Rules of Procedure for the Coordination Group (CG) under Regulation (EU) No 528/2012

Document history

Version	Changes	Date of agreement	Date of applicability
1.0	First edition (original unnumbered version)	XX between 1 February-March 2014 [via written procedure following CG-3]	February-March 2014
2.0	Main changes in the document: • Implementation of the "preferred referral submission window" in Article 9; • Introduction of the preparation of a chronogram with the meeting dates for the following year (including preferred referral submission windows) at the end of each year by the SECR.	11 November 2014 [at CG-8]	November 2014
2.1	Main change in the document: • Inclusion of indication in Article 13 that CG members and specially those cMSs in a formal referral shall be involved in the resolution of the disagreement by providing contributions to the discussions and adopting a formal position on these disagreements.	23 January 2015 [at CG-9]	January 2015
2.2	Main change in the document: • Inclusion of reference to CH as a member of the CG in Article 2, as a result of the agreement on mutual recognition between the European Community and the Swiss Confederation.	19 May 2015 [at CG-11]	May 2015
2.3	Main change in the document: • Implementation of CG-11 agreement on making the executive summaries of closed formal referrals publicly available after the confidentiality check with the applicant, is carried out; • Implementation of CG-14 agreement on the publication of non-confidential documents discussed at CG together with the non-confidential minutes of CG meetings in the public CIRCABC platform.	20 January 2016 [at CG-15]	January 2016

2.4	Main change in the document: • Correction that adoption of decisions on issues other than referrals shall be decided by two thirds majority of votes in case of no consensus.	15 March 2017 [at CG-22]	March 2017
2.5	Main changes in the document: • Update of the Annex containing the declarations of confidentiality form due to changes in the form.	10 May 2017 [at CG-23]	May 2017
3.0	Main change in the document: • Removal of the Annex containing the declarations of confidentiality form and inclusion of a link to the form in Article 11.	17 February 2021 [at CG-45]	February 2021
4.0	Main changes in the document: • Introduction of distinction between `regular' and `additional meetings'; • More detailed rules on organisation of meetings; • Facilitation of the possibility to amend the RoP every 1.5 years; • Clarification concerning the rules of agreement on amendments of the RoP.	1 July 2021 [at CG-47]	1 July 2021 and in case of formal referrals, only applicable for formal referrals accepted after 1 July 2021
5.0	Main changes in the document: • Clarification on the participation of ASO representatives and other observers in CG meetings; • Change of timelines for SECR to provide draft minutes of regular CG meetings.	23 February 2023 [at CG-55]	23 February 2023
6.0	Main changes in the document: • Revision throughout the document to reflect the new interpretation of Article 35 of the BPR that agreement on referrals should only be reached between cMSs and the rMS; • Inclusion of examination of questions other than related to Article 37 of the BPR among the responsibilities of CG in Article 1 and removal of consideration of secondary legislation.	26 April 2023 [at CG-56]	2 May 2023
7.0	Main changes in the document: • Revision throughout the document to reflect the different rules concerning participating in	29 November 2023 [at CG-59]	21 December 2023

	reaching agreement for disagreements described in Article 35 of the BPR and voting on other matters; • Removal of CG Contact Points and expansion of the role of CG members; • Clarification on the election of the Chair and Vice-Chair.		

Article 1
Coordination Group responsibilities

1. The Coordination Group (CG) is responsible for:

   a. Examining any question, other than matters referred to in Article 37 of Regulation (EU) No 528/2012, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 33 or 34 of Regulation (EU) No 528/2012 meets the conditions for granting an authorisation laid down in Article 19;

   b. Using best endeavours to solve disagreements arising from mutual recognition:

      - In accordance with Article 35 of Regulation (EU) No 528/2012 (including those applications subject to Article 91 of Regulation (EU) No 528/2012);

      - Disagreements on conclusions of assessment reports, or, where relevant, on the revised summary of biocidal product characteristics, in accordance with Article 10 of Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012;

      - Disagreements on conclusions of the assessment report, or, where relevant, on the revised summary of the biocidal product characteristics, in accordance with the Delegated Regulation[1] on the renewal of authorisations subject to mutual recognition in accordance with Regulation (EU) No 528/2012;

   c. Using best endeavours to solve disagreements arising from:

      - The making available on the market of biocidal products authorised in accordance with the simplified authorisation procedure as provided for by Article 27(2) of Regulation (EU) No 528/2012);

      - The cancellation or amendment of authorisations issued under mutual recognition in accordance with Article 48(3) of Regulation (EU) No 528/2012).

   d. Discussion of technical and procedural issues in relation to product authorisation in order to avoid future disagreements.

