

## **RULES OF PROCEDURE FOR THE MEMBER STATE COMMITTEE**

### *Article 1*

#### *Responsibilities*

In accordance with Article 76(1)(e) of Regulation (EC) No 1907/2006 the Member State Committee (hereinafter, referred to as "the Committee") shall be responsible for resolving potential divergences of opinions on draft decisions proposed by the Agency or the Member States under Title VI of Regulation (EC) No 1907/2006 and proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII of Regulation (EC) No 1907/2006.

### *Article 2*

#### *Tasks*

1. The Committee shall undertake the following tasks:
  - a) resolving potential divergences of opinions on draft decisions proposed by the Agency or the Member States on dossier and substance evaluation under Title VI;
  - b) resolving potential divergences of opinions on proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII;
  - c) providing opinions on draft recommendations on priority substances to be included in Annex XIV of Regulation (EC) No 1907/2006;
  - d) providing an opinion on a draft Community rolling action plan for substances which could constitute a risk to human health or the environment, and on any proposed additions to it; and
  - e) seeking agreement in cases where two or more Member States have expressed an interest in evaluating the same substance under substance evaluation.
2. In accordance with Article 77(3) of Regulation (EC) No 1907/2006, the Committee shall undertake other tasks at the Executive Director's request.

### *Article 3*

#### *Membership*

1. In accordance with Article 85(3) and (4) of Regulation (EC) No 1907/2006, each Member State shall appoint one member to the Committee, and the Committee may co-opt a maximum of five additional members.
2. Members nominated by Iceland, Liechtenstein and Norway shall have the same rights and obligations as other members, except the right to vote.
3. Members co-opted by the Committee referred to in Article 4, shall have the same rights and obligations as other members, except the right to vote and right to appoint an alternate.

#### *Article 4*

##### *Co-opting members*

1. In accordance with Article 85(4) of Regulation (EC) No 1907/2006 the Committee shall aim to have a broad range of relevant expertise among their members. To this end the Committee may co-opt a maximum of five additional members chosen on the basis of their specific competence.
2. The Committee may decide whether additional members should be co-opted and shall agree on the required specific competences and on the selection procedure by two-thirds majority of all members having the right to vote.
3. Co-opted members shall be appointed for a term of three years.
4. Members can be co-opted at any point in time.

#### *Article 5*

##### *Term of office and replacing members*

1. In accordance with Article 85(4) of Regulation (EC) No 1907/2006, the term of office of the members of the Committee shall be three years starting from the date of appointment. The appointment shall be renewable.
2. A member's term of office shall end before the expiry of the three-year period with his or her resignation submitted in writing to the Agency or, in the case of non co-opted members, following a communication to the Agency from the Member State concerned indicating another appointment. The new member thus appointed shall start serving a full term of three years starting from the date of the appointment by the Member State.
3. The members may, in exceptional cases when they are prevented from participating in a meeting of the Committee, identify in advance a person who shall be invited by the Agency to participate in a meeting as an invited expert or as his/her alternate if such has been appointed.
4. Members referred to in Articles 3(1) and 3(2) may have an alternate. Appointment of an alternate to the member shall be communicated to the Agency by the State concerned. This appointment may take place at any point in time. The term of office of an alternate member starts from the date of appointment. All the provisions of these Rules of Procedure for the members are, where relevant, applicable also to the alternate members,
5. Where relevant, alternates shall represent and vote for the appointed member in the absence of the member when he/she is not in attendance at the meeting. At the request of the member, the alternate may respond on behalf of the member in case of written procedures or any request for urgent advice from members between meetings.
6. If prevented from participating in a meeting or from sending an alternate, in case one has been appointed, members of the Committee having the right to vote may vote by proxy. If they wish to use this right, they should inform this to the Secretariat before the meeting. In addition to his/her own vote each member having the right to vote may cast a maximum of two votes by proxy. The proxy shall be notified to the Committee at the beginning of the meeting and shall be recorded in the minutes.

