# Resolving disagreements on mutual recognition, renewal, changes, simplified notification and Article 48 procedure: working procedure for the Coordination Group (CG)

# Contents

# Document history

| Version | Changes | Date of agreement | Date of applicability |
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| 1.0 | First edition (original unnumbered version) | January-February 2014 [via written procedure following CG-3] | January-February 2014 |
| 2.0 | Main change in the document:<br>• Clarification that in case of a disagreement concerning a mutual recognition in sequence procedure resulting in the need to amend the authorisation, Article 48 of the BPR should be applied. | 11 March 2014 [at CG-4] | March 2014 |
| 3.0 | Main change in the document:<br>• Inclusion of the possibility of closing a formal disagreement by its withdrawal and that a cMS different than the initial cMS can take over the disagreement. | 16 September 2014 [at CG-7] | September 2014 |
| 4.0 | Main change in the document:<br>• Inclusion of the timelines, the preferred submission windows and CG meeting dates in 2015 (Annex II). | 11 November 2014 [at CG-8] | November 2014 |
| 5.0 | Main changes in the document:<br>• Inclusion of the additional task of SECR sending a reminder to MSs during referral commenting (Section 4 and 5) in order to increase the efficiency of reaching agreement;<br>• Inclusion of the additional task of SECR organising a preparatory conference call before CG meetings between the icMS, rMS, SECR and COM in order to establish a way forward for the discussion at the CG meeting;<br>• Inclusion that after the commenting period the initiating cMS will prepare a short document for the CG meeting with the key points for discussion and the position of the cMS's on these points;<br>• Revision of the timlines, including the preferred submission windows and CG meeting dates in 2015 (Annex II). | 23 January 2015 [at CG-9] | January 2015 |
| 6.0 | Main changes in the document:<br>• Elaboration on how CG agreements on referrals should be recorded during the meeting; | 15 September 2015 [at CG-13] | September 2015 |

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| | • Inclusion that upon request of the applicant the CG minutes of their referral would be provided to them by the SECR;<br>• Establishment of publication of the executive summaries of CG agreements on the public CIRCABC platform;<br>• Inclusion that in case unresolved objections are referred to the COM by the rMS in line with Article 36 of the BPR, the document would be shared with MSs by SECR via CIRCABC;<br>• Inclusion of changes to the schedule of the CG-14 meeting. | | |
| 7.0 | Main changes in the document:<br>• Amendment how to proceed when an application for mutual recognition is withdrawn in the icMS, how rMS and other cMSs will need to be informed, and how to proceed with the disagreement, as it will still be relevant for the other cMSs;<br>• Removal of the possibility of withdrawing the referral by the initiating cMS as an alternative to a CG agreement. | 10 November 2015 [at CG-14] | November 2015 |
| 8.0 | Main changes in the document:<br>• Alignment of Annex I with the updated document "R4BP3 MANUAL for authority users; How to run BPR processes with R4BP 3 in Member State competent authorities";<br>• Inclusion of meeting dates for the CG in 2016 and the timelines for disagreements, including the preferred referral submission (Annex II). | 20 January 2016 [at CG-15] | January 2016 |
| 9.0 | Main changes in the document:<br>• Clarification that MSs that did not contribute during the initial commenting period of a referral are assumed to support the position of the rMS during this phase, but this does not prevent those MSs to provide opinions on the referral during a later stage of the process;<br>• Clarification that the title of the public document of the executive summary of CG agreements will contain the product name. | 24 May 2016 [at CG-17] | May 2016 |
| 10.0 | Main change in the document:<br>• Inclusion of a deadline for referral submission and a footnote describing exceptions to the timeline in case of | 15 November 2016 [at CG-20] | For referrals submitted after 1 January 2017 |

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| | holidays or unforeseen technical issues (Step 2). | | |
| 11.0 | Main changes in the document:<br>• Removal of the preferred submission window concept in order to align with the referral submission deadline of 10 days after the 90 day period of the mutual recognition procedure;<br>• Simplification of the procedure related to informal exchange of information mentioned in Step 1;<br>• Clarification that additional points added to the referral should be considered as a referral and follow the same timelines as those defined for the initial referral, that is, communication of the referral to the SECR before the expiration of the 90 day period of the mutual recognition phase, and submission of the documentation 10 days after, at the latest;<br>• Clarification that only points of disagreement raised by the icMS(s) during the first 60 days of the 90-day period of the mutual recognition phase would be accepted;<br>• Inclusion of an additional step for the acceptance of the referral. | 20 June 2017 [via written procedure following CG-23] | 20 June 2017 |
| 12.0 | Main change in the document:<br>• Amendment that for all mutual recognition in parallel processes the referral would be launched on the working day after the referral submission deadline to increase efficiency. | 20 November 2018 [at CG-32] | November 2018 |
| 13.0 | Main changes in the document:<br>• Clarification for the situation when an applicant decides to withdraw an application for authorisation from a cMS during the 90 days period mutual recognition phase, and that those comments can be taken over by another cMS with on-going mutual recognition procedure for the product and may be referred to the CG by another cMS. Where no other cMS takes over comments, those comments will be considered as closed;<br>• Clarification that the acceptance of the formal referral template marks the start of the 60-day process;<br>• Clarification concerning the responsibility of the icMS in relation to the content of the filled out referral submission document, including confidentiality. | 13 May 2019 [at CG-35] | 13 May 2019 |

