

Working procedure for e-consultations in the Coordination Group

Contents

| | |
|---|----------|
| Document identifier..... | 3 |
| 1. Purpose | 5 |
| 2. Scope..... | 5 |
| 3. General considerations..... | 5 |
| 4. Description of the steps of the processes | 6 |
| 5. Annex – Instructions for preparation of the final document..... | 9 |
| Document identifier..... | 9 |
| Document history | 9 |
| 6. Definitions and acronyms..... | 9 |

Document identifier

Working Procedure for e-consultations_v4

Document history

| Version | Changes | Date of agreement | Date of applicability |
|---------|--|---|--|
| 1.0 | First edition (original unnumbered version) | 7 July 2016 [at CG-18] | 25 August 2016 |
| 2.0 | Main changes in the document: <ul style="list-style-type: none"> • Adaptation of the text regarding the use of Interact Portal; • Introduction of a template for e-consultations; • Differentiation between formal and informal e-consultations (i.e., informal enquiries). Establishment of the concept and process of informal enquiries (table 2); • Amendment of the text to make involvement of ASOs from the start of e-consultations in case of general topics and in case of informal enquiries possible; • Establishment of a dedicated collaboration for MSs to record initiated informal enquiries, their outcomes and upload documents. | 1 July 2021 [at CG-47] | For e-consultations submitted after 2 July 2021 (publication date) |
| 3.0 | Main changes in the document: <ul style="list-style-type: none"> • Amendments related to the use of collaboration in Interact Portal for commenting on e-consultations; • Clarification on the preparation of the final document once an e-consultation has been agreed. | 27 April 2023 [at CG-56] | For e-consultations where the iMS submits the final document to the SECR after 2 May 2023 (publication date) |
| 4.0 | Main changes in the document: <ul style="list-style-type: none"> • Modification of the structure (addition of the document history and rewording of section 1); • Replacement of the reference to CG Contact Points by CG Members and CG Alternates to reflect the same change in the Rules of Procedures; • Modification of the instructions for the preparation of the final document once an e-consultation has been agreed; • Update of the link to the template for e-consultations; | 2 April 2024 [via written procedure] | For e-consultations where the final document is published after 2 April 2024 (publication date) |

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| | <ul style="list-style-type: none">• Inclusion of reference to the Interact Portal collaboration for informal enquiries and detailed information about the mailing list to be used for informal enquiries. | | |
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1. Purpose

This document forms the basis for carrying out, reporting and archiving formal e-consultations (hereby referred to as 'e-consultations') discussed at the Coordination Group (CG), as well as the concept and process for informal e-consultations (hereby named and referred to as 'informal enquiry').

This document is to be applied by participants in the work of the CG for carrying out e-consultations, including all Member States (CG Member and CG alternate Members) and the Secretariat. This working procedure will be reviewed and updated in the light of experience.

2. Scope

This document details the steps to be taken during the initiation, commenting, conclusion and archiving phases of e-consultations. The working procedure is intended to clarify the steps of the process and facilitate the accessibility to the information gathered during e-consultations.

This document also clarifies the concept and steps of the process of informal enquiries.

3. General considerations

e-Consultations are initiated in order to raise questions and discussions related to technical and policy issues on product authorisation.

The initiating Member State (iMS) should consider, especially in case the topic of the e-consultation or informal enquiry is general, to involve ASOs in the process from the beginning and in case of e-consultations to also indicate this to the CG SECR in accordance with point 1.1.b) in section 4 of this document.

Informal enquiries aim to provide the possibility to MSs to contact other MSs via email directly and collect feedback from them (the CG SECR should be kept in cc for information). The informal enquiry itself and the outcome are not recorded by the CG SECR and not binding like the agreements reached in case of e-consultations in the CG.

MSs should consider the difference in the process and the outcome of e-consultations and informal enquiries when deciding on the type of e-consultation they would like to initiate.¹ If the iMS considers during the informal enquiry that the raised topic would be better discussed as an e-consultation, the iMS can initiate it as such.

