Working procedure for active substance approval and renewal

Version 9.1

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) for preparing opinions on applications for approval of biocidal active substances. Participants include WG and BPC members, alternates, rapporteurs, the secretariat, applicants and accredited stakeholder organisations.

Document history

Document history			
Version	**Changes**	**Date of agreement**	**Date of applicability**
1.0	First edition (original unnumbered version)	10 October 2013 at BPC-3	
2.0	Main changes in the document: • The CIRCABC site for submitting any documents is included; • 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 Assessment Reports finalised at the TM are now specifically addressed; • 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, AR and study results; • A new step was included to cover the 'other' documents for the WG and BPC meetings; • The annex on the accordance check criteria has been clarified and updated based on CA meeting agreements and Regulation 1062/2014 (the Review Programme Regulation); • An additional annex was included to clarify the documents to be provided by the eCA, considering both the old and the new format.	6 February 2015 at BPC-9	
3.0	Main changes in the document: • R4BP 3 in use for communication with the applicants, eCAs and COM from 1 March 2016 onwards.	8 December 2015 at BPC-13	

Document history			
Version	**Changes**	**Date of agreement**	**Date of applicability**
4.0	Main changes in the document: • Implementing the revision of the working procedure as agreed at BPC-15 (BPC-15-2016-07); • Including the need for a proposal for the reference specification in the accordance check.	14 June 2016 at BPC-16	
5.0	Main changes in the document: • Criteria for accordance check amended for consultation of PBT and ED EG in the light of experience: obligatory consultation by eCA removed. • eCA in charge of the communication with the applicant	6 March 2018 at BPC-24	
6.0	Change in the document: • Clarification on tasks eCA with respect to whether the conditions of Article 5(2) is met in section 5.1.2.	25 April 2018 at BPC-25	
7.0	Changes in the document: • Requirement for RAC opinion if Muta 2 is proposed • Footnote on commenting period for applicants vs commenting according to Article 8(1) • Clarification on applicants possibility to re-open closed points for discussion prior to the Working Groups • Clarification that the eCA should update the applicant on progress of ad hoc follow up discussions. • Update of Active substances Functional mailbox.	6 October 2020 at BPC-36	
7.1	Changes in the document: • Link to the BPC opinion template	2 March 2021 at BPC-38	
8.0	Changes in the document: • Use of Interact Collaboration	22 November 2022 at BPC-45	

Document history			
Version	**Changes**	**Date of agreement**	**Date of applicability**
	and Interact meetings is included • Applicant's involvement in opinion -forming based on BPC-44 agreement • Section 7. Assessment Reports coming from Technical Meetings (TM) has been removed • Clarification on confidentiality checks and dissemination of documents • A document mapping table with summary of the case relevant documents is added. • Update of criteria included in the Accordance check		
9.0	Changes in the document: • Addition of active substance renewal for full and limited evaluations. • Earlier consultation on candidates for substitution (with flexibility) to improve the analysis of alternatives, in line with the CA-June23 – Doc 5.9.	21 November 2023 at BPC-49	01 December 2023 Applicable for PF 52 onwards
9.1	Changes in the document: • Approach for one substance, one assessment • Avoidance of embedded files in public Assessment Reports. • Inclusion of the consultation on derogations to the exclusion criteria in line with the CA-Dec23 – Doc 5.5.	26 February 2024 at BPC-50	05 March 2024 Applicable for PF 53 onwards

1. Purpose

This document establishes the working procedures of the BPC for the opinion forming process of biocidal active substance evaluation. According to the Biocidal Products Regulation (BPR), the opinion on the initial approval of an active substance, as well as the opinion on the full evaluation of the renewal application of an active substance, has to be submitted by ECHA to the Commission within 270 days of the receipt of the conclusions of the evaluating Competent Authority (eCA[1]). For the Review Programme, the opinion has to be submitted by ECHA within 270 days of the start of the preparation (Article 7 of Regulation (EU) No 1062/2014). Where the eCA has carried out a limited evaluation of the renewal application, ECHA has to submit the opinion within 90 days to the Commission.

2. Scope

This document details the steps to be taken during the opinion-forming process of an active substance under the BPR. The steps covered are those starting from the eCA submitting the Assessment Report (AR)[2] until the dissemination of the finalised opinion of the BPC. The steps are described for all actors in the process including eCA, ECHA secretariat (SECR), applicant, WG members and BPC members.

The same principles and processes apply to substances in the Review Programme, *mutatis mutandis*. Where different from the process under BPR, the corresponding steps are described also for the Review Programme.

In addition, a distinction is made between ARs submitted by the Member State competent authorities (MSCA) before and after the entry into operation of the BPR on 1 September 2013.

3. Description

The individual steps and indicative timelines for the process are described in Table 1 for the approval and renewal applications with full evaluation and in Table 2 for renewal applications with limited evaluation. The actual dates for each step are given in the separate document "Timelines for the opinion forming of active substance evaluations". The actions and responsibilities of the applicant are included separately in the tables below each relevant step.

3.1 Submitting ARs

ARs need to be submitted in the agreed format[3]. For a limited evaluation renewal, a BPC opinion on the renewal of the substance[4] should be submitted together with the AR as a separated document.

SECR will perform an accordance check for each AR submitted by the eCAs to verify that the AR can proceed to opinion forming (see 5.1 Accordance check). For limited-evaluation renewal applications, the accordance check verifies the criteria for limited evaluations established by

[1] eCA refers to the rapporteur or other representative of the eCA. It also refers to the Rapporteur Member State (RMS) of the substances in the Review Programme.
[2] AR refers to the assessment report for both the initial approval and subsequent renewal(s).
[3] The AR template for approval/renewal is available from ECHA website: Formats and templates - ECHA (europa.eu)
[4] Template for BPC opinion on approval, template for BPC opinion on renewal of the approval and instruction manual on preparing BPC opinions are available here: https://webgate.ec.europa.eu/s-circabc/w/browse/2333a050-9cdd-4514-99e3-f7e59fbfecc2

the Renewal Guidance.[5] The 270-day and 90-day timeline respectively begins on the predefined date given in *Timelines for the opinion-forming of active substance applications* and the *Timelines for the opinion forming of the active substance renewal for limited evaluations,* following the AR submission and provided that the conclusion of the accordance check is positive. Failing to pass the accordance check will result in returning the AR to the eCA for revision and submission of the revised AR during a subsequent submission window.

3.2 Submitting other documents

When the application for active substance approval was made before 1 September 2013 and the study summaries are in the BPD format (Document III), this will be considered as acceptable also when submitting the AR. Note that the study summaries or the IUCLID dossier are not part of the AR (for further information see 5.2 AR structure and terminology).

3.3 Specific rules for ARs submitted before 1 September 2013

Active substances for which ARs were submitted by MSCAs **before 1 September 2013** will be approved on the basis of the BPD principles but following the BPR processes. The assessment report will need to be updated according to the format in use in order to address the change in legislative context and the exclusion and substitution criteria.

Active substances for which ARs were submitted **after 1 September 2013** will be approved on the basis of the BPR principles, regardless of whether the substance is new or in the Review Programme.

3.4 Additional notes

3.4.1 One substance, one assessment

The "one substance, one assessment" approach has been set out by the Commission in its Chemicals Strategy for Sustainability (CSS)[6] with a view to align assessments of substances under different regulatory framework as much as possible. The competent authorities for BPR and other related regulations are called to collaborate together with other EU bodies towards a harmonised risk and hazard assessment of Biocidal active substances that are also subject to another legislations.

ECHA aims at overseeing parallel assessments and to ensure contact between the actors involved, facilitate their collaboration and share information on these assessments. ECHA established as practice to invite Member States of other regulatory frameworks and EU bodies as invited experts to the WG meetings and as observers to the BPC meetings, in line with the Rules of Procedure of the BPC.

ECAs are expected to engage into a discussion on ongoing parallel assessments and seek overcoming divergencies in views during evaluation and opinion forming.

3.4.2 Redacted final AR

Public documents shall be in pdf format and not contain embedded files to ensure that all

[5] Guidance on the data requirements and assessment of applications for renewal of approval of active substances under BPR, https://echa.europa.eu/documents/10162/2324906/data_req_assessment_applications_renewal_of_approval_as_en.pdf/29b50033-cb42-65c4-359f-168ce75d4989?t=1605007269214, section 2, page 10.
[6] https://environment.ec.europa.eu/strategy/chemicals-strategy_en.

information in the redacted ARs becomes publicly accessible.

