Renewal of Active Substances: Practical experiences

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Biocide Forum 2023 – 12 October 2023

Health
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Content

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General introduction

- **Biocidal Products Regulation ((EU) No 528/2012) (BPR)**
  - Chapter III
  - Annex II / Annex III

- **ECHA**
  - Practical guide on the renewal of approval of biocidal active substances
  - https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/renewal-of-active-substances

General introduction

- **Applicant**
  - Same person/task force who applied for the original active substance approval

  AND/OR
  - Different company(ies)

    → If several companies are interested in supporting the same active substance, they should preferably cooperate and submit a single common application (CA-July17-Doc.5.3-Final).

- **Timeline**
  - Submission at the latest 550 days before the expiry date of the approval of the active substance for a given PT;
  - The active substance is approved for less than 10 (15) years when it meets the exclusion or substitution criteria.

General introduction

- **Information requirements and sources**
  - A written confirmation signed by the evaluating competent authority (eCA) that agrees to evaluate the application for renewal;
  - All data required under Article 20 of the BPR that has been generated since the initial approval or previous renewal has been granted (i.e. new relevant data regarding requirements listed in Annexes II or III to the BPR);
  - A reasoned assessment of whether the conclusions of the initial or previous assessment of the active substance are still valid;
  - Any supporting information related to that assessment.

ECHA guidance: *guidance on the data requirements and assessment of applications for renewal of approval of active substances under BPR*

Procedure

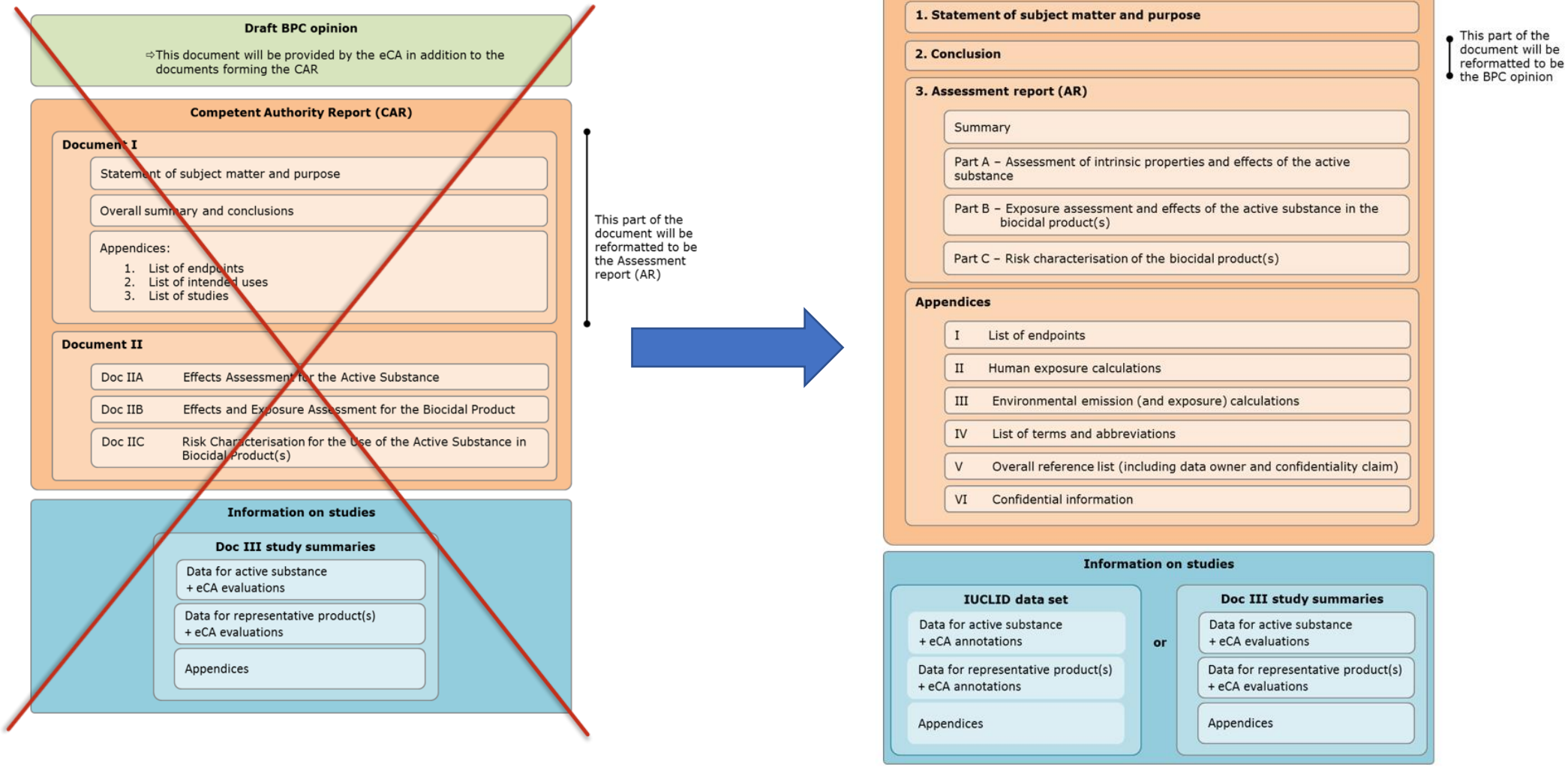
- **Preparing the submission of the application**
  - Express the intention to renew the active substance approval
    - ECHA form / Public list of intentions
  - PSM with the eCA
    - Preferably 3 years before the deadline of submission
  - Renewal Document (RNL DOC)
    - Quick overview of the active substance approval and the new information and revisions that the applicant intends to submit at RNL
    - Include list of new studies

