

23 September 2013

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

(Decision ED/89/2013 by the Executive Director)

Purpose of the attendance 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 attendance 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 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 are properly addressed and understood in the context of the case under discussion.
2. Attendance of case owners is not in any way 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 and ECHA's draft decision on the specific case. Attendance of a case owner is only considered when the case is addressed by the Committee in a meeting.
3. At the meeting the case owner cannot open issues beyond the topics addressed in the proposed amendments to the draft decision made by the Member State Competent Authorities or ECHA (in substance evaluation cases) as other topics cannot be considered as part of the formal decision making process in dossier and substance evaluation and cannot affect ECHA's decision that has to be based on the content of the registration dossier and the processes described in Articles 50, 51 and 52 of REACH.

¹ Rules of Procedure for the Member State Committee as available on ECHA website (http://echa.europa.eu/about/organisation/committees/memberstate_en.asp)

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 (http://echa.europa.eu/documents/10162/13578/wp_for_msc_consultation_on_draft_decisions_en.pdf)

⁴ MSC Working procedures on processing draft decisions under substance evaluation (http://echa.europa.eu/documents/10162/13578/msc_working_procedure_for_processing_sev_draft_decisions_en.pdf)

4. Non-availability of a case owner will not prevent the Committee to proceed with the case.

General rules

5. Normally the sessions of MSC meetings which are open for a case owner are also open for nominated representatives of stakeholder observers unless confidentiality rules prevent their participation.
6. The case owner will be informed about the stakeholders present in the Committee discussions before the meeting.
7. The opportunity to attend MSC meetings carries certain responsibilities. It is the duty of each case owner: (i) to behave with due and proper respect for the meeting proceedings and towards all the members and other participants and (ii) to abide by the rules of procedure of MSC and this code of conduct.
8. Case owners are expected to 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 a case owner in dossier evaluation

9. The case owner is to be informed about the meeting where the case is to be discussed and is invited to identify one representative to participate in this specific session.
10. The case owner will communicate the name and contact details of its representative to the ECHA Secretariat ("Secretariat") if it wishes its representative to be present at the meeting session where the case is to be discussed.
11. Only one representative per case is allowed, but when a justified case is made, the Secretariat may permit the case owner representative to be accompanied by an expert. The case owner must, at least 5 days prior to the meeting concerned, notify in writing to the Secretariat its reasoned request to be accompanied by an expert and include the identity of that expert. Should such participation be allowed, the same rules applicable to the case owner will apply to the accompanying expert.
12. The case owner representative attending the meeting shall be considered formally representing the legal entity (registrant) or the only representative in question.
13. ECHA will not intervene in the selection of the case owner representative.

Identification of the representative of case owners in substance evaluation

14. In line with the leaflet for registrants and downstream users on *Substance evaluation under REACH*, ECHA recommends that the registrants would speak with one voice and that addressees of a draft decision nominate one representative to send comments on behalf of the whole group. On this basis, normally, only one representative per case is invited to the meeting from among those who provided comments on the proposals for amendment. The Secretariat will normally invite the case-owner who was acting for the other case-owners in submission of comments on the proposals for amendment. However, when a justified case is made, the Secretariat may permit additional case-owner representatives to the meeting from among those who provided comments on the proposals for amendment. Where a (main) case-owner representative should be accompanied in the meeting by further case owners of the group, the (main) case-owner must, at least 5 days prior to the meeting concerned, notify in writing to the Secretariat its reasoned request to be accompanied by additional case-owner(s). Should such participation be allowed, the same rules applicable to the (main) case owner representative will apply to the accompanying case-owner representative(s).

15. When a justified case is made in line with the MSC working procedure, a case owner may be accompanied by an expert.
16. The case owner representative on behalf of other registrants of the substance in question is to be informed about the meeting where the case is to be discussed and is invited to participate in this specific session.
17. The invited case owner(s) will communicate the name and contact details of its representative(s) to the Secretariat if it wishes its representative to be present at the meeting session where the case is to be discussed.
18. The case owner representative attending the meeting will be considered as formally representing its own legal entity as well as those other registrants that he/she is acting for.

Participation at the meetings

General

19. Case owners shall respect the work of MSC. Case owners shall not interfere with members, their advisers, invited experts, other observers or the Secretariat, in any way which, in the view of the Chair, constitutes inappropriate behaviour and/or may hinder the work of MSC.
20. Case owners shall attend meetings at the discretion of the Chair and shall not attend other sessions of the meeting than those specifically indicated to them in advance of the meeting when their own case is under initial discussion. The Chair can decide to close a session at any point in time before or during a meeting.
21. Case owners are allowed to listen and present their main comments on the amendments of the draft decision proposed by Member State competent authorities and to respond to any questions or comments by the members and the nominated representatives of stakeholder organisations. The case owner's interventions should be brief and the time allocated by the Chair shall be respected.
22. Case owners are not allowed to attend the meeting during the decision-making session(s) of the Committee.

Use of recording equipment

23. The use of audio and/or visual recording or photographing equipment shall be prohibited in the meetings and its breaks.

Mobile telephones

24. Mobile telephones shall be switched off in the meeting room.

Confidentiality

25. Case owners 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 attendance to a meeting. The case owners shall as a rule 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.

26. The declaration of confidentiality referred to in paragraph 20 in practice implies that case owners may report to the members of the group of registrants of the same substance (SIEF) and to relevant persons within their own legal entity about the discussions held at the meeting. 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 owners 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

27. If deemed appropriate and subject to prior permission from the Chair, case owners may submit documents to the meeting. Such documents will be circulated by the Secretariat. The documents shall be marked 'for information' and shall indicate clearly which case owner is responsible for them.
28. Case owners submitting such documents shall remain responsible for their content and distribution cannot be interpreted as a validation or agreement to their content by the Secretariat. The documents shall not repeat information already submitted (e.g. draft decision, registrant's comments, proposed amendments and the full registration dossier which are already available to the members, experts and advisers of MSC from the Secretariat).
29. Only documents that have been submitted to the Secretariat at the latest 20 days before the meeting will be made available to the members of the Committee electronically. Late documents can only in exceptional cases be distributed at the meeting in hard copies. In these circumstances case owners are requested to bring a sufficient number of hard copies for distribution. Members of MSC have the prerogative not to take into consideration such late documents in any decisions taken at the meeting since they have been distributed after the formal deadline for distribution of documents.

Meeting minutes

30. A record of key points made by case owners may be included in the minutes but the final decision on the wording of the minutes will be made by the Committee. Attendance of a representative of a case owner shall be recorded in the minutes but personal data will not be disclosed.

Respect of the code of conduct

31. 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 attend the meeting.
32. 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.