## Article 6

### *Other participants at the meetings*

1. The meetings of the Committee and its working groups, unless otherwise stated, shall be open to advisers, invited experts and observers, as specified in paragraphs 2 to 10.
2. Advisers are participants of the Committee meetings or its working groups accompanying members to provide advice on scientific, technical or regulatory matters. The members shall notify the names of their advisers to the Secretariat before the meeting which they are due to attend.
3. Invited experts are experts in technical or scientific fields who can, upon proposal of a member or the Secretariat, be invited by the Agency to participate for one or more points of the agenda in a meeting of the Committee or its working groups.
4. Observers are other participants of the meetings of the Committee or its working groups under paragraphs 5 to 10 who are not members, advisers or invited experts.
5. The Executive Director and his representatives and representatives of the Commission shall be entitled to take part in the meetings of the Committee and its working groups as observers.
6. Representatives of stakeholder organisations may be admitted as observers to the meeting of the Committee or its working groups upon request of members of the Committee or the Management Board. The list of regular observers shall be updated on an annual basis by the Committee, while the Chair may in addition allow occasional stakeholders on an *ad hoc* basis from among the Agency's accredited stakeholder organisations, taking due account of capacity limitations. These stakeholder observers shall conform to the 'ECHA Code of Conduct for observers from stakeholder organisations at ECHA meetings'.
7. A case-owner, *i.e.*, a concerned registrant or a representative of a group of concerned registrants in the case of joint submissions, may be admitted as an observer when their specific case is addressed by the Committee. The case-owners shall conform to the ECHA Code of Conduct for Case Owner Observers at MSC meetings.
8. Unless confidentiality rules prevent participation, both nominated representatives of stakeholder organisations and case-owners concerned may, as appropriate, be admitted to the Committee meetings when draft decisions on dossier or substance evaluation referred to in Article 2(1)(a) are presented to the Committee and initially discussed by the Committee<sup>12</sup>.
9. Pursuant to Articles 106 and 107 of Regulation (EC) No 1907/2006, representatives of third countries and international organisations may take part in the meetings as observers if the Management Board has invited them, in agreement with the Committee, to participate in the work of the Agency.
10. Other observers may be admitted upon request of a member of the Committee or of the Chair.
11. The Committee shall agree by two-thirds majority of all members having the right to vote on the procedure for the admission of observers referred to in paragraphs 6 and 9.
12. The Chair may decide to hold the meeting in a closed session excluding observer(s) referred to in paragraphs 6 to 10 at any point in time before or during a meeting on a written or oral request of a member or when she/he considers this otherwise appropriate.
13. Invited experts and observers referred to in paragraphs 6, 9 and 10 shall have the same access as the members to the documents of the meeting or the documents for

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<sup>1</sup>[http://echa.europa.eu/documents/10162/13578/wp\\_for\\_msc\\_consultation\\_on\\_draft\\_decisions\\_en.pdf](http://echa.europa.eu/documents/10162/13578/wp_for_msc_consultation_on_draft_decisions_en.pdf)

<sup>2</sup>[http://echa.europa.eu/documents/10162/13578/msc\\_working\\_procedure\\_for\\_processing\\_sev\\_draft\\_decisions\\_en.pdf](http://echa.europa.eu/documents/10162/13578/msc_working_procedure_for_processing_sev_draft_decisions_en.pdf)

the relevant agenda points in which they take part, except in relation to the issues that the Chair identifies as confidential for reasons of confidential business information, including the protection of intellectual property rights or for other justified reasons, or where their participation is excluded for other reasons. Observers identified in paragraphs 6 and 7 are not provided with access to the meeting documents related to draft decisions on dossier and substance evaluation, except for non-confidential presentations at an open session of a MSC meeting introducing specific cases. Advisers' access to documents is at the discretion of the respective member.

#### *Article 7*

##### *Chair*

1. In accordance with Article 85(9) of Regulation (EC) No 1907/2006, the Committee shall be chaired by an employee of the Agency assigned by the Executive Director.
2. In case of absence of the Chair, the Executive Director will assign a replacement.

