

Helsinki, 4 March 2010 Doc: MB/04/2010 final

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:
 - 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.

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. Only members (including co-opted members) have voting rights.
- 2. Members nominated by Iceland, Liechtenstein and Norway have the same rights and obligations as other members except the right to vote.

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, which may be renewed by the Committee, if it decides that the specific competence of the co-opted member continues to be necessary for the Committee.
- 4. These additional 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 the first plenary meeting to which they were invited. 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. A member with a voting right may have an alternate. Appointment of an alternate to the member shall be communicated to the Agency by the Member 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 other provisions of these Rules of Procedure for the members are applicable also to the alternate members, except the possibility of acting as a rapporteur or corapporteur. Co-opted members shall not have alternates.
- 5. 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.

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 8.
- 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 8 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 by the Committee as observers to the meeting of the Committee or its working groups upon request of members of the Committee or the Management Board. These stakeholder observers shall conform to the ECHA Code of conduct for observers from stakeholder organisations at ECHA meetings.
- 7. 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.
- 8. Other observers may be admitted upon request of a member of the Committee or of the Chair.
- 9. 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 8.
- 10. The Chair may decide to hold the meeting or parts thereof in a closed session
- 11. Invited experts and observers referred to in paragraphs 6 to 8 shall have the same access to the documents of the meeting or the documents for the relevant agenda points that they take part in as the members, 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.

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.

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 models contained in Annex 1 and Annex 2. 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).
- 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 independence¹ 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.

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¹ "ECHA Guidance on conflicts of interest for ECHA Committees and Forum members, their advisers and invited experts" provides guidance on identifying interests that could potentially present conflicts.

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 a model laid down in Annex 3.
- 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.
- 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 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.

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.
- 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.

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 shall be distributed to all 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.

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.
- 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.
- 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. 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.
- 6. 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.
- 7. 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.

Written Procedure

- 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.
- 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 1 Declaration of commitment form

ANNEX 2 Declaration of interests form ANNEX 3 Declaration of confidentiality form

ANNUAL DECLARATION OF COMMITMENT OF ECHA MEMBER STATE COMMITTEE MEMBERS

I, hereby declare that I shall make all reasonable efforts to fulfil my duties as a member/an alternate member ² of the Member				
State Committee of the European Chemicals Agency. More particularly, I undertake not to seek or accept any instructions from any party other				
than the Member State which appointed me. I understand that this Declaration will be entered in a register held by the European Chemicals Agency which is accessible to the public, on request, at the Agency's offices.				
Done at on/ 20				
Signature:				

² Strike through the text that is not relevant.

ANNUAL DECLARATION OF INTERESTS OF ECHA **COMMITTEES AND FORUM MEMBERS**

Title (Ms., Mr., Dr., Prof.):

Surname: Position: [] Member of the Committee for Risk [] Member of the Committee for Socio [] Member of the Member State Comm [] Member of a Forum for Exchange of [] Alternate Member of the Member S	o-economic Analy mittee of Information on l		cement
hereby declares to have the following in	nterests		
1. Work and activities in organi ECHA during the past 5 years ³ :	sations relevant	to the	operating area of
Name of organisation	Position/Tasks		Period
2. Financial interests in a companduring the past 5 years and excorr more per company ⁴ :			
Name of the company	(Curren	t/Past
3. Other interests or facts whether you consider should be made relating to the members of your	known to the A household ⁶ :	gency 	, including matters
		• • • • • •	

³ Work and activities, whether or not remunerated, for and/or on behalf of such a company or organisation and other links with the industry and organisations of REACH relevance. See points 3.3 and 3.4 of the ECHA Guidance on conflicts of interest ⁴Investment funds excluded. See point 3.2 of the ECHA Guidance on conflicts of interest.

⁵ See point 3.6 of the ECHA Guidance on conflicts of interest.
⁶ A household member means: spouse, partner, or child living at the same address as the Committee/Forum member concerned. The names of these persons do not need to be declared.

