More efficient protection from endocrine disrupting chemicals in REACH

In view of the REACH revision: Statement from the EDC-Free Europe coalition on the generic approach to risk management for endocrine disrupting chemicals

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Summary

European citizens and nature are currently not sufficiently protected from the impacts of endocrine-disrupting chemicals (EDCs). EDCs are regularly being detected - even in concerning amounts - in human bodies and wildlife, where they can contribute to changes in hormone-governed processes and may lead to the development or progression of various diseases, including certain types of cancer[1]. As one of the measures crucial to minimise exposures to EDCs, the ongoing REACH revision should extend the generic approach to risk management (GRA) to these chemicals. This will achieve a faster and simpler approach to risk management, in line with the commitments made under the Chemicals Strategy for Sustainability (CSS).

Like carcinogens, mutagens, and substances toxic to reproduction (CMRs), EDCs can cause severe and irreversible damage to human health and the environment, affect future generations, and act at extremely low levels. Therefore, being of similar concern to CMRs, EDCs should also be included in the GRA. This would be consistent with the approach followed in the recent revision of EU toys safety legislation[2].

Importantly, the future REACH provisions to extend GRA to EDCs should include both substances classified as Category 1 and Category 2 for human health and the environment to ensure adequate protection.

The classification of substances as EDCs has only recently been introduced into the CLP Regulation, and standard information requirements tailored to the detection of endocrine disruption, as part of REACH annexes, are currently in preparation. It is essential to understand that the distinction of Category 1 and 2 EDCs, as defined by the CLP Regulation, is based on available evidence, not on severity or adverse effects[3]. Therefore, a substance classified in Category 2 can still lead to similar harmful impacts as a substance classified in Category 1. In addition, given the lack of comprehensive data to adequately identify endocrine disruptors, means it will highly likely be challenging to classify many substances as Category 1 EDCs.

The ability to include Category 2 EDCs in a GRA restriction will ensure better controls of avoidable exposures of citizens and the environment to EDCs that are known or suspected to cause severe and potentially long-lasting effects on current and future generations. It will give a clear steer to the development and design of safer products and processes in all transparency.

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[1] WHO/UNEP (2012) State of the Science of Endocrine Disrupting Chemicals: https://www.who.int/publications/i/item/state-of-the-science-of-endocrine-disrupting-chemicals

[2] European Parliament (2025) Press release: https://www.europarl.europa.eu/news/en/press-room/20250407IPR27704/toy-safety-deal-on-new-measures-to-protect-children-s-health

[3] ECHA guidance on the application of the CLP criteria: https://echa.europa.eu/guidance-documents/guidance-on-clp

Full text

EDC-Free Europe is a coalition representing more than 70 public interest groups, who share a concern about endocrine-disrupting chemicals (EDCs) and their impact on our health and wildlife. Our coalition partners include trade unions, consumers, public health and healthcare professionals, advocates for cancer prevention, environmentalists and women's groups. The EDC-Free Europe coalition 2024 position paper outlines "seven priorities to protect people and environment from endocrine-disrupting chemicals"[4], recommending key actions needed to ensure the EU regulatory framework reflects the latest science and tackles the urgent need to reduce - and ultimately eliminate - EDC exposure.

In view of the ongoing discussions on the revision of the REACH Regulation, we call on EU decision makers to address the current shortcomings in the EU's flagship framework for industrial chemicals. Decades of research have shown that the EU population and ecosystems are widely exposed to harmful substances, including EDCs[5]. The health costs of exposure to endocrine disruptors were estimated at €163 billion per year in Europe back in 2016[6].