N.B.: To avoid confusion and unnecessary duplication of work, topics that are discussed in other fora (e.g. BPC WGs, CA meeting) should not be discussed in parallel through e-consultations of the CG.

Communication with the SECR should take place through the Coordination Group functional mail box biocides-coordination-group@echa.europa.eu

¹ In case of technical questions related to national or simplified authorisation processes the iMS should especially consider choosing informal e-consultations as the type of the e-consultation.

4. Description of the steps of the processes

The individual steps for the process of e-consultations are described in Table 1 and the individual steps for informal enquiries are described in Table 2.

Table 1: Description of the process steps for e-consultations

| Step | Description of process step | Responsible actor |
|------|--|---|
| 1 | <p>Submission of request to initiate an e-consultation</p> <ol style="list-style-type: none"> 1. A request to initiate an e-consultation is sent to the SECR via email by the iMS. The request will include: <ol style="list-style-type: none"> a. A document² with a clear description of the discussion topic. b. Indication of the confidential nature of the topic (in view of a discussion in an open or closed session of a CG meeting), area of discussion and whether ASOs could be involved directly from the start of the e-consultation (i.e. for the commenting). <p>The e-consultation commenting period is 3 weeks. If a different timeframe is required, this should be requested and justified by the iMS.</p> 2. The SECR requests the approval from the Chair of the CG and the opinion of the COM to initiate the e-consultation. In case of the absence of the Chair, the Vice-Chair will be consulted. In case of the absence of the Chair and Vice-Chair, the SECR will decide whether to approve the request in consultation with the COM. | <p>iMS</p> <p>SECR/Chair/COM/Vice-Chair</p> |
| 2 | <p>Initiation of the e-consultation if ASOs is not involved directly from the start:</p> <ol style="list-style-type: none"> 1. Once approval from the Chair of the CG is received, the SECR will initiate the e-consultation: 2. The SECR launches a collaboration via Interact Portal for the CG Contact Points. 3. The SECR sends a communication to the Contact Points via email stating the discussion topic, the deadline for comments and a link to the collaboration in Interact Portal. <p>Initiation of the e-consultation if ASOs is involved directly from the start:</p> <ol style="list-style-type: none"> 1. Once approval from the Chair of the CG is received, the SECR will initiate the e-consultation. 2. The SECR launches a collaboration via Interact Portal for both the CG Members, CG alternate Members, and ASOs. 3. The SECR sends a communication to the CG Members, CG alternate Members, and ASOs, via email stating the discussion topic, the deadline for comments and a link to the collaboration in Interact Portal. | SECR |
| 3 | <p>Commenting phase if ASOs is not involved directly from the start:</p> <ol style="list-style-type: none"> 1. MSs provide comments. 2. After the deadline for commenting, the SECR informs via email the iMS that the commenting period ended and that the workspace in Interact Portal is frozen. 3. Exceptionally, the deadline of the e-consultation can be extended | <p>All MSs SECR</p> <p>iMS, SECR</p> |

² "Template_CG e-consultation_ver2" is available at: <https://webgate.ec.europa.eu/s-circabc/w/browse/b980f8f8-33c8-40f9-8f25-0e5e9c580c69>. The disclaimer should be deleted from the filled out template before it is sent to the SECR.

