Working procedure for Union authorisation applications

Version 4.0

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

Document history		
Version	**Changes**	**Date**
1.0	First edition (original unnumbered version)	10 October 2013 at BPC-3
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 ("peer review 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
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
4.0	Main changes in the document: • The commenting period in Step 6 is reduced • The trilateral discussion and preparation and distributionof the RCOM are now merged and rephrased • The revised minutes of WG meeting can also be approved electronically/by email.	27 February 2019 at BPC-29

1. Purpose

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

2. Scope

This document details the steps to be taken during the peer review 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 ECHA website. The steps are described for all the actors in the process including the evaluating Competent Authority (eCA[1]), ECHA secretariat (SECR), applicant, Working Group (WG) members and BPC members.

3. Description

The individual steps and indicative timelines for the process are described in Table 1, and the actual dates for each step are given in the separate document *Timelines for the peer review of Union authorisation applications*[2]. 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 xml format *via* ad hoc communication in R4BP 3. The PAR should be in the format available on the ECHA website[3].

SECR performs an accordance check on the submitted draft PAR and draft SPC to verify that they comply with the requirements for the peer review (see 5.1 Accordance check). If the conclusion of the accordance check is positive, the peer review phase will start on the predefined date given in *Timelines for the peer review of Union authorisation applications*[2]. 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. The eCA should perform this assessment and implement its consequences in the IUCLID dossier and in the draft PAR during the evaluation phase.

[1] eCA in the working procedure refers to the rapporteur or other representative of the eCA.
[2] Available at https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee
[3] http://echa.europa.eu/documents/10162/17169198/bpr_par_template_union_authorisation_en.doc

3.2 Communications

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

The tool specified in table 1 (i.e. R4BP 3 or e-mail) should be used to contact 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-bpc-union-authorisation@echa.europa.eu.

Figure 1. *Flowchart of the peer review process of Union authorisation applications.*