Procedure

- **Preparing the submission of the application**
  - IUCLID
    - Full data package + assessments (endpoints: new? unchanged?)
  - Template for draft risk assessment – Renewal Assessment Report (RAR)
    - Combined CAR and CLH report template

! Any generation of new data should be finalised by the time of the submission of the dossier (e.g. ED studies).

Procedure


Draft BPC opinion
⇨This document will be provided by the eCA in addition to the documents forming the CAR
Competent Authority Report (CAR)
Document I
Statement of subject matter and purpose
Overall summary and conclusions
Appendices:
1. List of endpoints
2. List of intended uses
3. List of studies
Document II
Doc IIA Effects Assessment for the Active Substance
Doc IIB Effects and Exposure Assessment for the Biocidal Product
Doc IIC Risk Characterisation for the Use of the Active Substance in Biocidal Product(s)
Information on studies
Doc III study summaries
Data for active substance + eCA evaluations
Data for representative product(s) + eCA evaluations
Appendices
This part of the document will be reformatted to be the Assessment report (AR)
Competent Authority Report (CAR)
1. Statement of subject matter and purpose
2. Conclusion
3. Assessment report (AR)
Summary
Part A – Assessment of intrinsic properties and effects of the active substance
Part B – Exposure assessment and effects of the active substance in the biocidal product(s)
Part C – Risk characterisation of the biocidal product(s)
Appendices
I List of endpoints
II Human exposure calculations
III Environmental emission (and exposure) calculations
IV List of terms and abbreviations
V Overall reference list (including data owner and confidentiality claim)
VI Confidential information
Information on studies
IUCLID data set
Data for active substance + eCA annotations
Data for representative product(s) + eCA annotations
Appendices
or
Doc III study summaries
Data for active substance + eCA evaluations
Data for representative product(s) + eCA evaluations
Appendices
This part of the document will be reformatted to be the BPC opinion

Procedure

- **Preparing the submission of the application**

The objectives of the renewal are the following and the assessment report should be revised as necessary to meet them:

- Check if the active substance still meets the conditions of approval in accordance with BPR Article 12 (1, 2);
- Assess mandatory endpoints or criteria that have not been previously assessed (e.g. under the BPD);
- In light of new information and scientific and technical progress, consider possible change to the main conclusions and the reference values.