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| 14.0 | Main changes in the document:<br>• Clarification of the scope of the document to encompass applicability for the mutual recognition, renewal, simplified notification, changes, and Article 48 procedures, as well as update of the steps (mainly timelines);<br>• Clarification on the rMS identification for Article 48 procedure related referrals;<br>• Clarification on the scope issues raised during the mutual recognition process;<br>• Shortening of the commenting period from three weeks to two weeks to enable more time to be dedicated for an active discussion of the referrals. | 7 July 2020<br>[at CG-42] | For referrals submitted after 13 July 2020 (publication date) |
| 15.0 | Main changes in the document:<br>• Adaptation of the text that referrals can be raised for simplified notifications to reflect the content of the document CA-March16-Doc.4.6–Final.rev3 on Q&As related to the simplified authorisation procedure;<br>• Clarification on calculation of timelines and communication from SECR to the applicant/authorisation holder during the referral;<br>• Amendment in line with the content of the revised referral submission templates. | 29 April 2021<br>[at CG-46]<br><br>It was also agreed that in case the use of CIRCABC would be replaced by use of Interact Portal in regards of referrals, the change would be effective immediately (i.e., not only after the update of the Working Procedure for resolving of disagreements) and the Working Procedure for resolving of disagreements would be amended accordingly. | For referrals submitted after 30 April 2021 (publication date) |
| 16.0 | Main changes in the document:<br>• Amendment of the text that a referral could be raised in case of a non-authorisation assessment conclusion when the national authorisation application is subject to mutual recognition in parallel;<br>• Alignment with the legal text of Regulation (EU) No 354/2013 and Regulation (EU) No 492/2014 that the rMS needs to refer the referral to the CG;<br>• Clarification that if a point of disagreement is raised for a biocidal product, the same point cannot be | 28 April 2022<br>[at CG-51] | For referrals accepted after 29 April 2022 (publication date) |

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| | raised for the same biocidal product again;<br>• Clarification concerning the role of CG Contact Points in the submission of referrals;<br>• Revision throughout the document concerning the references to CIRCABC and teleconferences. | | |
| 17.0 | Main changes in the document:<br>• 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;<br>• Inclusion of an explanation in footnotes why referrals in case of non-authorisation of a simplified authorisation were not relevant and possible;<br>• Addition of timelines in case of post-authorisation data of simplified authorisation cases. | 27 April 2023 [at CG-56] | For already ongoing referrals and those launched after 2 May 2023 (publication date) |
| 18.0 | Main changes in the document:<br>• Changes in the structure (addition of document history and rephrasing of Section 1);<br>• Update of version number of reference submission templates in footnotes;<br>• Replacement of reference to CG Contact Point with CG Member and CG alternate Member to reflect the same change in the Rules of Procedures. | For alignment with the Rules of Procedure on 30 November 2023 [at CG-59] | For already ongoing referrals and those launched after 8 January 2024 (publication date) |

# 1. Purpose

This document forms the basis for handling disagreements (on mutual recognition, renewal, changes, simplified notification and Article 48 procedures) under Article 35 of the BPR referred to the Coordination Group (CG). The process is divided into two stages: 1) bilateral discussion during the simplified notification (SN) and the mutual recognition (MR) phase (for mutual recognition, renewal, minor and major changes procedures[1]; and 2) resolution of formal referrals sent to the CG according to the BPR. The legal dispute resolution period for formal disagreements as specified in the BPR is 60 days.

The document is to be applied by participants in the work of the CG for resolving disagreements referred to the CG, including all Member States (CG Member and CG alternate Members), including the reference and concerned Member States/evaluating Competent Authority and notified Member States, the Commission, the Secretariat, the applicants and authorisation holders.

This working procedure will be reviewed and updated in the light of experience.

# 2. Scope

This document details the steps to be taken both during the bilateral discussion of the MR phase, if applicable for the relevant procedure, and the resolution process of the formal referral. The working procedure is intended to assist members and other actors to carry out the work of the CG within the available time.

# 3. Description

The scope of the CG is as follows:

- 1st priority: resolution of disagreements at the CG;
- 2ndpriority: upstream brokering of disputes during the MR phase (to minimise disagreements coming to the CG);
- 3rd priority: discussion of technical and procedural issues in relation to product authorisation in order to avoid future disagreements.

This document focuses only on the 1st and 2nd priorities. In this context the upstream brokering of disputes during the MR phase is considered to be an important first step and a prerequisite before a formal referral is launched and the 60-day period starts. In case of parallel processes if agreement is reached between the reference and all concerned MSs (rMS and cMSs) during the bilateral exchange of the MR phase, a formal referral is not needed.

