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Rules of procedure for the Biocidal Products Committee

Article 1

Responsibilities

In accordance with Article 75 of Regulation (EU) No 528/2012 the Biocidal Products Committee (hereinafter, referred to as "the Committee") shall be responsible for preparing the opinion of the Agency in relation to the tasks set out in Article 2.

Article 2

Tasks

1. The Committee shall be responsible for preparing the opinion of the Agency on the following issues:
 - a) Applications for approval and renewal of approval of active substances;
 - b) Review of approval of active substances;
 - c) Applications for inclusion in Annex I of active substances meeting the conditions laid down in Article 28 of Regulation (EU) No 528/2012 and review of the inclusion of such active substances in Annex I;
 - d) Identification of active substances which are candidates for substitution;
 - e) Applications for Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisations, except where the applications are for administrative changes;
 - f) Scientific and technical matters concerning mutual recognition in accordance with Article 38 of Regulation (EU) No 528/2012;
 - g) At the request of the Commission or of Member States' Competent Authorities, any other questions that arise from the operation of Regulation (EU) No 528/2012 relating to technical guidance or risks to human health, animal health or the environment.

Article 3

Members and Alternates

1. In accordance with Article 75(2) of Regulation (EU) No 528/2012, each Member State shall be entitled to appoint one member to the Committee.
2. Member States may appoint an alternate. Appointment of an alternate to the Committee 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, where relevant, applicable also to the alternate members, except the possibility of being nominated as rapporteur or co-rapporteur.

¹ Amendment of Annex 2 approved by the Management Board on 20 March 2014.

² Switzerland invited to participate in the biocides-related activities of the Agency by the Management Board of 19-20 March 2015.

3. Members have the right to vote. Where relevant, alternates shall represent and vote for the appointed member in the absence of the member from the meeting. At the request of the member, the alternate may respond on behalf of the member in written procedures or any request for urgent advice from members between meetings.
4. The members of the Committee appointed by a Member State shall ensure that there is appropriate coordination between the tasks of the Agency and the work of their Member State Competent Authority.
5. The members of the Agency's Management Board may not be members of the Committee.
6. Members and alternates appointed by Iceland, Liechtenstein and Norway³ and by Switzerland⁴ shall have the same rights and obligations as other members, except the right to vote.

Article 4

Term of office and replacing members

1. In accordance with Article 75 (4) of Regulation (EU) No 528/2012 (which in turns refers to Article 85(4) of Regulation (EC) No 1907/2006) the term of office of the members of the Committee shall be three years starting from the date of appointment. The date of appointment shall be the date of the first meeting of the Committee during this term of office. The appointment shall be renewable.
2. A member's term of office shall end before the expiry of the three-year period with their resignation submitted in writing to the Agency and a letter from the Permanent Representation of the Member State concerned to the Agency indicating another appointment. The new member thus appointed shall serve for the remaining period of the three-year term which started at the date of appointment referred to in paragraph 1.
3. In exceptional cases when members are prevented from participating in a meeting of the Committee, they should notify the Agency and request the alternate, if one has been appointed, to be invited by the Agency to participate in the respective meeting.
4. If prevented from participating in a meeting or from sending an alternate, if 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 their own vote, each member having the right to vote may cast a maximum of two votes by proxy. The proxy shall be notified to the Committee at the beginning of the meeting and shall be recorded in the minutes.

Article 5

Co-opted members

1. In accordance with Article 75 (4) of Regulation (EU) No 528/2012 (which in turns refers to 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. These additional members can be co-opted at any point in time.
3. Co-opted members shall be appointed for a term of three years and the date of appointment will be determined by the Secretariat and the term of office will end at the

³ Subject to Regulation (EU) No 528/2012 being incorporated into the EEA Agreement.