Procedure

- **Submission**
  - R4BP3 application
  - ECHA fees + eCA fees
  - No validation phase for renewal process

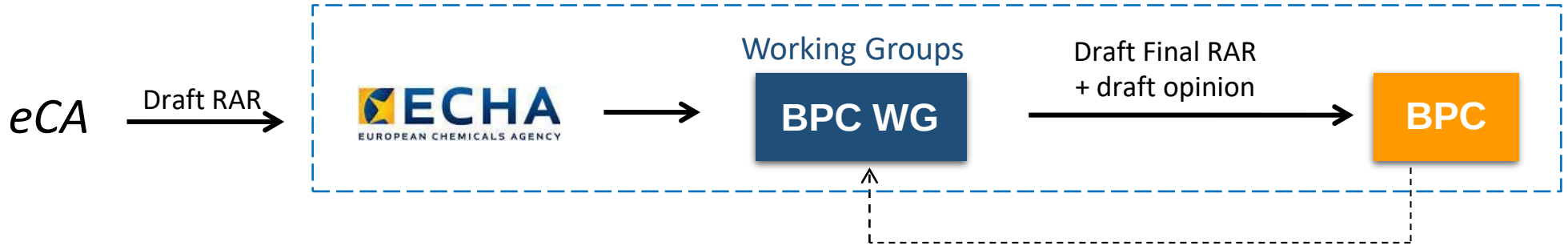
Procedure

- **Submission**
  - R4BP3 application
  - ECHA fees + eCA fees
  - No validation phase for renewal process

- **Evaluation**
  - Full or limited evaluation
    - Full evaluation -> 365 days and allows applicants to submit additional data requested by the eCA (maximum 180 days)
    - Limited evaluation -> 180 days
  - “Relevant Renewal Data” (Article 95(7) of the BPR /CA-Sept20-Doc.7.1.b)
  - 30 days RCOM period