However, if any of the cMSs/notified MSs (nMSs) considers that a biocidal product assessed by the rMS/eCA does not meet the conditions laid down in Article 19 or Article 25 of the BPR, a point of disagreement should be referred to the CG in accordance with provisions of Article 35 and Article 27 of the BPR.

In accordance with provisions of Article 35(3) of the BPR the rMS and all cMSs, or the eCA and all nMSs shall use their best endeavours to reach an agreement on the points of disagreement. However, Member States that are not concerned can and are encouraged to participate in and provide contributions to the discussions which the rMS and all cMSs, or the eCA and all nMSs should take into consideration.

The ECHA Secretariat of the Coordination Group (SECR) will provide organisational and administrative support to the MSs in the discussions on the points of disagreements in order to reach an agreement in meetings or by written procedure (see Table 1).

The individual steps and indicative timelines for the process are described in Table 1.

The rMS/eCA will be responsible to inform the applicant or authorisation holder about the progress and ongoing discussions of the referral. During the referral the SECR will only communicate the following to the applicant, and/or the authorisation holder:

- the launch of the referral (sharing the referral documents that can be shared with the applicant and/or authorisation holder) and the request for comments[2] (sharing the commenting table),

[1] Bilateral discussion is not forseen for administrative changes and Article 48 procedures.

[2] In case several legal entities are indicated in the referral document the SECR will inform all legal entities with whom the referral document can be shared, that comments should be provided in a coordinated manner.

- date and invitation to regular or additional CG meetings where the referral will be discussed,
- the discussion table reflecting a brief summary of the points to be discussed during the regular or additional CG meeting,
- the conclusions of the regular or additional CG meeting,
- the outcome for confidentiality check before making it available for the public on CIRCABC.

N. B. If the rMS proposes the non-authorisation of the biocidal product and a cMS disagrees with this proposal, such a disagreement also falls within the scope of Art. 35(3) of the BPR[3].

It should be noted that the referral should be submitted by the CG Member or CG alternate Member of the initiating concerned MS (icMS)/initiating notified MS (inMS) via email, unless it is signed by the CG Member or the CG alternate Member.

In case of disagreements related to changes (ADC, MIC and MAC) and renewal (RNL) processes, the disagreement needs to be referred to the CG by the rMS in line with Regulation (EU) No 354/2013 and Regulation (EU) No 492/2014, respectively. This means that the icMS needs to inform the rMS of the intention of the initiation of a referral in line with step 5 (cMSs agree or indicate disagreement) of the relevant Standard operating Procedure via email, so the rMS is able to refer it to the SECR before the end of the referral submission deadline (i.e., at the latest 10 days following the MR phase) in case of ADC, MIC, MAC and RNL processes (indicating the name and case type of the product/product family, as well as the identity of the icMS). However, the preparation and submission of the supporting document for the referral to the SECR before the end of the referral submission deadline is still the responsibility of the icMS. In case the intention of the initiation of a referral was communicated to the SECR, but all disagreement points are resolved during the 10 days following the MR phase, the icMS should inform the SECR that a referral will not be raised.

It should also be noted that for disagreements submitted in accordance with the provisions of Article 48(3) of the BPR, the 'reference' Member State for the purpose of Articles 35 and 36, which applies *mutatis mutandis* according to Article 48(3), is the competent authority of the Member State that cancelled or amended their national authorisation.

An eCA can cancel or amend an authorisation granted under the simplified procedure by using Article 48 of the BPR. In such a situation, if a nMS disagrees with the amendment or cancellation, such a disagreement also falls within the scope of Art. 35(3) of the BPR and a referral should be initiated in accordance with Article 27(2) of the BPR.

In addition, if a cMS in the context of a **mutual recognition procedure** considers that the biocidal product cannot be authorised because it should not be considered as falling within the scopeof the BPR, the question of disagreement should be resolved in accordance with Article 35 of the BPR, i.e. through a referral to the CG. The question whether a product is a biocidal product or not is a precondition for the application of the conditions of authorisations set out in Article 19 of the BPR.

Similarly, if a nMS in the context of a **simplified notification procedure** considers that the biocidal product cannot be authorised because it should not be considered as falling within the scope of the BPR, the question of disagreement should be resolved in accordance with Article 35 of the BPR, i.e. through a referral to the CG. The question whether a product is a biocidal product or not is a precondition for the application of the conditions of authorisations set out in Article 25 of the BPR.

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In case of parallel procedures where the MR applicant in the icMS (case owner) is different from the applicant in the rMS, the referral document will be shared with the applicant in the icMS provided that the latter has the necessary access rights to the information contained therein (the referral document prepared by the icMS should not contain any confidential data, e.g. reference to other referrals, information that should not be shared with the applicant and/or the authorisation holder) and the icMS applicant will be asked by SECR to contact the applicant in the rMS and involve it in the discussion.
In the context of sequence procedures for MR, the applicant (case owner) in the icMS and the authorisation holder (asset owner) in the rMS receives the referral document, if they are different legal entities and provided that the former has the necessary access rights to the information contained therein (the referral document prepared by the icMS should not contain any confidential data, e.g. reference to other referrals, information that should not be shared with the applicant and/or the authorisation holder).