When providing the Agency with the redacted version of the final AR the eCA ensures that the redacted ARs for dissemination does not contain embedded files, so that all information will be accessible in the public AR.

For already approved substances, the eCA reviews the redacted AR for dissemination with regard to the accessibility of embedded files (if any) at the latest when the approval is renewed. On voluntary basis, the amendment of the AR can be performed earlier.

The eCA decides how to include information in the AR (e.g., adding attachments in the portfolio-pdf file, adding annexes to the AR, copying text directly in the AR) instead of embedding documents. The redacted AR shall be a single, self-standing document, i.e., there should be no separate annex files to the redacted AR.

3.5 Communications

All formal communications will take place through R4BP 3. The applicant will communicate with eCA and SECR through R4BP 3. Documents restricted to members/alternates/advisers/rapporteurs of the BPC and the WGs, will be distributed via the Interact Portal. The eCA is responsible for all communication with the applicant with the exception of where it is clearly indicated otherwise in the document.

The contact point between the eCA and SECR is the dossier manager appointed by SECR for each application.

To contact SECR, please use the following e-mail addresses:

- bpc@echa.europa.eu for organisational issues of the BPC meetings;
- BPC-WGs@echa.europa.eu for organisational issues of the WG meetings;
- biocides-active-substance@echa.europa.eu for issues related to active substance approval, renewal and the related process and procedures.

These functional mailboxes have to be used for those steps in the tables where the communication with the SECR is not indicated to take place via R4BP 3 or the Interact Portal.

Figure 1. *Flowchart of the biocidal active substance approval and full renewal process.*

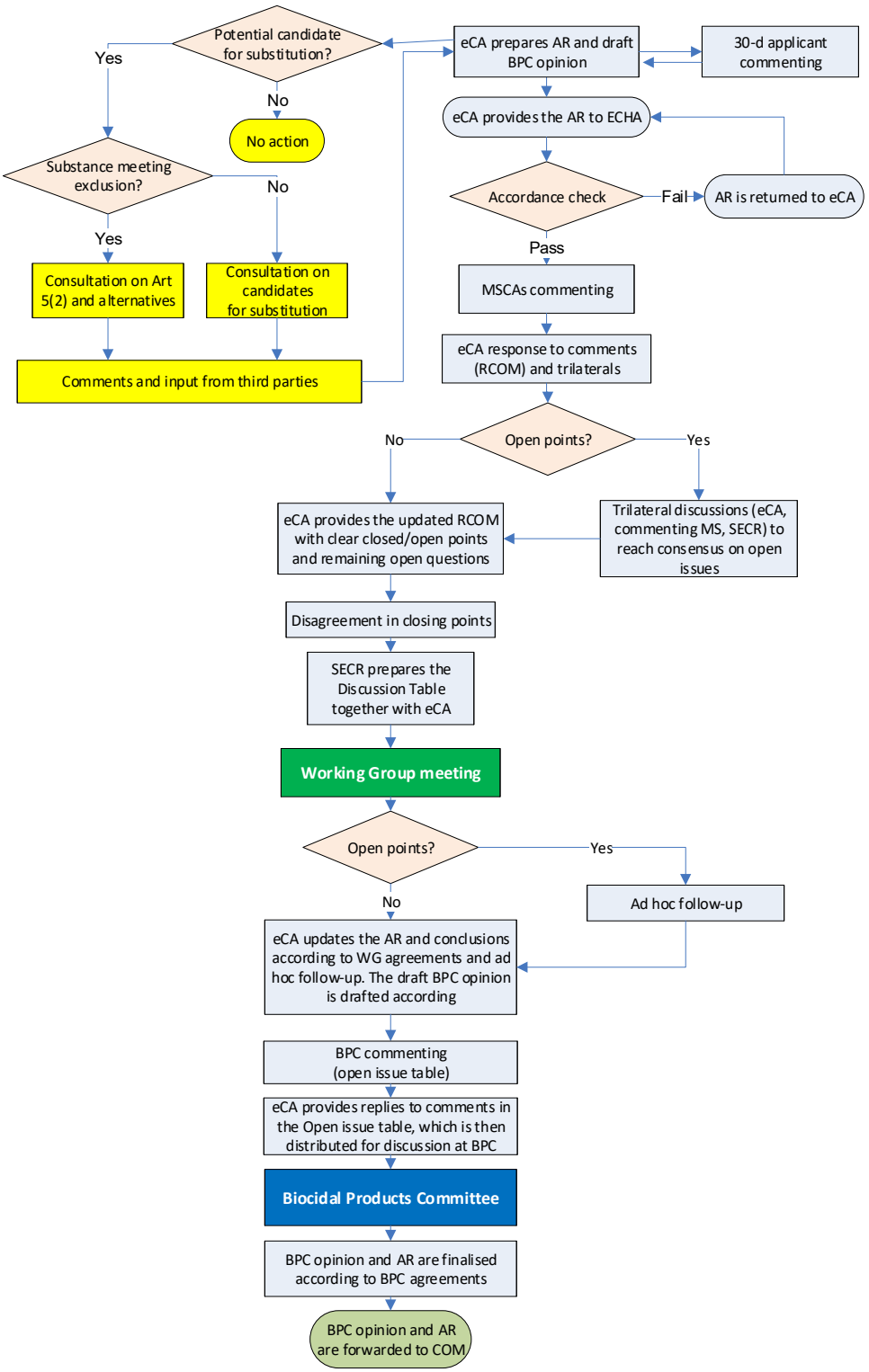


Figure 2. *Flowchart of the biocidal active substance renewal with limited evaluation process.*

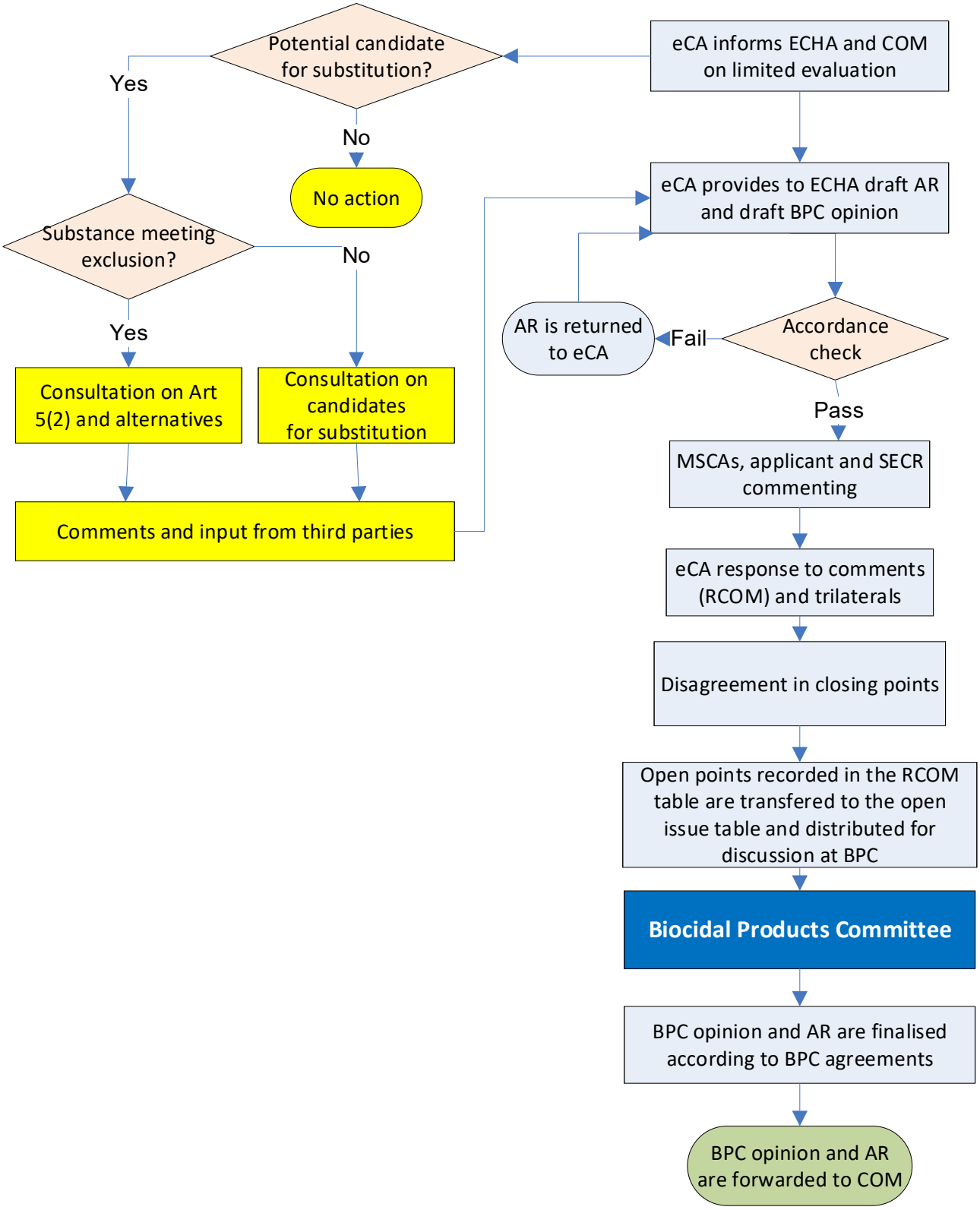


Table 1. Description of the steps in the biocidal active substance opinion forming process for approval and full evaluation renewal

The Agency has to provide its opinion within 270 days. The timeline starts after a positive accordance check by the Secretariat.

