Working procedure for active substance approval

Version 6.0

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) 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**
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 CARs 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
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:	25 April 2018 at

	• Clarification on tasks eCA with respect to whether the conditions of Article 5(2) is met in section 5.1.2.	BPC-25

1. Purpose

This document establishes the working procedures of the BPC for the peer review process of biocidal active substance evaluation. According to the Biocidal Products Regulation (BPR) the opinion on the approval 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).

2. Scope

This document details the steps to be taken during the peer review process of an active substance under the BPR. The steps covered are those starting from the eCA submitting the Competent Authority Report (CAR) until the dissemination of the finalised opinion of the BPC. The steps are described for all the 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 CARs submitted by the 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, and the actual binding calendar dates for each step are given in the separate document “Timelines for the peer review of active substance evaluations”. The actions and responsibilities of the applicant are included separately in Table 1 below each relevant step.

3.1 Submitting CARs

CARs should be submitted in the agreed format[2]. If the eCA wishes to use the old format, they should contact the ECHA dossier manager as early as possible to ensure that the eCA and ECHA are in agreement on the format to be used (see 3.4 Communications).

SECR will perform an accordance check for each CAR submitted by the eCAs to verify that the CAR can proceed to peer review (see 5.1 Accordance check). The 270-day timeline begins on the predefined date given in *Timelines for the peer review of active substance evaluations*, following the CAR submission and provided that the conclusion of the accordance check is positive. Failing to pass the accordance check will result in returning the CAR to the eCA for revision and submission of the revised CAR 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 old format (Document III), this will be considered as acceptable also when submitting the CAR. This is valid regardless of whether the CAR is in

[1] eCA in the working procedure 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] https://echa.europa.eu/documents/10162/17169198/car_template_eca_en.doc

the new or old format; note that the study summaries or the IUCLID dossier are not part of the CAR (for further information see 5.2 CAR structure and terminology).

3.3 Specific rules for CARs submitted before 1 September 2013

Active substances for which CARs 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 new format in order to address the change in legislative context and the exclusion and substitution criteria.

Active substances for which CARs 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 Communications

All formal communications will take place through either R4BP 3 or S-CIRCABC Interest Groups (IG). The applicant will communicate with eCA and SECR through R4BP 3. Any documents outside of R4BP 3 will be distributed via S-CIRCABC, which will be restricted to members/alternates/ advisers/rapporteurs of the BPC and the WGs. During the peer review process up to the BPC discussions) the eCA is responsible for all communication with the applicant: this means from the first step to step 34 in Table 1. This is indicated in detail in the individual steps in Table 1.

The contact point between the eCA and SECR is the dossier manager (DM) 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-bpc-active-substance@echa.europa.eu for issues related to active substance approval and the related process and procedures.

These functional mailboxes have to be used for those steps in table 1 where the communication with the SECR is not indicated to take place via R4BP 3 or S-CIRCABC.