[3] The conclusion of the assessment of the rMS being non-authorisation is not relevant for applications for MRS, as if the rMS decided not to authorise the product/product family, there would be no authorisation that can be mutually recognised and therefore an application for MRS in accordance with Article 33 of the BPR cannot be submitted.
Similarly, the conclusion of the assessment of the eCA being non-authorisation is not relevant for SA applications, as if the eCA decided not to authorise the product/product family, there would be no authorisaiton that can be notified and therefore an application for SN in accordance with Article 27 of the BPR or Article 9 of Regulation (EU) No 354/2013 cannot be submitted.

**Table 1**: *Description of the process steps and indicative timelines in the resolution of the disagreements referred to the CG*

| Step | Description of process step | Responsible actor (indicative timeline) |
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| 0 | **Notification of the applicant**[4]<br><br>The nMS should inform the applicant via R4BP 3 when the submitted documentation is considered complete.<br><br>If the nMS has objections regarding the submitted application it should inform the applicant within 30 days (defined in Article 27(1) of the BPR) of the time when the submitted documentation is considered complete, that further discussions are needed with the eCA, so in line with Article 27(2) of the BPR the applicant cannot proceed to place the product on the market until the matter is resolved.<br><br>If the nMS does not notify the applicant within 30 days of the time when the submitted documentation is considered complete, step 1 bilateral discussion period (60d) is not triggered and a formal referral cannot be submitted. | nMS to notify the applicant within 30 days of the time when the submitted documentation is considered complete, that they cannot proceed to place the product on the market until the matter is resolved. |
| 1 | **Bilateral discussion during the MR phase**[5]<br><br>Either for MRP or MRS (also for MAC and RNL applications), the 90-day period is divided into two periods:<br>- a first phase (40 days) for any cMS to check the dossier and if necessary to send comments on the evaluation made by rMS (all cMSs where a MR procedure is ongoing in cc),<br>- a second phase (50 days) for rMS to check the comments received and respond to cMSs (i.e. the time for the bilateral exchange).<br><br>In case an applicant decides to withdraw an application for authorisation from a cMS during the 90 day period MR phase, the cMS should inform cMSs where a MR procedure is ongoing and the rMS via ad hoc communication in R4BP3. Afterwards, those comments can be taken over by another cMS with ongoing MR procedure for the product and those comments may be referred to the CG by another cMS. Where no other cMS takes over the comments, those comments will be considered as closed.<br><br>**Bilateral discussion in case of SN procedure**[6]<br><br>The 60-day period (following the 30-day period set in step 0) is divided into two periods: | cMSs to formulate comments within the first 40-day period.<br><br>rMS to provide responses to the comments made by cMSs in due time, so that cMSs may have some time to decide on either agreeing on the SPC[7] or submitting a referral by day 90[8]. |

[4] This is only applicable for SN applications, with the exception when the notification is done due to the amendment or cancellation of the SA.
[5] SoP for the MR process should be followed: https://webgate.ec.europa.eu/s-circabc/w/browse/916f1e1f-0de7-4748-aeb2-2ed81f91e90c
[6] This is only applicable for SN applications.
[7] Agreement on the SPC is not applicable in case of parallel processes where the conclusion of the assessment of the rMS is non-authorisation.
[8] The decision that a referral will be submitted needs to be made by day 90, however, the referral itself needs to be submitted by day 100.

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| | - a first phase (30 days) for any nMS to send comments on the evaluation made by the eCA (all nMSs where a SN procedure is ongoing in cc),<br>- a second phase (30 additional days) for the eCA to check the comments received and respond to nMSs (i.e. the time for the bilateral exchange).<br><br>In case an applicant decides to withdraw an application for notification from an nMS during the 60 day bilateral discussion period, that nMS should inform the other nMSs and the eCA via ad hoc communication in R4BP3. Afterwards, those comments can be taken over by another nMS with an ongoing notification for the product and those comments may be referred to the CG by another nMS. Where no other nMS takes over the comments, those comments will be considered as closed. | nMSs to formulate comments within the first 30-day period.<br>eCA to provide responses to the comments made by nMSs in due time, so that nMSs may have some time before day 60 to decide on either agreeing on the SPC or submitting a referral. |
| 2 | **Submission of formal referrals:**<br><br>cMSs[9]/rMS[10] may submit a formal referral if:<br>- the icMS and rMS have exhausted the time period (90d for MRS, MRP, MAC, RNL and 45 d for MIC) for mutual recognition without reaching agreement.<br>- the rMS has not provided a response to comments that have been raised by day 40 of the MR phase.<br>- where relevant, the icMS disagrees with the updated PAR or SPC after the commenting period of the MR phase.<br>- during the sequence processes (changes applications, mutual recognition) the rMS and the icMS agree that the SPC needs to be amended, then this should be considered as a disagreement on the conditions of authorization of the product and, therefore, the disagreement should be referred to the CG[11].<br><br>Formal referrals to the CG should be submitted by the icMS[9]/rMS[10] to the SECR[12] at the latest 10 days following the expiration of the 90-day period (for MRS, MRP, MAC and RNL) for agreement on the SPC.[13] The confirmatory email between the rMS and icMS regarding the confidentiality of the referral template (i.e., whether the template and/or annex(es) can be shared with the applicant, and where applicable the authorisation holder) should be attached when the | Initiating cMS/rMS<br><br>SECR to check whether point 2 has been followed by icMS(s) and rMS (considering information in the formal referral document). |