Table 1. 1. Consultations on Candidates for substitution (CfS) and on derogation to the exclusion criteria[7] (per BPR Articles 10(3) and 5(2))		**Responsible actor** (Indicative time limit)
These steps are performed when the active substance is a candidate for substitution (CfS) according to Article 10(1) BPR, including substances meeting the exclusion criteria according to Article 5(1). When the substance meets the exclusion criteria, a combined consultation per Article 10(3) (focusing on the availability of alternatives) and on the derogation criteria (Article 5(2)) is initiated. If the substance is a CfS but does not meet the exclusion criteria of Article 5(1) only the consultation related to Article 10(3) is initiated. Where possible, the consultation(s) is(are) performed during the evaluation phase, preferably within 6 months before the AR submission. In other cases, before scheduling discussions in WGs.		
1.	**Preparation**. Until the implementation of the ECHA guidance on analysis of alternatives[8] ("AoA guidance"), there are two possible scenarios: a) The eCA informs SECR that the active substance is a candidate for substitution and if it meets exclusion; and provides their analysis of alternatives (AoA)[9] (if available) and, when available, the non-confidential AoA submitted by the applicant and the justification on derogation to Article 5(2). The applicant's non-confidential AoA and justification[10], with their explicit consent, are published on the ECHA website as part of the consultation. If the eCA prepared their own AoA, the non-confidential version is also published on the ECHA website as part of the third-party consultation. b) In the absence of an AoA which can be published, the eCA provides SECR and the applicant with the minimum relevant information for the consultation: substance identity (name and EC/CAS numbers), PT, a description on the intended uses and the conditions of BPR Article 10(1) that are met.	eCA (during the evaluation, and preferably no later than 6 months before the submission of the AR to ECHA) (when during the opinion forming, at the time of the AR submission)
	Applicant. Upon SECR request via R4BP 3: **a)** the applicant's explicit consent to have the document published on the ECHA website as part of the consultation. **b)** The applicant reviews the text proposal to check for confidentiality issues and correctness of the information before the consultation is published.	Applicant (7 days)

[7] Consultations should be performed as indicated in the CA documents "CA-JUNE23-DOC.5.9 - AOA_ GUIDANCE_IMPLEMENTATION_FINAL_CORR.DOCX" and "CA-DEC23-DOC.5.5- EXCLUSION SUBSTANCES". If performed during the opinion forming, the consultation(s) is/are parallel to Section 3. *Commenting phase*.
[8] https://echa.europa.eu/documents/10162/1276600/guidance_analysis_alternatives_biocides_en.pdf/10646cd2-8ec9-36a8-2f00-201fcc49c43e?t=1675846602684.
[9] The Analysis of alternatives is part of the AR and is provided as an annex.
[10] The applicant's justification for meeting the derogation criteria can be e.g. in the form of a socio-economic analysis (SEA) or impact assessment.

2.	**Consultation.** SECR launches the consultation on the ECHA website.	SECR (7 days)
3.	**Input by third parties**. Once the information has been published, interested third parties provide information via the webform.	Third parties (60 days)
4.	**Summary of the consultation**. All the input received in response to the consultation (compiled into confidential and non-confidential) and a brief description is prepared and provided to the WG and BPC via S-CIRCABC. The non-confidential contributions are also published in ECHA website. The eCA will refer to ECHA website for the public comments and provide the rest as a confidential annex to the AR. Comments received during consultation will be considered by the eCA and reflected in the BPC opinion, taking into account the confidentiality status of the information.	SECR (14 days)
	Applicant: The applicant will have access to the non-confidential input submitted during the consultation via the website for consultation.	

Table 1.2. Submission of AR		**Responsible actor** (Indicative time limit)
5.	**Submission**. The eCA submits to the SECR through an ad hoc communication in R4BP 3: - the results of the evaluation in the form of an AR. Please see 3.2 Submitting other documents for information on in which cases using the BPD format (study summaries in Doc III) is still acceptable. - the RCOM table used for the 30-day commenting period by the applicant (30d-RCOM)[11] during the evaluation step that includes also the eCA's reply to the applicant's comments. 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 6a).	eCA (365 days after validation of application[12])
6.	**Accordance check**. SECR performs a check to verify that the AR fulfils the requirements as indicated in Annex 5.1.	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 *3. Commenting phase*) and to consultation, if relevant (see 1. *Consultation*). The SECR informs the eCA of the result of the accordance check via R4BP 3. The eCA closes the evaluation task in R4BP 3 and the case is promoted; the ECHA opinion task is created.	SECR, eCA

[11] Template available at Formats and templates - ECHA (europa.eu).
[12] For renewals, where there is no validation, after the decision on full or limited evaluation as per BPR Article 14(1).

	b) Accordance check: fail. The AR is returned to the eCA for modifications. The SECR informs the eCA of the result of the accordance check via R4BP 3, and the eCA will revise the AR as well as the IUCLID dossier if necessary, and resubmit the AR.	SECR
7.	**Rapporteur**. SECR appoints the BPC rapporteur according to Article 17(2) of the BPC Rules of Procedure (RoPs).	SECR

Table 1.3. Commenting phase[13]		**Responsible actor** (Indicative time limit)
8.	**Distribution of AR**. SECR distributes the AR, the template for commenting, the outcome of the accordance check and the 30d-RCOM to the MSCAs[14] *via* Interact Collaboration Tool. Study summaries will also be distributed if a IUCLID dossier is not available.	SECR (Without delay)
	Applicant: The applicant will receive for their information the AR and the 30d-RCOM from the eCA via R4BP 3.	eCA (Without delay)
9.	**Commenting phase**. SECR launches the commenting phase by sending an e-mail to all BPC and WG members. The MSCAs use the template for commenting and upload their comments directly to the appropriate Collaboration in Interact indicated by the SECR in the launching message.	SECR (Without delay) MSCAs (35 days)
10.	**Response to comments table (RCOM)**. As soon as the MSCAs and SECR provide their comments, the eCA will start providing responses to the comments with the aim of reaching an agreement bilaterally with the commenting body. The eCA prepares a consolidated table including all comments received together with the eCA responses. Where possible, during this time the eCA will verify whether the commenting MSCA agrees with the response and include information on this in the table. The eCA provides the responses directly in the Collaboration document.	eCA, MSCA, (28 days)

Table 1.4. Working Group meeting and preparations		**Responsible actor** (Indicative time limit)
11.	**Draft agenda.** The provisional draft agenda for the WG meeting is published on ECHA website and in Interact Meetings Portal.	SECR (21 days[15] before the WG)

[13] Commenting phase might be in parallel to section 1.C*onsultations*, when applicable.
[14] MSCA in the working procedure refers to any MSCA representative having access to the S-CIRCABC interest groups for BPC or BPC Working Groups.
[15] 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.

