

EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL Water, Marine Environment & Chemicals Chemicals, Biocides and Nanomaterials

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL Resources Based, Manufacturing and Consumer Goods Industries REACH Chemicals Industry

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11th Meeting of Competent Authorities for REACH and CLP (CARACAL)

28-29 November 2012

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

- Agenda Point: 3.2
- Action Requested: For endorsement.

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

The expert group consisting of the Competent Authorities for the REACH and Classification, Labelling and Packaging (CLP) Regulations (hereafter referred to as CARACAL),

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 Article 43 thereof,

Article 1

Tasks

The Member State Competent Authorities (hereafter referred to as "MSCAs") for REACH were appointed according to Article 121 of the REACH Regulation for performing the tasks allotted to competent authorities under that regulation and for cooperating with the European Commission (hereafter referred to as "the Commission"), the European Chemicals Agency (hereafter referred to as "ECHA"), and each other in its implementation.

The MSCAs for CLP were appointed according to Article 43 of the CLP Regulation for performing the tasks allotted to competent authorities under that regulation and for cooperating with the Commission, ECHA, and each other in its implementation.

The expert group "Competent Authorities for the REACH and CLP Regulations" (hereafter referred to as "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.

CARACAL shall carry out its activities in accordance with the prerogatives of the Commission and ECHA according to the REACH and CLP Regulations.

Article 2

Composition and Appointment

CARACAL shall have the following composition:

- a) The responsible Commission services for REACH and CLP shall provide the secretariat of the meeting. The meetings will be chaired jointly by Directorates General Environment and Enterprise, reflecting their joint responsibility for REACH and CLP. The Directorates General are usually represented at Head of Unit level or their representatives.
- b) ECHA participates 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.
- c) Members: Representatives from the appointed REACH and CLP competent authority or authorities of each Member State³ may attend the meetings of the CARACAL. Upon request of the MSCA, they may be accompanied by advisers. The appointed REACH and CLP competent authority or authorities of each Member State may decide to replace its (their) representatives. It (they) shall inform the Commission thereof.
- d) Observers appointed as representatives of 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 non-EEA EFTA countries: A maximum of one representative of each non-EEA EFTA country 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.

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The term Member State(s) shall be understood to include the EEA EFTA states

e) Observers appointed as stakeholder representatives

The Commission may appoint stakeholders as observers; they shall appoint their representatives. 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.

Appointed stakeholder representatives may be substituted at a meeting by another representative on behalf of the same organisation, upon prior agreement of the Commission, at the latest 10 working days before the meeting.

The represented stakeholder organisation may decide to replace its representative. It shall inform the Commission thereof.

f) External experts

The Commission may invite external experts to participate in the groups or subgroup works where appropriate and/or necessary.

Article 3

Convening a meeting

Meetings of CARACAL are convened by the Commission, either on its own initiative or at the request of a simple majority of members, subject to the availability of meeting facilities, after the Commission's services has given its agreement.

The meeting will be convened by the Commission with the following **minimum** deadlines:

3 months before the meeting: Members of CARACAL are informed of the tentative dates of the meeting;

3 weeks before the meeting: Invitations and registration forms, if necessary, are sent to members of CARACAL.

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.

Article 4

Agenda

The Commission in co-operation with ECHA shall draw up the agenda in accordance with their respective responsibilities and send it to the members of the group. 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.

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 Article 11).

The agenda shall be adopted by the group at the beginning of each meeting.

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.

Article 5

Documents

All documents shall be distributed electronically by the Commission or ECHA *via* CIRCA. The Commission is responsible for setting the nomenclature for documents.

If a Member State considers that a paper submitted by it contains confidential information within the meaning of Annex II to the Framework Agreement on relations between the European Parliament and the European Commission⁴ ("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 Article 13.

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.

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 group members no later than 2 weeks before the date of the meeting.

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.

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.

Article 6

Opinions of the group

The group shall adopt its opinions by a consensus of its members. Consensus is understood as the absence of any major objection. Where consensus cannot be reached,

OJ L 304, 20.11.2010, p. 47.

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different views expressed, including their grounds and the Member State(s) expressing them, shall be recorded in the minutes of the meeting.

Article 7

Sub-groups

The Commission or ECHA in agreement with the Commission may create sub-groups of experts of the CARACAL to examine particular issues.

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.

The sub-groups may invite external experts, as appropriate.

The sub-groups shall report back to the CARACAL.

Sub-groups shall be disbanded as soon as they have fulfilled their mandate.

The rules of procedure of the CARACAL apply to its sub-groups, unless otherwise specified in their respective mandates.

Article 8

Written procedure

If necessary, the group's opinion 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.

Members that do not respond within the set deadline on the endorsement are taken to give a favourable opinion on the draft(s).

Where the Chair recognises major objections, (s)he shall decide whether the written procedure shall be suspended and the discussion postponed to the next meeting of CARACAL. (S)he shall immediately inform the CARACAL about the decision.

The same deadlines will apply to written consultation of CARACAL sub-groups.

The Commission or ECHA shall, fourteen calendar days after a written consultation, provide a report on the outcome of the consultation. Views expressed, including their grounds and the Member State(s) expressing them, shall be recorded in this report.

Article 9

Minutes of the meetings

The Commission Services shall prepare the minutes of the meetings. ECHA shall prepare the minutes on those agenda points where it has consulted CARACAL. Upon request of the concerned participants or upon decision by the Chair, the minutes may not mention the individual position of the members during the group's deliberations.

The minutes of the meetings shall also record the results of written procedures that have been concluded between the previous and current meetings of CARACAL.

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.

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.

Article 10

Attendance list

At each meeting, the secretariat shall draw up, under the responsibility of the Chair, an attendance list specifying, 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.

Article 11

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 summarized in separate minutes.

Article 12

Prevention of conflicts of interest

At the start of each meeting, any participant whose participation in the group's deliberations would raise a conflict of interest on a specific item on the agenda shall inform the Chair. The Chair may decide that the participant shall refrain from participating in the group's deliberations on that specific agenda item. This paragraph shall also apply to deliberations taken by the group in written procedure.

Article 13

Transparency

Documents submitted for meetings of the group shall be transmitted to the European Parliament in accordance with the provisions of the Framework Agreement. The principle of originator consent and the rules on forwarding of confidential information provided in Annex II to the Framework Agreement shall be observed when transmitting documents of a confidential nature to the European parliament.

The Commission will publish all relevant documents (such as agendas, minutes and participants' submissions) either in 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 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.

The group's deliberations are confidential.

Upon request of the European Parliament, the Commission may invite the European Parliament to send its experts to attend meetings of this group.

In agreement with the Commission, the group may decide to open its deliberations to the public.

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.

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).

Article 14

Access to documents

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

Article 15

Protection of personal data

All processing of personal data for the purpose of these rules of procedure shall be in accordance with Regulation (EC) No $45/2001^7$.

Article 16

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. The Commission may circulate this for endorsement by Written Procedure.

⁷ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).