

Rules of Procedure for the Competent Authorities for REACH and CLP (CARACAL)

The expert group consisting of the Competent Authorities for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging of substances and mixtures (CLP) Regulations (hereafter referred to as “CARACAL” or “the Group”),

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p.1)¹ (hereafter referred to as “REACH” or “the REACH Regulation”), and in particular Article 121 thereof,

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006² (hereafter referred to as “CLP” or “the CLP Regulation”), and in particular Articles 43 and 53a(4) thereof,

Having regard to the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making³,

Having regard to the creation of the Group by Directorate General for Environment and Directorate General for Internal Market, Industry, Entrepreneurship and SMEs,

Having regard to the standard rules of procedure of expert groups⁴,

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE

Point 1 - Tasks

- (1) CARACAL shall provide advice to the Commission on policy issues and to the Commission and ECHA on the implementation and the functioning of the REACH and CLP Regulations in their respective areas of responsibility.

¹ Corrected by OJ L 136, 29.5.2007, p.3 and OJ L 36, 5.2.2009, p. 84.

² OJ L 353 of 31 December 2008, p.1.

³ OJ L 123 of 12 May 2016, p. 1.

⁴ Annex 3 of Commission Decision C(2016) 3301 final of 30.05.2016 establishing horizontal rules on the creation and operation of Commission expert groups.

- (2) CARACAL shall assist the Commission in relation to the preparation of delegated acts in accordance with the CLP Regulation.
- (3) CARACAL shall carry out its activities in accordance with the prerogatives of the Commission and ECHA, in compliance with the REACH and CLP Regulations.

Point 2 - Operation

- (1) The responsible Commission services for REACH and CLP shall provide the secretariat of the meeting. The meetings will be chaired jointly by the Commission's Directorate-General for Environment and the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, reflecting their joint responsibility for REACH and CLP. The Directorates General shall usually be represented at Head of Unit level or their representatives.
- (2) ECHA shall participate in the meeting of CARACAL and can, in agreement with the Commission, take the lead for a specific part of the agenda covering topics related to its responsibility. In particular, it can, under its own responsibility, consult the meeting on implementation issues for which it would like to get advice from CARACAL.
- (3) The European Parliament and the Council may each send experts to the CARACAL meetings dealing with the preparation of delegated acts.
- (4) For CARACAL agenda points not dealing with the preparation of delegated acts, upon request of the European Parliament, the Commission may invite the European Parliament to send its experts to attend meetings of this Group, in compliance with point 15 and Annex I of the Framework Agreement on relations between the European Parliament and the European Commission ("the Framework Agreement").
- (5) The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the Group or sub-groups on an ad hoc basis, when necessary.

Point 3 - Composition and appointment

- (1) Members shall be the Member States' authorities and ECHA. Members shall appoint their representatives, as follows:
 - (a) Representatives from the appointed REACH and CLP competent authority or authorities of each Member State ("MSCA"). Upon request of the MSCA, designated representatives may be accompanied by advisers. The REACH and CLP competent authority or authorities may decide to replace their representatives, in which case they shall inform the Commission services thereof;
 - (b) Experts of Member States' authorities designated by each Member State, representing the national interests for the agenda points on delegated acts.
- (2) Observers shall be public authorities other than Member States' authorities, together with stakeholders. Observers shall appoint their representatives, as follows:
 - (a) As regards other public authorities:

- Representatives of accession or candidate countries: A maximum of two representatives of each accession or candidate country may attend the meetings of CARACAL;
- Representatives of EFTA countries (including both EEA and non-EEA countries): A maximum of one representative of each EFTA country (including both EEA and non-EEA countries) may attend the meetings of CARACAL;
- Representatives of other third countries: A maximum of one representative of third countries may attend the meetings of CARACAL. The representative of third countries shall co-ordinate his/her positions with other third countries;
- Representatives of international organisations: A maximum of one representative of each of the OECD and EFTA secretariats may attend the meetings of CARACAL.

The represented public authority may decide to replace its representative. It shall inform the Commission thereof.

(b) As regards stakeholders:

The stakeholders shall appoint their representatives. The identity of the stakeholders, as well as the number of stakeholders' representatives, shall be fixed by the Commission with a view to ensuring a broad and balanced representation of stakeholders concerned by REACH and CLP.

Stakeholders may decide to replace their appointed representative, permanently or in one or more individual meetings. They shall inform the Commission thereof.

(3) Observers' representatives may be permitted by the Chair to take part in the discussions of the Group and provide expertise. However, they shall not adopt opinions as provided for in Point 7.

Point 4 - Convening a meeting

(1) Meetings of CARACAL are convened by the Commission services, either on their own initiative or at the request of a simple majority of Members, subject to the availability of meeting facilities.