	Applicant: The applicant should check periodically the ECHA website for the WG agenda and contact the SECR (BPC-WGs@echa.europa.eu) to indicate their interest in attending the WG-meeting. The BPC Work Programme[16] indicates the active substances which are scheduled to be discussed in the upcoming WG meetings.	Applicant
12.	**Invitations for the WG meeting.** SECR will send invitations to WG members and Accredited Stakeholder Organisation representatives.	SECR (21 days[15] before the WG)
	Applicant: SECR will send invitations via R4BP 3 to applicants with substances scheduled for discussion and provide the link to register to the meeting.	
13.	**Registration.** SECR opens the registration for members, applicants, rapporteurs and stakeholders. All core members are expected to register. All participants register by the deadline.	SECR, WG members (21 days[15] before the WG)
	Applicant: The applicants should register in the meeting by the deadline provided in the invitation. They may nominate one representative (and one accompanying expert when a justified case is made) per application for each WG meeting in which their substance is discussed. Not more than two participants of the applicant can be present in the meeting room at any point of time. The applicants should contact BPC-WGs@echa.europa.eu to receive instructions for registration.	
14.	**Trilateral discussions and updated RCOM**. Immediately following the RCOM distribution (steps 9-10), the eCA will contact the commenting MSCAs and SECR in order to continue discussions, with the intention to reach an agreement for each open issue before finalising the updated RCOM in Interact Collaboration. The eCA marks all points as closed or open and highlights the open points by colour coding. For each open point, the eCA together with the commenting MS/SECR need to formulate a proposal for a question to be discussed at the WG and include it in the RCOM. The updated RCOM remains in the same Collaboration in Interact where the comments were collected. The eCA informs SECR about the finalisation of the updated RCOM including all agreements achieved. Note: Any RCOM table shared with the applicant should not contain confidential business information from a third party.	eCA (Updated RCOM - 21 days before the WG)
	Applicant: The eCA provides the updated RCOM to the applicant via R4BP 3.	eCA

[16] Available at the Committee home page at http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee.

15.	**Disagreement in closing a point**. The MSCAs have one week to request re-opening a point for discussion at the WG noting the disagreement in the RCOM table available in Interact Collaboration tool. The 7-day timeline is strict because of the preparation of the discussion tables (see the next step). If disagreement to closing a point is not communicated within the time limit, this will be considered as tacit agreement to close it.	MSCAs (14 days before the WG)
	Applicant: The eCA provides the consolidated RCOM after disagreement in closing points to the applicant via R4BP 3 for their information.	eCA
16.	**Discussion table**. SECR prepares the discussion table in consultation with the eCA, by including in the discussion table all points that the eCA marked as open in the updated RCOM (step 14) and those reopened under disagreement in closing a point (step 15). Irrespective of a possible bilateral/trilateral agreement, SECR may additionally include any issues that are of special relevance for the assessment (e.g. reference values, additional studies required); these will then be concluded by the relevant WG. 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 Meetings.	SECR in collaboration with eCA (10 days before the WG)
	Applicant: The eCA provides the discussion tables to the applicant via R4BP 3.	eCA
17.	**Other documents**. Any documents intended for discussion/agreement 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 Interact Meetings and to the applicant via R4BP 3.	eCA; MSCAs; SECR; Applicant (11 days before the WG)
	Applicant: If the applicant wishes to provide e.g. position papers, these have to be sent to SECR via R4BP 3 no later than 11 days before the meeting.	
18.	**Identifying further discussion items**. If MSCAs wish to discuss an issue that is not in the discussion table, they should immediately contact SECR (biocides-active-substance@echa.europa.eu copying the WG Chair). SECR will include such issues in the discussion table before the WG only when they are considered critical in deciding on the (non-)approval/renewal of the active substance, severe restrictions on a specific use and/or on the fulfilment of exclusion or substitution criteria. Any new items in the discussion table are immediately communicated to the eCA, MSCAs and the applicant by the SECR.	MSCAs; SECR (Before the WG)
	Applicant: The applicant can contact SECR via 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 (non-)approval/renewal of the active substance, severe restrictions on a specific use and/or on the fulfilment of exclusion or substitution criteria.	Applicant

19.	**Working Group meeting**. The issues identified in the discussion table are discussed with the aim of finding an agreement. The representatives of accredited stakeholder organisations (ASO) can be present unless the applicant has sent a written justified objection on grounds of confidential business information and SECR has accepted the objection (see RoPs). The ASOs do not have access to documents concerning the substances.	n.a.
20.	**WG: Discussion table**. The conclusions, action points and deadlines are finalised at the WG meeting and included in the discussion table.	n.a.
21.	**WG: Open issues**. If an agreement cannot be reached during the WG meeting, this is identified as an open point in the discussion table. WG appoints the members to an ad hoc follow-up group coordinated by SECR (steps 23-26); the members are indicated in the discussion table. Any WG participant (except ASOs) can join the group; the core members and the eCA are expected to participate.	n.a.
	Applicant: The applicant can participate as an observer in the ad hoc follow-up of their case.	
22.	**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. Note that these are not the minutes of the WG meeting as the discussions are included into the discussion table in the next step (see section 6 of this table).	SECR, eCA (without delay)
	Applicant: The eCA provides the conclusions and action points to the applicant via R4BP 3.	

Table 1.5. Ad hoc follow-up		**Responsible actor** (Indicative time limit)
These steps are followed only if there are open points after the WG meeting[17].		
23.	**Ad hoc follow-up discussion** Following the WG meeting, the SECR will initiate timely discussions with all participants of the ad hoc follow-up group established at step 21. The intention is to reach an agreement for all remaining open points from the WG meeting related to that specific substance.	SECR, eCA, MSCAs, Applicant (n.a.)
	Applicant: The applicant can 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 progress of the ad hoc follow-up.	

[17] Ad hoc follow-up will not be used for 'early' WG discussions, i.e. those taking place before the eCA has submitted the AR.

24.	**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, taking into account the need of the eCA to finalise the AR 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
25.	**Reporting: points closed**. SECR in cooperation with the eCA will draft the text that, once agreed by the ad hoc follow-up participants, will be included in the draft minutes as the result of the ad hoc follow-up. Note that this will take place after providing the draft minutes (see section 6 below). This will include a brief explanation of the discussion/commenting 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
26.	**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

Table 1.6. Minutes of the Working Group meeting		**Responsible actor** (Indicative time limit)
27.	**Draft minutes**. SECR drafts and distributes the draft minutes to MSCAs *via* Interact Collaboration for commenting.	SECR, eCA (14 days after the WG)
	Applicant: The eCA provides the draft minutes to the applicant via R4BP 3 for information only.	eCA
28.	**Commenting minutes**. MSCAs include their comments to the draft WG minutes in the Interact Collaboration. Comments should concern only the WG meeting discussion unless a clear error is identified elsewhere.	MSCAs; (21 days before the next WG)
29.	**Updating minutes**. SECR will revise the minutes and distribute them to MSCAs via Interact meetings. The results of ad hoc follow-up (section 5), if available, are included in the minutes and are considered as finalised.	SECR (10 days before the next WG meeting)
	Applicant: The eCA provides the updated minutes to the applicant via R4BP 3.	eCA
30.	**Finalising minutes**. The updated minutes are agreed at the following WG meeting and uploaded in Interact meetings. If the results of the ad hoc follow-up are not yet available/included, the document will be called "agreed minutes". The public version of the final minutes will be uploaded at the ECHA website.	SECR (without delay)

	Applicant: The eCA provides the final minutes to the applicant via R4BP 3.	eCA

Table 1.7. Biocidal Products Committee meeting and preparations		**Responsible actor** (Indicative time limit)
31.	**Draft agenda.** The draft agenda for the BPC meeting is published on ECHA's website. An invitation is sent to the BPC members, applicants and ASOs.	SECR (21 days before the BPC)
	Applicant: The applicant should periodically check the ECHA website for the BPC agenda. The applicant can also anticipate the timing of the discussions based on the BPC Work Programme[16] published on ECHA's website. SECR will inform the applicant(s) of their applications being discussed at the BPC, as far as the appropriate contact information is available.	Applicant
32.	**Registration.** SECR opens the registration for members, advisers, ASOs and applicants. All participants register by the deadline.	SECR, BPC members, applicant (14 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.	
33.	**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 (ending 26 days before the BPC meeting)
34.	**Submitting the updated AR and the draft BPC opinion**. The eCA will begin modifying the AR 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. The eCA submits the AR and the draft BPC opinion to SECR *via* R4BP 3 (see also the template and instruction manual on preparing the BPC opinion[4]). Where the BPD AR format is used, the eCA provides a draft BPC opinion using the relevant parts of the AR (Section 3).	eCA (35 days before the BPC meeting)
	Applicant: SECR provides the updated AR to the applicant via R4BP 3.	
35.	**Drafting BPC opinion**. The SECR will finalise the draft BPC Opinion in cooperation with the eCA.	SECR; eCA (20 days before the BPC meeting)
36.	**Distribution**. SECR distributes the AR, and the draft BPC Opinion to the BPC members *via* Interact meetings	SECR (without delay)
	Applicant: SECR provides the AR and the draft BPC Opinion to the applicant via R4BP 3.	

