

## **RULES OF PROCEDURE FOR THE COMMITTEE FOR RISK ASSESSMENT**

### *Article 1*

#### *Responsibilities*

In accordance with Article 76(1)(c) of Regulation (EC) No 1907/2006 the Committee for Risk Assessment (hereinafter, referred to as "the Committee") shall be responsible for preparing the opinion of the European Chemicals Agency (hereinafter, referred to as "the Agency") on evaluations, applications for authorisation, proposals for restrictions and proposals for classification and labelling, and any other questions that arise from the operation of the Regulation relating to risks to human health or the environment.

### *Article 2*

#### *Tasks*

The Committee, in accordance with Article 77(3) of Regulation (EC) No 1907/2006 and Article 37(4) of Regulation (EC) No 1272/2008, shall undertake the following tasks:

- a) performing the tasks allotted to it under Titles<sup>1</sup> VI to X of Regulation (EC) No 1907/2006;
- b) performing the task allotted to it under Title V of Regulation (EC) No 1272/2008;
- c) at the Executive Director's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;
- d) at the Executive Director's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles

### *Article 3*

#### *Membership*

1. In accordance with Article 85(1) and (4) of Regulation (EC) No 1907/2006, the Committee is composed of members appointed by the Management Board of the Agency (hereinafter, referred to as the "Management Board") and a maximum of five additional members co-opted by the Committee.
2. Co-opted members and members nominated by the EEA-EFTA States i.e. Iceland, Liechtenstein and Norway, have the same rights and obligations as other members except the right to vote.

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<sup>1</sup> It should be noted that tasks are allotted to the Committee under Titles VII, VIII and X

## 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 present and 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 and adding 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 on the date of the appointment by the Management Board. 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 death.
3. The Executive Director may request the member to resign or the appointing body<sup>2</sup> to revoke the appointment following a justified proposal from the Chair in any of the following cases:
  - a) the appointed member does not sign the declarations of commitment, interests and confidentiality referred to in Articles 9(1) and 10(1) within three months of the date of appointment;
  - b) the member does not attend three consecutive meetings without justification or notification; or
  - c) the member is not fulfilling his/her duties.The Member State which nominated the member referred to in a) to c), may nominate a replacement candidate in accordance with paragraph 4.
4. Member States which have no or only one appointed member in the Committee, may nominate one or more candidates at any point in time. After receiving nominations, the Executive Director of the Agency shall request the Management Board to decide on the appointment of new members.
5. Members are appointed for their qualifications and therefore shall not have alternates. The members may, in exceptional cases when they are prevented from participating in a meeting of the Committee, identify in advance a person who may, without the need to have a recourse to the procedure laid down in Article 6(3), be invited by the Agency to participate in a meeting as an invited expert.

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<sup>2</sup> The ECHA Management Board or the Committee in the case of co-opted members.

## *Article 6*

### *Other participants at the meetings*

1. The meetings of the Committee and its working groups shall be open to advisers, invited experts and observers, as specified in paragraphs 2 to 9.
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 and in agreement with the Committee or with the Chair 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 9 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 the participation of 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 organizations at ECHA meetings".
7. Where relevant, applicants for authorisation and parties submitting a proposal for restriction may be admitted as observers when their proposal or application is addressed by the Committee.
8. Pursuant to Articles 106 and 107 of Regulation (EC) No 1907/2006, representatives of third countries and international organisations may take part as observers if the Management Board has invited them, in agreement with the Committee or the Chair to participate in the work of the Agency.
9. Other observers may be admitted upon request of a member of the Committee or of the Chair.
10. 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, 7 and 9.
11. The Chair may decide to hold the meeting or parts thereof in a closed session.
12. Invited experts and observers referred to in paragraphs 6 to 9 shall have access to the documents of the meeting or the documents for the relevant agenda points that they take part in, except in relation to the issues that the Chair identifies as confidential or where their participation is excluded. 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) Ensure, together with the Committee and the Secretariat, the regulatory and scientific consistency of the Committee's opinions and recommendations;
- f) Ensure that scientific grounds are adequately reflected in the Committee opinions;
- 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 adoption of opinions within the set deadline and endeavour to reach consensus in the opinions of the Committee; and
- i) Execute any powers entrusted to the Chair by the Committee, such as representing the Committee towards other parties.

## Article 9

### *Independence*

1. Based on Article 88(2) of Regulation (EC) No 1907/2006, members shall make a declaration of commitment to fulfil their duties and a declaration of 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. Concurrent employment of a member by a Member State Competent Authority or an entity delegated by it submitting a proposal or a dossier to the Committee for adoption, even if that member has not been involved in its preparation, shall be considered an interest to be declared. In such cases the member concerned shall not participate in any voting on the relevant agenda point, but may have his/her opinion recorded in the minutes.
4. According to Article 87(1) of Regulation (EC) No 1907/2006, for each case, rapporteurs and co-rapporteurs 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.
5. Following Article 85(7) of Regulation (EC) No 1907/2006, members, their advisers and

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

invited experts of the Committee or its working groups shall not accept from any Member States any instructions incompatible with their individual tasks or with the tasks, responsibilities and independence of the Agency. Similarly, these persons should refrain from accepting any such instructions from any other parties.

6. Members who work as private consultants or who are employed by a consultancy company (including employees of universities or public institutes) and provide such services and who currently have contracts with 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 the aforementioned legal entities.
7. Members may not be employed by a private enterprise that could have any direct interest in matters 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, in principle, resign from the Committee before entering into service in any such enterprise or association.
8. Individual members or the Chair can be mandated by the Committee to represent the Committee on specific issues and/or occasions.