(2) Meetings will be convened by the Commission with the following minimum deadlines:

3 months before the meeting: Members and Observers of CARACAL are informed of the tentative dates of the meeting. When the meeting is convened for the assistance of the Commission in the preparation of delegated acts, the European Parliament and the Council are informed simultaneously;

3 weeks before the meeting: Invitations and if necessary registration forms, are sent to Members and Observers of CARACAL. In the case of Member States' experts consulted for the preparation and drawing up of delegated acts, invitations are sent to the Permanent Representations of Member States and simultaneously to the European Parliament and the Council, to their respective functional mailboxes.

- (3) Joint meetings with other groups may be convened to discuss matters falling within their respective areas of responsibility. The deadlines for CARACAL apply to joint meetings.

Point 5 - Agenda

- (1) The Commission in co-operation with ECHA shall draw up the agenda in accordance with their respective responsibilities and send it to the Members and Observers of the Group and, when the meeting is convened for the preparation of delegated acts, to the European Parliament and the Council. The provisional draft agenda shall be made available to the Group *via* CIRCA at the latest *6 weeks* before the meeting. The final draft agenda, taking into account comments and suggestions by the Members and Observers of the Group, shall be made available at the latest *2 weeks* before the meeting.
- (2) The draft agenda may include points which are to be discussed without the presence of Observers in a Competent Authorities session consisting of MSCAs only (see Point 13).
- (3) The agenda shall be adopted by the Group at the beginning of each meeting.
- (4) If the Group so decides, additional items may be added to the agenda and items on the agenda may be deleted or carried over to a subsequent meeting.

Point 6 - Documents

- (1) All documents shall be distributed electronically by the Commission or ECHA *via* CIRCA. The Commission is responsible for setting the nomenclature for documents.
- (2) If a Member State considers that a paper submitted by it contains confidential information within the meaning of Annex II to the Framework Agreement, such Member State should clearly indicate this on the cover sheet and attach a short statement of reasons. In this case, the cover page shall also indicate whether the originator of the document consents to its transmission to the European Parliament pursuant to Point 17.
- (3) If publication of a document on the Commission website pursuant to Article 13 would undermine protection of an interest covered by Article 4(1) to (3) of Regulation (EC) No 1049/2001, this shall be explained on the cover page of the document.
- (4) Without prejudice to Article 8, the Commission or ECHA shall distribute drafts on which the Group is consulted and all other working documents to the Members no later than *3 weeks* before the date of the meeting in the case of delegated acts and *2 weeks* before the meeting in other cases.
- (5) When preparing and drawing up delegated acts, the Commission shall ensure a timely and simultaneous transmission of all documents, including draft acts, to the European Parliament and the Council at the same time as to Member States' experts.
- (6) Classified documents shall be processed in accordance with internal administrative procedures drawn up by each institution with a view to providing all the requisite guarantees.

- (7) In urgent or exceptional cases, the time limits for distributing the documents may be reduced to seven calendar days before the date of the meeting.
- (8) Room documents or documents that are distributed less than seven calendar days prior to the meeting shall only be placed on the agenda for information or discussion purposes.

Point 7 - Opinions of the Group

- (1) As far as possible, the Group shall adopt its opinions by consensus of its Members. In the event of a vote, the outcome of the vote shall be decided by simple majority of the Members. The Members that voted against or abstained shall have the right to have a document summarising the reasons for their position presented together with the opinions.
- (2) When the Group assists the Commission in relation to the preparation of delegated acts in accordance with the CLP Regulation as set out in Point 1(2), the Group shall not adopt opinions on draft delegated acts.

Point 8 - Sub-groups

- (1) The Commission or ECHA in agreement with the Commission may create sub-groups of experts of the CARACAL to examine particular issues.
- (2) A sub-group is established through the following procedure:
 - The Commission Services shall develop a mandate of the sub-group, including its composition, the expected output and the timelines.
 - The mandate shall be endorsed by the Members of CARACAL, either at a meeting or through a written procedure.
- (3) The sub-groups may invite external experts, as appropriate. The sub-groups shall report back to the CARACAL.
- (4) Sub-groups shall be disbanded as soon as they have fulfilled their mandated.
- (5) The rules of procedure of the CARACAL apply to its sub-groups, unless otherwise specified in their respective mandates.

Point 9 - Written procedure for request of an opinion

- (1) If necessary, the Group's opinion as set out in Point 7 on a specific question may be delivered *via* a written procedure. To this end, the Commission or ECHA delivers the draft(s) on which the Group is being consulted and any other working documents, at the latest 3 *weeks* before the opinion of the Group is requested. In exceptional cases and unless any of the Members objects, the deadlines may be altered upon request of the Commission Services or ECHA.
- (2) Members that do not respond within the set deadline on the requested opinion(s) are taken to give (a) favourable opinion(s) on the draft(s).

