E-consultations and early Working Group discussions

This document intends to further harmonise the practices and terminology used in e-consultations and early Working Group (WG) discussions. The approach is based on the presentation provided to all permanent WGs at WG-I-2021. The principles are common to all permanent WGs[1] and can be extended to ad hoc WGs[2] where relevant.

Note: the term "e-consultation" is also used in other forums. This document only concerns e-consultations in the context of the BPC Working Groups.

Table 1. Terminology.

Term	Explanation
E-consultation	Electronic consultation of the views of the Member State Competent Authorities (MSCAs) (and Accredited Stakeholder Organisations if relevant) on specified questions
Early WG discussion	Discussion in a WG meeting where specific topics on an application are discussed before the evaluating Competent Authority (eCA) submits the assessment to ECHA for opinion forming.
Requesting MSCA	The MSCA requesting SECR to launch an e-consultation or schedule an early WG discussion

Table 2. Contact information. To request an e-consultation or an early WG discussion, the following contact information should be used. Please always include the Chair of the relevant WG and the ECHA Dossier Manager (DM) where available, in addition to both a WG specific and process specific mailbox where relevant. For case specific issues, always include the process specific mailbox.

Type	Working Group	E-mail
WG specific[3]	Administrative (all WGs)	BPC-WGs@echa.europa.eu
	AHEE	bpc-environmentalexposure@echa.europa.eu
	APCP	BPC-APCPWG@echa.europa.eu
	ARTFood	BPC-artfood@echa.europa.eu
	EFF	BPC-EFFWG@echa.europa.eu
	ENV	BPC-ENVWG@echa.europa.eu
	HEAdhoc	BPC-Human-Exposure@echa.europa.eu
	TOX	BPC-TOXWG@echa.europa.eu
Process specific	Active substances	biocides-active-substance@echa.europa.eu
	Union authorisation	biocides-union-authorisation@echa.europa.eu
	Article 38	biocides-article-38@echa.europa.eu
	Article 75(1)(g)	biocides-article-75@echa.europa.eu

[1] Analytical Methods and Physico-chemical Properties (APCP), Efficacy (EFF), Environment (ENV), Human Health (TOX)
[2] Ad Hoc Environmental Exposure Working Group (AHEE), Ad hoc Working Group - Assessment of Residue Transfer to Food (ARTFood), Ad hoc Working Group - Human Exposure (HEAdhoc), Ad hoc Working Group – Micro-organisms (MO)
[3] A functional mailbox for the MO WG is not available as this would seem unnecessary with the current numbers of micro-organism applications. Any messages on micro-organisms can be sent to the relevant process specific mailbox, or BPC-WGs@echa.europa.eu for administrative matters.

1. E-consultations

1.1 Scope of an e-consultation

The topics expected to be handled in e-consultations are normally, but not exclusively in the context of:

a) Active substances: approval, renewal, Annex I inclusion, review of approval;

b) Union authorisation application, change and renewal

c) Commission mandates in the context of Articles 38 and 75(1)(g) of the BPR;

d) Guidance.

Questions regarding national authorisations (including mutual recognition) are handled within the Coordination Group[4].

Policy aspects should not be handled in e-consultations.

1.2 Requesting an e-consultation

In an e-consultation, one MSCA (or SECR) is asking for input from the other MSCAs on specific questions regarding any of the topics listed in section 1.1 above. To request an e-consultation, see "Contact information" in the Introduction above.

The requesting MSCA should contact SECR asking for an e-consultation to be launched, providing the questions and supporting information in the template[5]. The information should be selected not to be excessive while ensuring that it is sufficient to allow responding to the questions. SECR may also launch e-consultations on its own initiative.

If the intention of the requesting MSCA is to proceed to a WG discussion after the e-consultation, it is advisable to request the e-consultation at the latest two months before the first day of the WG meeting as indicated in the timelines[6]

1.3 SECR input

Before launching an e-consultation, SECR may provide bilateral input to the requesting MSCA regarding aspects such as the following:

a) Whether the topic is within the remit of the respective WG

b) Whether the information provided is sufficient

c) Whether the documentation is clear

d) Whether the questions are appropriate and clear.

Normally the requesting MSCA is expected to consider the SECR input and revise the documentation as appropriate, but ultimately the requesting MSCA decides on the content of the e-consultation. In exceptional cases, SECR may decide not to launch an e-consultation if the topic is not appropriate, or the information is insufficient.

In some cases, SECR may be able to provide input that is sufficient for the requesting MSCA, rendering an e-consultation unnecessary.

1.4 Launching an e-consultation

To launch an e-consultation, SECR distributes[7] the e-consultation documentation

[4] Link to the working procedure in Confluence: https://activity.echa.europa.eu/sites/act-16/process-16-10/_layouts/15/DocIdRedir.aspx?ID=ACTV16-23-25712
[5] Available to MSCAs at: https://webgate.ec.europa.eu/s-circabc/w/browse/ff961899-bd09-4849-be58-18e5866df8a2 (Path: /CircaBC/echa/BPC-WG/Library/Confidential/07. Templates)
[6] See the BPC webpage: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee
[7] The current tools to be used are Interact Collaboration for MSCAs, and S-CIRCABC for Associated Stakeholder Organisations (where relevant). The tools used are not the topic of the current document, but the aim is to harmonise the principles.

provided by the requesting MSCA and questions to all MSCAs, who are asked to give written input. Normally at least three weeks should be allowed for an e-consultation, but shorter commenting time is possible in exceptional cases. More than three weeks should be considered where the documentation is extensive, or during holiday periods.