#### *Article 8*

##### *Responsibilities of Chair*

The Chair is responsible for the efficient conduct of the business of the Committee and shall in particular:

- a) plan the work of the Committee together with the members and the Secretariat;
- b) monitor that the Rules of Procedure are respected and propose measures in case of breach;
- c) ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the Committee;
- d) ensure that the work of the Committee is consistent with its tasks indicated in Article 77(3) of Regulation (EC) No 1907/2006, including the requests from the Executive Director;
- e) endeavour to ensure, together with the Committee and the Secretariat, consistency of the Committee's work;
- f) ensure that all underlying argumentation is adequately reflected in the deliberations of the Committee;
- g) co-ordinate together with the Secretariat the work of the Committee with that of other Committees of the Agency and the Forum for Exchange of Information on Enforcement as well as with other relevant Community committees or bodies;
- h) facilitate reaching unanimous agreements and providing opinions within the set deadlines; and
- i) execute any additional powers entrusted to the Chair by the Committee.

#### *Article 9*

##### *Independence*

1. Pursuant to Article 88(2) of Regulation (EC) No 1907/2006, members shall make a declaration of commitment to fulfil their duties and a declaration of any interests which could be considered to be prejudicial to their independence. The declarations shall be made in accordance with the templates available at the links provided in the Annex. These declarations shall be made annually in writing and be entered in a register held by the Agency. In addition, the declarations of interests shall be published on the Agency's website without prejudice to Article 11(1). Members who have not submitted the declaration of interests shall not take part in meetings of the Committee and its working groups or decisions by written procedure.

2. According to Article 88(3) of Regulation (EC) No 1907/2006, members, their advisers and invited experts participating in the meeting shall declare at each meeting any interest which could be considered to be prejudicial to their independence<sup>3</sup> with respect to any point on the agenda. Any members declaring such interests shall not participate in any voting on the relevant agenda point. The Chair may decide if other measures are necessary.
3. According to Article 87(1) of Regulation (EC) No 1907/2006, for each case, the rapporteur and co-rapporteur referred to in Article 17 shall undertake to act in the interest of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing. A member of the Committee shall not be appointed as rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case.
4. Members who work as private consultants or who are employed by a consultancy company (including employees of universities or public institutes providing such services on an occasional basis) and who currently have contracts with the chemical industry or downstream users associations, chemical companies, or other potential registrants or authorisation applicants, or other bodies which can be considered as an interest group in the context of the field dealt with by the Committee, should withdraw from current contracts and refrain from entering into any new contracts with potential registrants, applicants and chemical industry or downstream user associations.
5. Members may not be employed by a private enterprise that could have any direct interest in the matter dealt with by the Committee nor by an industry association or other body which can be considered as an interest group in the context of the field dealt with by the Committee. The member shall resign from the Committee before entering into service in any such enterprise or association.
6. The Chair is representing the Committee towards other parties. Individual members can be mandated by the Chair to represent the Committee on specific issues or occasions

#### *Article 10*

##### *Confidentiality*

1. Members, their advisers, invited experts and observers of the Committee and its working groups shall not disclose to any persons other than representatives of relevant competent authorities of the Member States, the Commission and Community bodies any information acquired as a result of their work in the Committee unless otherwise stipulated in Community or national law or already publicly available. They shall make a written declaration of confidentiality in accordance with the template available at the link provided in the Annex.
2. The obligation to maintain confidentiality shall continue to apply even after participation of members, their advisers, invited experts and observers in the work or in the meetings of the Committee has ceased.

#### *Article 11*

##### *Transparency*

1. In accordance with Article 88(1) of Regulation (EC) No 1907/2006, the membership shall be made public unless the Executive Director decides not to publish the appointment at a request of an individual member.
2. The Committee shall operate in accordance with the need for a high level of transparency, without prejudice to legitimate requests for confidentiality or the independence of members, their advisers and invited experts vis-à-vis external influence.

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<sup>3</sup> MB/07/2014

3. The following documents of the Committee shall be published on the Agency's web site, subject to respect of confidentiality requirements:
  - Rules of Procedure;
  - Final minutes of plenary meetings in accordance with Article 16(1);
  - Draft agendas;
  - The annual declarations of interests in accordance with Article 9(1);
  - The names of the members of the Committee together with their brief CVs.
4. With the exception of minority opinions referred to in Article 19(5) and (6), individual views, whether expressed orally or in writing by members or other meeting participants during deliberations within the Committee or a working group, shall not be ascribed to a particular individual unless this is explicitly requested by the individual.