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| | <p>on request of a MS, if approved by the iMS and the Chair. The extension would be 1 week unless otherwise specified in the request.</p> <p>Commenting phase if ASOs is involved directly from the start:</p> <ol style="list-style-type: none"> 1. MSs and ASOs provide comments. 2. After the deadline for commenting, the SECR informs via email the iMS that the commenting period ended and that the workspace in Interact Portal is frozen. 3. Exceptionally, the deadline of the e-consultation can be extended on request of a MS or an ASO, if approved by the iMS and the Chair. The extension would be 1 week unless otherwise specified in the request. | <p>All MSs, ASOs SECR</p> <p>iMS, SECR</p> |
| 4 | <p>Finalization phase:</p> <p>After receiving the comments from the SECR, the iMS prepares a summary document with the conclusions of the e-consultation to be presented in the next regular CG meeting.</p> <p>For non-confidential e-consultations (i.e., e-consultations discussed in the open session), the prepared document should not include the comments of the MSs and ASOs, only a summary of the different views and the number of MSs and ASOs supporting them.</p> <p>The iMS sends the document to the SECR at the latest 12 days before the next regular CG meeting and indicates whether the e-consultation should be discussed in the closed or the open session of the meeting.</p> | <p>iMS (12 days before the CG meeting)</p> |
| 5 | <p>Discussion by the CG</p> <p>The SECR distributes the overview list of all the on-going e-consultations 10 days before the CG meeting, at the latest. This list will be updated with the new e-consultations to be discussed in the next regular CG meeting. The list will include:</p> <ul style="list-style-type: none"> • Reference number • Title of e-consultation • Date of initiation • iMS • Confidentiality nature • CG-meeting corresponding to the presentation of conclusions • Location in S-CIRCABC or Interact Portal <p>In addition, the SECR will also distribute the summary document with the conclusion of the e-consultations 10 days before the regular CG meeting, at the latest.</p> <p>During the CG meeting, each iMS will present the conclusions of the e-consultations for discussion and agreement.</p> <p>The outcome of the discussion and the follow-up actions will be recorded in the minutes of the regular CG meeting.</p> | <p>SECR (10 days before the CG meeting, at the latest)</p> <p>iMS/CG members</p> <p>SECR</p> |
| 6 | <p>Final document</p> <p>The iMS will prepare and send to the SECR the final document (in .docx format) reflecting the discussion and agreement at the regular CG meeting by the deadline established in the action points of the regular CG meeting during which agreement was reached on the e-consultation. Instructions for the preparation of the final document are listed under section 5 of this Working Procedure.</p> | <p>SECR</p> |
| 7 | <p>Making the final document available</p> <p>The SECR will upload the final document of the e-consultation to the latest</p> | <p>SECR</p> |

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| | <p>collaboration related to the e-consultation in Interact Portal. In case the e-consultation was non-confidential the final document will also be uploaded to the public CG S-CIRCABC site.</p> <p>A complete overview of the e-consultations discussed so far at the CG will be regularly updated and stored in the public CG S-CIRCABC site.</p> | |
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Table 2: Description of the process steps for informal enquiries

| Step | Description of process step | Responsible actor |
|-------------|--|--|
| 1 | <p>Initiation of the informal enquiry</p> <p>An informal enquiry is launched via email by the iMS, including the CG Members, CG alternate Members, and the MSCA experts of the indicated field^{3,4}, as well as SECR in copy. The email will include:</p> <ol style="list-style-type: none"> A document⁵ with a clear description of the discussion topic. Indication of the area of discussion (e.g. efficacy), as well as any other information considered necessary (e.g. product name, R4BP3 case number, list of concerned MSs, submission date of the application). Indication of the deadline for the commenting period. | iMS |
| 2 | <p>Commenting phase:</p> <ol style="list-style-type: none"> MSs (and ASOs if they are involved) provide comments by replying to the initial email of the iMS and including all CG Members and CG alternate Members in copy, as well as SECR. Exceptionally, the iMS can choose to extend the deadline of the informal enquiry. | All MSs (and ASOs if they are involved) iMS |
| 3 | <p>Finalisation phase:</p> <p>After the commenting phase, the iMS prepares a summary document with the comments of the MSs and the outcome (i.e. the approach of the iMS that it will take regarding the raised topic) of the informal enquiry and sends the document to the CG Members, CG alternate Members, and the MSCA experts of the indicated field (and ASOs if they were involved), as well as the SECR, as soon as possible.</p> <p>The iMS uploads the summary document of the informal enquiry to the Interact Portal collaboration `CG collaboration – Informal enquiries`⁶ used for recording the outcomes of informal enquiries and records the outcome in the designated excel file.</p> <p>The iMS may inform the applicant in regards of the outcome of the informal enquiry, if deemed necessary.</p> <p>If there is no clear outcome for the informal enquiry, the iMS may organise an informal virtual meeting with the representatives of other MSs in order to discuss critical points in order to resolve issues in a timely manner.</p> | iMS |