⁴ In accordance with the revised Annex I, Chapter 18 of the Mutual Recognition Agreement (MRA, RS 0.946.526.81) between EU and Switzerland.

same time as the term of office of Committee members referred to in Article 4(1). The appointment 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. A co-opted member's term of office shall end before the expiry of the three-year period if their resignation is submitted in writing to the Agency.
5. Co-opted members shall have the same rights and obligations as other members, except the right to vote and right to appoint an alternate.

Article 6

Other participants at the meetings

1. The meetings of the Committee and its working groups as referred to in Article 18, unless otherwise stated, shall be open to advisers, invited experts and observers, as specified in paragraphs 2 to 10.
2. Advisers are participants of Committee meetings or its working groups accompanying members to provide advice on scientific, technical or regulatory matters. The members shall notify the names of their advisers to the Secretariat before the meeting which they are due to attend.
3. Invited experts are experts in technical or scientific fields who can, upon proposal of a member or the Secretariat, be invited by the Agency to participate for one or more points of the agenda in a meeting of the Committee or its working groups.
4. Observers are other participants of the meetings of the Committee or its working groups under paragraphs 5 to 10 who are not members, advisers or invited experts.
5. The Executive Director and his representatives and representatives of the European Commission shall be entitled to take part in the meetings of the Committee and its working groups as observers.
6. Nominated representatives of accredited stakeholder organisations may be admitted by the Committee as regular observers to the meetings of the Committee or its working groups upon request of the ECHA Management Board and agreement with members of the Committee. These representatives contribute with their scientific and technical expertise and ensure the multiplication of information within their sectors. These accredited stakeholder observers shall conform to the Code of Conduct for Stakeholder Observers at ECHA meetings, other rules specifying the procedure for the admission of observers and any other applicable Agency rules.
7. An applicant⁵ may be admitted as an observer when their specific case is addressed by the Committee or its working groups. Applicants shall conform to any particular applicable Committee rules, working procedures or codes of conduct that may be drawn up by the Committee, or other applicable Agency rules.
8. Admittance to the meetings of the Committee or its Working Groups by nominated accredited stakeholder organisations or applicants may be refused on a case-by-case basis for reasons of confidential business information, including the protection of intellectual property rights or for other justified reasons related to the information to be discussed in a particular meeting.
9. Representatives of third countries and international organisations may take part in the meetings as observers upon request by the ECHA Management Board and agreement with the members of the Committee.
10. Other observers may be admitted upon request of a member of the Committee or of the Chair.

⁵ For approval of an active substance or authorisation of a biocidal product.

11. The Committee shall agree by two-thirds majority of all members having the right to vote on rules specifying the procedure for the admission of observers referred to in paragraphs 6 to 10.
12. The Chair may decide to hold the meeting in a closed session excluding observer(s) referred to in paragraphs 6 to 10 at any point in time before or during a meeting on a written or oral request of a member or when the Chair considers this otherwise appropriate.
13. Invited experts and observers referred to in paragraphs 3 and 6 to 10 shall have the same access as the members to the documents of the meeting or the documents for the relevant agenda points in which they take part, except in relation to the issues that the Chair identifies as confidential for reasons of confidential business information, including the protection of intellectual property rights or for other justified reasons, or where their participation is excluded. The access of advisers to documents is at the discretion of the respective member.

Article 7

The Chair

1. In accordance with Article 75 (4) of Regulation (EU) No 528/2012 (which in turns refers to Article 85(9) of Regulation (EC) No 1907/2006), the Committee shall be chaired by an employee of the Agency.
2. If the Chair is absent or has a conflict of interest for an agenda item, the Executive Director of the Agency will assign a replacement.

Article 8

Responsibilities of the 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 ECHA support Unit(s);
- b) Monitor that these 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 75(1) of Regulation (EU) No 528/2012;
- 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 as well as with other relevant European Union committees or bodies;
- h) Facilitate adoption of opinions within the set deadlines and endeavour to reach consensus in the opinions of the Committee; and
- i) Execute any additional powers entrusted to the Chair by the Committee.