The newly introduced hazard classes for endocrine disruptors in the CLP Regulation and the revision of the REACH Regulation provide a timely opportunity to enhance protection for both human health and the environment. **We strongly recommend that the revision process incorporates the commitments made under the CSS and extends the generic approach to risk management (GRA) to include known and presumed (Category 1), and suspected endocrine disruptors (Category 2), for both human health and the environment.**

This position is also shared by the Endocrine Society, European Society of Endocrinology and European Society for Paediatric Endocrinology in a recent statement on the REACH revision.[7]

Our recommendation is grounded in three key aspects that highlight the need to ensure consistent risk management for EDCs:

- **EDCs are of similar concern to CMRs**

Like CMRs, EDCs are associated with severe and irreversible damage to human health and the environment, and have the potential to affect future generations[8]. EDCs can act at extremely low levels and can have a significant impact, making the concept of a threshold inappropriate for EDCs.[9] Additionally, transient effects occurring during critical development periods that rely heavily on hormone signaling – such as specific time points during pregnancy, mini-puberty, and puberty – can lead to delayed effects later in life[10]. For the environment, additional challenges

[4] EDC-Free Europe (2024), Position Paper "Seven priorities to protect people and environment from EDCs": https://www.edc-free-europe.org/articles/position-paper/seven-priorities-to-protect-people-and-environment-from-endocrine-disrupting-chemicals

[5] Govarts, Eva et al. Harmonized human biomonitoring in European children, teenagers and adults: EU-wide exposure data of 11 chemical substance groups from the HBM4EU Aligned Studies (2014-2021). *International journal of hygiene and environmental health* vol. 249 (2023): 114119. doi:10.1016/j.ijheh.2023.114119

[6] Trasande L, Zoeller RT, Hass U, et al. Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis. *Andrology*. 2016;4(4):565-572. doi:10.1111/andr.12178

[7] ESE/ESPE Statement: https://www.ese-hormones.org/media/ow1plgyg/european-and-international-endocrine-community-response-to-caracal-reach-revision.pdf

[8] Gore, A.C., et al. The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals. *Endocrine reviews*, *36*(6), E1–E150. https://doi.org/10.1210/er.2015-1010

[9] Endocrine Society (2025) "Endocrine-disrupting chemicals in the European Union": https://www.endocrine.org/-/media/endocrine/files/advocacy/position-statement/position_statement_endocrine_disrupting_chemicals_2025.pdf

[10] Svingen T, Andersson AM, Angelova J *et al.* Enhanced identification of endocrine disruptors through integration of science-based regulatory practices and innovative methodologies: The MERLON Project [version 1; peer review: 2 approved]. Open Res Europe 2024, 4:68 (https://doi.org/10.12688/openreseurope.17319.1)

arise due to the large number of species with largely unknown biological variability in their endocrine systems[11]. In combination, the severe and irreversible adverse impacts and the challenges in the hazard assessment of EDCs warrant a precautionary approach to the risk management of these chemicals, analogous to the generic risk management of CMRs.

Restricting harmful chemicals in Europe takes several years and needs many resources[12]. For instance, between 2011 and 2022 an average of only 2.5 restrictions per year were adopted under REACH – significantly below the 11 annual restrictions originally anticipated at the time REACH was adopted[13].

GRA applies to carcinogens, mutagens, reproductive toxicants (CMR), or CMRs in mixtures, and it has been applied to articles such as textiles[14]. It is a procedure currently implemented under REACH (Article 68(2)) which simplifies the restriction of CMRs classified as Category 1A or 1B for consumer uses. Unlike the specific risk management in REACH Article 68(1) and given the gravity of the health concerns at stake, GRA mandates the Commission to 'bypass' the preparation of a specific restriction dossier, as well as RAC and SEAC opinions, thereby ensuring a faster and more efficient approach to risk management.

Therefore, the revision of the REACH Regulation needs to establish coherent control frameworks to reduce exposures to EDCs once they are classified under the CLP Regulation.

- **EDCs Category 2 are not less harmful than Category 1**

EDCs can now be classified under the CLP Regulation as "known or presumed endocrine disruptors" (ED Category 1) or "suspected endocrine disruptors" (ED Category 2), with separate classifications for human health and the environment. To classify a substance for either category, three criteria must be met, meaning a very high level of evidence to demonstrate: endocrine activity, adverse effect, and a biologically plausible link between the two.