³ The iMS may send the email to ASOs as well, if involvement of ASOs is deemed necessary or useful.

⁴ The mailing list for CG Members, CG alternate Members, MSCA experts and ASOs (only accessible for MSs) is available under the Supporting Documents folder in the collaboration `CG collaboration – Informal enquiries` at: <https://interact-toolbox-collaboration.echa.europa.eu/collaboration-frontend/collaborations/919988>. The mailing list is updated regularly and the MS should always use the latest list.

⁵ "Template_CG_e-consultation_ver2" is available at: <https://webgate.ec.europa.eu/s-circabc/w/browse/b980f8f8-33c8-40f9-8f25-0e5e9c580c69>. The disclaimer should be deleted from the filled out template before it is sent to the SECR. In case the document contains confidential information it might be uploaded in the Interact Portal collaboration used for recording the outcomes of informal enquiries.

⁶ The collaboration (only accessible for MSs) is available at: <https://interact-toolbox-collaboration.echa.europa.eu/collaboration-frontend/collaborations/919988>

5. Annex – Instructions for preparation of the final document

This final document should be in .docx format and should include the following:

- document identifier section after the table of the basic details of the e-consultation (part of the template for e-consultation) stating the number and name of the final document (as assigned for the regular CG meeting), as well as the version number (vf, or the applicable version number in case the document is updated):

Document identifier

CG-XX-20YY-0X AP X.X Document name_vf

- document version history stating the changes, the date and regular CG meeting of agreement:

Document history

| Version | Changes | Date of agreement | Date of applicability |
|---------|---|--------------------------|----------------------------------|
| 1.0 | First edition (original unnumbered version) | DD MM 20YY [at CG-XX] | DD MM 20YY |
| 2.0 | Main changes in the document: <ul style="list-style-type: none"> Description of the change | DD MM 20YY [at CG-XX] | DD MM 20YY (publication date) |

If the exact date of applicability is agreed during the CG meeting it should be indicated by the iMS in the last column of the table. Otherwise, the SECR will include the date of applicability (also publication date).

In case it is the first agreement on a topic, the second row in the above table should be removed.

- description of the discussion topic and the proposed questions,
- the reached agreement,
- indication during which regular CG meeting the agreement was reached and whether it was done so by consensus or two thirds majority.

The final document should **not** include:

- any reference to the iMS in the headers and footers,
- link(s) to the collaboration(s) where discussion of the e-consultation took place in writing,
- comments of the MSs or ASOs (indication of the number of commenting MSs and ASOs per written commenting round can be included in the background)⁷,
- discussion details, like amendment of the initial proposal to the raised issue **Error! Bookmark not defined.**

6. Definitions and acronyms

| Abbreviation | Definition |
|--------------|--|
| ASOs | Accredited Stakeholder Organisations |
| CG | Coordination Group |
| S-CIRCABC | Communication and Information Resource Centre for Administrations, Businesses and Citizens |

⁷ E-consultations concerning a particular national or simplified biocidal product/product family authorisation application would be an exception from this.

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| COM | European Commission |
| ECHA | European Chemicals Agency |
| MS | Member State |
| iMS | Initiating Member State |
| MSCA | Member State competent authority |
| n.a. | Not applicable |
| SECR | ECHA secretariat |