I,	, hereby declare on
my honour that, to the best of my knowledge, have in organisations relevant to the operat position referred to above are those listed above	ing area of ECHA related to my
I further declare that should any changes occur acquire additional interests that should be m forthwith declare them and complete a new d changes.	ade known to the Agency, I shall
I understand that this Declaration will be public Agency's website and entered in a register hel accessible to the public, on request, at the Agency	d by the Agency which is
Signature:	Date:

DECLARATION OF CONFIDENTIALITY OF ECHA MEMBER STATE COMMITTEE MEMBERS, THEIR ADVISERS, INVITED EXPERTS AND OBSERVERS

exercise the greatest discr knowledge in the course member/adviser/invited e Committee of the Europea than representatives of r Commission or Communit the Committee unless oth publicly available. I acce obligation also after these	etion with regard of or in connect expert/alternate in in Chemicals Agen- relevant competer ty bodies ⁸ any informative stipulated per without reserve	to all facts ion with the nember/observy. I shall not authorities ormation acquin Communation that I	and informate performance performance of the ot disclose to so of the Muired as a relatity or nation	tion coming ce of my do ne Member o any person lember State esult of my w nal law or a	to my uties a State s other es, the vork in
Done at	on _	/20)		
Signature:			_		
Position:					

 $^{^{7}}$ Strike through the text that is not relevant. 8 For observers from stakeholder organisations, the provisions of the ECHA Code of Conduct for observers from stakeholder organisations at ECHA meetings apply.



Helsinki, 4 March 2010 Doc: MB/05/2010 final

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 Titles⁹ 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

⁹ It should be noted that tasks are allotted to the Committee under Titles VII, VIII and X

- 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.

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 members coopted by the Committee. Only members (including co-opted members) have voting rights.
- 2. Members nominated by the EEA-EFTA States that are Iceland, Liechtenstein and Norway have the same rights and obligations as other members except the right to vote.

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, which may be renewed by the Committee, if it decides that the specific competence of the co-opted member continues to be necessary for the Committee.
- 4. These additional members can be co-opted at any point in time.

Article 5

Term of office, nomination and resignation/revocation

- 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 ¹⁰ to revoke the appointment following a justified proposal from the Chair in any of the following cases:

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¹⁰ The ECHA Management Board or the Committee in the case of co-opted members.

- 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 four 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.

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, 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. These stakeholder observers shall conform to the 'ECHA Code of Conduct for observers from stakeholder organisations at ECHA meetings'.
- 7. Applicants for authorisation and, where relevant, other case-owners may be admitted as observers when their application or case 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, 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 the same access to the documents of the meeting or the documents for the relevant agenda points that they take part in as the members, 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.

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;
- i) execute any powers entrusted to the Chair by the Committee, such as representing the Committee towards other parties.

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 models contained in Annex 1 and Annex 2. 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).
- 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 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, 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.
- 4. Following Article 85(7) of Regulation (EC) No 1907/2006, members, their advisers and 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.
- 5. 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.
- 6. 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

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¹¹ 'ECHA Guidance on conflicts of interest for ECHA Committees and Forum members, their advisers and invited experts' provides guidance on identifying interests that could potentially present conflicts.

- dealt with by the Committee. The member shall, in principle, resign from the Committee before entering into service in any such enterprise or association.
- 7. Individual members or the Chair can be mandated by the Committee to represent the Committee on specific issues and/or occasions.

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 public 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 a model laid down in Annex 3.
- 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.
- 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.

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.

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 summary record of the proceedings;
 - c) reference to the opinions adopted by the Committee;
 - d) the list of attendees;
 - e) action points.
- 2. 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 be approved at a following meeting or by a written procedure.

Article 17

Rapporteurs

- 1. Where the Committee is required to provide an opinion 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 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.
- 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 Socio-economic Analysis 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 6 and the Chair of the joint working group.

Quorum and opinions or decisions of the Committee

- 1. The quorum necessary for a meeting is achieved when at least sixty 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 having the right to vote, including their grounds. Members not supporting the majority position shall provide their minority position(s) 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 sixty 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 their 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 suspended, 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, 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.

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 1 Declaration of commitment form

ANNEX 2 Declaration of interests form

ANNEX 3 Declaration of confidentiality form

ANNUAL DECLARATION OF COMMITMENT OF ECHA COMMITTEE FOR RISK ASSESSMENT MEMBERS

I, hereby declare that I shall make all reasonable efforts to fulfil my duties as a member of the Committee for Risk Assessment of the European Chemicals Agency.
More particularly, I undertake to exercise the functions entrusted to me by the Committee for Risk Assessment and not to seek or accept any instructions incompatible with my individual tasks or with the tasks of the Risk Assessment Committee from any other party.
I understand that this Declaration will be entered in a register held by the European Chemicals Agency which is accessible to the public, on request, at the Agency's offices.
Done at on/ 201
Signature:

