



## EUROPEAN COMMISSION

Directorate-General for Environment  
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Ecosystems I: Chemicals, food, retail

**REACH**  
**Bioeconomy, Chemicals & Cosmetics**

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### **42<sup>nd</sup> Meeting of Competent Authorities for REACH and CLP (CARACAL)**

#### **Open session**

**17-18 November 2021**

**Online**

**Subject: CASG-ED – update and prolongation of mandate**

Following five meetings that were held with the CASG-ED since its mandate was approved, a short update on the work done is proposed. The mandate for a CARACAL Subgroup on Endocrine Disruptors is proposed to be prolonged.

**Agenda point: 4.2**

**Action Requested: For endorsement**

## **Update on the work of the CARACAL sub-group on endocrine disruptors**

### **Update on the amendment of REACH Annexes to include data requirements on endocrine disruption**

At the CASG-ED meeting of 19<sup>th</sup> October 2020, two initial draft proposals were presented as a starting point for discussion on the way forward for updating the REACH Annexes to include data requirements on endocrine disruption (Annex I and Annexes VII to X).

Following feedback received from CASG-ED experts, revised versions of the two proposals were drafted and presented for discussion at the CASG-ED meeting of 22<sup>th</sup> March 2021.

The revised proposals are used as policy options to be considered in a study aimed to gather further information in support of an Impact Assessment of potential options for the update of REACH Annexes for inclusion of data requirements on endocrine disruption, launched in March 2021 and currently ongoing. This study will feed in the impact assessment for the REACH revision.

The CASG-ED may need additional meetings to discuss specific technical points of the REACH Annexes update at a later stage.

### **Update on the inclusion of ED hazard classes in the CLP Regulation**

Following the adoption of the Chemicals Strategy for Sustainability in 2020, the CASG-ED discussed in March 2021 an initial draft proposal of hazard classes for endocrine disruptors in CLP. This preliminary draft included:

- Separate hazard classes for endocrine disruptors (human health/environment);
- Introduction of category (“known or presumed”, and “suspected”)

To gather further inputs on outstanding points on the draft proposal on hazard classes for endocrine disruptors in CLP, another meeting of the CASG-ED took place on 13<sup>th</sup> September 2021.

Based on this meeting and the written comments received, the Commission is currently working on a new proposal of criteria. This new draft will be used in the framework of a study launched to support the impact assessment of the revision of the CLP Regulation.

This study will cover endocrine disruptors and provide an evaluation of the number of substances that will be captured by the criteria on endocrine disruptors and the impacts (positive and negative ones) of the introduction of this substance.

The CASG-ED may need additional meetings to discuss other specific technical points of the criteria at a later stage.

# **Mandate for the CARACAL sub-group on endocrine disruptors (changes to the original mandate are highlighted in blue)**

## **Objective**

The objective of the CARACAL sub-group on endocrine disruptors (CASG-ED) is to provide advice and exchange views on legislative and policy issues and other considerations of a policy nature in relation to endocrine disruptors in REACH and CLP. The Commission will keep CARACAL informed of progress and results of the work of the CASG ED.

## **Expected output**

The CASG ED should provide advice to the Commission and serves as a platform for the exchange of views, in particular on the following regulatory and policy issues:

- Endocrine disruptors (ED) in REACH, in particular in view of the Communication of the Commission “Towards a comprehensive European Union framework on endocrine disruptors” and the document CA/56/2019 on update of REACH Annexes for inclusion of data requirements on endocrine disruption:
  - Regulatory aspects and identification of adaptation needs regarding REACH annexes I and VII to X.
  - Update of relevant ECHA guidance documents to include the available approaches (e.g. OECD GD 150) and new standard tests (*in silico*, *in vitro* and *in vivo*) for evaluating ED properties.

The CASG ED should also provide advice and exchange views on the following issues:

- Potential follow-up actions of the Fitness Check on Endocrine Disruptors, which is expected to be finalised in 2020.
- Information needed for the identification of substances as endocrine disruptors and how to use such information.
- Implication of the update of the Annexes on the process of Dossier Evaluation and Substance Evaluation regarding ED concerns.
- Information on endocrine disruptors.
- Explore possibilities to include endocrine disruptors in the existing international system for classification of chemicals (UNGHS) and in CLP.
- International co-operation on regulatory issues (e.g. with OECD).

## **Composition**

The meetings of the CASG-ED will be chaired by the Commission services. ECHA, and other EU agencies, will participate in the meetings of the sub-group.

If necessary, specific meetings could be organised to discuss either toxicological or ecotoxicological issues. As toxicologist and ecotoxicologist experts may be different in some Member States, each Member State may nominate up to two members of the CASG-ED. If two members are nominated, each Member State should indicate the field of expertise (toxicological or ecotoxicological) of each expert.

For sub-group meetings, the two experts will be invited. However, if a specific meeting is planned only on “toxicological information” or “ecotoxicological information”, only the relevant nominated expert will be invited.

EEA, accession and candidate countries may each nominate two observers to the CASG-ED. The same rules as for Member States apply regarding invitation of relevant experts.

Other observers to the CARACAL meeting may nominate experts until a maximum of 10 observers to the subgroup is reached. The Commission will assign observer seats to the subgroup meetings based on nominations received and the field of expertise, with a view to ensure a balanced representation between various interests groups. The Commission may invite external experts to participate in the sub-group as appropriate.

The rules for the replacement of members/observers of the CARACAL apply *mutatis mutandis*.

## **Operation and Timeline**

The Rules of Procedure of the CARACAL apply with regard to convening the subgroup meetings, the agenda and the documents. Subject to the needs identified by the Commission and advised by the members of the CASG-ED, three annual meetings will be organised.

The CASG-ED activities will start indicatively in November 2019. Subject to the delivery of the expected outputs, future needs and discussions in CARACAL, the CASG-ED will be disbanded on 31 December 2023.