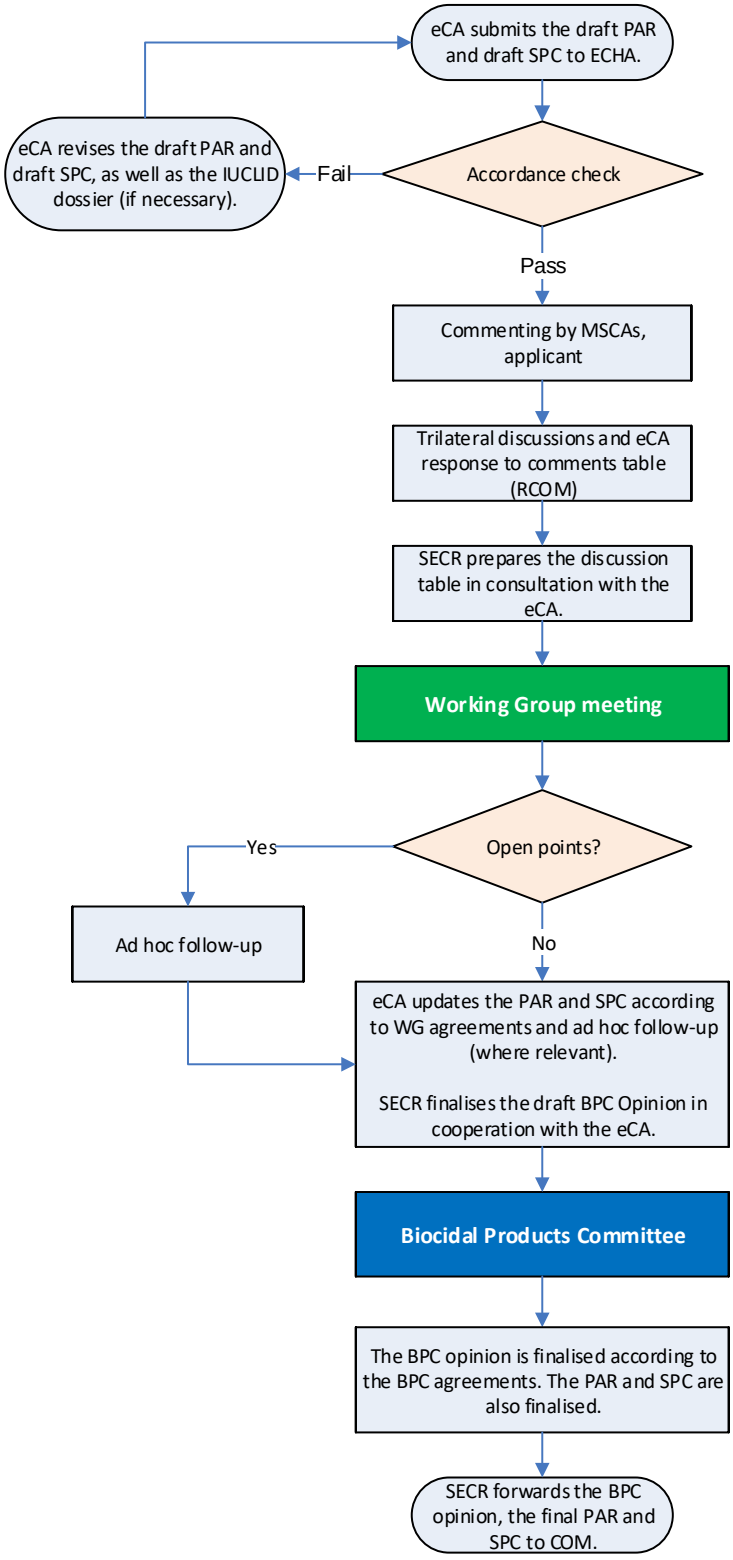

Table 1. *Description of the steps in the peer review process of Union authorisation applications.*

1. Submission of draft PAR and draft SPC		**Responsible actor** (Indicative time limit)
1.	**Submission**. The eCA submits the results of the evaluation in the form of a draft PAR and a confidential annex to the draft PAR[4] in word format. The eCA also submits the draft SPC in xml format. The submission is done *via* ad hoc communication in R4BP 3. The access level of the documents in R4BP 3 should be "Restricted"[5]. 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**. SECR performs a check to verify that the draft PAR and the draft SPC fulfil the peer review requirements, as indicated in Annex 5.1. 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 stage (see *2. Commenting phase*).	
	b) Accordance check: fail. The eCA will revise and resubmit the draft PAR and 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 closes the evaluation task in R4BP 3. The case is promoted and the "ECHA opinion" task is created.	eCA (without delay)
4.	**Rapporteur**. 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 draft PAR, the confidential annex to the draft PAR, the draft SPC and a template for commenting**. SECR distributes the draft PAR, the confidential annex to the draft PAR, the draft SPC and a template for commenting to the MSCAs *via* S-CIRCABC Union authorisation Interest Group (IG).	SECR (Without delay)
	Applicant: The applicant will receive the draft PAR, the confidential annex to the draft PAR, the draft SPC and the template for commenting from the eCA *via* ad hoc communication in R4BP 3.	eCA (Without delay)

[4] 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.