ANNUAL DECLARATION OF INTERESTS OF ECHA COMMITTEES AND FORUM MEMBERS

Title (Ms., Mr., Dr., Prof.):		
First Name:		
Surname:		
Position:		
[] Member of the Committee for Risk		
[] Member of the Committee for Socie	•	
[] Member of the Member State Com		
[] Member of a Forum for Exchange of	of Information on Enf	orcement
hereby declares to have the following in	nterests	
1. Work and activities in organi ECHA during the past 5 years ¹²		the operating area of
Name of organisation	Position/Tasks	Period
2. Financial interests in a compar during the past 5 years and excor more per company ¹³ :		
Name of the company	Curi	rent/Past
3. Other interests or facts whether you consider should be made relating to the members of your	known to the Agen	cy, including matters
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Work and activities, whether or not remunerated, for and/or on behalf of such a company or organisation and other links with the industry and organisations of REACH relevance. See points 3.3 and 3.4 of the ECHA Guidance on conflicts of interest
 Investment funds excluded. See point 3.2 of the ECHA Guidance on conflicts of interest.
 See point 3.6 of the ECHA Guidance on conflicts of interest.
 A household member means: spouse, partner, or child living at the same address as the Committee/Forum member concerned. The

names of these persons do not need to be declared.

I,	, hereby declare on
my honour that, to the best of my knowledge, have in organisations relevant to the operat position referred to above are those listed above	ing area of ECHA related to my
I further declare that should any changes occur acquire additional interests that should be m forthwith declare them and complete a new d changes.	ade known to the Agency, I shall
I understand that this declaration will be pub. Agency's website and entered in a registeraccessible to the public, on request, at the Agen	er held by the Agency which is
Signature:	Date:

DECLARATION OF CONFIDENTIALITY OF ECHA COMMITTEE FOR RISK ASSESSMENT MEMBERS, THEIR ADVISERS, INVITED EXPERTS AND OBSERVERS

I, hereby declare that I shall undertake to exercise the greatest discretion with regard to all facts and information coming to my knowledge in the course of or in connection with the performance of my duties a member/adviser/invited expert/observer ¹⁶ of the Committee for Risk Assessment of the European Chemicals Agency. I shall not disclose to any persons other than representatives of relevant public authorities of the Member States, the Commission and Community bodies, any information acquired as a result of my work in the Committee unless otherwise stipulated in Community or national law or already publicly available. I accept without reservation that I continue to be bound by this obligation also after these duties have ceased.
Done at on/ 201
Signature:
Position:

¹⁶ Strike through the text that is not relevant.



Helsinki, 4 March 2010 Doc: MB/06/2010 final

RULES OF PROCEDURE FOR THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS

Article 1

Responsibilities

In accordance with Article 76(1) of Regulation (EC) No 1907/2006, the Committee for Socio-economic Analysis (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 applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of that Regulation relating to the socio-economic impact of possible legislative action on substances.

Article 2

Tasks

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

- a) performing the tasks allotted to it under Titles¹⁷ VI to XI of Regulation (EC) No 1907/2006;
- b) 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;

¹⁷ It should be noted that tasks are allotted to the Committee under Titles VII, VIII and X.

c) 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.¹⁸

Article 3

Membership

- 1. In accordance with Article 85(2) 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. Only members (including co-opted members) have voting rights.
- 2. Members nominated by the EEA-EFTA States that are Iceland, Liechtenstein and Norway have the same rights and obligations as other members except the right to vote.

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, which may be renewed by the Committee, if it decides that the specific competence of the co-opted member continues to be necessary for the Committee.
- 4. These additional 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. If 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 after the decision of the appointing body, the appointment will be revoked.

¹⁸ The Committee would deal with tasks described in (b) and (c) as far as socio-economic aspects are concerned.

- 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. Following a justified proposal from the Chair, the Executive Director of the Agency may request a member to resign if the member is not fulfilling his/her duties. The Member State may nominate a replacement candidate in accordance with Article 5(3). If a member does not attend four consecutive meetings without justification, following a proposal from the Chair, the Executive Director of the Agency may request the appointing body to take a decision to revoke the appointment of the member
- 3. 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.
- 4. 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.

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, 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. These stakeholder observers shall conform to the ECHA "Code of conduct for observers from stakeholder organizations at ECHA meetings".
- 7. Applicants for authorisation and, where relevant, other case owners may be admitted as observers when their application or case 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, 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 the same access to the documents of the meeting or the documents for the relevant agenda points that they take part in as the members, 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.

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;

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 models contained in Annex 1 and Annex 2. 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).
- 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 independence¹⁹ 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, 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.
- 4. Following Article 85(7) of Regulation (EC) No 1907/2006, members, their advisers and 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.
- 5. 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.
- 6. 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

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Committee before entering into service in any such enterprise or association.