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

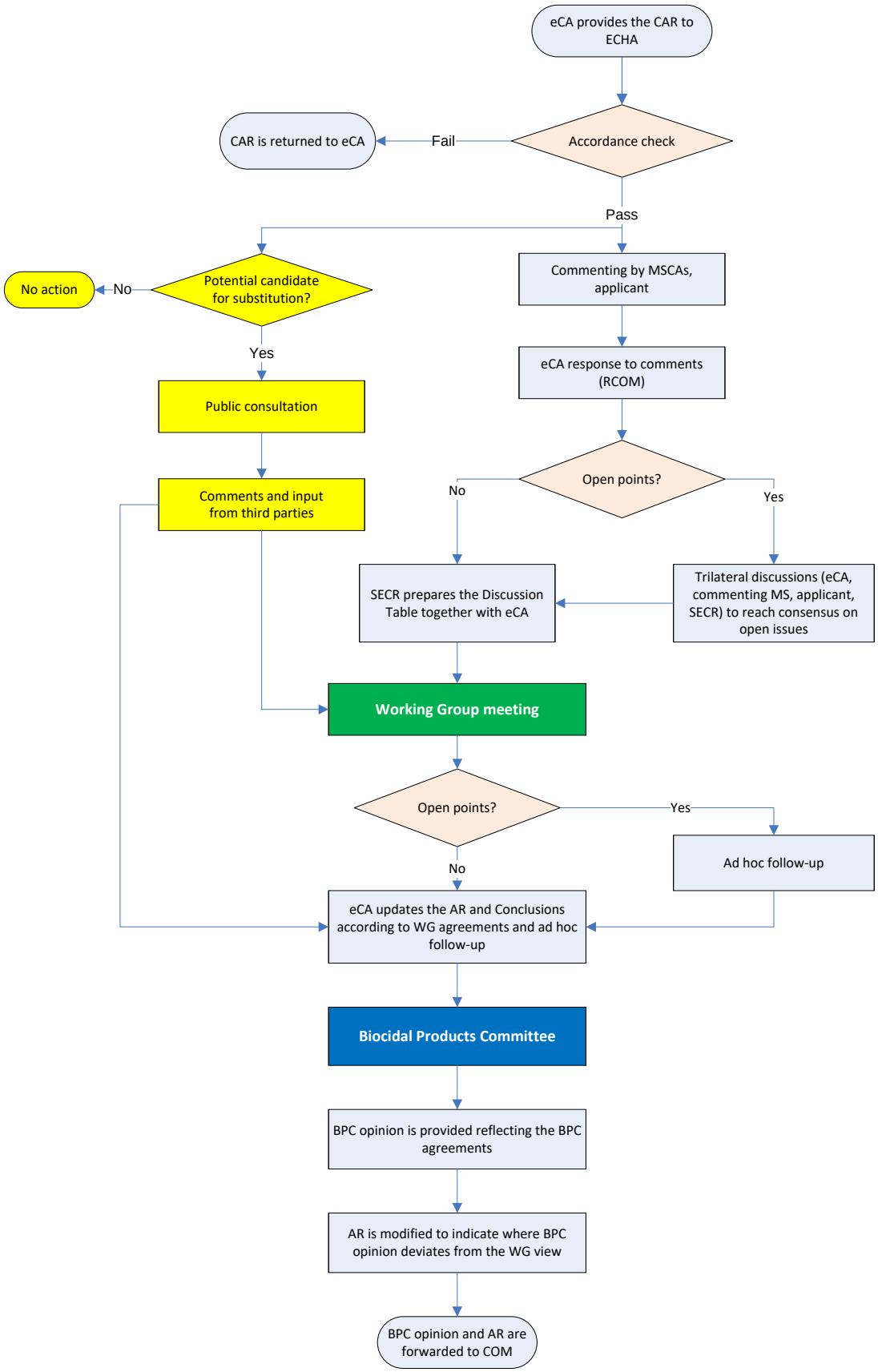


Table 1. *Description of the steps in the biocidal active substance peer review process*

1. Submission of CAR		**Responsible actor** (Approximate time limit)
1.	**Submission**. The eCA submits the results of the evaluation in the form of a CAR including the reference specification and reference source(s) either as an annotated IUCLID dossier or study summaries (Doc III). Please see 3.2 Submitting other documents for information on using the old format (study summaries in Doc III). The submission should be done via R4BP 3 ad hoc communication. 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 2a).	eCA (365 days after validation of application)
2.	**Accordance check**. SECR performs a check to verify that the CAR 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 public consultation, if relevant (see 2. *Public 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
	b) Accordance check: fail. The CAR and the IUCLID dossier are 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 and resubmit the CAR, as well as the IUCLID dossier, if necessary.	SECR
3.	**Rapporteur**. SECR appoints the BPC rapporteur according to Article 17(2) of the BPC RoPs	SECR