2. The CG shall not deal with derogations from mutual recognition in accordance with Article 37 of the BPR.

3. The CG shall not duplicate the work of the Commission, Biocides Competent Authorities Meeting or the Agency in the field of biocides.

[1] Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition

Article 2
Participants in the Coordination Group from the Member States

1. Member States shall be entitled to participate in the CG, and they may appoint one Member and one alternate Member for the CG. The Member shall act as the Contact Point for the appointing Member State.
   In exceptional circumstances[2] the Member State may appoint a second alternate Member.

2. A maximum of one Member per Member State will be entitled to participate in each meeting of the CG. In case an alternate Member wishes to also participate in the same meeting, the alternate Member may do so as an advisor.

3. A maximum of two advisers may accompany the Member of each Member State. In case of meetings organised as virtual meetings held via teleconference, more than two advisors may support the representative of each Member State.

4. Members shall have one expressed view per Member State in case of reaching agreement in relation to issues described in Article 1(1b-c), and one vote per Member State in case of reaching agreement in relation to issues described in Article 1(1a) and 1(1d). Members from Iceland, Liechtenstein and Norway[3] as well as from Switzerland[4] shall have the same rights and responsibilities as Members from EU Member States, except the right to vote.

Article 3
Other participants in the Coordination Group

1. The meetings of the CG shall be open to representatives of ECHA, accredited stakeholder organisations (ASOs), invited experts, other observers and applicants.

2. Representatives of the European Commission shall be entitled to take part in meetings of the CG.

3. Invited experts are experts in technical or scientific fields, who can be invited by the Chair to participate in meetings of the CG for one or more points of the agenda.

4. Any representative of ASOs may be admitted to meetings of the CG upon consent of the Chair and the Members of the CG[5]. Such requests should be made at least 7 calendar days before regular CG meetings[6]. Their attendance shall be subject to all applicable rules or consent of the CG.

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[2] An additional second alternate Member might be nominated in exceptional cases (e.g., when different institutes are concerned regarding biocides in a MS) and if adequate justification is provided.
[3] Decision Of the EEA Joint Committee No 225/2013 of 13 December 2013 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement
[4] Decision No 1/2015 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment on the amendment of Chapter 16 on construction products, Chapter 18 on biocidal products and the update of legal references listed in Annex 1
[5] In case of discussions of disagreements referred to in Article 1(1b-c) of the meetings, ASOs and their representatives may only be admitted to meetings of the CG upon consent of the Chair and the Members of the CG, if applicants explicitly request their attendance for their agenda item.
[6] In exceptional cases (e.g., replacement needed due to sickness) these requests could be made even closer to the date of the regular meeting.

5. Applicants may be admitted to meetings of the CG for matters relating to their applications. Their attendance shall be subject to all applicable rules or consent of the CG.

6. Other observers[7] may be admitted to the CG upon consent of the Chair and the Members of the CG. Such requests should be made at least 7 calendar days before regular CG meetings[6].

Article 4
Role of the Agency

1. The Agency shall provide the Secretariat for the CG and shall carry out the following duties in consultation with the Chair:

    a. Prepare the agenda for meetings and circulate it to CG Members and alternate Members;

    b. Provide the meeting documents to CG Members and alternate Members;

    c. Prepare the draft action points, conclusions and minutes for each meeting;

    d. Organise and administer reaching agreement in meetings or by written procedure;

    e. Produce and update a record of agreements;

    f. Facilitate liaison between the CG and the Biocidal Products Committee;

    g. Assist the Chair in other tasks related to the functioning of the CG.

Article 5
Role of members

1. Members and alternate Members are responsible for the following:

    a. Coordinating within the Member State all correspondence between the Agency and the Member State on the CG activities to ensure multiple channels of communication are avoided. To that end, the Members shall provide contact details in form of an e-mail address to which the Agency may send all relevant communication;

    b. Ensuring the monitoring of the e-mail address provided and making certain that requests from the Agency are handled within the timelines specified;

    c. Ensuring that a Member representing the Member State is available to participate in CG meetings and its work, if appropriate;

[7] Representatives of any member of an ASO may only be admitted as other observers upon consent of the Chair and the Members of the CG, if the request is made by the ASO to which the entity belongs. As part of such a request made by the representative of an ASO to which the entity belongs, a justification should be submitted.

d. Ensuring that the Member representing the Member State and advisers are familiar with these Rules of Procedure, relevant working procedures and any other applicable rules;

e. Initiating, discussing and expressing their opinion on any general proposals or technical documents related to the responsibilities specified in Article 1(1);

f. Being committed to actively contribute to the efficient conduct of the business of the CG: taking on their fair share of the workload, respecting agreed deadlines and taking part in the discussions of the CG;

g. Ensuring that the actions and conclusions of CG meetings and other relevant matters from the discussions are communicated within their Member State.