[5] 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

6.	**Commenting phase**. SECR launches the commenting phase by sending an e-mail to MSCAs. The MSCAs use the template for commenting and upload their comments directly to the appropriate S-CIRCABC newsgroup indicated by SECR in the launching message.	SECR (Without delay) MSCAs (at least 14 days)
	Applicant: The applicant may provide comments using the template for commenting and send these to the eCA *via* ad hoc communication in R4BP 3. The eCA uploads these comments to the appropriate S-CIRCABC newsgroup.	Applicant, eCA (at least 14 days)
7.	**Trilateral discussions and preparation of the agreed response to comments table (RCOM)**. Upon receipt of a comment, the eCA immediately initiates trilateral discussions with the commenting body (MSCAs/applicant/SECR) and SECR, to reach an agreement. The eCA prepares the consolidated response to comments table (RCOM) including - 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, and - a clear indication marking each point as open (i.e., for discussion in the WG) or closed. The eCA sends the consolidated RCOM[6] to SECR and the applicant *via* ad hoc communication in R4BP 3. SECR makes the RCOM available to the MSCAs *via* S-CIRCABC Union authorisation IG. Note: The consolidated RCOM should not contain information of confidential nature, including, for example, explicit reference to Union authorisation applications previously discussed or data on the representative product for active substance approval. In case confidential information is disclosed in the RCOM or will be addressed during the WG meetings, the eCA should prepare and upload to R4BP 3 a separate RCOM[7].	eCA, MSCA, SECR, applicant (at least 21 days)
	Applicant: The applicant receives the RCOM from the eCA and will discuss bilaterally with the eCA on the responses.	eCA, applicant
8.	**Disagreement in closing a point**. When the RCOM is provided *via* ad hoc communication in R4BP 3 indicating a point to be closed by the eCA, the other MSCAs and the applicant have 7 days to request re-opening the point for discussion at the WG. The request will be directed to the SECR and the eCA using ad hoc communication in R4BP 3. 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. Following the disagreement to close a point, the RCOM will not be amended, but the point will be included in the discussion table.	MSCAs, applicant (7 days)

[6] The name of the file should be "Name of the product (family)_RCOM". The access level of this document in R4BP 3 should be "Restricted".
[7] The name of the file should be "Name of the product (family)_RCOM_MSCAs only". The access level of this document in R4BP 3 should be "Restricted - Authority".

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-CIRCABC BPC Working Groups IG.	SECR (21 days[8] before the WG)
	Applicant: The eCA informs the applicant that their application is on the draft agenda.	eCA (without delay)
10.	**Invitations for the WG meeting**. SECR will send invitations to WG members and representatives of Accredited Stakeholder Organisation (ASO).	SECR (21 days[8] before the WG)
	Applicant: The eCA informs the applicant when the agenda item is confirmed. SECR provides the applicant with the link to register for the meeting. 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 delay) SECR (no later than 15 days before the WG)
11.	**Registration.** Registration is opened for members, applicants and stakeholders. All core members are expected to register.	SECR (21 days[8] before the WG)
	Applicant: The applicants should register for the meeting by the deadline provided in the invitation. 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 table**. SECR prepares columns[9] a) and b) of the discussion table in consultation with the eCA. SECR includes in the discussion table all points that the eCA marked as open in the consolidated RCOM. Irrespective of a possible bilateral/trilateral agreement, SECR may additionally include any issues that are of special relevance for the assessment (e.g. additional studies required) and on which 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* S-CIRCABC BPC Working Groups IG.	SECR in collaboration with eCA (10 days before the WG)
	Applicant: The eCA provides the discussion tables for each WG to the applicant *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 SECR no later than 11 days before the meeting. SECR will make these documents available, if relevant, to the MSCAs *via* S-CIRCABC BPC Working Groups IG no later than 10 days before the meeting.	eCA; MSCAs (11 days before the WG) SECR (10 days before the WG)

[8] 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.
[9] a) Sequential number; b) Issue and background, Ref. in RCOM; c) WG discussion, ad hoc follow-up where relevant; d) Conclusions and action points