Article 9

Independence

1. Pursuant to Article 75(4) of Regulation (EU) No 528/2012 (which in turns refers 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 made⁶ in accordance with the models (direct links provided in Annex 1) and according to the applicable ECHA Conflicts of Interest Policy. These declarations shall be made annually in writing and be entered in a register held by the Agency. If at any point in time changes occur to the situation of the member's interests, they shall make an updated declaration without delay. In addition, 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. The Chair may impose the same requirements on members of working groups that are not Committee members.

2. According to Article 75(4) of Regulation (EU) No 528/2012 (which in turns refers 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 75(4) of Regulation (EU) No 528/2012 (which in turns refers to Article 87(1) of Regulation (EC) No 1907/2006), for each case, the rapporteur and, when applicable, co-rapporteur shall undertake to act in the interest of the Union and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing.
4. A member of the Committee shall not be appointed as rapporteur or co-rapporteur for a particular case if they indicate any interest that might be prejudicial to the independent consideration of that case.
5. The Committee may agree to replace the rapporteur or co-rapporteur by another one of its members at any time, if an interest that might be prejudicial to their independent consideration of a case comes to light.
6. In general, the Chair represents the Committee including towards other parties. Individual members can be mandated by the Chair to represent the Committee on specific issues or occasions.
7. Without prejudice to Article 10(1), members have a duty to ensure any view relevant to the work of the Committee they express outside of the Committee is presented as their own view, unless mandated by the Chair.
8. Members have a duty to act in accordance with the applicable General Principles and Guidance for Committee members of the Agency in relation to this Article and Article 10.
9. Following their appointment members shall at all times comply with the eligibility guidelines applicable to the Committee.

Article 10

Confidentiality

1. Members, their advisers, invited experts and observers of the Committee and its working groups shall not disclose to any persons other than representatives of relevant public authorities of the Member States, the Commission and Union bodies, any information acquired as a result of their participation in work in the Committee unless otherwise stipulated in Union or national law or already publicly available. Members, their advisers, invited experts and observers of the Committee and its working groups shall make a

⁶ http://echa.europa.eu/documents/10162/13607/ed_decision_67_2011_en.pdf

written declaration of confidentiality in accordance with the model (direct link is provided in Annex 1).

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 75(4) of Regulation (EU) No 528/2012 (applies as *mutatis mutandis*, 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.
3. The following documents of the Committee shall be published on the Agency's web site, without prejudice to confidentiality requirements:
 - Rules of Procedure;
 - Agreed 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, individual views, whether expressed orally or in writing by members or other meeting participants during deliberations within the Committee or a working group, shall not be ascribed to a particular individual unless this is explicitly requested by the individual.

Article 12

Organisation of Committee 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 Secretariat will provide provisional dates for the following year at the earliest possible time in the preceding year.
3. The invitation to an ordinary meeting shall be circulated well in advance, but no later than 21 calendar days before the meeting.
4. In urgent cases when it is necessary to convene the Committee immediately, the Executive Director may shorten the time limit for invitations to a minimum of five calendar days before the start of the meeting.
5. The working language of the Committee is English.

Article 13

Agenda for ordinary meetings

1. A provisional draft agenda shall be drawn up by the Chair and circulated to the Committee together with the invitation to the meeting. The provisional draft agenda shall indicate if an item is intended to be addressed in an open or closed session.

2. A revised draft agenda shall be established by the Chair and circulated no later than ten calendar days before the meeting. The agenda shall be agreed at the beginning of each meeting.
3. 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 meetings 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 or information only.

Article 15

Agenda and documentation for urgent meetings

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

Article 16

Minutes

1. Final minutes of plenary meetings shall include:
 - a) Any specific interests declared by the participants and follow-up actions 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 and their underlying argumentation;
 - d) The list of attendees;
 - e) The action points and conclusions agreed at the meeting.
2. Draft minutes or relevant parts of it shall be distributed to participants of the meeting no later than 28 calendar days after the meeting. Written comments shall be provided to the Secretariat within a specified deadline which shall be a minimum of seven calendar days. The minutes shall be agreed at the following meeting or by written procedure.

