

ESE key recommendations towards a less toxic EU environment to the benefit of human and animal health

Background

Endocrinology is the study of the complex communication between different organs to regulate essential body functions through signalling by chemical messengers – hormones. These complex and sensitive functions must be maintained in balance throughout life to avoid various illnesses, impaired fertility and/or problems of growth and brain development.

Endocrine Disrupting Chemicals (EDCs) are chemicals that may obstruct, imitate, or interfere with the normal biological functions of hormones, and as such can cause many adverse effects to the wellbeing of humans. Disruption of hormones at sensitive life stages e.g. during foetal development can for example increase risk of illnesses later in life.

Exposure to EDCs has been associated with a variety of rare cancers (especially in children), impaired reproduction, osteoporosis, thyroid disease, metabolic illnesses (e.g. diabetes, hypertension and obesity), birth defects and numerous other diseases or impairments.

Economically, EDCs cost the EU28 (including the UK) approximately €157 billion a year in actual healthcare expenses and lost earning potential. This is a conservative estimation; costs may be as high as €270 billion or 2% of European GDPⁱ. Large contributors are the healthcare costs for neurodevelopmental and metabolic disorders (e.g. obesity and diabetes).

Summary of key ESE recommendations towards a less toxic EU environment and better health for human and animal life

➤ ***Harmonise the EU regulatory framework in line with the WHO definition for EDCs and ensure horizontal interpretation and application***

Currently, definitions, criteria for identification data requirements and testing requirements for EDCs widely diverge in EU legislation, which has led to numerous legislative loopholes. These loopholes give the industry the opportunity under EU law to ‘rehabilitate’ a compound identified as an EDC under other EU legislation. For example, some phthalates are banned in cosmetics but are allowed in food contact materials. Triclosan cannot be used in food contact materials and is banned as a biocide, yet it is still allowed in personal care products. Other unauthorized chemicals may be used in food contact plastics if their migration into food is below the detection limit of 10 ppb (10 µg/kg food), and if they have not been shown to be genotoxic, mutagenic, toxic to reproduction, or substances in nano-form. No provisions are currently made for endocrine disruptors.

Also, the criteria for identification of EDCs have so far not been harmonised, nor cross-sectorial regulations appliedⁱⁱ. The EU biocide vs. the EU pesticide regulations are for example not identical in their data requirements to identify a substance as being an EDC. They are only ‘very similar’ which already creates a fundamental issue provoking confusion, conflicts and lack of practicability and credibility. This is strengthened by the fact that also the information requirements within the two regulatory frameworks diverge, leading to different levels of confidence in the identification. Animal testing is inconsistent as well in EU law, no animal test data can for example be requested under the cosmetic EU legislation. It is dependent on animal data obtained from other regulatory frameworks (e.g. REACH) which increases the risk for missing an EDC compound under cosmetics regulations.

Unfortunately, the different assessments are currently seldom compared and scrutinised properly, which enables products qualified as hazardous under some EU law to still enter the EU market by taking the line of the least resistance.

➤ **Create a new category of “Suspected EDCs” and increase capacity for their examination**

Suspected EDCs should be labelled as *hazardous* under the EU Classification, Labelling and Packaging (CLP) legislation and their usage should be limited or restricted, in line with the precautionary principle, until a proper independent peer-reviewed scientific assessment has taken place and/or a less harmful substitute has been identified.

Currently, only 40 out of 350.000 chemicals being used in commerce globally are properly regulatedⁱⁱⁱ. In the EU approximately 17.000 frequently used chemicals (>10-ton use/production per year) lack proper risk assessment with many more chemicals on the market falling below that high threshold^{iv}.

Hence, more ambitious goals should be set for the many chemicals examined yearly by national bodies and EU agencies, with emphasis on greater international cooperation and coordination. Industry must take its responsibility by contributing to this effort.

➤ **Follow a hazard-based approach to decide which chemicals should be allowed within the EU**

ESE is concerned about the current tendency within the EU to follow a risk but not hazard - based approach to decision making. Now, experimental (animal) data with adequate dose groups to allow proper risk assessment are not available, inconsistent, incomplete and controversial (e.g. bisphenol A debate). In addition, different population groups may have different susceptibility along various life phases, which is not adequately addressed in current evaluations. Lastly, data is available for single compounds but not for mixtures which may result in very different effects and outcomes.