37.	**Commenting period.** The MSCAs and SECR may provide written comments on the AR and the draft BPC Opinion, especially where issues have not been included as agreed earlier in the process. SECR will open a collaboration in Interact Collaboration tool for each substance.	MSCAs, SECR (13 days before the BPC meeting)
	Applicant: The applicant may provide written comments to SECR and eCA via R4BP3.	
38.	**eCA responses to open issues.** The eCA includes the comments provided by the applicant and prepares responses to the open issues listed.	eCA; SECR (10 days before the BPC meeting)
39.	**Open issues.** SECR downloads the *open issues* document based on comments received from MSCAs, SECR and the applicant. This is the discussion document for the BPC meeting. SECR distributes the document to MSCAs *via* Interact meetings.	SECR (10 days before the BPC meeting)
	Applicant: SECR provides the *open issues* document to the applicant via R4BP 3.	
40.	**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 BPC members via Interact meetings and to the applicant via R4BP 3.	eCA; MSCAs; SECR (10 days before the BPC meeting)
41.	**BPC meeting**. The BPC adopts the opinion unless written procedure is requested (see RoPs). Subject to the agreement of the applicant, the representatives of ASO may be present. The ASOs have access to the draft opinions but not to other documents concerning the substances.	n.a.
	Applicant: The applicant may participate in the discussion at the BPC meeting.	

Table 1.8. Finalisation and dissemination steps		**Responsible actor** (Indicative time limit)
42.	**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 (18 days after the BPC meeting)
43.	**BPC opinion finalisation and publication**. The SECR, in consultation with the eCA, finalises the BPC opinion according to the agreements at the BPC and forwards it to COM. The finalised opinion is published on the ECHA website. Minority positions will have to be submitted to the SECR by the involved member within 7 days after the BPC meeting.	SECR (18 days after the BPC meeting)

44.	**Renewal documents finalisation and publication (*only for renewals*)** In parallel with the opinion finalisation step, the eCA provides the SECR with: • An updated list of companies that supported the AS renewal. • The non-confidential version of the final list of 'relevant data'[18] identified by the eCA, taking account all studies submitted for the AS renewal, including those submitted during the opinion forming[19]. The SECR publishes on ECHA's website the non-confidential list of 'relevant data'.	eCA; SECR (18 days after the BPC meeting)
45.	**Updating the AR[20] and IUCLID file (or Doc III)**. The eCA provides to SECR via R4BP 3 the final AR based on the agreements reached at the BPC. The eCA updates the relevant annotations in the IUCLID file (or Doc III) based on the discussions and agreements.	eCA (42 days after the BPC meeting)
46.	**AR distribution**. The confidential AR is available to the MSCAs in the relevant cases/asset in R4BP 3.	N.A.
47.	**Confidentiality check for the AR and IUCLID file (or study summaries).** The applicant will provide to the eCA the AR and, in case of approval also the IUCLID file (or Doc IIIA), indicating any confidentiality claims to ensure that no confidential information is disclosed to the public[21] (if still relevant as normally the confidentiality check should take place during the evaluation phase).	Applicant (72 days after the BPC meeting)
48.	**Non-confidential AR and IUCLID file or Doc IIIA.** The eCA will assess the confidentiality claims[22] and prepare a non-confidential version of the AR and IUCLID extract/Doc IIIA and provide them to SECR[21] together with any confidential annexes. The submission is done via R4BP 3.	eCA (120 days after the BPC meeting)
49.	**Dissemination.** The non-confidential AR is disseminated. The non-confidential IUCLID extract or Doc IIIA is also disseminated in case of an approval or renewal proposal. ECHA disseminates the relevant information on the ECHA website: http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances	ECHA (without delay)

[18] Template: List of 'relevant data' identified by the evaluating Competent Authority in the renewal assessment.
[19] The list can be updated based on the list in Appendix V: "Overall reference list" and should contain only renewal data and a clear indication as relevant renewal data or not.
[20] If the BPD format is still used, documents II, and confidential annexes if relevant, are submitted together with the AR.
[21] See *CA-March14-Doc.7.2.1 - Biocide confidentiality requests key steps and guidelines.docx* and *CA-March14-Doc.7.2.2 - Biocide confidentiality requests subsequent assessment by ECHA.docx*. Both documents are available in CIRCABC:
Path: /CircaBC/env/BPR - Public/Library/CA meetings/55th CA meeting March 2014
Link: https://circabc.europa.eu/w/browse/af767168-75db-4e3e-8f32-2d53a850d54e
[22] Guidelines for assessment the confidentiality of the information contained in the CAR and PAR: 3c579364-5a0b-b098-06bf-3323f5b8a496 (europa.eu).

Table 2. Description of the steps in the biocidal active substance opinion forming process for limited evaluation renewal

The Agency has to provide its opinion within 90 days for limited-evaluation renewals. The timeline starts after a positive accordance check by the Secretariat.

Table 2.1. Consultations on Candidates for substitution (CfS) and on derogation to the exclusion criteria[7] (per BPR Articles 10(3) and 5(2))		**Responsible actor** (Indicative time limit)
	These steps are performed when the active substance is a candidate for substitution (CfS) according to Article 10(1) BPR, including substances meeting the exclusion criteria according to Article 5(1). When the substance meets the exclusion criteria, a combined consultation per Article 10(3) (focusing on the availability of alternatives) and on the derogation criteria (Article 5(2)) is initiated. If the substance is a CfS but does not meet the exclusion criteria of Article 5(1) only the consultation related to Article 10(3) is initiated. Where possible, the consultation(s) is(are) performed during the evaluation phase, preferably within 6 months before the AR submission. In other cases, before scheduling discussions in WGs.	
1.	**Preparation**. Until the implementation of the AoA guidance[8], there are two possible scenarios: a) The eCA informs SECR that the active substance is a candidate for substitution and if it meets exclusion; and provides their analysis of alternatives (AoA)[9] (if available) and, when available, the non-confidential AoA submitted by the applicant and the justification on derogation to Article 5(2). The applicant's non-confidential AoA and justification[10], with their explicit consent, are published on the ECHA website as part of the consultation. If the eCA prepared their own AoA, the non-confidential version is also published on the ECHA website as part of the third-party consultation. b) In the absence of an AoA which can be published, the eCA provides SECR and the applicant with the minimum relevant information for the consultation: substance identity (name and EC/CAS numbers), PT, a description on the intended uses and the conditions of Article 10(1) of the BPR that are met.	eCA (As soon as the eCA decided on a limited evaluation)
	Applicant: Upon SECR request via R4BP 3: **c)** The applicant gives explicit consent to have the document published on the ECHA website as part of the consultation. **d)** The applicant reviews the text proposal to check for confidentiality issues and correctness of the information before the consultation is published.	Applicant (7 days)
2.	**Consultation.** SECR launches the consultation on the ECHA website.	SECR (7 days)
3.	**Input by third parties**. Once the information has been published, interested third parties provide information via webform.	Third parties (60 days)

4.	**Summary of the consultation**. All the input received in response to the consultation (compiled into confidential and non-confidential), and a brief description is prepared and provided to the WG and BPC via S-CIRCABC. The non-confidential contributions are also published in ECHA website. The eCA will refer to ECHA website for the public comments and provide the rest as a confidential annex to the AR. Comments received during consultation will be considered by the eCA and reflected in the BPC opinion, taking into account the confidentiality status of the information.	SECR (14 days)
	Applicant: The applicant will have access to the non-confidential input submitted during the consultation via the website for consultation.	