For e-consultations on a specific application (e.g. AS approval, Union authorisation), the eCA is encouraged to provide the same documentation and questions to the applicant, as the applicant will not have access to Interact Collaboration documents. Having the input from the applicant will increase the transparency of the process and ensure that the eCA gets all the relevant input from the applicant. The applicant may be able to provide further information regarding e.g. use patterns, testing strategy, or suggestions to apply risk management measures.

1.5 Outcome of an e-consultation

The requesting MSCA is expected to take the input into account in the assessment, considering it as advice from peers. It should be noted that the input from an e-consultation is not to be taken as a conclusion even when the input is unanimous. However, to deviate from unanimous advice from several MSCAs, the requesting MSCA should have valid reasons. If major divergencies in views are evident, it is advisable to request for a WG discussion.

Where the requesting MSCA's view remains different from other MSCAs, the requesting MSCA should carefully consider the views and rationale in the input and include such considerations in any follow-up (Product Assessment Report, Competent Authority Report, revised documents).

1.6 Follow-up

Using the template[5], the requesting MSCA should summarise the input received and provide it for information to the following WG meeting, where the requesting MSCA should also explain the selected way forward. Where relevant, this document could also be provided as background information when submitting the CAR or PAR for opinion forming.

Apart from summarising the input, no specific follow-up is required for an e-consultation.

If considered necessary, the requesting MSCA may ask for an early WG discussion to reach a conclusion on an application (e.g. AS approval, Union authorisation). To agree on guidance related topics, a WG discussion is always necessary.

2. Early WG discussions

2.1 Scope of an early WG discussion

An early WG discussion is a scheduled discussion in a WG meeting where specific topics on an application (e.g. AS approval, Union authorisation) are discussed before the eCA submits the CAR/PAR/RAR to ECHA. It has to be noted that the purpose of an early WG discussion is not to verify the final evaluation made by the eCA already before the submission of the dossier for the opinion-forming process.

The eCAs are encouraged to ask for an early WG discussion in cases where the assessment includes deviations from standard approaches or refinements/RMMs that have not been agreed earlier, or where they are unsure of conclusions that would have a major impact on the approval of the AS[8] or the authorisation of certain uses/products (e.g. new exposure/emission scenarios or deviations from agreed ones), or where they are unsure of the information that should be requested from

[8] For active substances, "major impact" could concern key conclusions relevant to the assessment of exclusion criteria, setting of reference values and outcome of efficacy and exposure assessment if essential for the approval or conditions for the approval.

the applicant (e.g. need of follow-up testing, or waiving particular data requirements).

2.2 Requesting an early WG discussion

The eCA can send a request including brief outline of the issue for an early WG discussion; see "Contact information" in the Introduction above. The request should be made at least 6 weeks before the first day of the WG meeting as indicated in the timelines[9].

In preparation for an early WG discussion it is recommended to first launch an e-consultation (note that this would need to be requested 2 months before the WG meeting; see Chapter 1.2). This can help to identify any additional problematic issues that need to be addressed during the WG discussion.

2.3 WG conclusions

In an early WG discussion, the WG will in principle be able to conclude on any aspects within the mandate[10] of the WG.

The conclusions may have to be considered provisional for example if:

a) the final conclusion requires consideration of the complete assessment (e.g. whether the data package is complete);

b) general discussions are on-going, e.g. guidance is under development; or

c) a policy/regulatory decision is expected in other fora such as BPC, CA or CG meetings

For all the above cases, the WG can make definite conclusions in a regular WG discussion (during the peer review of the PAR/CAR/RAR), while conclusions of an early WG meeting have to be considered provisional.

Conclusions should be considered as final and should not be reopened unless justified by new information or guidance that should be applied according to the established rules[11].

Provisional conclusions should be followed in the eCA's assessment and should not be questioned anymore during the opinion-forming unless further assessment justifies deviating from it. Deviations may become necessary due to e.g. additional information or as a result of the full context of the assessment.

2.4 WG advice

For some topics, the WG discussion should be of an advisory nature, as the WG does not have the mandate to conclude on them. Such topics include:

a) Information to be requested from the applicant

During the evaluation stage, it is the legal responsibility of the eCA to decide which information should be requested from the applicant.

b) CLH for active substances

Conclusions on CLH can only be made by RAC. Note however that while a WG does not conclude on CLH (harmonised classification) of active substances, WG conclusions are required on C&L for products.

[9] See the BPC webpage: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee
[10] The mandates are available at https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups
[11] For applicability of guidance, see the BPC document (https://echa.europa.eu/documents/10162/763823/applicability_guidance_jan_16_en.pdf) and CA-July12-Doc.6.2d – Final (https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/a6704d11-5de2-4e17-906f-4bc76fa856aa/details)

c) Policy related issues

d) Risk management measures

The WG can make recommendations on RMMs but concluding on them is reserved for BPC.

The outcome of discussions on such topics should be considered similarly as advice coming from individual experts participating at the WG meeting. Such advice should be considered in the assessment but this is not binding for the conclusions the eCA is making in the PAR/CAR/RAR to be submitted later for peer review.

For these points there is no difference between an early WG discussion and a regular WG discussion.

2.5 Follow-up

Regardless of the nature of the outcome, the eCA should indicate the conclusions of the WG discussions in the relevant sections of the PAR/CAR/RAR and explain how this was considered in the evaluation.