#### *Article 12*

##### *Invitations to meetings*

1. The meetings of the Committee shall be convened either by an initiative from the Chair or, where necessary, by the Executive Director following a request of a majority of the members. The meetings are convened by means of a written invitation from the Agency.
2. The invitation to an ordinary meeting shall be circulated no later than 15 calendar days before the meeting.
3. In urgent cases when it is necessary to convene the Committee immediately, the Executive Director may, at the request of a member of the Committee or on his own initiative, shorten the time limit for invitations to a minimum of five calendar days before the start of the meeting.

#### *Article 13*

##### *Agenda for ordinary meetings*

1. A provisional agenda shall be drawn up by the Chair and circulated to the Committee together with the invitation to the meeting. The provisional agenda shall indicate if an item is intended to be addressed in an open or closed session.
2. Members may request items to be included in the agenda. Such requests shall be submitted to the Secretariat at an appropriate time but no later than 12 calendar days before the meeting.
3. A final draft agenda shall be established by the Chair and circulated no later than ten calendar days before the meeting. The agenda shall be adopted at the beginning of each meeting.
4. If the Committee so decides, urgent questions may be added to the agenda at any time prior to the end of the meeting, and items on the agenda may be deleted or carried over to a subsequent meeting.

#### *Article 14*

##### *Documentation for meetings*

Documentation for the meeting shall be made available as early as possible to allow preparation for the meeting. With due consideration of their volume and complexity, documents shall be made available no later than ten calendar days before the meeting. This period can be shortened by the Chair in justified and exceptional cases. Unless the Committee otherwise agrees, documents available less than ten calendar days before the meeting would be for discussion only.

### Article 15

#### *Agenda and documentation for urgent meetings*

The draft agenda and documents for an urgent meeting referred to in Article 12(3) shall be circulated together with the invitation no later than five calendar days before the start of the meeting.

### Article 16

#### *Minutes*

1. Final minutes of plenary meetings shall include:
  - a) any specific interests declared by the participants to any points of the agenda pursuant to Article 9(2);
  - b) a summary record of the proceedings;
  - c) reference to the agreements and opinions reached by the Committee and their underlying argumentation;
  - d) the list of attendees;
  - e) action points.
2. Taking into account Article 6(11), draft minutes or relevant parts of it shall be distributed to participants of the meeting no later than 28 calendar days after the meeting. Written comments shall be provided to the Secretariat within a specified deadline which shall be a minimum of seven calendar days. The minutes shall be approved at a following meeting or by a written procedure.

### Article 17

#### *Rapporteurs*

1. Pursuant to Article 87(1) of Regulation (EC) No 1907/2006, where the Committee is required to provide an opinion under Articles 44(2), 45(5), 58(3) or 77(3)(c) of Regulation (EC) No 1907/2006, it shall identify and appoint one of its members as a rapporteur as early as possible. The Committee may appoint a second member to act as co-rapporteur.
2. The Committee shall agree by two thirds majority of all members having the right to vote on the role and tasks of the rapporteur and possible co-rapporteur, and how they are appointed.

### Article 18

#### *Working groups*

1. Where appropriate, the Committee may establish *ad hoc* or permanent working groups. A working group shall be chaired by a member of the Committee or the Secretariat and shall report to the Committee.
2. The mandate, composition and the objectives of a working group as well as the duration of its activity shall be determined and reviewed periodically by the Committee. The Committee decision establishing the mandate and objectives of a working group shall also include its composition and shall be recorded in the minutes of the meeting.
3. Working groups are composed of volunteering members of the Committee and invited experts on the basis of the required expertise. Members of the Working Group should receive an invitation from the Chair of the Committee.
4. Draft agendas, meeting dates and minutes of the working group meetings shall be made available to the Committee.

5. Working groups under the Committee shall apply these Rules of Procedure of the Committee, as applicable.
6. Where appropriate, the Committee may establish with other ECHA Committees, a joint working group by mutual consent. The provisions of paragraphs 2-5 shall apply *mutatis mutandis* to the joint working group. The mandate referred to in paragraph 2 shall specify the applicable rules of procedure referred to in paragraph 5 and the Chair of the joint working group.