Article 6
Role of the Commission

1. The Commission shall provide assistance to the CG, in particular with respect to the following:

   a. Providing clarification of the legal framework and EU policy, where possible;

   b. Facilitate liaison with the Biocides Competent Authorities Meeting.

Article 7
Election of the Chair and Vice-Chair

1. The CG shall be chaired by one of its Members or alternate Members. The Chair shall be supported by a Vice-Chair. Both shall be elected by the procedure specified in this Article.

2. The term of office of the Chair and the Vice-Chair shall be 1.5 years (unless stated otherwise during the election), which shall be renewable once.

3. The election of the Chair and Vice-Chair shall be by secret ballot of the Members unless the nominee for the position(s) is unopposed. Each Member shall have one vote and the winner shall be the candidate with the simple majority of votes of the members present that are eligible to vote. Candidates may vote for themselves.

4. The Member acting as the Chair shall be replaced by an alternate Member as a Member representing their Member State during the meetings.

Article 8
Role of Chair and Vice-Chair

1. The Chair will be responsible for the efficient conduct of the business of the CG. The Chair has, in particular, the following responsibilities in collaboration with the Vice-Chair:

   a. Planning the work of the CG together with the Members and the Secretariat;
   b. Monitoring and promoting compliance with these Rules of Procedure;

c. Convening meetings of the CG;

d. Ensuring that any potential conflict of interests in relation to the agenda is declared at the start of the meeting and appropriate action is taken in accordance with Article 10;

e. Managing the business of the agenda by:
   - Giving the floor to all Members equitably, taking into account time constraints,
   - Formulating questions and proposals,
   - Summing up discussions,
   - Concluding on all items of discussions.

f. Ensuring consistency of agreements to the extent reasonably possible;

g. Using their best endeavours to promote consensual approaches.

2. The Vice-Chair will replace the Chair of the CG in their absence, or if the Chair has declared a conflict of interest in accordance with Article 10. The Secretariat will replace the Chair in the absence of both the Chair and the Vice-Chair. The CG may draw up more detailed instructions of the duties of the Vice-Chair.

3. Where both the Chair and Vice-Chair have declared a conflict of interest in accordance with Article 10, the Secretariat will replace the Chair and Vice-Chair of the CG for that agenda item(s).

4. If the Chair resigns, the Vice-Chair shall take the Chair's role until another Chair is elected. Where no Vice-Chair has been appointed, the Secretariat shall take the Chair's role until another Chair is elected.

Article 9
Meeting organisation

1. The CG shall normally meet 5 times per year with an approximate interval of 2 months. Such meetings – hereinafter referred to as regular meetings shall be convened by the Chair with the support of the Secretariat. When deemed appropriate, regular meetings might be organised as a virtual meeting held via teleconference.

2. Additional meetings may be convened by the Chair if workload or timelines for reaching the agreement in relation to issues described in Article 1(1b-c) dictates the necessity for such meetings – hereinafter referred to as additional meetings. Additional meetings shall normally be organised as virtual meetings held via teleconference.

3. An invitation to a regular meeting and a provisional draft agenda shall be circulated by the Secretariat to the Members and alternate Members in consultation with the Chair at the latest 21 calendar days before the meeting. An invitation to the additional meeting and an agenda shall be circulated by the

Secretariat to the Members and alternate Members in consultation with the Chair at the latest 7 calendar days before the additional meeting[8].

4. Members may request items to be included on the agenda of the regular meeting. Such requests shall be submitted to the Secretariat within at least 14 calendar days before the meeting[9].

5. An alternate Member may replace a Member for the purpose of the meeting. Unless the Member specifies otherwise, the alternate Member takes over all the Member's responsibilities.
   The Member shall indicate to the Secretariat that an alternate Member or a proxy is to replace the Member at least 10 calendar days before the regular[10], and 5 days before the additional meeting[11], or together with any request to include items on the agenda of the meeting submitted under point 4 above. In case there are two alternate Members for that Member State, the Member shall indicate to the Secretariat which alternate Member is to act as the replacement.

6. Documents and a revised draft agenda for the regular meeting will be circulated to the Members and alternate Members no later than 10 calendar days before the meeting[12]. Documents for the additional meeting will be circulated to the Members and alternate Members no later than 3 calendar days before the meeting[12].

