

THE DEFINITION OF ENDOCRINE DISRUPTORS IN THE CLASSIFICATION, LABELLING AND PACKAGING OF CHEMICALS REGULATION

The context

- Communication “Towards a comprehensive European Union framework on endocrine disruptors” of November 2018:
 - Action: horizontal approach to the identification of endocrine disruptors across all relevant Union legislation, based on the broadly accepted definition of the World Health Organisation.
- Others actions such as update of REACH on information requirements on endocrine disruptors

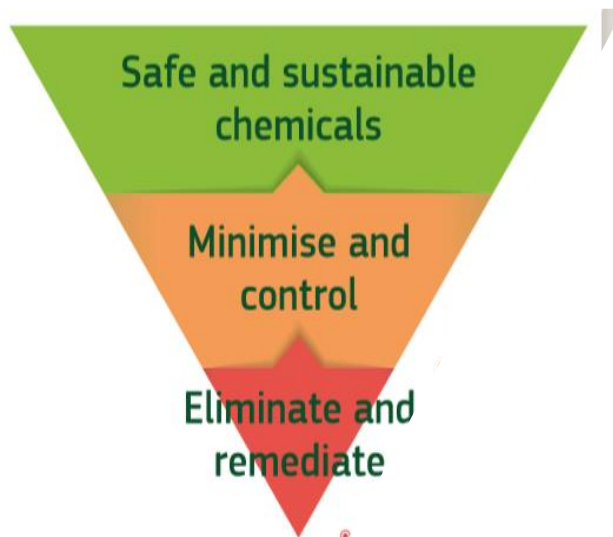
The context

- Creation of a sub-group of CARACAL (Competent Authorities for REACH and CLP) on Endocrine Disruptors to implement the action.
 - 3 meetings in 2020 with discussion on different options to implement ED criteria in CLP.
- Discussion were taken into consideration in the development on the Chemicals Strategy for Sustainability.

The Chemicals Strategy for sustainability

- Adopted on 14 October 2020
- Building on an advanced framework and extensive policy evaluations and input:
 - Fitness check of the most relevant chemicals legislation (excluding REACH)
 - REACH Review
 - Many other specific evaluations
 - Conference in June 2019
 - Roadmap consulted
 - Council Conclusions 2019
 - EP Resolution 2020
- On Endocrine Disruptors:
 - Fitness Check on Endocrine Disruptors performed by JRC

2030 vision – towards a toxic-free environment



- Chemicals are produced/used in a way that **maximises their benefits to society** while **avoiding harm to planet & people**
- **Production and use of *safe and sustainable chemicals*** becomes the EU market norm and a global standard

Strengthening legislation



- **REACH and CLP Regulations** should be reinforced as **EU's cornerstones** for regulating chemicals, and be complemented by coherent approaches in existing sectorial legislation (especially products).
- Introduce **new hazard classes in CLP** on endocrine disruptors.
- Introduce **generic approaches** to manage the risks from endocrine disruptors to ensure that **consumer products** do not contain endocrine disruptors.

Strengthening legislation on ED



- Proposal to amend **REACH Article 57** to add endocrine disruptors to the list of substances of very high concern
- Ensure that **sufficient and appropriate information** is made available to authorities to allow the identification of endocrine disruptors by reviewing and strengthening information requirements across legislation (**REACH**, Biocidal Products Regulation, Plant Protection Products Regulation, Food Contact Materials Regulation, Cosmetic Products Regulation)
- Accelerate the development and uptake of **methods to generate information** on endocrine disruptors through screening and testing of substances.

Proposal for Hazard Classes for Endocrine Disruptors

- Introduction of **new hazard classes** under CLP:
 - in line with the spirit of the CLP Regulation and the GHS,
 - most robust one from a legal point of view.
- **Other options** discussed with the CARACAL sub-group on EDs, but rejected, were:
 - new supplemental (EU) hazard statement(s), or
 - new or modified hazard statement code(s) to existing hazard classes.

Introduction of new hazard classes under CLP

- Based on the definition of the **WHO**.
- Building on **criteria already developed** for pesticides and biocides.
- To be applied **across all legislation**.

Introduction of new hazard classes under CLP

- Separation of classes between **human health** and the **environment**.
- Different applications in the **downstream legislation** of the distinction of ED (human health or environment) already today across the legislative framework.
- **Sub-categories**: to be considered as part of the discussion on the proposal of criteria under CLP.
- Development of **new labels elements** (H- and P-statements) potentially combined with existing ones.

Processes and participation

- February 2021: **proposal of criteria** to be discussed with CARACAL sub-group on Eds.
- Targeted impact assessment to **estimate the number of substances**, depending on the selected criteria, that will fall under each hazard class and category (to be used during the review process of each downstream legislation).
=> Classification and labelling should remain useful: avoid over-classification and under-classification.

Next steps

- Official **proposal** by the Commission in 2021.
- After adoption, criteria to be proposed under **GHS** as a new building block.
- Each **downstream legislation** will need to be modified to take into account the new criteria when establishing risk management measures (implementation of the Chemicals Strategy).

Thank you

EU Chemicals Strategy for Sustainability

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