Procedure

- **Opinion-forming process of biocidal active substance evaluation**

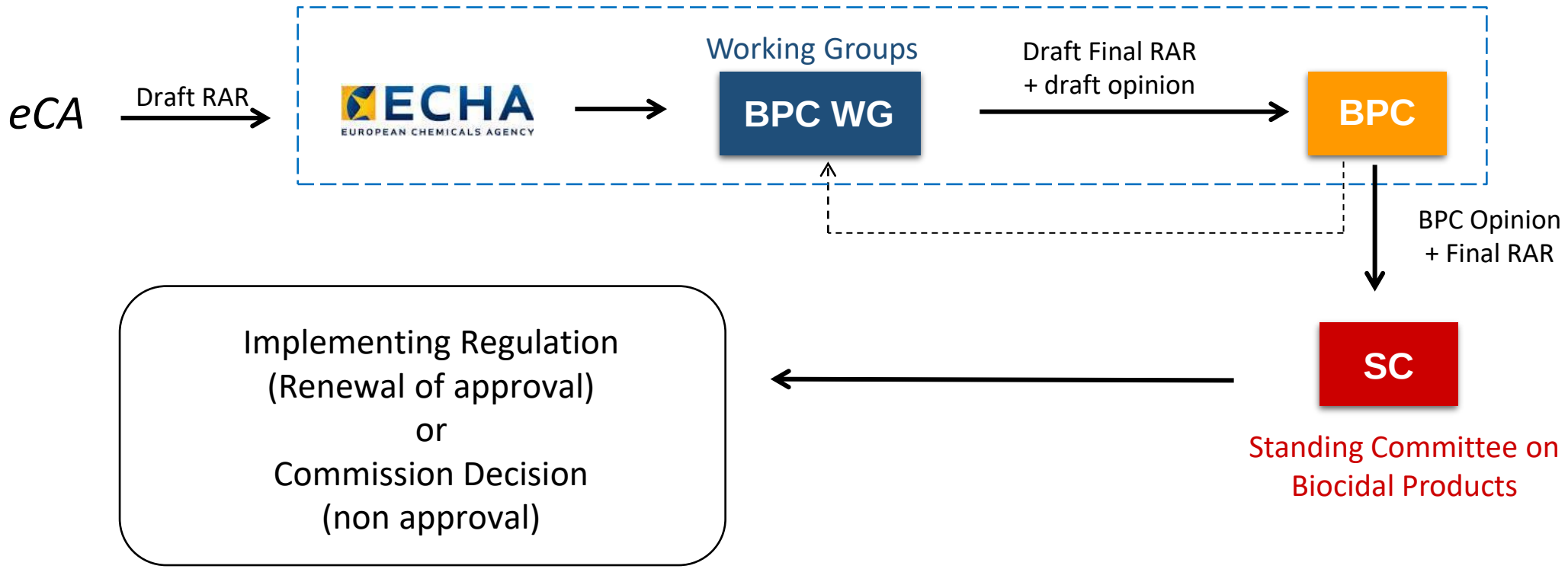


! New *"Working procedure for active substance approval v 8"* (from PF 49)

Procedure

- **Opinion-forming process of biocidal active substance evaluation**
  - Submission of RAR (+ other documents) for accordance check
  - *Public consultation*
    - *Only if the eCA proposes the active substance to be a potential candidate for substitution*
  - Commenting phase
    - Change in the applicant's involvement from PF 49
  - Working Group meeting and preparations
  - *Ad Hoc follow-up*
    - *Only if there are open points after the WG meeting*
  - Biocidal Products Committee meeting and preparations
  - Finalisation and dissemination steps

Procedure


eCA
Draft RAR
ECHA
EUROPEAN CHEMICALS AGENCY
Working Groups
BPC WG
Draft Final RAR
+ draft opinion
BPC
BPC Opinion
+ Final RAR
SC
Standing Committee on
Biocidal Products
Implementing Regulation
(Renewal of approval)
or
Commission Decision
(non approval)

First experiences

- **Data set/Assessment**
  - ED assessment

  The assessment of ED properties is now required in accordance with CA document CA-March18.Doc.7.3.a- Final

  → Commission Delegated Regulation (EU) No 2017/2100

  - 5-Batch analysis and reference specifications of the active substance

  - Substitution/exclusion criteria
    - ECHA guidance: *Analysis of alternatives to biocidal active substances for applicants and MSCAs - a recommended framework guidance*

First experiences

- **Data set/Assessment**
  - CLP

  The CLP Regulation has fully entered into application in 2015 and **Physical / Human Health and Environmental** hazards have to be addressed according to its requirements.
    - Delegated act on new hazard classes has entered into force on 20 April 2023 (Delegated Regulation (EU) 2023/707)
      - → CLP consolidated version available

  - Efficacy
    - The development of resistance
    - Treated articles (reference biocidal product)

First experiences

- **“One substance, one assessment” approach**

  Described in the Chemical Strategy for Sustainability, the substance intrinsic properties, like the ED, should be aligned between the different assessments

  - Support the information exchange and collaboration between the parties involved

- **Revision of the harmonized classification?**

  Submission of CLH dossier before the submission of the RAR to ECHA

  - RAC opinion necessary for active substance that meets the exclusion criteria

- **Representative product**

  The change of the reference product and its uses should normally be avoided

  - Minimize the work needed

First experiences

- **Prepare the submission sufficiently in time!**
  - Contact the eCA as early as possible.
  - PSM: The discussion should start sufficiently in advance (i.e. several years) of the submission to avoid delays due to missing data.
  - If studies on vertebrates are required (e.g. for ED assessment), the applicant should always confirm this with the eCA and the Agency as instructed in BPR Annex II and Article 62(2).

Thank you for your attention

Further information

Belgian Biocides website

www.biocide.be

Any questions?

