DISCUSSION PAPER

27 MAY 2020

Chemicals Strategy for Sustainability

This paper was developed in the context of a stakeholder dialogue that followed our submission to the EU Commission's Roadmap consultation on the future Chemicals Strategy for Sustainability. It is meant to trigger an exchange of policy ideas or suggestions to inform the dialogue but does not constitute the agreed position of Cefic or its Members.

Endocrine Disruptors

Issue

- Next to the Fitness Check on chemicals legislation (excl. REACH), the Fitness Check of EU legislation on Endocrine Disruptors (ED) in still on-going.
- There is a broad call for a horizontal approach for ED identification. The call is supported by the European Parliament and the Council who asked for concrete measures for horizontal management of EDs across all EU legislation (REACH, food contact materials, cosmetics, toys).
- ED criteria have been adopted for biocides and plant protection products in 2017 and 2018 respectively.
- Even though there are no horizontal criteria that apply across legislation, REACH has demonstrated its ability to identify and assess Endocrine Disrupting (as SVHCs, based informally on the WHO definition of EDs and under Article 57(f) for equivalent level of concern).

Approach proposed

- The best way to apply a horizontal approach is through **REACH implementing** a **re-application of the criteria already adopted** under the EU Plant Protection Products and Biocidal Products Regulations for the **identification** of EDs (that are based on the WHO definition).
- This would be an efficient and proportionate way of ensuring consistency across various EU legislation and achieving horizontal harmonisation.
- Risk and **regulatory management are best achieved via sector legislation**, taking the specifics of uses and exposure into account.
- We do **not support the introduction of a new hazard class for EDs under UN GHS or EU CLP**. For human health, adverse effects are already captured by the existing hazard classes. Endocrine action encompasses many modes of action and GHS/CLP are not intended to classify modes of action.
    - CLP/GHS address substances and mixtures, while the public concerns and political requests relate mostly to EDs in articles (e.g. toys) or in the consumer products that are exempted from CLP (e.g. cosmetic products).
    - We should maintain as much **consistency as possible between the UN GHS and the EU CLP**. Rushing to introduce a new CLP hazard class for ED that does not exist under GHS does not support the principle of global harmonisation and facilitating trade. This goes against the general objective the EU has set for itself to "promote the highest standards of environmental and health protection globally" (text of the Roadmap). Consistent and coherent ED identification can best be achieved by horizontal criteria using the criteria already adopted under EU Plant Protection Products and Biocidal Products Regulations.

European Chemical Industry Council - Cefic aisbl
Rue Belliard 40 b.15 B-1040 Brussels Belgium
Tel. +32.2.436.93.00 mail@cefic.be www.cefic.org
EU Transparency Register n° 64879142323-90

- Adverse effects from ED substances are already captured by existing CLP/GHS hazard classes, so introducing a new hazard class for EDs would be redundant.
- We support further **EU research** to better understand mechanisms of action, Adverse Outcome Pathways, tiered testing strategies and develop reliable OECD test methods with the focus where feasible on non-animal based methods.

Cases/evidence/examples

- Under REACH, 88 substances have been listed under CoRAP (Community Rolling Action Plan) for Substance Evaluation due to potential ED properties and **16 substances or groups of substances have been included in the Candidate List due to ED properties corresponding to 49 substances** (by end 2019). Out of the 16 entries listed as SVHC, 7 are subject to Authorisation and 5 fall under Restriction. Many of the 88 substances are still under Evaluation, awaiting additional information. Building on REACH as the overall identification and assessment framework for potential harmful effects would be logical. This means that when an ED is listed as an SVHC under REACH, it is *de facto* regulated as stringently as any substance determined to be an SVHC.
- In 2016, the JRC ran an impact assessment and ruled out the 'categories' option.
- Some Member States/MEPs are calling for 3 ED categories: 'known', 'presumed', and 'suspected'. In addition to not seeing the need for a categorisation approach (as noted, this option has previously been ruled out after an extensive impact assessment), it should be noted that several substances thought to be potential EDs (that would have been seen as 'suspected') have been cleared as 'not ED' after a detailed CoRAP evaluation, with conclusions supported by the ECHA Member States Committee. Therefore, calling for substitution, restricting or banning substances on this 'suspected' basis does not constitute evidence-based policy and may lead to unnecessary black-listing of substances which are not problematic.
- The 'factual summary report on the Fitness Check targeted stakeholders' consultation shows that
    - About half of the respondents are in favour of a hazard category under CLP and/or GHS to identify EDs but the other half is against.
    - A majority of respondents view positively a combination of hazard-based criteria and risk-based regulation.

How to do it concretely (which legislation/article, etc)

- In the form of a new Annex under REACH (similar to a PBT assessment).
- For the time being, it is managed under Article 57f (SVHC). This can be maintained.
- The Substance Evaluation process can be used to request additional data if there is an ED concern.