2. Public consultation[3]		**Responsible actor** (Approximate time limit)
	These steps are performed only if the eCA proposes the active substance to be a potential candidate for substitution. Where relevant, public consultation is always performed before scheduling discussions in WGs.	
4.	**Public consultation**. SECR drafts the text for public consultation and submits it to the applicant via R4BP 3 and to the eCA for consultation before publishing. In addition to the substance identity (name and EC/CAS numbers), the public consultation indicates the PT and eCA, describes the intended uses and indicates the conditions of BPR Art 10(1) that are met.	SECR (14 days after accordance check)
	Applicant: The applicant will review the text proposal to check for confidentiality issues and correctness of the information before the consultation is published.	Applicant (Without delay)

[3] Public consultation is parallel to 3. *Commenting phase*.

5.	**Input by third parties**. Once the information has been published, interested third parties provide information via the templates for confidential and non-confidential submissions.	Third parties (60 days)
6.	**Summary of the public consultation**. All the input received in response to the public consultation and a brief description is prepared and provided to the WG and BPC via S-CIRCABC and the eCA will then include this as a confidential annex to the CAR. Comments received during public consultation will be taken into account 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 public consultation via the website for public consultation.	

3. Commenting phase[4]		**Responsible actor** (Approximate time limit)
7.	**Distribution of CAR**. SECR distributes the CAR and a template for commenting to the MSCAs[5] *via* S-CIRCABC Biocides Active Substances IG. Study summaries will also be distributed if a IUCLID dossier is not available.	SECR (Without delay)
	Applicant: The applicant will receive the CAR and the template for commenting from the eCA via R4BP 3.	eCA, (Without delay)
8.	**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 S-CIRCABC newsgroup forum indicated by the SECR in the launching message.	SECR (Without delay) MSCAs (35 days)
	Applicant: The applicant may provide comments using the template for commenting and send these via R4BP 3 to eCA. The eCA uploads these comments to the respective S-CIRCABC newsgroup forum.	Applicant, eCA (35 days)
9.	**Response to comments table (RCOM)**. As soon as the MSCAs, SECR and applicant 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/applicant agrees with the response, and include information on this in the table. The eCA sends this RCOM to SECR *via* S-CIRCABC and to the applicant via R4BP 3. The eCA clearly marks as confidential any comments on confidential information. The eCA submits the RCOM in the same Newsgroup forum where the comments were collected and informs the SECR.	eCA, MSCA, (28 days)

[4] Commenting phase is parallel to 2. *Public consultation*.
[5] MSCA in the working procedure refers to any MSCA representative having access to the S-CIRCABC interest groups for BPC or BPC Working Groups.

	Applicant: The applicant receives the RCOM from the eCA and will discuss bilaterally with the eCA on the responses.	Applicant (28 days)

4. Working Group meeting and preparations		**Responsible actor** (Approximate time limit)
10.	**Draft agenda.** The provisional draft agenda for the WG meeting is published on ECHA website and in S-CIRCABC.	SECR (21 days[6] 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 Work Programme[7] indicates the substances which are scheduled to be discussed in the upcoming WG meetings.	Applicant
11.	**Invitations for the WG meeting.** SECR will send invitations to WG members and Accredited Stakeholder Organisation representatives.	SECR (21 days[6] before the WG)
	Applicant: SECR will inform those applicants having indicated their interest of the discussion on their application and provide the link to register to the meeting.	
12.	**Registration.** Registration is opened for members, applicants, rapporteurs and stakeholders. The deadline provided in the invitation should be respected. • All core members are expected to register.	SECR (21 days[6] 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.	Applicant
13.	**Trilateral discussions**. Immediately following the RCOM distribution (steps 9-10), the eCA will contact the commenting MSCAs/applicant and SECR in order to continue discussions, with the intention to reach an agreement for each open issue before providing the updated RCOM (step 14). The SECR (biocides-bpc-active-substance@echa.europa.eu) should be kept in copy to all messages.	eCA (ending 26 days before the WG)
	Applicant: The applicant may discuss any open points trilaterally with the eCA and SECR.	Applicant
14.	**Updated RCOM**. The eCA provides to SECR and the applicant an updated RCOM including all agreements achieved. The eCA marks all points as closed or open and highlights the open points by colour coding. The updated RCOM should be uploaded in the same Newsgroup topic in S-CIRCABC were the comments were collected.	eCA (21 days before the WG)

[6] 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.
[7] Available at the Committee home page at http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee.