Table 2.2. Submission of draft AR and draft BPC opinion		**Responsible actor** (Indicative time limit)
5.	**Submission**. The eCA submits to the SECR through an ad hoc communication in R4BP 3: - The results of the evaluation in the form of an AR. The eCA should clearly identify all the changes introduced to the draft AR by highlighting them; - the draft BPC opinion, classified as "Restricted" [23]. 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 6a).	eCA (180 days after ECHA's acceptance of the application[12])
	Applicant: The applicant receives a copy of the draft AR via R4BP 3.	
6.	**Accordance check**. SECR performs a check to verify that the AR fulfils the requirements as indicated in Annex 5.1.3; which is limited to assessing the justification for a limited renewal.	SECR (14 days after the end of a submission window for the limited-evaluation renewal
	a) Accordance check: pass. The submission is accepted, and the evaluation will proceed to the commenting stage (see *3. Commenting phase*). The SECR informs the eCA of the result of the accordance check via R4BP 3. The eCA closes the evaluation task in R4BP 3 and the case is promoted; the ECHA opinion task is created.	SECR, eCA

[23] 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.

	b) Accordance check: fail. The AR and is returned to the eCA for modifications. The SECR informs the eCA of the result of the accordance check via R4BP 3, and the eCA will revise the AR, as well as the IUCLID dossier if necessary, and resubmit the AR[24].	SECR
7.	**Rapporteur**. SECR appoints the BPC rapporteur according to Article 17(2) of the BPC Rules of Procedure (RoPs).	SECR

Table 2.3. Commenting phase		**Responsible actor** (Indicative time limit)
8.	**Distribution of AR and draft BPC opinion**. SECR distributes the AR, the draft BPC opinion, the template for commenting and the outcome of the accordance check to the MSCAs[14] *via* the Interact Collaboration Tool.	SECR (Without delay)
	Applicant: The applicant will receive the AR, the draft opinion, and the template for commenting from the eCA via R4BP 3.	eCA (Without delay)
9.	**Commenting phase**. SECR launches the commenting phase by sending an e-mail to all BPC and WG members. MSCAs and SECR are expected to comment only on the sections of the draft AR which are changed compared to the initial approval or previous renewal and on the draft BPC opinion. The MSCAs use the template for commenting and upload their comments directly to the appropriate Collaboration in Interact indicated by the SECR in the launching message.	MSCAs, SECR, eCA (14 days)
	Applicant: The applicant may provide comments using the template for commenting to the eCA *via* ad hoc communication in R4BP 3. The eCA uploads these comments into the RCOMs available in Interact collaboration.	Applicant (14 days)

[24] Following a discussion between ECHA and the eCA, the opinion forming procedure might be aligned with the steps set out above in Table 1.

10.	**Trilateral discussions and RCOM**. **Discussions** As soon as MSCAs, applicant and SECR provide their comments, the eCA provides responses to them and approaches the commenting body with the aim of reaching an agreement. Discussions between the eCA and the MSCAs/SECR should take place directly in the RCOM tables available via Interact Collaboration. Discussions with the applicant should take place via R4BP 3. The eCA is responsible to include the comments received from the applicant in the relevant RCOM tables available in Interact Collaboration. An agreement to close a point should be reached by the eCA with the commenting and supporting MSCA(s) and, where relevant, the SECR. In case of a lack of reply from the commenting/supporting MSCA(s) and, where relevant, the SECR, the eCA will make a proposal whether the point is closed. For each open point, the eCA together with the commenting MS/SECR need to formulate a proposal for a question to be discussed at the BPC and include it in the RCOM. **Preparation of the consolidated RCOM** The eCA consolidates the RCOM (consolidated RCOM) by ensuring that the following is included: - all comments received, - all eCA responses, - the result of the discussions, e.g. the compromise wording that was agreed with the commenting body or an explanation why no such agreement could be reached, - a clear indication marking each point as open or closed, and- for each open point identification of the remaining open question for discussion at the BPC. The day following the end of this step, the SECR downloads the RCOM tables. The SECR locks those columns in the RCOM tables which were used for the commenting and discussions, uploads the consolidated RCOM tables back to the Interact Collaboration and informs the MSCAs by email on the start of the step - disagreement in closing a point (see step 10). Note: Any RCOM table shared with the applicant should not contain confidential business information from a third party.	eCA, MSCA, SECR, applicant (21 days)
	Applicant: The applicant receives the consolidated RCOM from the eCA via R4BP 3 and discusses bilaterally with the eCA on the responses.	eCA, applicant

11.	**Disagreement in closing a point**. The MSCAs have one week to request re-opening a closed point for discussion at the BPC directly, noting the disagreement in the consolidated RCOM tables available in Interact Collaboration tool. The 7-day timeline for this step is strict because of the preparation of the open issue table. If disagreement to closing a point is not communicated within the time limit, this will be considered as tacit agreement to close it. If the eCA and the commenting body agree to close a point, this point should still be marked by the eCA as provisionally closed. Note: Any consolidated RCOM table shared with the applicant should not contain confidential business information from a third party.	eCA, MSCA, SECR, applicants (14 days before the WG)
	Applicant: The eCA sends the consolidated RCOM tables after the discussion step (step 9) to the applicant for their information.	eCA (without delay)

Table 2.4. Biocidal Products Committee and preparations		**Responsible actor** (Indicative time limit)
12.	**Draft agenda.** The draft agenda for the BPC meeting is published on ECHA's website. An invitation is sent to the BPC members, applicants and ASOs.	SECR (21 days before the BPC)
	Applicant: The applicant should periodically check the ECHA website for the BPC agenda. The applicant can also anticipate the timing of the discussions based on the BPC Work Programme[16] published on ECHA's website. SECR will inform the applicant(s) of their applications being discussed at the BPC, as far as the appropriate contact information is available.	Applicant
13.	**Registration.** SECR opens the registration for members, advisers, ASOs and applicants. All participants register by the deadline.	SECR, BPC members, applicant (14 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.	
14.	**Open Issue table.** SECR prepares the open issue table in consultation with the eCA, by including in the open issue table all points that the eCA marked as open in the updated RCOM (step 10) and those reopened under disagreement in closing a point (step 11). The eCA provides their responses. **Distribution of the documents for BPC**. The SECR distributes the open issue table, the draft AR and the draft BPC opinion via the Interact meetings as open issue document and basis for discussion at the BPC meeting.	SECR (10 days before the BPC meeting)

	Applicant: SECR provides the open issue table, the draft AR, and the draft BPC opinion via ad hoc communication in R4BP 3.	
15.	**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 makes these documents available to BPC members via Interact meetings and the applicant via ad hoc communication in R4BP 3.	eCA; MSCAs; SECR (10 days before the BPC meeting)
16.	**BPC meeting**. The 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 at the BPC meeting. The ASOs have access to the draft opinions but not to other documents concerning the substances under consideration.	n.a.
	Applicant: The applicant may participate in the discussion at the BPC meeting.	

Table 2.5. Finalisation and dissemination steps		**Responsible actor** (Indicative time limit)
17.	**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 (18 days after the BPC meeting)
18.	**BPC opinion finalisation and publication**. The SECR, in consultation with the eCA, finalises the BPC opinion according to the agreements at the BPC and forwards it to COM. The finalised opinion document is published on the ECHA website. Minority positions have to be submitted to the SECR by the involved member within 7 days after the BPC meeting.	SECR (18 days after the BPC meeting)
19.	**Renewal documents finalisation and publication** In parallel with the opinion finalisation step, the eCA provides the SECR with: • An updated list of companies that supported the AS renewal. • The non-confidential version of the final list of 'relevant data'[18] identified by the eCA, taking account all studies submitted for the AS renewal, including those submitted during the opinion forming[19]. The SECR publishes in ECHA website the non-confidential list of 'relevant data'.	eCA; SECR (18 days after the BPC meeting)
20.	**Updating the AR and IUCLID file**. The eCA provides to SECR via R4BP 3 the final AR based on the agreements reached at the BPC. The eCA updates the relevant annotations in the IUCLID file based on the discussions and agreements.	eCA (42 days after the BPC meeting)

21.	**AR distribution**. The confidential AR is available to the MSCAs in the relevant cases/asset in R4BP 3.	N.A.
22.	**Confidentiality check for the AR and IUCLID file.** The applicant will provide to the eCA the AR and also the IUCLID file, indicating any confidentiality claims to ensure that no confidential information is disclosed to the public[21] (if still relevant as normally the confidentiality check should take place during the evaluation phase).	Applicant (72 days after the BPC meeting)
23.	**Non-confidential AR and IUCLID file.** The eCA will assess the confidentiality claims[22]. It will prepare a non-confidential version of the AR and IUCLID file and provide them to SECR[21] together with any confidential annexes. The submission is done via R4BP 3.	eCA (120 days after the BPC meeting)
24.	**Dissemination.** The non-confidential AR is disseminated. The non-confidential IUCLID extract is also disseminated in case of a renewal proposal. ECHA disseminates the relevant information on the ECHA website: http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances.	ECHA (without delay)

4. Definitions and acronyms

Abbreviation	Definition
AoA	Analysis of alternatives
AR	Assessment Report of the competent authority for approval and renewal of active substances
ASO	Accredited Stakeholder Organisation
BPC	Biocidal Products Committee
BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
S-CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
COM	European Commission
eCA	Evaluating Competent Authority
ECHA	European Chemicals Agency
MSCA	Member State Competent Authority
n.a.	Not applicable
R4BP 3	Register for Biocidal Products
RCOM	Response to comments table
RoPs	Rules of procedure for the Biocidal Products Committee
SECR	ECHA Secretariat
TM	Technical Meeting
WG	Working Group

5. Annexes

5.1 Accordance check

Fulfilling the following criteria would constitute a "pass" in the accordance check performed on the AR following the submission by the eCA. If one of the conditions is not fulfilled, the result is "fail".

