COMMENTS

31 August 2020

Cefic comments on the information point 'Inclusion of ED in CLP Regulation' of CARACAL 35

Cefic calls for a balanced assessment of different policy options for horizontal identification of EDs and for a thorough policy discussion to take place in CARACAL 36.

Proposal for a discussion on policy options regarding Endocrine Disruptors (ED) in CARACAL 36:

Agenda point number 6 included for the CARACAL 35 meeting of July 2020 entitled 'Inclusion of ED in CLP Regulation' (for discussion) indicates that the Commission seems to have already taken the decision to regulate ED horizontally via the CLP Regulation.

This is not in line with the mandate agreed for the CARACAL Sub-Group on ED's. No supporting arguments have been tabled to justify disregarding other policy options (e.g. REACH). There was no time to discuss the subject matter in CARACAL itself. In fact, a superficial policy discussion whether ED classification should be included in CLP took place the day after in the CARACAL Sub-Group on EDs, pre-empting a CARACAL decision on preferred policy options.

A transparent and thorough policy discussion needs to take place among policy makers at CARACAL level, taking into account the outcome of the Fitness Check on Endocrine Disruptors, to clarify the policy objectives being sought and to have an open exchange on the different policy options, with their respective advantages and disadvantages. Such discussion is a key step towards an effective and workable proposal.

For that reason, Cefic would like to ask the European Commission to include ED policy options as a discussion point for the next CARACAL meeting to give the opportunity to the MSCAs and stakeholders to present their positions and exchange views.

In the next bullet points we highlight some of the issues requiring further discussion.

Most adverse effects of substances which can act via an endocrine mode of action are already captured by existing GHS/CLP hazard classes. CLP is the tool to inform about potential adverse effects of chemicals. Therefore, Cefic does not consider it appropriate to include ED in the CLP nor in the GHS.

However, if the European Commission and Member States decide to follow that route, regardless of the confusion in hazard classification and communication that will arise, then the following aspects are important:

- **First the discussion should be taken to UN GHS:**

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Any policy decision, if taken, to unilaterally include an ED classification in the CLP Regulation, in particular as a new hazard class, before tabling the proposal at UN GHS level would effectively lead to the CLP fundamentally deviating from GHS. This contradicts statements made by the European Commission to step up international standards, promote the implementation of GHS globally and avoid deviations (as per Recital 12 of the CLP Regulation).

Such deviation effectively means losing the 'G' and the 'H' of GHS, thus hampering clear and consistent classification and communication on chemical hazards globally; this would also lead to inconsistent classification at the international level and introduce non-tariff trade barriers, and will send a clear signal to other regions that GHS is being abandoned.

- **Harmonisation across EU legislation:**

  To achieve coherence with already adopted EU legislation on EDs, ED identification criteria from the Biocides and Plant Protection Products Regulations (BPR[1] and PPPR[2]) should be re-applied and implemented in the REACH Regulation (in the form of a new Annex). These criteria are in line with the WHO/IPCS definition of ED's. REACH has demonstrated its ability to identify, assess and regulate EDs based on the WHO IPCS definition and under Article 57(f) of REACH which includes the demonstration of equivalent level of concern.

- **'Double classification' issues:**

  The potential inclusion in CLP is, in our view, not appropriate. ED involves a mode of action that leads to an adverse effect, with the WHO definition requiring an adverse effect, a mode of action and evidence of a link between the two. Most adverse effects from exposure to ED substances are already captured by existing GHS/CLP hazard classes. The introduction of a new hazard class for ED would in many cases lead to 'double classification' and further confusion. CLP and GHS are designed for the classification and communication of hazards and not modes of action. Confusing communication could lead to reduced attention to labels by people handling chemicals and with that, ultimately may lead to a loss of overall protection.

- **Broader considerations:**

  - Before proceeding with such a major policy decision conclusions from the European Commission Fitness Check need to be taken into account. These conclusions should be presented to CARACAL to support the policy discussions.
  - There are also major resource implications since if a CLP classification for EDs is introduced, many CLH proposals will likely be submitted. As is already seen in the ECHA ED Expert Group such proposals themselves require significant Member State and ECHA resources. It should also be assessed as to whether RAC, which is already stretched when it comes to resources, would have sufficient capacity to conduct thorough scientific assessments of potential new CLH dossiers covering ED. All this would be for limited added

[1] Biocidal Product Regulation

[2] Plant Protection Product Regulation

value since the hazards/adverse effects of substances which can act via an endocrine mode of action are mostly already identified under CLP/GHS.

Cefic position on ED policy:

For the aforementioned reasons, Cefic believes that the best policy option for ED is:

- The WHO definition of ED is globally accepted and used; it must be at the core of EU legislation on endocrine disruptors (it is already included in the Biocides (BPR) and Plant Protection Products Regulations).
- There should be horizontal ED criteria fully aligned with the BPR and the PPPR criteria.
- Implementation of ED identification criteria under REACH, should be via an 'Annex XIII-B' (PBT-like approach); this is an approach that provides most policy coherence.
- The existing provisions in REACH for Communication on SVHCs in articles (Article 33) should be fully utilised, which is one of the key objectives of the suggested policy proposal.
- REACH restrictions, based on risk assessment, should continue to be used to exclude the use of ED substances in products and articles, where needed. This would help meeting another key objective of ensuring enhanced consumer protection.

We remain available for any further clarification and thank the European Commission in advance for their consideration of these points.

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 16% of world chemicals production.