Article 17

Rapporteurs

1. Pursuant to Article 75(4) of Regulation (EU) No 528/2012, which in turn refers to Article 87(1) of Regulation (EC) No 1907/2006, where the Committee is required to provide an opinion, where appropriate, 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 rapporteur for an application as defined in Article 75(1) (a), (b) and (e) of Regulation (EU) No 528/2012 shall usually be from the same Member State as the evaluating Competent Authority (eCA).
3. For cases pertaining to Article 75(1) (g) of Regulation (EU) No 528/2012 the Committee shall appoint one of its members as a rapporteur and agree by two thirds majority of all

members present having the right to vote on the role and tasks of the rapporteur and possible co-rapporteur.

4. If either the rapporteur or co-rapporteur are unable to fulfil their duties within the prescribed time limits, the Committee may at any time agree to replace the rapporteur or co-rapporteur by two thirds majority by another one of its members.
5. Notwithstanding the applicable provisions in the Fee Regulation, any remuneration from the Agency of the rapporteur and co-rapporteur 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 their employer.
6. The Committee may decide to designate a working group to support the rapporteur and co-rapporteur in their task(s).

Article 18

Working groups

1. Where appropriate, the Committee may establish ad hoc or permanent working groups. Working groups shall be chaired by the Secretariat and shall report to the Committee in accordance with their mandate.
2. The mandate and composition of a working group as well as the duration of its activity shall be determined and reviewed periodically by the Committee. The Committee agreement establishing the mandate shall be recorded in the minutes of the meeting.
3. Working groups may be composed of volunteering members of the Committee, rapporteurs and/or other persons proposed by the Member State Competent Authorities and other experts invited on the basis of the required expertise. Prospective members and invited experts of the Working Group will receive an invitation from the Chair of the Committee. The mandate and composition of the working groups shall be made public by the Secretariat.
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 far as applicable.
6. Where appropriate, the Committee may establish with other ECHA Committees, a joint working group by mutual consent. The provisions of paragraphs 2-5 shall apply *mutatis mutandis* to the joint working group. The mandate referred to in paragraph 2 shall specify the applicable rules of procedure referred to in paragraph 5 and the Chair of the joint working group.

Article 19

Quorum and 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. A member having declared a conflict of interest regarding an agenda point shall not give a proxy to another member for that agenda point but may be replaced by their alternate member in the vote.
3. If the quorum is not achieved the Chair may decide to launch a written procedure in accordance with Article 20.
4. When preparing an opinion, the Committee shall use its best endeavours to reach a consensus. If consensus cannot be reached, the opinion adopted by the Committee shall

consist of the position of the simple majority of the present members having the right to vote, including their grounds. Members having minority position(s) shall provide them to the Committee in writing within seven calendar days of the adoption of the opinion, clearly stating their grounds. The provision of minority position(s) shall be recorded in the minutes and published.

5. 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 decisions by written procedure. To this end, the Chair of the Committee shall send the members the draft document(s) on which their opinion is sought and indicate the response period.
2. The response period shall normally not be shorter than 15 calendar days.
3. Without prejudice to paragraph 4, 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 following the tacit or express agreement of all members having the right to vote.
4. When opinions 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.
5. Members having minority position(s) shall provide them to the Secretariat in writing within seven calendar days of the completion of the written procedure, clearly stating their grounds. The provision of minority position(s) shall be recorded in the minutes and be recorded in the written procedure report.
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 opinion or the agreement of the 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, 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 applicable rules adopted by the ECHA Management Board on the reimbursement of travel and other expenses.

Article 22

General provisions

1. These Rules of Procedure or any amendment to them shall apply from the date they have been approved by the ECHA 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 ECHA Management Board.

Annex 1

Links to the Declarations

[Declaration of interests and commitment](#)

[Declaration of confidentiality](#)