	Applicant: If the applicant wishes to provide e.g. position papers, these have to be provided to 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 (10 days before the WG)
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 SECR using the functional mailbox biocides-bpc-union-authorisation@echa.europa.eu and copying the Chair(s) of the respective WG(s). SECR will include such issues in the discussion table before the WG meeting only when they are considered critical in deciding on the authorisation of the biocidal product. The eCA is consulted before new items are added to the discussion table and the discussion table is updated. SECR distributes the updated discussion table to MSCAs *via* S-CIRCABC BPC Working Groups IG.	MSCAs; SECR; eCA (before the WG)
	Applicant: The applicant can contact SECR using ad hoc communication in R4BP 3 to request including further issues in the discussion table. 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. The eCA is consulted before new 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 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 columns d) of the discussion table.	n.a.
	• **WG: open issues**. Where an agreement cannot be reached during the WG meeting, this is identified as an open point in the meeting minutes. The WG appoints the members to an ad hoc follow-up group coordinated by SECR (see *4. Ad hoc follow-up*); the members are indicated in column d) of the discussion table. Any WG participant can join the group; the core members are normally expected to participate and the eCA should always participate.	n.a.
16.	**Distribution of conclusions and action points**. The discussion table with conclusions, action points and deadlines is distributed to MSCAs *via* S-CIRCABC BPC Working Groups IG after the WG meeting. Please note that these are not the minutes of the WG meeting as the discussions are included in column c) (see *5. Minutes of the Working Group meeting*).	SECR (without delay)
	Applicant: The eCA provides the conclusions and action points to the applicant *via* ad hoc communication in R4BP 3.	eCA (without 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 all participants of the established ad hoc follow-up group. 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.	
18.	**Ad hoc follow-up: arrangement**. The ad hoc follow-up is initiated by SECR indicating the arrangement and timelines. The deadline for providing the outcome is established on a case-by-case basis at the WG meeting, 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, SECR will contact the Chair of that WG to agree on the appropriate procedure.	SECR, eCA
19.	**Reporting: points closed**. 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 *5. Minutes of the Working Group meeting*). This will include a brief explanation and the conclusion in column c) of the minutes. The point will be marked as closed in column d) of the minutes, where the conclusion is also reported. These entries will be clearly marked to indicate that the discussion took place in the ad hoc follow-up and not during the WG meeting.	SECR, eCA
20.	**Reporting: open points**. Where no agreement is reached and there is no clear 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.	eCA

5. Minutes of the Working Group meeting		Responsible actor (Indicative time limit)
21.	**Minutes in the form of discussion table**. Column c) of the discussion table is drafted by SECR after the WG meeting and the file is named as the draft minutes. SECR distributes the draft minutes to MSCAs *via* S-CIRCABC BPC Working Groups IG and a Newsgroup for commenting is created under BPC Working Groups IG.	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 delay)

22.	**Commenting minutes**. MSCAs send their comments to the appropriate newsgroup forum in S-CIRCABC BPC Working Groups IG. Comments should concern only the WG meeting discussion in column c) unless a clear error is identified elsewhere.	MSCAs (21 days)
23.	**Update of the minutes**. SECR will revise the minutes and distribute them to MSCAs *via* S-CIRCABC BPC Working Groups IG.	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 to S-CIRCABC BPC Working Groups IG. They are agreed at the following WG meeting(s) or by email / electronically and uploaded to S-CIRCABC BPC Working Groups IG 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. The public version of the final minutes will be uploaded to the ECHA webpage https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups.	SECR (without delay)
	Applicant: The eCA provides the final minutes to the applicant *via* ad hoc communication in R4BP 3.	eCA (without delay)

5. 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. An invitation is sent to the BPC members and representatives of ASOs.	SECR (21 days before the BPC)
	Applicant: SECR will inform the applicant(s) of their applications being discussed at the BPC, as far as the appropriate contact information is available.	
26.	**Registration**. SECR opens the registration for BPC members, advisers, representatives of ASOs and applicants.	SECR (21 days before the BPC)
	Applicant: The applicant may nominate a representative for the agenda item concerning their application. The applicants should contact BPC@echa.europa.eu to receive instructions for registration.	
27.	**Registration deadline for the BPC meeting**. The participants will register for the meeting by the deadline.	Members (14 days[10] before the BPC)
	Applicant: The same registration deadline concerns the applicant.	Applicant (14 days before the BPC)
28.	**SECR-eCA dialogue**. Immediately following the WG meeting, 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)