[9] The referral should be submitted by the CG CP of the icMS via email, unless it is signed by the CG CP.
[10] In case of ADC, MIC and MAC processes, in accordance with Art. 10(2) of Regulation (EU) No 354/2013, the rMS needs to refer the referral to the CG. In case of a RNL process, in accordance with Article Art. 7(2) of Regulation (EU) No 492/2014, it is also the rMS that needs to refer the referral to the CG. Although the rMS needs to inform the SECR about the initiation of the referral via email before the end of the referral submission deadline (i.e., at the latest 10 days following the MR phase) in case of ADC, MIC, MAC and RNL processes, the preparation and submission of the supporting document for the referral to the SECR before the end of the referral submission deadline is still the responsibility of the icMS. The referral should be submitted by the CG CP of the icMS via email, unless it is signed by the CG CP.
[11] If an agreement between the rMS and the icMS is found for a point of disagreement, it should be noted in the referral document in the third column of table A.
[12] ECHA Secretariat to the Coordination Group
[13] This timeline could be extended only in very exceptional cases when the period falls under holidays, or in case of technical issues, e.g. IT issues. However, it should be agreed by the Commission, the Chair and the SECR, and accordingly by all MSs.

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| | referral is submitted[14].<br><br>By analogy, a formal referral to the CG should be submitted at the latest 10 days following the expiration of the 45-day period for minor changes applications (MIC), the 30-day period for administrative changes (ADC), and the 120-day period for Article 48 procedure.<br><br>The referral template should be used for submitting a referral.[15,16]<br><br>Referrals on the same product for MR can be submitted by different cMSs at the latest 10 days following the expiration of the 90-day period for agreement on the SPC. The referral template should be used for submitting additional referrals. All the referrals submitted by different cMSs on the same product within the 90+10 days will be combined and treated as a single case.[17] This procedure is applied by analogy for MIC, MAC, ADC, RNL applications and Article 48 procedure.<br><br>When submitting the referral, the icMS should send the referral template to the rMS, COM, the Chair and the SECR to the CG functional mail box[18]. | Initiating nMS |
| | nMSs may submit a formal referral if:<br>- the inititating nMS (inMS) informed the applicant within 30 days of the submission of the application that the product's placing on the market should be halted[19]. Following this 30d period the inMS and eCA have exhausted the time period (60d) for bilateral discussion without reaching agreement.<br>- the eCA has not provided a response to comments that have been raised by day 30 of the 60d bilateral discussion period.<br>- where relevant, the inMS disagrees with the SPC after the bilateral discussion period.<br>- the eCA and the inMS agree that the SPC needs to be amended related to the conditions of Article 25 of the BPR, then this should be considered as a disagreement in the conditions of authorization of the product and, therefore, the disagreement should be referred to the CG[20].<br><br>Formal referrals to the CG should be submitted by the CG Member or CG alternate Member of the inMS to the SECR[21] at the latest 10 days following the expiration of | SECR to check whether point 2 has been followed by inMS(s) and eCA (considering the information in the formal referral document). |

[14] If the rMS did not provide an answer to the icMS on the matter this should be indicated and the email sent to the rMS should be attached.
[15] "Template_disagreement to CG_rev7" is available at https://webgate.ec.europa.eu/s-circabc/w/browse/e98fe9c0-cd2e-4829-9523-2bb128796c19
[16] The referral document should be referenced using the product name as mentioned in R4BP 3 in the rMS.
[17] In case of MRS procedures, it will be evaluated case-by-case whether the referrals can be combined considering the 90+10 day timeline for submission.
[18] In case of ADC, MIC, MAC and RNL processes, the rMS needs to inform the SECR about the initiation of the referral via email before the end of the referral submission deadline. However, the preparation and submission of the supporting document for the referral to the SECR before the end of the referral submission deadline is still the responsibility of the icMS.
[19] This is not applicable when the notification is done due to the amendment or cancellation of the SA.
[20] If an agreement between the eCA and the inMS is found for a point of disagreement, it should be noted in the referral document in the third column of table A.
[21] ECHA Secretariat to the Coordination Group