#### *Article 19*

##### *Quorum and agreements or opinions of the Committee*

1. The quorum necessary for a meeting is achieved when at least 60 percent of all members having the right to vote are present or represented by a proxy at the meeting at the time of the agenda point in question. Any member neither present nor represented by a proxy at the meeting is considered to have given his/her tacit agreement to the consensus or majority view of the Committee when an issue is under voting.
2. Members having declared a conflict of interest regarding the relevant agenda point shall not be regarded as a part of the quorum for the purposes described under paragraph 1, and shall not participate in voting on that agenda point. A member having declared a conflict of interest regarding an agenda point shall not give a proxy to another member for that agenda point but may be replaced by his/her alternate member in the vote.
3. If the quorum is not achieved the Chair may decide to launch a written procedure in accordance with Article 20, where appropriate, shortening the deadline in its paragraph 2 to five calendar days.
4. When the task of the Committee is to seek agreement it shall use its best endeavours to reach unanimity.
5. Abstentions by members present in person or represented by a proxy shall not prevent the adoption by the Committee of tasks which require unanimity.
6. Where unanimous agreement by members present and entitled to vote cannot be reached, the opinion of the Committee shall, for the purposes of Articles 45(3) and 59(9) of Regulation (EC) No 1907/2006, consist of the position of the majority of members having the right to vote, including its grounds, and minority position(s), including their grounds. Members having minority position(s) shall provide them to the Committee in writing, stating clearly their grounds. These minority position(s) shall also be indicated in the opinion. The provision of minority position(s) shall be recorded in the minutes and published.
7. When preparing an opinion for the purposes of Articles 44(2), 45(5) and 58(3) of Regulation (EC) No 1907/2006, the Committee shall use its best endeavours to reach a consensus. If consensus cannot be reached, the opinion shall consist of the position of the majority of members having the right to vote, including its grounds. Members having minority position(s) shall provide them to the Committee in writing, stating clearly their grounds. The provision of minority position(s) shall be recorded in the minutes and published. When adopting opinions the provisions described under paragraph 5 for possible abstentions apply.
8. Unless these Rules of Procedure specify otherwise, decisions on any procedural issues need to be supported by a simple majority of all members having the right to vote.



*Article 20**Written Procedure*

1. The Committee can adopt agreements, establish opinions and take decisions by written procedure. To this end, the Chair of the Committee shall send the members the draft documents on which their opinion is sought and indicate the response period.
2. The period shall normally not be shorter than ten calendar days. If the case is urgent, the period can be shortened to a minimum of five calendar days.
3. Without prejudice to paragraph 5, any member who does not comment within the response period is considered to have given his/her tacit agreement to the document. A document is agreed by consensus following the tacit or express agreement of all members having the right to vote. If a member abstains from the vote, Article 19(5) applies.
4. If the document is not agreed by consensus, the minority position(s) shall be duly recorded in the written procedure report.
5. When agreements are being adopted, at least 60 percent of the members having the right to vote have to respond for the written procedure to be regarded as valid.
6. If major and justified objections are submitted to the Secretariat, or under other exceptional circumstances, the Chair shall decide whether the written procedure shall be suspended or terminated, in whole or in part. If the written procedure is terminated, the adoption of the agreement, opinion or decision shall be postponed to the next meeting of the Committee.
7. The Secretariat shall inform the Committee of the outcome of the written procedure and present the written procedure report to the Committee at its next meeting.

*Article 21**Reimbursement*

The Agency shall reimburse members of the Committee and, where appropriate, other participants invited to attend meetings of the Committee in accordance with the rules adopted by the Management Board on the reimbursement of travel and other expenses.

*Article 22**General provisions*

1. The Rules of Procedure or any amendment to them shall apply from the date they have been approved by the Management Board.
2. The decision to amend these Rules of Procedure shall be taken by a two thirds majority of all members having the right to vote. Amendment of the Rules of Procedure shall be approved by the Management Board.

ANNEX

## **Links to the ECHA Declaration templates**

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- [Declaration of interest and commitment](#)
  - [Declaration of confidentiality](#)
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