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

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, WG meeting and ad hoc follow-up where relevant. The eCA may consult the SECR, the commenting MSs and the applicant as relevant.	eCA (without delay)
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, 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 delay)
31.	**Submission of the updated PAR, the confidential annex to the updated PAR, 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 SECR the updated PAR[11], the confidential annex to the updated PAR, the updated SPC (in xml format) and the draft BPC opinion *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 updated SPC and the draft BPC opinion**. SECR distributes the updated PAR, the confidential annex to the updated PAR, the updated SPC and the draft BPC opinion to MSCAs *via* S-CIRCABC Biocidal Product Committee IG. A Newsgroup for commenting is created under S-CIRCABC Biocidal Product Committee IG. **Applicant**: 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 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. SECR will make these documents available to the MSCAs *via* S-CIRCABC Biocidal Product Committee IG and to the applicant *via* R4BP 3.	eCA; MSCAs; SECR (10 days before the BPC meeting)
35.	**Commenting period**. The MSCAs and 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 and discussion table have not been included. SECR will open a dedicated newsgroup in S-CIRCABC for each Union authorisation application. **Applicant**: The applicant may provide written comments by replying to the ad hoc communication in R4BP 3 sent by SECR.	MSCAs, SECR, applicant (14 days)

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

36.	**Preparation of the open issues document**. SECR prepares the open issues document based on comments received from MSCAs, SECR and the applicant. The eCA prepares responses to the open issues listed. This is the discussion document for the BPC meeting. SECR distributes the document to MSCAs *via* S-CIRCABC Biocidal Product Committee IG.	SECR, eCA (5 days before the BPC meeting)
	Applicant: 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. The representatives of ASOs have access to the draft opinions but not to other documents concerning the biocidal products.	n.a.
	Applicant: The applicant may participate in the discussion at the BPC meeting.	

6. 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* S-CIRCABC Biocidal Product Committee IG.	SECR (10-14 days after the BPC meeting)
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 (10-14 days after the BPC meeting)
40.	**Preparation of the final PAR, the confidential annex to the final PAR and SPC and update of the IUCLID dossier**. The eCA prepares the final PAR, the confidential annex to the final PAR 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[12].	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.	

[12] 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 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[13]. The eCA submits to SECR the final PAR, the confidential annex to the final PAR and the SPC (in xml format) *via* ad hoc communication in R4BP 3.	eCA (10-14 days after the BPC meeting)
43.	**Closure of the "ECHA opinion" task in R4BP 3**. 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 and the SPC in xml format. SECR makes the documents available to the MSCAs *via* S-CIRCABC Union authorisation IG. SECR informs the applicant to submit the SPC in all official languages of the Union[14]. **Applicant**: SECR provides the BPC opinion and its annex, the final PAR and the confidential annex to the final PAR to the applicant *via* R4BP 3.	SECR (Without delay)
44.	**Sending the redacted final PAR to SECR for dissemination**. The eCA prepares the redacted final PAR and provides it to SECR *via* ad hoc communication in R4BP 3.	eCA (at the latest 60 days after the BPC meeting)
45.	**Sending the redacted final PAR to COM**. SECR sends the redacted final PAR to COM *via* ad hoc communication in R4BP 3.	SECR (without delay)
46.	**Dissemination**. Once the asset is generated by COM in R4BP 3, ECHA disseminates the relevant information on the ECHA webpage https://echa.europa.eu/information-on-chemicals/biocidal-products.	ECHA (without delay)

[13] 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.

[14] 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.

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

Fulfilling the following criteria would constitute a "pass" in the accordance check performed on the draft PAR and the draft SPC following the submission by the eCA. If one of the conditions is not fulfilled, the 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 Editor tool and is in xml 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) The applicant was allowed the 30-day commenting period before submission.

   A check will be carried out if this occurred and if the comments provided by the applicant have been taken into account when finalising the evaluation.

6) Any further information requested and then provided in time by the applicant has been taken into account.

   If the eCA has requested the applicant to provide further information within a specified time, and the applicant has provided this information in time, then the PAR needs to reflect this information.

7) For a biocidal product family, the accordance check will verify if a justification is provided demonstrating the similarity of the products in the product family in line with the definition in Article 3(1)(s).

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

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

6. References

1) Rules of procedure for the Biocidal Products Committee

http://echa.europa.eu/documents/10162/4221979/bpc_procedure_rules_en.pdf

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

http://echa.europa.eu/documents/10162/4221979/bpc_conduct_code_applicants_en.pdf

7. Links

1) Template for PAR

http://echa.europa.eu/documents/10162/17169198/bpr_par_template_union_authorisation_en.doc

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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