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| | the 60-day period for agreement on the SPC.[22] The confirmatory email between the eCA and inMS regarding the confidentiality of the referral template (i.e., whether the template and/or annex(es) can be shared with the applicant, and where applicable the authorisation holder) should be attached when the referral is submitted[23].<br><br>The referral template should be used for submitting a referral.[24,25]<br><br>In case an applicant decides to withdraw an application for authorisation from a cMS that expressed their intention to submit/had already submitted (before the referral submission deadline) a referral and the withdrawal takes place after the 90-day period MR phase and before any initiated referrals are accepted, that cMS should inform the other cMSs where a MR procedure is ongoing and the rMS via ad hoc communication in R4BP3. The SECR should be notified as well, via email. Afterwards, those comments can be taken over by another cMS with ongoing MR procedure for the product and referred to the CG by another cMS within 7 days of being informed of the situation. Where no other cMS takes over the comments, those comments will be considered as closed for that procedure.[26]<br><br>Referrals on the same product for notification can be submitted by different nMSs at the latest 10 days following the expiration of the 60-day period for agreement on the SPC. The referral template should be used for submitting additional referrals. All the referrals submitted by different nMSs on the same product within the 60+10 days will be combined and treated as a single case.[27]<br><br>In case an applicant decides to withdraw an application for notification from an nMS that expressed their intention to submit/had already submitted (before the referral submission deadline) a referral and the withdrawal takes place after the 60 day bilateral discussion period and before any initiated referrals are accepted, that nMS should inform the other nMSs and the eCA via ad hoc communication in R4BP3. The SECR should be notified as well, via email. Afterwards, those comments can be taken over by another nMS with an ongoing notification for the product and referred to the CG by another nMS within 7 days of being informed of the situation. Where no other nMS takes over the comments, those comments will be considered as | |

[22] This timeline could be extended only in very exceptional cases when the period falls under holidays, or in case of technical issues, e.g. IT issues. However, it should be agreed by the Commission, the Chair and the SECR, and accordingly by all MSs.
[23] If the rMS did not provide an answer to the icMS on the matter this should be indicated and the email sent to the rMS should be attached.
[24] "Template_disagreement to CG_SN procedures_ver3": is available at https://webgate.ec.europa.eu/s-circabc/w/browse/e98fe9c0-cd2e-4829-9523-2bb128796c19
[25] The referral document should be referenced using the product name as mentioned in R4BP3 in the eCA.
[26] The 90+10 day timeline for referral submission might be exceeded in such cases.
[27] The referral should be submitted by the CG Member or CG alternate Member of the inMS via email, unless it is signed by the CG Member or CG alternate Member. In addition, it will be evaluated case-by-case whether the referrals can be combined considering the 60+10 day timeline for submission.

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| | closed for that procedure.[28]<br><br>When submitting the referral, the inMS should send the referral template to the eCA, COM, the Chair and the SECR to the CG functional mail box. | |
| 3 | **Acceptance of referrals**:<br><br>The SECR will assess whether the correct referral template is submitted, that it is filled out properly and signed. The SECR will also check that the adequate confirmatory email between the rMS and icMS / eCA and inMS regarding the confidentiality of the referral template (i.e., whether the template and/or annex(es) can be shared with the applicant, and where applicable the authorisation holder) is attached. The SECR will inform the Chair and COM on the referral received and within three working days the Chair and COM will assess whether the referral is accepted.<br><br>For parallel processes the acceptance of the referrals will be initiated on the next working day after the deadline for submission of referrals.<br><br>Referrals will only be accepted in exceptional situations[29] when the submission of the referral is outside of the following timelines:<br>• 90+10 days (for MRP, MRS, MAC and RNL),<br>• 45+10 days (for MIC),<br>• 30+10 days (for ADC),<br>• 60+10 days (for SN)<br>• 120+10 days (for Article 48 procedure).<br><br>A point of disagreement will not be accepted where it was not raised within the first 40 days of the MR phase for MRP, MRS, MAC and RNL procedures[30,31]. A point of disagreement will not be accepted where it was not raised within the first 30 days of the bilateral discussion period for SN procedures.<br><br>The acceptance of the formal referral marks the start of the 60-day process[32]. | The SECR to check whether the conditions of point 3 are followed by the MSs and to inform the Chair and COM on the referral received.<br><br>The Chair and COM to inform the SECR within three working days whether the referral can be accepted.<br><br>The SECR to inform CG Member and CG alternate Member(s) of the icMS and the rMS/inMS and the eCA, if the referral is not accepted. |
| 4 | **Distribution of the relevant documents**:<br><br>After acceptance, the SECR will distribute the referral documents to all CG Members, CG alternate Members and the applicant (and where applicable, the authorisation holder).<br><br>For all procedures in parallel, the SECR will launch the referral(s) on the same product at the latest within 2 working days after the acceptance of the referral(s). | The SECR (within the next 2 working days after acceptance)<br>- to create a collaboration in Interact Portal;<br>- upload supporting document(s) for the referral (and where applicable, annex(es)) & commenting table;<br>- inform CG Members and CG alternate Members; |

[28] The 60+10 day timeline for referral submission might be exceeded in such cases.
[29] In such cases (e.g. technical difficulties in submitting the referral) a justification for the delay will need to be provided by the icMS/inMS and they will be considered on a case-by-case basis by the Chair and COM.
[30] Where the point of disagreement concerns the updated PAR or SPC after the commenting period of the MR phase, it can be accepted.
[31] This is not applicable for ADC and MIC applications, as well as Article 48 procedure.
[32] The day of acceptance is considered day 0 of the 60 day process.