#### *Article 10*

##### *Confidentiality*

1. Members, their advisers, invited experts and observers of the Committee and its working groups shall not disclose any information acquired as a result of their work in the Committee unless otherwise stipulated in European Union or national law, or already publicly available. The above is without prejudice to the sharing of documents with persons assisting the above individuals in the discharge of their duties in the Committee. The above individuals shall take all necessary measures to ensure that the persons to whom they provide access to their information respect the same obligations that they are subject to.
2. All members, their advisers, invited experts and observers of the Committee having access to Committee information shall make a written declaration of confidentiality in accordance with the template available at the link provided in the Annex.
3. The obligation to maintain confidentiality shall continue to apply even after their duties and participation as members, 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.
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, including the list of attendees and any specific interests declared by the participants to any points of the agenda pursuant to Article 9(2);
  - Draft agendas;

- Final opinions;
  - The annual declaration 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 positions referred to in Article 19 (5), individual views, whether expressed orally or in writing by members or experts 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 21 calendar days before the meeting.
3. In urgent cases, and where the measures to be adopted need to apply 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 seven 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.
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 to the meeting shall be made available as early as possible to allow preparation for the meeting. With due consideration of their volume, documents shall normally be made available at least ten calendar days before the meeting.

#### *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 at the latest seven calendar days before the start of the meeting.

## *Article 16*

### *Minutes*

1. Minutes of each meeting shall as a general rule include:
  - a) Any specific interests declared by the participants to any points of the agenda pursuant to Article 9(2);
  - b) A brief summary record of the proceedings;
  - c) Reference to the opinions reached by the Committee;
  - d) The list of attendees;
  - e) Action points.

2. The minutes shall be agreed either:

– at the end of the plenary meeting in question pursuant to Article 19, or

– via written procedure. In the latter case, taking into account Article 6(12), draft minutes 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 the specified deadline which shall be a minimum of seven calendar days. The minutes shall then be approved by a written procedure in advance of the next meeting.

## *Article 17*

### *Rapporteurs*

1. According to Article 87(1) of Regulation (EC) No 1907/2006, where the Committee is required to provide an opinion or consider whether a dossier conforms to the requirements of Annex XV, 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 the members present and having the right to vote on details of the roles and tasks of the rapporteurs and possible co-rapporteurs, and on how they are appointed.
3. Any remuneration of the rapporteur and co-rapporteur or their employer shall be based on the rules established by the Management Board and laid down in a written contract between the Agency and the person concerned or his/her employer.
4. The Committee may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if an interest that might be prejudicial to the independent consideration of a case comes to light.
5. The Committee may decide to designate a working group to support the rapporteur and co-rapporteur in their task.
6. Where relevant and in view of Articles 64(3) and 71(3) of Regulation (EC) No 1907/2006, the rapporteur and co-rapporteur shall co-operate with the rapporteur and co-rapporteur of the Committee for Risk Assessment in order to ensure the necessary coordination when the opinions are prepared.

## *Article 18*

### *Working groups*

1. Where appropriate, the Committee may establish ad hoc or permanent working groups as well as subgroups to these 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. The working group members should receive an invitation from the Chair of the Committee.
4. Any remuneration of invited experts serving on a working group shall be based on the rules established by the Management Board and laid down in a written contract between the Agency and the person concerned or his/her employer.
5. Draft agendas, meeting dates and minutes of the working group meetings shall be made available to the Committee.
6. Working groups under the Committee and their subgroups shall apply the Rules of Procedure of the Committee, as applicable.
7. Where appropriate, the Committee may establish with other ECHA Committees, a joint working group by mutual consent. The provisions of paragraphs 2-6 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 7 and the Chair of the joint working group.

#### *Article 19*

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

1. The quorum necessary for a meeting is achieved when at least fifty percent of all members having the right to vote are present at the meeting at the time of the agenda point in question.
2. Members having declared a conflict of interest regarding an agenda point under Article 9(2) 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.
3. If the quorum is not achieved, the Chair may decide to immediately launch a written procedure in accordance with Article 20.
4. When preparing an opinion the Committee shall use its best endeavours to reach a consensus.
5. Unless these Rules of Procedure specify otherwise, if consensus cannot be reached, the opinion adopted by the Committee shall consist of the position of the simple majority of all members present and having the right to vote, including their grounds. Members present but having minority positions 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.
6. 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 opinions and take other 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, or if agreed beforehand by the Committee by consensus, the period can be shortened to a minimum of five calendar days.
3. When opinions are being adopted, at least fifty percent of the members having the right to vote have to respond for the procedure to be regarded as valid.
4. If the opinion is not adopted by consensus, the position of the simple majority of all members having the right to vote, including their grounds, and the minority



position(s), including their grounds, shall be duly recorded in the written procedure report.

5. When other decisions are being taken, 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 when the members having the right to vote have agreed expressively or tacitly. In the event of non-consensus, Article 19(6) shall apply.
6. If major and justified objections are submitted to the Secretariat, or under exceptional circumstances, the Chair shall decide, in agreement with the rapporteur and co-rapporteur, whether the written procedure shall be suspended or terminated, in whole or in part. If the written procedure is terminated, the Chair may decide that the adoption of the draft opinion or decision should be postponed until 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, including any opinion or decision.

#### *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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<sup>4</sup> The Annex was amended by the Management Board on 29 September 2017 to replace the declarations with a hyperlink (MB/39/2017 final).