5.1.1 Criteria concerning all ARs

1) An AR is provided in the correct format, and it is complete.

   Using the AR template, all sections must be included and filled. In principle, the AR template provided for applications under the BPR should be used. It is however still possible to submit evaluations using the template provided for applications under the BPD e.g. for ARs that are near to finalisation or whose finalisation has been delayed due to missing guidance, or where an evaluation of a new PT can be provided using a AR submitted earlier for another PT (see 3.1 Submitting ARs). When this BPD format is used, the submission must also contain the Conclusion section of the new AR template. The draft BPC opinion is also provided at the accordance check.

2) The AR unambiguously specifies the proposed conclusion on the approval or non-approval of the active substance and any conditions for the approval.

3) The AR includes explicit reporting of the fulfilment of exclusion criteria and the criteria for candidates for substitution. Each of the criteria needs to be discussed individually, clearly indicating whether the criteria are fulfilled or not. The exclusion and substitution criteria need to be assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR" and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

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[25].

   The comments provided by the applicant need to be taken into account when finalising the evaluation.

6) Any additional information the applicant provided as requested has been taken into account.

[25] Not applicable for renewal applications with limited evaluation

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

7) In case of multiple applications for one substance, the evaluation is provided in a single AR.

8) A proposal for a reference specification and reference source(s) is available.

9) Early Working Group discussion
The agreements from early Working Group discussion(s) should be adequately incorporated in the draft AR.

10) An assessment of endocrine disruption is included in the AR.

11) In case of AS renewal, the 'relevant renewal data'[26] are clearly identified in appendix V of the AR (see combined template) or separate Appendix.

12) The uses assessed and the concentrations used in the HH and ENV exposure estimation are consistent with the EFF section.

5.1.2 Additional criteria for AS/PT combinations in the Review Programme

These additional criteria are as set out in Regulation (EU) No 1062/2014 (the Review Programme Regulation) and as agreed at the Competent Authority meeting on 13 September 2013.

The requirements for submissions of ARs in the Review Programme are as follows, depending on the status of the dossier and the properties of the active substance:

Substances considered to meet the exclusion criteria:

a. If the CMR-based exclusion criteria are met, the RAC opinion on harmonised C&L needs to be available at the time of submitting the AR[27].

b. If the PBT/vPvB criteria are met, the recommendation of the PBT Expert Group, if consulted by the eCA, needs to be available at the time of submitting the AR[27].

c. If the substance is considered as an endocrine disruptor, the recommendation of the ED Expert Group, if consulted by the eCA, needs to be available at the time of submitting the AR[27].

Active substances meeting the exclusion criteria for which the AR is submitted after 1 September 2013 can normally not be approved unless the conditions of Article 5(2) are met (see CA-Nov14-Doc4.5 -Final -Further guidance on application of Article 5(1) and 5(2) on

[26] CA-Sept20-Doc.7.1.b - Relevant Renewal Data under Article 95_FINAL.

[27] CA meeting agreement *CA-Nov14-Doc.4.5 – Final.* The ED or PBT EG can be consulted by the eCA on the assessment for these properties. In Regulation (EU) No 1062/2014 it is stated in Article 6(7)(b) that the Agency needs to be consulted if the eCA considers that an active substance is meeting the criteria of Article 5(1)(d) or (e) or the conditions of Article 10(1)(d). With respect to this working procedure "consultation" is interpreted that either the PBT/vPvB or ED assessment is discussed in the opinion forming process in the relevant Working Group(s) and BPC, where this assessment may in addition have been discussed in the ED or PBT EG. Discussion at these Expert Groups is not a requirement as in clear cases it is considered sufficient to discuss the assessment only in the relevant Working Groups.

exclusion criteria). A proposal on whether the conditions of Article 5(2) are met needs to be included in the AR by the eCA. This proposal can be included by the eCA in the AR after the results of the consultation are available (see step 1 of Tables 1 and 2) or submitted to ECHA in step 2 of Table 1.

Substances considered to meet the substitution criteria:

d. If the substitution criteria are met because of CMR properties, it is highly preferable and therefore strongly recommended that the RAC opinion on harmonised C&L is available at the time of submitting the AR[27]. In any case a CLH dossier needs to have been submitted by the time of submitting the AR[27].

e. If 2 out of 3 of the PBT criteria are met, it is highly preferable and therefore strongly recommended that the recommendation of the PBT Expert Group, if consulted by the eCA, is available on the PBT/vPvB status at the time of submitting the AR[27].

Substances not considered to meet the exclusion or substitution criteria:

f. If changes are proposed to an already existing harmonised classification, or no harmonised classification is available for the active substance, a CLH dossier needs to have been submitted by the time of submitting the AR[27].

g. If the eCA proposes Muta. 2 classification, the RAC opinion on CLH needs to be available at the time of submitting the AR, because the risk characterisation may be very restrictive as exposure would need to be minimised without an identifiable threshold of safety[28].

5.1.3 Criteria for renewal with limited evaluation applications

Fulfilling the following criteria would constitute a "pass" in the accordance check performed on the AR of a limited evaluation following the submission by the eCA. If one of the conditions is not fulfilled, the result is "fail".

a) The eCA submit an AR and draft opinion.

b) The original or previous assessment report contain an assessment of the substitution and exclusion criteria including ED properties of the active substance according to the criteria in Commission Delegated Regulation (EU) No 2017/2100, and there is no new data that could question the validity of the key conclusions of this assessment.

c) The new data available, including any post-approval data requirement for the renewal specified in the BPC opinion of the initial/previous approval, is limited and not expected to impact either the key conclusions of the exclusion and substitution criteria, assessment on hazards, risks or efficacy or the conditions of the approval.

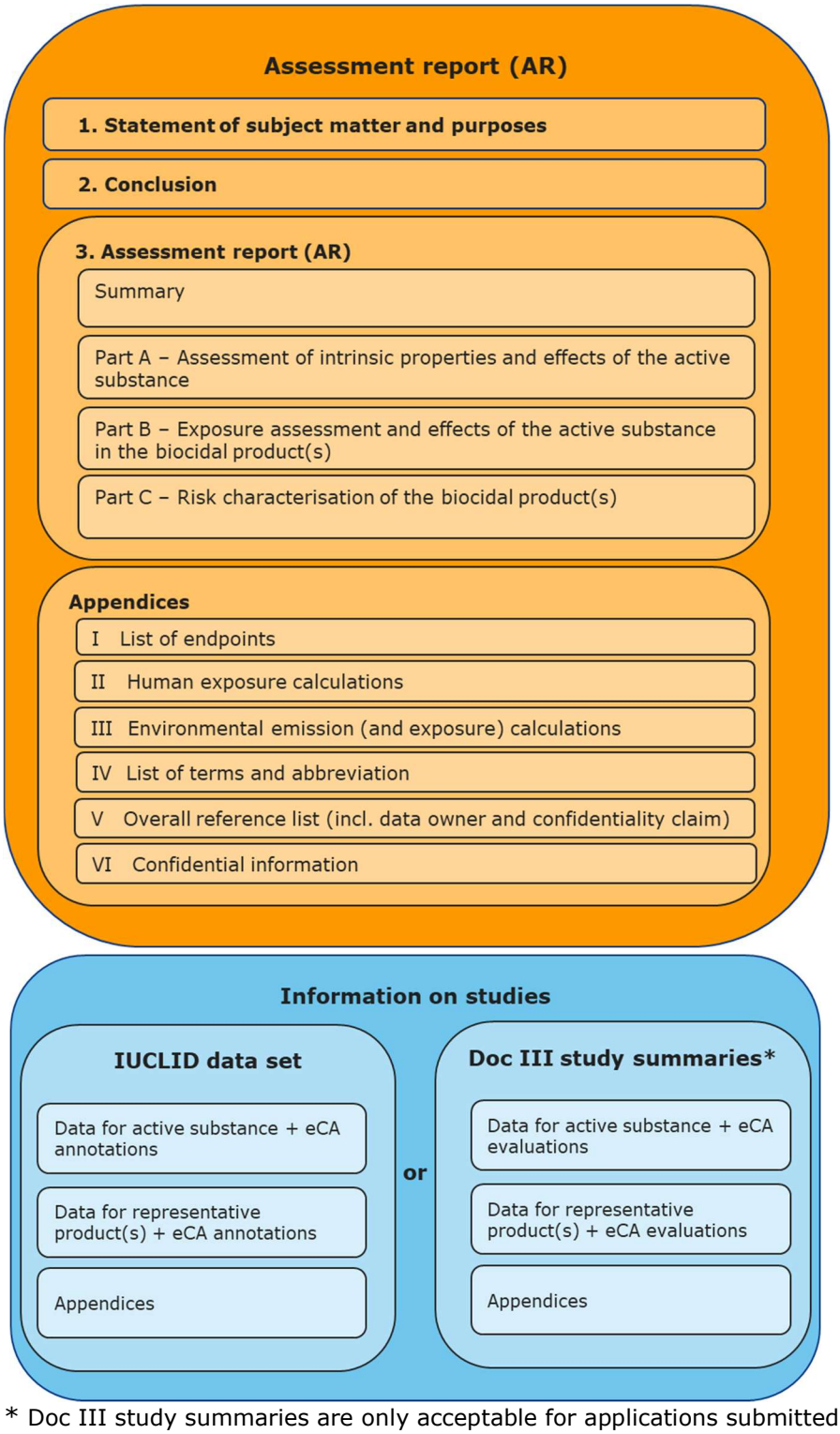
d) There is no need for re-assessment of data considered in the previous assessments or any re-assessment is not expected to impact either the key conclusions of the assessment on hazards, risks or efficacy or the conditions of the approval.