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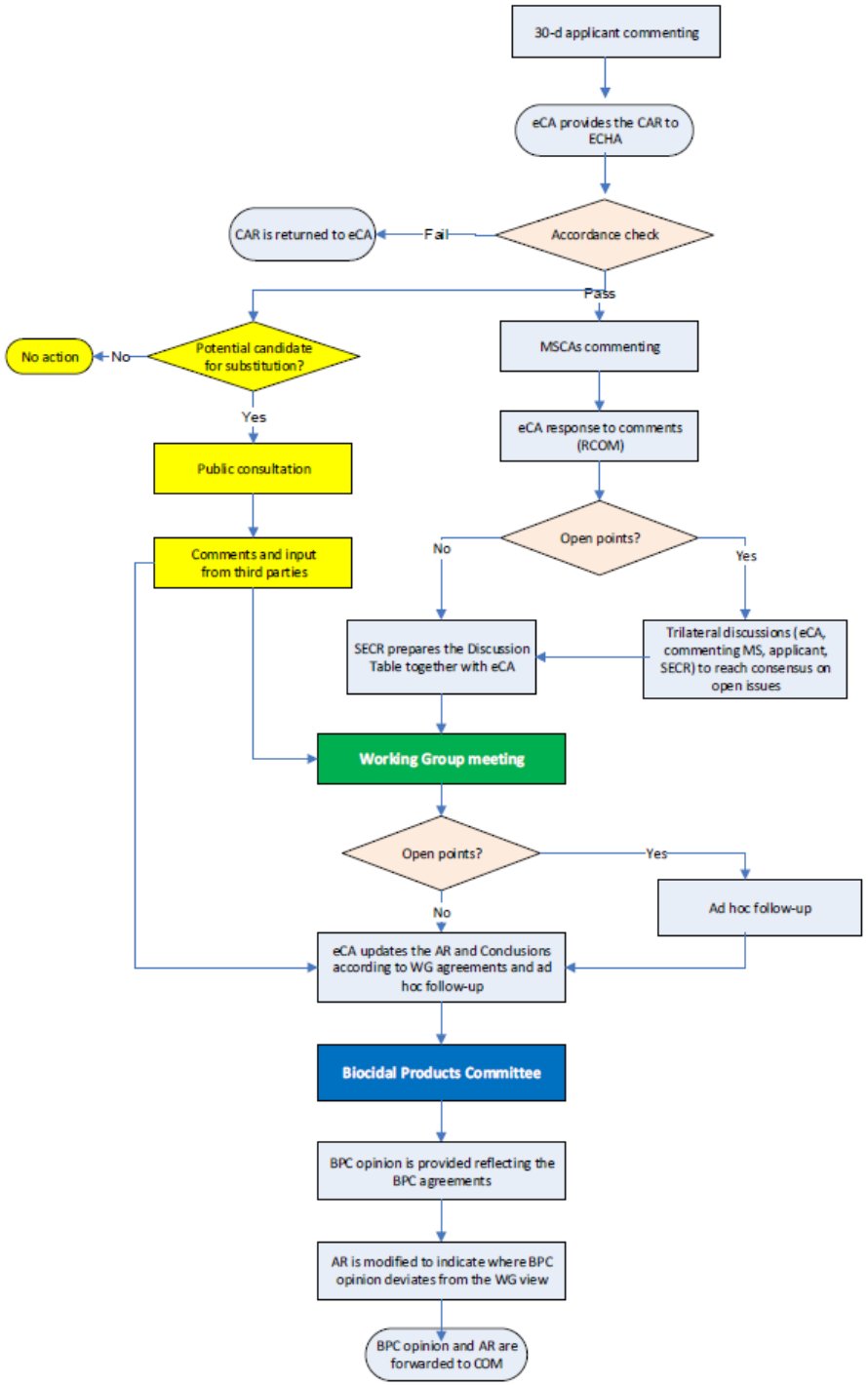
30-d applicant commenting
eCA provides the CAR to ECHA
Accordance check
Fail
CAR is returned to eCA
Pass
Potential candidate for substitution?
No
No action
Yes
MSCAs commenting
eCA response to comments (RCOM)
Open points?
No
Yes
Public consultation
Comments and input from third parties
SECR prepares the Discussion Table together with eCA
Trilateral discussions (eCA, commenting MS, applicant, SECR) to reach consensus on open issues
Working Group meeting
Open points?
Yes
No
Ad hoc follow-up
eCA updates the AR and Conclusions according to WG agreements and ad hoc follow-up
Biocidal Products Committee
BPC opinion is provided reflecting the BPC agreements
AR is modified to indicate where BPC opinion deviates from the WG view
BPC opinion and AR are forwarded to COM