The updated CLP guidance[15] states that, additionally, the classification of Category 1 versus Category 2 EDCs depends on the strength and consistency of the evidence available for the hazard. Factors like data reliability, study design, and exposure conditions play a role in this assessment. Importantly, the distinction between Category 1 and Category 2 is based on available evidence, as opposed to the level of concern about the adverse effects[16]. Considering the lack of data (see next point) and the resource-intense evaluation of the available evidence, Category 2 substances cannot be understood as "weak" endocrine disruptors, but that significant evidence is available for Category 2 classification.

The recent revision of EU legislation on toys safety marks a significant step forward as it introduces a ban on the use of endocrine disruptors in toys, including those in Category 1 and 2 under the CLP. Similarly, the legal status as "Substance of Concern" under the recently adopted Ecodesign for Sustainable Products Regulation (ESPR) is available to both Category 1 and 2 under the CLP. To ensure consistent and comprehensive protection, the same level of precaution must be applied under REACH by extending GRA to both Category 1 and Category 2 EDCs. This

[11] German Environment Agency (2022) Recommendations "The Revision of the REACH Authorisation and Restriction System" :https://www.umweltbundesamt.de/sites/default/files/medien/479/publikationen/scopp_the_revision_of_the_reach_authorisation_and_restriction_system.pdf

[12] EEB (2022) Report "Need for Speed – Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections": https://eeb.org/need-for-speed-on-chemical-protections-in-europe/

[13] Corporate Europe Observatory (2023) "Redacted documents suggest Commission's chemicals backsliding": https://corporateeurope.org/sites/default/files/2023-07/SWD%20IA%20REACH%20revision%20Annexes%20Redacted.pdf

[14] European Commission (2018) Press release: https://single-market-economy.ec.europa.eu/news/commission-takes-further-action-against-hazardous-chemicals-clothing-textiles-and-footwear-2018-04-26_en

[15] ECHA guidance on the application of the CLP criteria: https://echa.europa.eu/guidance-documents/guidance-on-clp

[16] Delegated Regulation (EU) 2023/707

would ensure children – as well as other vulnerable groups – are protected against EDCs in products other than toys, aligning REACH with recent advances in sector-specific legislations and closing critical regulatory gaps.

- **Lack of comprehensive data makes it challenging to achieve ED Category 1 classification for many substances**

Currently, REACH does only have very limited specific information requirements designed to detect endocrine disrupting effects (and only for higher volume chemicals). In addition, more methods to adequately identify endocrine disruptors are also needed. This indicates that in most cases data that could be used to classify substances as endocrine disruptors will be scarce and not tailored towards the detection of EDC in the near-to-medium-term future.

In the past, many EDC identifications remained inconclusive, due to the high level of evidence needed. Now, the introduction of Category 2 classification improves the ability to identify suspected EDCs. Furthermore, considering the lack of comprehensive data and the resource-intense evaluation of the available evidence, it can be expected that other methods such as read-across and grouping will need to play an increased role in future decisions.

In conclusion, given the current data scarcity and its impact on the classification of substances as endocrine disruptors, **we call for extending the generic approach to risk management to include both Category 1 (known, presumed) and Category 2 (suspected) EDCs. The extension to Category 2 EDCs is justified by the scientifically supported harmful potential effects of these substances, on both current and future generations, which warrant their exclusion from products that could be used by consumers and products of widespread use.**

Including both Category 1 and 2 EDCs for both human and environment would help ensure a more proactive and protective approach to managing EDCs, despite the limitations in available data. This measure would respond to the high concerns of EU citizens about living in an environment free from toxic substances[17], and it would deliver on the EU's commitment to a high level of health and environmental protection. Furthermore, such approach would also strengthen the predictability of potential regulatory measures on EDCs and would disincentivize regrettable substitutions (swapping from a "known" to a suspected EDC).

[17] Eurobarometer data (2024): https://europa.eu/eurobarometer/surveys/detail/3173?s=03