	Applicant: The eCA provides the updated RCOM to the applicant via R4BP 3.	eCA
15.	**Disagreement in closing a point**. The MSCAs and the applicant have one week to request re-opening a point for discussion at the WG. The request should be directed to the SECR, copying the eCA. It is important to note that the timeline for this must be 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)
16.	**Discussion table**. SECR prepares columns[8] 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 updated RCOM (step 16). 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 agreed 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* S-CIRCABC (BPC Working Groups IG).	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 S-CIRCABC 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-bpc-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 approval/non-approval of the a.s. 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 approval/non-approval of the a.s. and/or on the fulfilment of exclusion or substitution criteria.	Applicant

[8] a) Running number; b) Issue and background, Ref. in RCOM; c) WG discussion, *ad hoc* follow-up where relevant; d) Open/closed point, Conclusions; e) Action points, Deadlines

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 columns[8] d) and e) of 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 25-29); the members are indicated in column[8] e) of 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 S-CIRCABC after the WG meeting. Note that these are not the minutes of the WG meeting as the discussions are included in column[8] c) 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.	

5. Ad hoc follow-up		**Responsible actor** (Approximate time limit)
These steps are followed only if there are open points after the WG meeting. Ad hoc follow-up will not be used for 'early' WG discussions, i.e. those taking place before the eCA has submitted the CAR.		
23.	**Ad hoc follow-up discussion** Following the WG meeting, the SECR will initiate discussions with all participants of the ad hoc follow-up group established at step 23. The intention is to reach an agreement for all remaining critical 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.	
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 CAR 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[8] 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

6. Minutes of the Working Group meeting		**Responsible actor** (Approximate time limit)
27.	**Minutes**. Column[8] c) of the discussion table is drafted by SECR after the WG meeting and the file is named as the draft minutes. These draft minutes are distributed to MSCAs via S-CIRCABC and a Newsgroup for commenting is created under Working Groups IG.	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 send their comments to the appropriate newsgroup forum in S-CIRCABC. Comments should concern only the WG meeting discussion in column[8] c) unless a clear error is identified elsewhere.	MSCAs; (21 days before the next WG)
	Applicant: The applicant may send comments on the minutes to SECR via R4BP 3.	
29.	**Updating minutes**. SECR will revise the minutes and distribute them to MSCAs via S-CIRCABC. 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 S-CIRCABC. 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

7. CARs coming from Technical Meetings (TM)		Responsible actor (Approximate time limit)
These additional steps are necessary when the technical discussions were finalised in the TMs and not in WGs.		
31.	**Updated CAR**. The eCA will send the updated CAR to SECR via R4BP 3 and upload the document in the respective Newsgroup forum in S-CIRCABC.	eCA (70 days before BPC meeting[9])
	Applicant: The eCA provides the updated CAR to the applicant indicating the deadline for commenting via R4BP 3.	
32.	**CAR commenting**. SECR creates a Newsgroup forum for commenting the CAR and communicates the link to MSCAs.	SECR (without delay)
33.	**Commenting period**. The MSCAs upload their comments directly to the appropriate S-CIRCABC Newsgroup forum.	MSCAs, Applicant (30 days commenting period)
	Applicant: The applicant may send comments via R4BP 3 to eCA. The eCA uploads these comments to the respective S-CIRCABC newsgroup forum.	
34.	**Decision on the need to consult WG**. Based on the comments received, SECR will decide in consultation with the eCA whether a discussion at one or more WGs is still necessary before the CAR can proceed to the BPC.	SECR (without delay)