[28] BPC 2019 agreement: BPC-29-2019-13.

5.2 AR structure and terminology

The structure of the AR is indicated in Figure 3 below.

Figure 3. *Documents provided by the eCA (format as agreed by the BPC).*



* Doc III study summaries are only acceptable for applications submitted under the BPD.

5.3 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

3. Confidentiality claims check: key steps and guidelines. CA-March14-Doc.7.2.1 - Biocide confidentiality requests key steps and guidelines.docx.

   Available at CIRCABC:

   - Path: /CircaBC/env/BPR - Public/Library/CA meetings/55th CA meeting March 2014
   - https://circabc.europa.eu/w/browse/af767168-75db-4e3e-8f32-2d53a850d54e

4. Confidentiality claims check: separate assessment by ECHA. CA-March14-Doc.7.2.2 - Biocide confidentiality requests subsequent assessment by ECHA.docx.

   Available at CIRCABC:

   - Path: /CircaBC/env/BPR - Public/Library/CA meetings/55th CA meeting March 2014
   - https://circabc.europa.eu/w/browse/af767168-75db-4e3e-8f32-2d53a850d54e

5. Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2). CA-Nov14-Doc.4.5 - Final - Processus Art 5(1)&(2).doc

   Available at CIRCABC:

   - Path: /CircaBC/env/BPR - Public/Library/documents_finalised/CA-Nov14-Doc.4.5 - Final - Processus Art 5(1)&(2).doc
   - https://circabc.europa.eu/w/browse/eaae0dc2-1715-4906-a5d5-af3932fcd7c9

6. Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR. CA-Nov14-Doc.4.4 - Final - Further guidance on Art10(1).doc

   Available at CIRCABC:

   - Path: /CircaBC/env/BPR - Public/Library/documents_finalised/CA-Nov14-Doc.4.4 - Final - Further guidance on Art10(1).doc
   - https://circabc.europa.eu/w/browse/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c

5.4 Links

1. Template for AR and for draft risk assessment.

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

2. Website of the Biocidal Products Committee.

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

3. Website of the Working Groups of the BPC.

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

5.5 Summary of the case relevant documents - mapping for MSs

For approval and full evaluation renewal

Section	Step[29]	Type of document	Location of the documents
1. Consultation on CfS (per BPC Article 10(3))	Summary of the consultation (4)	• Summary of the consultation • Confidential comments • Non-confidential comments • AoA (when available)	S-CIRCABC (non-confidential documents -also on ECHA website)
2. Submission of the AR	Submission (5)	• Draft AR • 30d-RCOM	R4BP3 under the relevant case
	Accordance check (6)	• Outcome of the accordance check	R4BP3 under the relevant case
3. Commenting phase	Distribution of AR (8)	• Draft AR • 30d-RCOM • The outcome of the accordance check • Template for commenting	Interact collaboration
4. Working Group meeting and preparations	Trilateral discussions and updated RCOM (14) Disagreement in closing a point (15)	• Draft AR • 30d-RCOM • RCOM	Interact collaboration
	Discussion table (16) Other documents (17)	• Discussion tables for WGs • Other WG documents	Interact meetings
	Distribution of conclusions and action points (22)	• Discussion table with conclusions, action points and deadlines	Interact meetings
5. Ad hoc follow-up (if applicable)	Reporting point closed/opened (25/26)	• In the draft minutes of the WG (See section 6. Minutes of the Working Group)	
6. Minutes of the Working group meeting	Draft minutes (27)	• The draft minutes in the form of discussion table	Interact collaboration
	Updating minutes (29)	• Revised minutes	Interact meetings
	Finalising minutes (30)	• The revised minutes • The final/agreed minutes	Interact meetings
7. Biocidal Products	Submitting the	• Updated AR	R4BP3 under the

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

Committee and preparations	updated AR and the draft BPC opinion (34)	• Draft BPC opinion	relevant case
	Distribution (67)	• Updated AR • Study summaries • Draft BPC opinion • Template for commenting	Interact Collaboration
	Open issues (39)	• Open issues document • Updated AR • Study summaries • Draft BPC opinion	Interact meetings
	Other documents (40)	• Any other documents (where applicable)	Interact meetings
8. Finalisation and dissemination steps	Finalisation of the open issues document (42)	• Final open issues document	Interact meetings
	BPC opinion finalisation and publication (43)	• BPC opinion	R4BP3 under the relevant case
	Renewal documents finalisation and publication (only for renewals) (44)	• Non-confidential version of the final list of relevant data • Updated list of companies that supported the AS renewal	R4BP3 under the relevant case
	Updating the AR and IUCLID file (or Doc III) (45)	• Final AR • Study summaries	R4BP3 under the relevant case
	Non-confidential AR and IUCLID file or Doc IIIA (48)	• Redacted final AR • Redacted study summaries	R4BP3 under the relevant case
	Dissemination (49)	• The BPC opinion • Redacted final AR • Redacted study summaries • Relevant renewal data (only for renewals)	On the ECHA website

For limited evaluation renewal

Section	Step[29]	Type of document	Location of the documents
1. Consultation on CfS (per BPC Article 10(3))	Summary of the consultation (4)	• Summary of the consultation • Confidential comments • Non-confidential comments • AoA (when available)	S-CIRCABC (non confidential documents -also on ECHA website)
2. Submission of the AR and draft BPC	Submission (5)	• Draft AR • Draft BPC opinion	R4BP3 under the relevant case

opinion	Accordance check (6)	• Outcome of the accordance check	R4BP3 under the relevant case
3. Commenting phase	Distribution of AR and draft BPC opinion (8)	• Draft AR • Draft BPC opinion • The outcome of the accordance check • Template for commenting	Interact collaboration
	Trilateral discussions and updated RCOM (10) Disagreement in closing a point (11)	• Draft AR • Draft BPC opinion • RCOM	Interact collaboration
4. Biocidal Products Committee and preparations	Distribution of the documents for BPC (14)	• Draft AR • Study summaries • Draft BPC opinion • Open issue table-RCOM	Interact meetings
	Other documents (15)	• Any other documents (where applicable)	Interact meetings
5. Finalisation and dissemination steps	Finalisation of the open issues document (17)	• Final open issues document	Interact meetings
	BPC opinion finalisation and publication (18)	• BPC opinion • Non-confidential version of the final list of relevant data • Updated list of companies that supported the AS renewal	R4BP3 under the relevant case
	Updating the AR and IUCLID file (20)	• Final AR • Study summaries	R4BP3 under the relevant case
	Non-confidential AR and IUCLID file (23)	• Redacted final AR • Redacted study summaries	R4BP3 under the relevant case
	Dissemination (24)	• The BPC opinion • Redacted final AR • Redacted study summaries	On the ECHA website