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| | icMS/inMS is responsible:<br>• to clearly identify the contact details of the applicant, to whom the referral document will be sent[33],<br>• to ensure and provide email communication between the rMS and icMS / eCA and inMS as proof that the referral documents do not contain any confidential information which cannot be shared with the applicant/authorisation holder. | - ask CG Members, CG alternate Members and the applicant/authorisation holder for comments.<br><br>icMS/inMS in cooperation with rMS/eCA |
| 5 | **Commenting phase:**<br><br>All MSs and applicant/authorisation holder to comment in 2 weeks.<br><br>When a MS does not provide comments, it is considered that this MS supports the position of the rMS/eCA during the Preparatory phase (point 6).<br><br>The SECR to input the comments received from the applicant/authorisation holder into the dedicated collaboration in Interact Portal.<br><br>- The SECR requests responses from the rMS/eCA indicating a deadline and records the deadline in the commenting table in the dedicated collaboration in Interact Portal.<br><br>- The rMS/eCA replies to the comments received from the MSs and applicant/authorisation holder by writing its answers in the commenting table in the dedicated collaboration in **Interact Portal.**<br><br>- The rMS/eCA and icMS/inMS continue with the bilateral discussions, involving, where relevant, the applicant/authorisation holder and inform all other MSs on the outcome of their discussion through Interact Portal.<br><br>- All discussions (comments and revised documents (revised PAR, revised SPC)) should be posted on **Interact Portal,** so that each MS is aware of the ongoing discussions.<br><br>- The rMS/eCA keeps the applicant or authorisation holder informed about the progress and ongoing discussions of the referral.[34] | MS(s) and applicant/authorisation holder (2 weeks)<br><br>The SECR<br><br>The SECR (within the next working day after the end of the commenting period; indicating if time allows, 1 week after the deadline for commenting, or otherwise 3 days prior to the discussion in the CG meeting)<br><br>rMS/eCA (within the deadline indicated by SECR)<br><br>rMS/eCA and icMS(s)/inMS(s)<br><br>rMS/eCA, icMS(s)/inMS(s), the SECR<br><br>rMS/eCA |

[33] If the authorisation holder and the applicant are different legal entities, this is up to the icMS, in cooperation with the rMS, to prepare a referral document with the points of disagreements which can be shared with the applicant/authorisation holder.
[34] This is applicable thorugh all referral process.

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| 6 | **Preparatory phase:**<br><br>- Optional: The SECR organises a preparatory conference call before the CG meeting and invites all MSs, COM and the applicant or authorisation holder to participate in the meeting. | <br><br>The SECR, MSs and COM |
| 7 | **Discussion by the CG**<br><br>**Addressing the comments received**<br><br>**icMS(s)/inMS(s)** to:<br>- reply to comments in a written form, before the CG discussion.<br><br>**The SECR** to:<br>- prepare a document including the open points for discussion (and comments of the MSs and applicant on these points).<br>- if a potential way forward arose from the preparatory phase, the SECR to distribute a written summary to the CG Members and CG alternate Members.<br>If written comments are received from the applicant/authorisation holder, the SECR to upload the document for the next CG discussion.<br><br>**Reaching an agreement / closing the referral:**<br><br>The SECR assists in organising a written procedure towards reaching an agreement on the case within the CG. The discussions held by the participation of the CG members in the context of the disagreement; or in case of MRS and SN the bilateral agreement between the icMS and the rMS / inMS and eCA, where one has been found, will serve as the basis for reaching the agreement within the CG. The procedure for reaching an agreement is detailed in the CG Rules of Procedure (Article 13: Agreements).<br><br>If the application for MR is withdrawn in the icMS during the referral time, the icMS informs the SECR, which will forward this information to the CG Members and CG alternate Members via e-mail. Afterwards, the referral may be taken over by another cMS with an ongoing MR procedure for the product, adhering to the deadlines for closing the referral from the first referral submission. Where no cMS takes over the referral, then it is considered as withdrawn.<br><br>If the application for SN is withdrawn in the inMS during the referral time, the inMS informs the SECR, which will forward this information to the CG Members and CG alternate Members via e-mail. Afterwards, the referral may be taken over by another nMS with an ongoing SN procedure for the product, adhering to the deadlines for closing the referral from the first referral submission. Where no nMS takes over the referral, then it is considered as withdrawn. | All MSs, COM and applicant/authorisation holder<br><br>icMS(s)/inMS(s) (within the deadline indicated by SECR)<br><br>The SECR<br><br>The SECR<br><br>icMS<br><br>inMS<br><br>The SECR |