8. Biocidal Products Committee meeting and preparations		Responsible actor (Approximate time limit)
35.	**Draft agenda.** The draft agenda for the BPC meeting is published on ECHA website. An invitation is sent to the BPC members 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 Work Programme[10] published at the ECHA 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
36.	**Registration.** SECR opens the registration for members, advisers, ASOs and applicants.	SECR (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.	
37.	**Registration deadline for the BPC meeting.** The participants will register for the meeting by the deadline.	Members (14 days before the BPC)

[9] This is to allow sufficient time for steps 36 and 37 and for the eCA to consider the comments before providing the draft opinion and AR (steps 42 and 44). The SECR publishes the deadlines for each substance in the BPC work programme.

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

	Applicant: The same registration deadline concerns the applicant.	Applicant (14 days before the BPC)
38.	**SECR-eCA dialogue**. Immediately following the WG meeting (for CARs coming from TM, following the 30-day commenting period), 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)
39.	**Submitting the updated CAR**[11]. The eCA will begin modifying the CAR 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 CAR and the draft BPC opinion to SECR *via* R4BP 3. Where the BPD CAR 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 CAR to the applicant via R4BP 3.	
40.	**Distribution**. SECR distributes the Assessment Report or if in the old format used under the BPD the updated Document II to MSCAs *via* S-CIRCABC	SECR (without delay)
	Applicant: SECR provides the AR or if in the old format the updated Document II to the applicant via R4BP 3.	
41.	**Checking the updated CAR.** It is up to each commenting MSCA to ensure that all the agreements in the RCOM and discussion table are carried over to the updated CAR. If an agreement is found to be disregarded in the updated CAR, the MSCA should contact the eCA and SECR without delay.	All MSCAs (22 days before the BPC meeting)
	Applicant: The applicant can ensure that the agreements are carried over to the updated CAR and if relevant should contact the eCA and SECR without delay.	
42.	**Drafting BPC opinion**. The SECR will finalise the draft BPC opinion in cooperation with the eCA.	SECR; eCA (20 days before the BPC meeting)
43.	**Distribution**. SECR distributes the draft BPC opinion to MSCAs *via* S-CIRCABC.	SECR (20 days before the BPC meeting)
	Applicant: SECR provides the draft BPC opinion to the applicant via R4BP 3.	
44.	**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 and to the applicant via R4BP 3.	eCA; MSCAs; SECR (10 days before the BPC meeting)

[11] The CAR refers to the Assessment Report and Conclusions. If the old format is still used, this refers to Documents I and II, and confidential annexes if relevant (as well as the AR that is essentially Doc I renamed at the BPC stage). Together with the CAR the reference specification and reference source(s) must be submitted.

45.	**Commenting period.** The MSCAs and SECR may provide written comments on the AR and the draft opinion, especially where issues have not been included as agreed earlier in the process. SECR will open a dedicated newsgroup in S-CIRCABC for each substance. **Applicant**: The applicant may provide written comments to SECR via R4BP3.	MSCAs, SECR (10 days before the BPC meeting)
46.	**Open issues.** 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. **Applicant:** SECR provides the *open issues* document to the applicant via R4BP 3.	SECR (5 days before the BPC meeting)
47.	**BPC meeting**. BPC adopts the opinion unless written procedure is requested (see Rules of Procedure). Subject to the agreement of the applicant, the accredited stakeholder organisations (ASO) may be present. The ASOs have access to the draft opinions but not to other documents concerning the substances. **Applicant:** The applicant may participate in the discussion at the BPC meeting.	n.a.