- (3) However, if a simple majority of Group Members asks for the question to be examined at a meeting of the Group, the written procedure shall be terminated without conclusion and the Chair shall convene a meeting of the Group as soon as possible. The same deadlines will apply to written consultation of CARACAL sub-groups.
- (4) The Commission or ECHA shall, fourteen calendar days after a written consultation, provide a report on the outcome of the consultation. Vote(s) against or abstention(s) expressed, including their grounds and the Member State(s) expressing them, shall be recorded in this report.

Point 10 - Written consultation of the Group in the preparation of delegated acts

- (1) CARACAL may be consulted in writing when assisting the Commission in relation to the preparation of delegated acts in accordance with the CLP Regulation.
- (2) To this end, the Commission delivers the draft(s) on which the Group is being consulted and any other working documents, at the latest 3 weeks before the views of the Group are requested.
- (3) The Commission shall, fourteen calendar days after a written consultation, provide a report on the outcome of the consultation.

Point 11 - Minutes of the meetings

- (1) The Commission Services shall prepare the minutes of the meetings. ECHA shall prepare the minutes on those agenda points where it has consulted CARACAL.
- (2) Minutes on the discussion on each point on the agenda and on the opinions delivered by the Group shall be meaningful and complete. The minutes shall mention the individual position of a participant during the Group's deliberations upon request of that participant. The minutes of the meetings shall record the results of written procedures that have been concluded between the previous and current meetings of CARACAL.
- (3) The minutes shall contain a list of agreed actions to be taken, as well as relevant deadlines. A list of agreed actions and contact points for comments will be issued at the latest 7 calendar days after the meeting.
- (4) The minutes of the meetings in which CARACAL assists the Commission in the preparation of delegated acts shall contain the conclusions the Commission has drawn from the discussion, including how the Commission will take the experts' views into consideration and how it intends to proceed.
- (5) Without prejudice to Article 11, the draft minutes shall be made available to all participants of the meeting no later than six weeks after the meeting. Written comments shall be provided to the Secretariat within the specified deadline, which shall be a minimum of two weeks. The minutes shall be adopted at a following meeting or by written procedure.

Point 12 - Attendance list

At each meeting, the secretariat shall draw up, under the responsibility of the Chair, an attendance list. The name of participants may be included in the minutes only subject to their

prior freely given, specific, informed and unambiguous consent, in compliance with Article 3(15) and Article 7 of Regulation 2018/1725. The attendance list shall specify, where appropriate, the authorities, organisations, countries or bodies to which the participants belong, including their e-mail address. This list shall be made available as an annex to the minutes of the meeting.

Point 13 - Competent Authorities sessions

The Commission or ECHA may decide on their initiative or at the request of a third of the Members present to discuss specific agenda points in a Competent Authorities session consisting of Commission, ECHA and Members only. If decided prior to the meeting, Competent Authorities sessions will be clearly indicated in the draft agenda. The outcome of Competent Authorities sessions shall be summarised in separate minutes.

Point 14 - Transparency

- (1) The Commission will publish all relevant documents (such as agendas, minutes, and participants' submissions) either on the Register of Commission Expert Groups and Other Similar Entities (hereinafter referred to as "Register) or *via* a link from the Register to a dedicated website, where information can be found. Exceptions to publication should be foreseen where it is considered by the Commission that disclosure of a document would undermine the protection of a public or private interest⁵ as defined in Article 4 of Regulation (EC) No 1049/2001⁶.
- (2) The Group's deliberations are confidential. In agreement with the Commission, the Group may decide to open its deliberations to the public.
- (3) In accordance with the Commission's policy on transparency, the rules of procedure, the list of authorities who are Members and Observers as well as the names of nominated Observers and the organisations they represent shall be made available on the Commission's website, as well as on the Register.

Point 15 - Access to documents

Applications for access to documents held by the Group will be handled in accordance with Regulation (EC) No 1049/2001 and detailed rules for its application.

Point 16 - Protection of personal data

All processing of personal data for the purpose of these rules of procedure shall be in accordance with Regulation (EU) 2018/1725⁷.

⁵ These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.

⁶ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

⁷ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39-98)

Point 17 - Modification of these rules of procedure

The Commission, ECHA or any Member of CARACAL may propose a modification to these rules of procedure by sending a request for amendment in the form of a proposed text and a justification to the Commission. An amendment to the rules of procedure shall be adopted by simple majority of the Group's members, in agreement with the Commission services. The Commission may circulate the proposed amendment(s) to obtain an opinion by written procedure as set out in Point 9.