated PAR, the updated SPC and the draft BPC opinion (31)	• The updated PAR • The confidential annex to the updated PAR, • The confidential annex for MSCA only (if applicable) • The updated SPC • The comparative assessment report (if applicable) • The draft BPC opinion	R4BP3 under the relevant case

[28] Step numbers are included in accordance with the procedure.

	Distribution of the updated PAR, the confidential annex to the updated PAR, the updated SPC and the draft BPC opinion (33)	• Template for commenting • The updated PAR • The confidential annex to the updated PAR, • The confidential annex for MSCA only (if applicable) • The updated SPC • The comparative assessment report (if applicable) • The draft BPC opinion	Interact Collaboration Interact meetings
	Other documents (34)	• Any other documents (where applicable)	Interact meetings
	Commenting period (35)	• Open issue document	Interact Collaboration
	Preparation of the open issue document (36)	• Open issues document prepared by the eCA •	Interact meetings
7. Finalisation and dissemination steps	Finalisation of the open issues document (38)	• The final open issues document	Interact meetings
	Submission of the final PAR, the confidential annex to the final PAR and the SPC (42)	• The final PAR • The confidential annex to the final PAR, • The confidential annex for MSCA only (if applicable) • The final SPC	R4BP3 under the relevant case
	Closure of the "ECHA opinion" task in R4BP 3 (43)	• The final PAR • The confidential annex to the final PAR, • The confidential annex for MSCA only (if applicable) • The final SPC • The BPC opinion	R4BP3 under the relevant case
	Sending the redacted final PAR to the SECR for dissemination (44) Informing the COM on the available redacted final PAR (45)	• The redacted final PAR	R4BP3 under the relevant case
	The BPC opinion dissemination (46)	• The BPC opinion	On the ECHA website
	Dissemination (47)	• The BPC opinion • The redacted PAR • The SPC • Authorisation	On the ECHA website

6. References

1) Rules of procedure for the Biocidal Products Committee

https://echa.europa.eu/documents/10162/763823/bpc_procedure_rules_en.pdf/4462dc96-b5ed-414b-b000-6dc5dbc799e7?t=1516375780324

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

93a7fabd-0fb5-410c-b300-64a8e7562645 (europa.eu)

7. Links

1) Template for PAR and confidential annex of the PAR and instructions for filling in the PAR template and confidential annex

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

2) Webpage of the Biocidal Products Committee

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

3) Webpage of the Working Groups of the BPC

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

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