9. Finalisation and dissemination steps		**Responsible actor** (Approximate time limit)
48.	**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.	SECR (18 days after the BPC meeting)
49.	**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 website of the BPC. 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)
50.	**Updating the CAR[11] and IUCLID file or Doc III**. The eCA provides to SECR the updated CAR based on the discussions and agreements. The assessment report should be provided in both a non-confidential version which will be disseminated, and the confidential version. The submission is done via R4BP 3. The eCA updates the IUCLID file or Doc III based on the discussions and agreements (if still relevant as normally the confidentiality check should take place during the evaluation phase, the eCA provides them to the applicant for a confidentiality check: see step 52).	eCA (42 days after the BPC meeting)
51.	**AR distribution**. SECR makes the confidential AR available to the MSCAs *via* S-CIRCABC in Active Substance IG.	SECR (Without delay)

52.	**Confidentiality check for the IUCLID file or study summaries.** The applicant will provide to the eCA the files indicating any confidentiality claims to ensure that no confidential information is disclosed to the public[12]. Steps 51, 52 and 54 will only apply in case of an approval decision.	Applicant (72 days after the BPC meeting)
53.	**Non-confidential IUCLID file or Doc IIIA.** The eCA will assess the confidentiality claims and prepare a non-confidential version of the IUCLID/Doc IIIA and provide them to SECR[12] together with any confidential annexes. The submission is done via R4BP 3.	eCA (120 days after the BPC meeting)
54.	**Distribution of the IUCLID file or Doc IIIA.** The SECR will make the confidential files available to the MSCAs via S-CIRCABC.	SECR (without delay)
55.	**Dissemination.** 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
AR	Assessment Report
BPC	Biocidal Products Committee
BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
CAR	Competent Authority Report (in the new CAR format the CAR consists of the Assessment Report and Conclusions; the IUCLID dossier is not a part of the CAR)
S-CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
COM	European Commission
DM	(ECHA) Dossier Manager
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

[12] 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

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 CAR following the submission by the eCA. If one of the conditions is not fulfilled, the result is “fail”.

5.1.1 Criteria concerning all CARs

1) A CAR is provided in the correct format and it is complete.

   Using the CAR template, all sections must be included and filled. In principle, the CAR 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 CARs 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 CAR submitted earlier for another PT (see 3.1 Submitting CARs). When this old format is used, the submission must also contain the Conclusion section of the new CAR template, which will later in the process be used as the basis for the draft BPC opinion.

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

3) The CAR 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.

   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.

   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 CAR needs to reflect this information.

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

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

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

These additional criteria are as set out in Regulation 1062/2014 (the Review Programme Regulation) and as agreed at the Competent Authority meeting on 13 September 2013.

The requirements for submissions of CARs 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 CAR[13].

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 CAR[13].

c. If the substance is considered as an endocrine disrupter, the recommendation of the ED Expert Group, if consulted by the eCA, needs to be available at the time of submitting the CAR[13].

Active substances meeting the exclusion criteria for which the CAR 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 exclusion criteria). A proposal on whether the conditions of Article 5(2) are met needs to be included in the CAR by the eCA. This proposal can either be included by the eCA in the CAR submitted to ECHA in step 1 of Table 1 or after the results of the public consultation are available (see step 6 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 CAR[13]. In any case a CLH dossier needs to have been submitted by the time of submitting the CAR[13].

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

[13] 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 peer review 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.

consulted by the eCA, is available on the PBT/vPvB status at the time of submitting the CAR[13].

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 CAR[13].

5.2 CAR structure and terminology

The structure of the CAR is indicated in Figures 2 and 3 below.

