

ECHA CODE OF CONDUCT FOR CASE OWNER REPRESENTATIVES OF EVALUATION DRAFT DECISIONS AS OBSERVERS AT MEETINGS OF THE MEMBER STATE COMMITTEE (MSC)

(Decision ED/82/2022 by the Executive Director)

Purpose of the participation of case-owners and their role

1. Pursuant to Article 85(4) of Regulation (EC) No 1907/2006 (REACH) and in order to facilitate appropriate decision making, ECHA permits the participation of observers from stakeholder organisations at the plenary meetings of the Committees, as appropriate, and as identified by the body in question. The Rules of Procedure of the MSC¹ provide a possibility to invite case-owners² to participate in a meeting or part of it as observers. The MSC Working Procedures on processing draft decisions under dossier evaluation³ and under substance evaluation⁴ further outline how case owners' and stakeholder organisations' participation in the MSC meetings is organised. The purpose of the admission of case owners is to:
 - a. Provide a possibility for the registrant to be heard orally about the views they have already provided in their comments on any proposals for amendment (PfAs) before the final assessment/evaluation and decision making
 - b. Provide a possibility for the registrant (case owner) to contribute to clarifying any discussion items, where necessary, directly to the Committee
 - c. Ensure that all aspects related to the PfAs are properly addressed and understood in the context of the case under discussion.

2. Participation of case-owners is not intended to circumvent or expand the procedure based on the legal provisions of Articles 50 and 51 of REACH which provide the formal possibility for the registrant to give comments and explanations related to the content of the registration dossier, ECHA's draft decision on the specific case and any PfAs. Participation of a case-owner is only considered when the case is addressed by the Committee in a meeting.

¹ Rules of Procedure for the Member State Committee as available on ECHA website (https://echa.europa.eu/documents/10162/17089/msc_procedure_rules_en.pdf/03e16e67-d1c2-4f58-9ceb-74fd1e099e9f?t=1618305435346)

² MSC Rules of Procedure in Article 6 paragraph 7 define a case owner as a concerned registrant or a representative of a group of concerned registrants in the case of joint submissions.

³ MSC Working procedures on processing draft decisions under dossier evaluation (https://echa.europa.eu/documents/10162/17089/msc_working_procedures_for_processing_draft_decisions_under_dev_en.pdf/4b723489-f67c-45f4-ab6f-73182fd42240?t=1625679380624)

⁴ MSC Working procedures on processing draft decisions under substance evaluation (https://echa.europa.eu/documents/10162/17089/msc_working_procedure_for_processing_sev_draft_decisions_en.pdf/b8e1ed7d-641d-4faf-845b-7283b48ffac2?t=1625679483992)

3. During the meeting, the case-owner cannot open issues beyond the topics addressed in the PfAs to the draft decision made by the Member State Competent Authorities or ECHA (in substance evaluation cases).
4. Non-availability of a case owner will not prevent the Committee to proceed with the case.

General rules

The case owner representative(s) are to:

5. be informed about the stakeholder organisations participating in the Committee discussions before the meeting.
6. behave with due and proper respect for the meeting proceedings and towards all the members and other participants and must abide by the rules of procedure of MSC and the MSC code of conduct.
7. apply the general principles of openness, transparency, honesty and integrity when participating in the work of ECHA while respecting applicable confidentiality requirements. They shall always ensure that, to the best of their knowledge, information which they provide is relevant to the case, unbiased, complete and up-to-date.

Identification of the representative of case owners in substance and dossier evaluation

8. In case the Secretariat has decided that PfAs to an evaluation decision are to be discussed in a meeting it may invite the case-owner to attend the meeting. In case of a decision addressed to registrants that are part of the same joint submission the Secretariat will normally only invite to the meeting the case-owner that has submitted comments on the PfAs on behalf of the joint submission. However, when sufficiently justified, the Secretariat may permit additional case-owner representatives to the meeting from among those who provided comments on the PfAs. The case-owner representative must, within 5 days prior to the meeting concerned, notify the Secretariat in writing of its justified request to be accompanied by additional case-owner(s). The Secretariat shall without undue delay decide whether the participation of an additional case-owner is allowed and inform the case-owner representative of its decision.
9. When a justified case is made in line with the MSC working procedure, an expert may also participate to support the case owner representative(s).
10. The case owner representative(s) will be informed about the meeting where the case is to be discussed and invited to participate in this specific session.
11. The invited case owner representative(s) will communicate to the Secretariat the name and contact details of all its intended participants.
12. The case owner representative participating during the meeting will be considered as providing the views of its legal entity.