7. Individual members or the Chair can be mandated by the Committee to represent the Committee on specific issues and/or occasions.

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- 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 public 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 a model laid down in Annex 3.
- 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.

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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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 - 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) and (6), 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.

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- 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.

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- 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.

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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.

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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.

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- 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 summary record of the proceedings;
 - c) reference to the opinions reached by the Committee;
 - d) the list of attendees;
 - e) action points.
- 2. 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 be approved at a following meeting or by a written procedure.

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 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.

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 sixty 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 having the right to vote, including their grounds. Members 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.

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 sixty 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 decisions, 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.

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 1 Declaration of commitment form

ANNEX 2 Declaration of interests form

ANNEX 3 Declaration of confidentiality form

ANNUAL DECLARATION OF COMMITMENT OF ECHA COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS MEMBERS

I, hereby declare that I shall make all reasonable efforts to fulfil my duties as a member of the Committee for Socio-economic Analysis of the European Chemicals Agency.
More particularly, I undertake to exercise the functions entrusted to me by the Committee for Socio-economic Analysis and not to seek or accept any instructions incompatible with my individual tasks or with the tasks of the Committee for Socio-economic Analysis from any other party.
I understand that this Declaration will be entered in a register held by the European Chemicals Agency which is accessible to the public, on request, at the Agency's offices.
Done at on/ 200
Signature:

ANNUAL DECLARATION OF INTERESTS OF ECHA COMMITTEES AND FORUM MEMBERS

Title (Ms., Mr., Dr., Prof.):

First Name: Surname: Position: [] Member of the Committee for [] Member of the Committee for [] Member of the Member State [] Member of a Forum for Exchange the Exchange of the Member State the Exchange of the Member of the Member State the Exchange of the Exchange of the Member of the Member State the Exchange of the Member of the Member State the Exchange of the Member of the Member of the Member State the Member of the Member of the Member of the Member of the Member State the Member of the Member of the Member of the Member State the Member of the Member of the Member of the Member State the Member of the Member State the Member of t	Risk Socio Comm	Assessment o-economic Ana nittee of Information of	lysis	cement
Work and activities in ECHA during the pass			ant to th	ne operating area of
Name of organisation		Position/Tasks		Period
Financial interests in ECHA during the pas right of 5 % or more p	st 5 ye	ears and exceed		
Name of the company			Curren	t/Past
 Other interests or fac which you consider s matters relating to the 	hould	be made know	n to the	Agency, including

Work and activities, whether or not remunerated, for and/or on behalf of such a company or organisation and other links with the industry and organisations of REACH relevance. See points 3.3 and 3.4 of the ECHA Guidance on conflicts of interest
 Investment funds excluded. See point 3.2 of the ECHA Guidance on conflicts of interest.
 See point 3.6 of the ECHA Guidance on conflicts of interest.
 A household member means: spouse, partner, or child living at the same address as the Committee/Forum member concerned. The

names of these persons do not need to be declared.

1,	, hereby declare on
my honour that, to the best of my knowledge, the have in organisations relevant to the operating ar position referred to above are those listed above.	rea of ECHA related to my
I further declare that should any changes occur a acquire additional interests that should be made a forthwith declare them and complete a new declar changes.	known to the Agency, I shall
I understand that this Declaration will be publish Agency's website and entered in a register held accessible to the public, on request, at the Agence	by the Agency which is
Signature:	Date:

Annex 3

DECLARATION OF CONFIDENTIALITY OF ECHA COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS MEMBERS, THEIR ADVISERS, INVITED EXPERTS AND OBSERVERS

I, hereby declare that I shall undertake to exercise the greatest discretion with regard to all facts and information coming to my knowledge in the course of or in connection with the performance of my duties a member/adviser/invited expert/observer ²⁴ of the Committee for Socio-economic Analysis of the European Chemicals Agency. I shall not disclose to any persons other than representatives of relevant public authorities of the Member States, the Commission and Community bodies ²⁵ , any information acquired as a result of my work in the Committee unless otherwise stipulated in Community or national law or already publicly available. I accept without reservation that I continue to be bound by this obligation also after these duties have ceased.
Done at on/ 200
Signature:
Position:

²⁴ Strike through the text that is not relevant.

²⁵ For observers from stakeholder organisations, the provisions of the ECHA Code of Conduct for observers from stakeholder organisations at ECHA meetings apply.