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| | **Record discussion:**<br>When the discussion takes place at a regular CG meeting, ECHA will record the actions, conclusions and prepare the draft minutes of the discussion. When the discussion takes place at an additional CG meeting, ECHA might only prepare the conclusions of the discussion on a case-by-case basis (e.g., if the items of the additional meeting are only related to referrals, separate minutes will not be prepared).<br><br>The outcome of the referral is drafted and agreed at the regular or additional CG meeting or by written procedure, and then made available to the CG members in the dedicated Interact Portal collaboration.<br><br>The SECR provides the applicant/authorisation holder with the conclusion of the meeting on the discussion of their biocidal product. The conclusions are also made available to the CG members in the dedicated Interact Portal collaboration. | |
| 8 | **Further dialogue via adhoc meetings:**<br><br>If unresolved disagreements remain and in order to respect the 60-day deadline:<br>- virtual discussions may be organised with the cMS(s)/nMS(s), rMS/eCA, applicant/authorisation holder, the SECR, Chair, COM and other MSs.<br>- additional meeting(s) might be organised.<br>- written procedure may be used.<br><br>If an agreement needs to be reached via written procedure, that needs to be communicated to the CG members. | The SECR |
| 9 | **Make the outcome publicly available:**<br><br>When the referral is closed, the SECR will prepare a short summary document, with the main points of disagreement discussed and the agreed outcome. After consultation with the applicant/authorisation holder, the summary document will be made available in the public CIRCABC platform. | The SECR |
| 10 | **No agreement is reached:**<br><br>After the expiry of the 60-day period, if no agreement is reached, the SECR informs the rMS/eCA that they may now proceed to refer the disagreement to COM according to Article 36 of the BPR. The detailed statement should be sent to the COM, cMSs/nMSs, the applicant, and where applicable to the authorisation holder and to ECHA via ad-hoc communication in R4BP3. | The SECR and rMS/eCA |

# 4. Document management

**S-CIRCABC Interest Group and Interact Portal collaboration**

One Coordination Group (CG) Interest Group in S-CIRCABC and collaborations in Interact Portal assist the work of the CG. These serve for exchange of the meeting documents concerning disagreements. For confidential information the Biocides Coordination Group S-CIRCABC and Interact Portal is used, while the public documents are available in the public CIRCABC platform.

**Document numbering**

For clarity, all general documents concerning disagreements to be distributed for a regular or additional CG meeting will have a numbering system, while documents concerning specific disagreements are not numbered.

The structure **CG-X-20YY-#** is used in case of general documents concerning disagreements for a regular CG meeting. Where '**CG**' reflects that the document corresponds to the Coordination Group meeting, '**X**' is the number of the regular meeting (first, second, third…) held in a certain year (**20YY**) and the last number (**#**), an ordinal provided to distinguish the different existing documents. Example: CG-1-2013-01.

This proposal also considers two types of special documents, which would be slightly different:

- Agenda: with an 'A', CG-**A**-X-20YY. Example: CG-A-1-2013;
- Minutes: with an 'M', CG-**M**-X-20YY. Example: CG-M-1-2013.

The structure **CG-AD-20YYMM-#** is used in case of general documents concerning disagreement. Where '**CG-AD**' reflects that the document corresponds to a document for an additional CG meeting held in a certain year and month (**20YYMM**) and the last number (**#**), an ordinal provided to distinguish the different existing documents. Example: CG-AD-2022Jan-01.

**CG functional mailbox**

The ECHA Secretariat for the CG uses the functional mailbox: biocides-coordination-group@echa.europa.eu to communicate with the CG Members and CG alternate Members. The communication includes: notification e-mails, with the corresponding links, informing the members that relevant documents are uploaded in CIRCABC, such as invitations to attend meetings, agendas, minutes, meeting documents, commenting rounds. The CG Members and CG alternate Members are invited to continue to use the CG functional mailbox to communicate with ECHA Secretariat with regard to meeting organisation or any other relevant matter, which is not a subject to the communication via Interact Portal or R4BP3 as described above in this working procedure.

**Disagreement template**

Two templates are provided to help MSs transmit the required information in a structured format: one for SN processes and one for all other processes.

# 5. Definitions and acronyms

| Abbreviation | Definition |
|---|---|
| ADC | Administrative change |
| BPR | Biocidal Products Regulation |
| CG | Coordination Group |
| CG alternate Member | Coordination Group alternate Member |

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|---|---|
| CG Member | Coordination Group Member |
| CIRCABC | Communication and Information Resource Centre for Administrations, Businesses and Citizens |
| cMS | Concerned Member State |
| COM | European Commission |
| eCA | Evaluating competent authority |
| ECHA | European Chemicals Agency |
| icMS | Initiating concerned Member State |
| inMS | Initiating notified Member State |
| MAC | Major change |
| MIC | Minor change |
| MR | Mutual recognition |
| MRP | Mutual recognition in parallel |
| MRS | Mutual recognition in sequence |
| MS | Member State |
| nMS | Notified Member State |
| PAR | Product Assessment Report |
| R4BP 3 | Register for Biocidal Products, Version 3 |
| RCOM | Response to Comments table |
| rMS | Reference Member State |
| RNL | Renewal |
| SECR | ECHA Secretariat of the Coordination Group |
| SoP | Standard operating Procedure |
| SPC | Summary of the product characteristics |
| SN | Simplified notification |