7. The working language of the CG is English.

8. The Secretariat shall prepare action points and conclusions in consultation with the Chair that are to be agreed by the Members at the end of each meeting. In case of additional meetings, a discussion table and conclusions might be prepared instead of action points and conclusions on a case-by-case basis (e.g., if the only item for the additional meeting is related to Article 1(1b-c)) and for additional meetings separate minutes will not be prepared.

9. The Secretariat will prepare draft minutes of each regular meeting in consultation with the Chair within 35 calendar days of the meeting. The minutes shall be agreed at the following regular meeting or by written procedure.

10. The Secretariat will prepare at the end of each year a chronogram with provisional dates for the regular meeting for the following year.

[8] In those exceptional situations, where the agreed date of the additional meeting is less than 7 calendar days away, the invitation and the provisional draft agenda/agenda should be sent out as soon as possible.

[9] Exceptions could be made for requests submitted less than 14 calendar days before a regular meeting if the delay of submission is justified, but their acceptance would still be up to the consideration of the Chair.

[10] Exceptions could be made for requests submitted less than 10 calendar days before a regular meeting if the delay of submission is justified.

[11] Exceptions could be made for requests submitted less than 5 calendar days before an additional meeting if the delay of submission is justified, or the agreed date of the additional meeting is less than 5 calendar days away.

[12] Documents related to Article 1(1b-c) might be an exception regarding this, depending on a case-by-case basis.

Article 10
Transparency and independence

1. Meetings shall normally be considered open sessions unless for reasons of confidential business information, at the request of an applicant or Member State, or on other justifiable grounds the Chair decides to close a part of the meeting.

2. If a request for a closed session is received from an applicant in accordance with Article 10(1), it shall be accompanied by a written justification sent to the Secretariat at least 14 calendar days before the meeting.

3. The following information will be made available in the public CIRCABC platform:
   a. Non-confidential documents agreed at CG meetings,
   b. The final minutes of non-confidential sections of CG meetings,
   c. Executive summaries of formal referrals on which the CG has reached an agreement by consensus, after confidentiality check with the applicant.

4. Members, advisers and invited experts shall not have any direct interests, financial or otherwise, in the biocides industry which could affect their impartiality. The Members, advisers and invited experts shall undertake to act in the public interest and in an independent manner.

5. At the start of each meeting, Members and invited experts shall make a declaration of any direct interests, financial or otherwise, in relation to the agenda items. The Chair shall decide what action to take as a result of such declarations.

Article 11
Confidentiality

1. All participants in the CG shall not disclose confidential business information (CBI) to any persons other than relevant persons (representatives of relevant public authorities of the Member States, the Commission and European Union bodies). ASOs and applicants are only permitted to share non-confidential meeting documents within their organisations, and they shall respect the confidential nature of deliberations and views of Members. All participants in the Coordination Group shall make a written declaration of confidentiality in accordance with the model available in the ECHA Website: Declaration of confidentiality of ECHA bodies**.**

Article 12
Working Parties

1. When necessary, the CG may decide to create working parties (referred to as 'working parties') to tackle issues within the scope of the CG as defined in Article 1. Such working parties should not duplicate the work of the Commission, the Agency or the Biocides Competent Authorities meeting in the field of biocides.

2. The CG shall agree on the mandate, including the objectives, of each working party and the duration of its activity.

Article 13
Agreements

1. The following applies for reaching agreement in relation to issues described in Article 1(1b-c):
    a. Agreement shall be reached by consensus of the Members representing the reference Member State and the concerned Member States (or the evaluating Competent Authority and the notified Member States in case of a disagreement arising from the making available on the market of biocidal products authorised in accordance with the simplified authorisation procedure as provided for by Article 27(2) of Regulation (EU) No 528/2012). When preparing an agreement either at meetings or by written procedure, these Members of the CG shall use all efforts to reach a consensus.
    All Members can provide contributions to the discussions for the resolution of disagreements referred to in Article 1(1b-c). The Members representing the reference Member State and the concerned Member States (or the evaluating Competent Authority and the notified Member States) shall adopt a formal position on these disagreements taking into consideration the contributions provided by all other Members.
    b. Members representing the reference Member State (or the evaluating Competent Authority), or the concerned Member State (or the notified Member State) shall express their view:
        - in person at a meeting, or
        - by a proxy indicated to the Secretariat, or
        - by directly indicating their view to the Secretariat beforehand[13, 14, 15], or
        - within the response period of a written procedure.