Figure 2. *Documents provided by the eCA (new format as agreed by the BPC).*

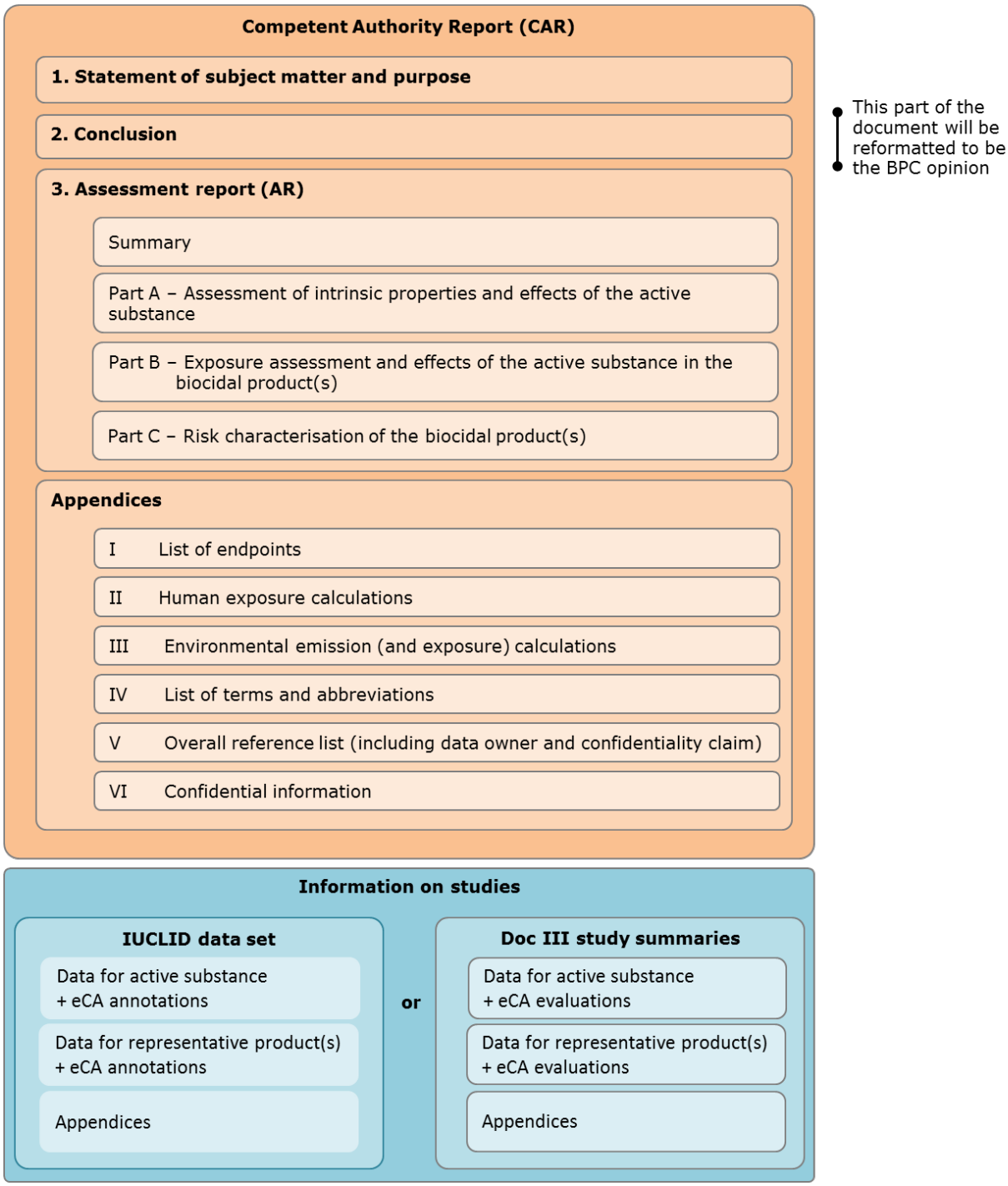
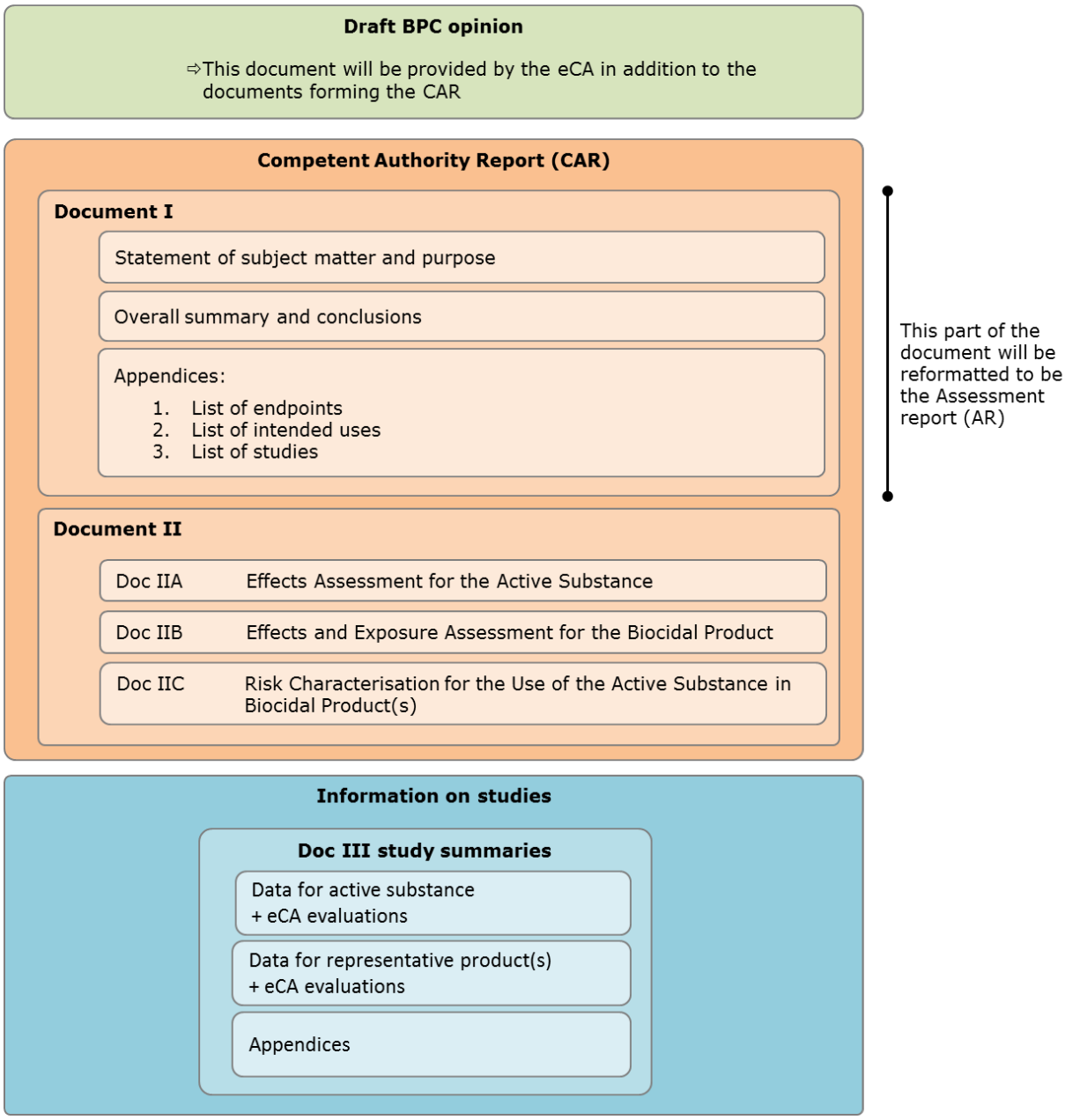


Figure 3. *Documents provided by the eCA (old format as used under the BPD).*



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 CAR and for draft risk assessment.

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

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

4. CIRCABC site for uploading documents.

   - Path: /CircaBC/echa/BPC-WG/Library/Confidential/05. Submissions
   - https://webgate.ec.europa.eu/echa-scircabc/w/browse/a080e867-292f-4cf4-9383-2a6282f2dcec