Participation at the meetings

General

The case owner representative(s):

- 13.** shall respect the work of MSC, and shall not interfere with members, their advisers, invited experts, other observers or the Secretariat, which, in the view of the Chair, constitutes inappropriate behaviour and/or may hinder the work of MSC.
- 14.** shall participate during meetings at the discretion of the Chair and shall not participate during other sessions of the meeting than those specifically indicated to them in advance of the meeting. The Chair can decide to close a session at any point in time before or during a meeting.
- 15.** are allowed orally to present their main comments on the PfAs by Member State competent authorities or ECHA (in substance evaluation cases), and to respond to any questions or comments by the members and the nominated representatives of stakeholder organisations. The case owner representative's interventions should be brief and the time allocated by the Chair shall be respected.
- 16.** are not allowed to participate during the decision-making session(s) of the Committee.

Remote meetings

- 17.** All the rules in this document also apply to meetings organised by ECHA that allow remote participation. Invitations to remote meetings remain personal and non-transferrable. Further rules are described in the Code of conduct for observers at ECHA meetings⁵.

Use of recording equipment

- 18.** Use of audio and/or visual recording or photographing equipment is prohibited at all times during the meetings and its breaks, irrespective of whether the meeting is held remotely or via physical attendance.

Mobile telephones

- 19.** Mobile telephones shall be switched off in the meeting room.

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https://echa.europa.eu/documents/10162/17203/conduct_code_stakeholder_observers_en.pdf/039e8710-5035-497d-aa3a-9047cb4c49c4?t=1610381837154

Confidentiality

The case owner representative(s):

- 20.** shall respect the rules on confidentiality laid down in the rules of procedure of MSC. They shall sign the declaration of confidentiality annexed to the rules of procedure of MSC before their first participation at a meeting. They shall not get access to the documents of the Committee. However, through the decision-making process the case owners already have in their possession the documents under discussion related to their specific case (*i.e.*, draft decision, proposed amendments, registration dossier). In exceptional cases where access to some meeting or confidential documents is granted, or accidentally received, the rules on confidentiality shall apply.
- 21.** may report to the other registrants of the substance in question who they were representing at the meeting, and to relevant persons within their own legal entity about the meeting discussions. In any reporting they shall respect the confidential nature of any deliberations and shall not disclose any views or statements of individual MSC members or other meeting participants. The case owner representatives are allowed to share any non-confidential meeting documents to which they have been granted access with the members of the group of registrants of the same substance that they were representing and with relevant members of their own entity, but they shall not make them or their content publicly available unless they already have been made publicly available. Furthermore, reports to the media or any media channels shall respect the same conditions.

Documents distributed by case owners

- 22.** Only in exceptional cases the case owner representatives may submit documents to the meeting. This may only happen if deemed appropriate and subject to prior permission from the Chair. Such documents will be circulated by the Secretariat. The documents shall not repeat information already submitted and shall be marked 'for information' and shall indicate clearly which case owner is responsible for them.

Meeting minutes

- 23.** A record of key points made by case owner representatives may be included in the minutes but the final decision on the wording of the minutes will be made by the Committee. Participation of a case owner representative shall be recorded in the minutes but personal data will not be disclosed.

Respect of the code of conduct

- 24.** Case owner representatives are requested to sign an acceptance notice of having received, read and accepted to respect this code of conduct, if they wish to participate during the meeting.

- 25.** Inappropriate behaviour or failure to conform to this code of conduct may lead the Chair to exclude a case owner representative from the meeting in question and potentially from future meetings. The corresponding case owner may subsequently be requested to consider another representative in the future.