    A Member or alternate Member representing the reference Member State (or the evaluating Competent Authority), or another concerned Member State (or another notified Member State) may act as a proxy for another Member. In case an alternate Member or a proxy is to represent the Member State, this should be indicated to the Secretariat at the latest 10 calendar days before the regular[14], and 5 calendar days before the additional meeting[15].
    In case of a written procedure, the right of an alternate Member to represent the Member State is presumed even without a confirmation from the Member.
    c. The position of the Member will not be taken into account for the purpose of reaching agreement, if any of the following conditions apply:
        - The Member is absent during agreement seeking at a regular, or an additional meeting and a proxy has not been notified, or the view of the Member has not been indicated to the Secretariat;
        - The Member does not express its view or comment within the response period of a written procedure and a proxy has not been notified to the Secretariat;

[13] Such indications shall be provided to the Secretariat at the latest 5 calendar days before the meeting. In those exceptional situations, where the agreed date of the additional meeting is less than 5 calendar days away, the indication should be provided to the Secretariat at the latest on the calendar day before the additional meeting.
[14] Exceptions could be made for requests submitted less than 10 calendar days before a regular meeting if the delay of submission is justified.
[15] Exceptions could be made for requests submitted less than 5 calendar days before an additional meeting if the delay of submission is justified, or the agreed date of the additional meeting is less than 5 calendar days away.

- The Member declared a conflict of interest regarding the relevant agenda point.

d. In cases where the Member and the alternate Member both take a position on behalf of the Member State, the position of the alternate Member shall be disregarded.
e. Once agreement has been reached, the reference Member State (or evaluating Competent Authority) shall record the agreement in the Register for Biocidal Products.
f. If agreement cannot be reached, the reference Member State (or evaluating Competent Authority) shall prepare a detailed statement of the matters on which it and the concerned Member States (or notified Member States) have been unable to reach agreement and the reasons for their disagreement, then provide it to the Commission as described in Article 36 of Regulation (EU) No 528/2012.

2. The following applies for reaching agreement in relation to all matters described in Article 1(1a) and 1(1d):
   a. Members shall endeavour to reach agreement by consensus. If consensus cannot be reached, the matter will be decided by two thirds majority of the Members having the right to vote[16].
   b. All Members with the right to vote shall vote:
      - in person at a meeting, or
      - by a proxy indicated to the Secretariat, or
      - by directly indicating their vote to the Secretariat beforehand[17, 18, 19], or
      - within the response period of a written procedure.

      Any Member or alternate Member with the right to vote may act as a proxy for a Member representing another Member State. In case an alternate Member, or a proxy votes on behalf of another Member, this should be indicated to the Secretariat at the latest 10 calendar days before the regular[18], and 5 calendar days before the additional meeting[19].
      In case of a written procedure, the right of an alternate Member to represent the Member State is presumed even without a confirmation from the Member.
   c. The vote of the Member will not be taken into account for the purpose of reaching agreement, if any of the following conditions apply:
      - The Member is absent during agreement seeking at a regular, or an additional meeting and a proxy has not been notified, or the vote of the Member has not been indicated to the Secretariat;
      - The Member does not vote or comment within the response period of a written procedure and a proxy has not been notified to the Secretariat;
      - The Member declared a conflict of interest regarding the relevant agenda point.

[16] Excluding any members with the right to vote that have declared a conflict of interest.
[17] Such indications shall be provided to the Secretariat at the latest 5 calendar days before the meeting. In those exceptional situations, where the agreed date of the additional meeting is less than 5 calendar days away, the indication should be provided to the Secretariat at the latest on the calendar day before the additional meeting.
[18] Exceptions could be made for requests submitted less than 10 calendar days before a regular meeting if the delay of submission is justified.
[19] Exceptions could be made for requests submitted less than 5 calendar days before an additional meeting if the delay of submission is justified, or the agreed date of the additional meeting is less than 5 calendar days away.

d. In cases where the Member and the alternate Member both vote on behalf of the Member State, the position of the alternate Member shall be disregarded.

Article 14

Final Provisions

1. These Rules of Procedure shall be reviewed every 1.5 years. Where an urgent change in these Rules of Procedure is required for the continued functioning of the CG the proposal(s) to amend these rules will be acted upon. Relevant associated documents, in particular the documents on working procedures and templates, shall also be reviewed and updated in line with any agreed amendments.

2. Members of the CG may also initiate proposals to amend the Rules of Procedure.

3. The decision to amend these Rules of Procedure shall be taken by consensus agreement of all Members having the right to vote.

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