➤ **Reduce the required evidence to classify a biocide product as an EDC**

An unrealistically high level of evidence is required to classify a substance as an EDC, as laid out in the ECHA/EFSA/JRC guidance document^v. Prochloraz is a good example of a biocide which, despite EDC evidence from industry and independent studies, had its EU approval period recently extended to 31 December 2023. This demonstrates that (potentially) harmful substance can currently remain a considerable amount of time on the EU market, or even forever as industry is not obliged to provide independent peer-reviewed data to demonstrate a chemical is safe for usage. However, even if available data indicates that a possibly already suspected EDC is hazardous, often following independent academic research, most of the EU Member States still allow the chemical on the market. Only one biocide substance has been recognised so far as an EDC (cholecalciferol), while many more are highly suspected to have endocrine disrupting properties.

➤ **Improve current testing methods and work towards a more horizontal framework**

Tests covering EDC modalities and endpoints, should be improved and adhere to more strict requirements, and, if available, made compulsory in all application dossiers submitted by the industry. While important tests are carried out (e.g. in the area of reproduction, effects on the thyroid hormone system, etc), many of these tests have a low sensitivity and sometimes high variability, thus limiting their impact.

Secondly, testing requirements vary, which contributes to the inconsistency of the EU legislative framework. For example, the significance of a legal definition for EDCs in the plant protection and biocide regulations remain inadequate if the test requirements are incomprehensive. For biocides,

the requirement regarding the testing of EDs still corresponds to that laid down in REACH regulation, which is rather limited.

A long priority list of in the EU frequently used substances for further evaluation of their role in EDCs by means of priority testing and other measures (e.g. identify gaps in knowledge and specific cases of consumer usage) could help future guidance and coordination in testing and contribute to a less toxic environment.

➤ ***Introduce EU policies and legislation to address the “cocktail effect”***

While the European Commission has acknowledged the existence of the “cocktail effect”, aggregated exposure of humans and wildlife to one or different EDCs, in its Communication “towards a comprehensive European Union framework on endocrine disruptors” ((COM(2018) 734)), this has not resulted yet in the necessary EU legislation or policies to ensure this is taken into account during the assessment/identification of EDCs. For example, the currently insufficiently tested plant protection products add to the effects of banned EDC pesticides, or “legacy pesticides” still present in human fluids, long after production has ceased due to their persistence. The list includes lindane, chlordane, DDT and hexachlorobenzene (HCB). Yet, concurrent presence of other potentially harmful EDCs is generally disregarded in the risk assessment of single compounds.

➤ ***More independent peer-reviewed (basic) research in the field of EDCs***

Additional funding is urgently needed to stimulate independent research in this field, so as to counterbalance the dominant industry position. The aim is to provide better insight on the EDC impact on EU environment and society, particularly of EDCs with wide usage in everyday life.

➤ ***Any data available to industry must be made publicly available in case of EDC evidence or suspected EDC***

If producers, industry and companies would make all their data publicly available, this would markedly reduce redundant testing for safety, reduce the number of animal experiments, provide input to build improved computer models to flag chemicals as potential EDCs based on their chemical structure (QSAR modelling), and speed up classification of EDC and lead to safer products across all sectors.

➤ ***The EU should take more measures to inform the public about the presence of EDCs in our environment and their potential impact on human and animal health***

There is currently insufficient easy to understand, evidence-based information available on EDCs and their impact on human and animal health and the environment. The Eurobarometer survey from 2016 found that two out of three European citizens are concerned about exposure to chemicals in their daily lives through food, air, drinking water and consumer products or other items, as well as in the workplace. Less than half of the same group felt well informed about the potential dangers of chemicals^{vi}. Measures like the creation of an easy to understand peer-reviewed, evidence-based website on the presence and potential effects of EDCs on our environment could be an important action of the EU to help closing this information gap.

ENDS

The [European Society of Endocrinology](#) was created to promote research, education and clinical practice in endocrinology by the organisation of conferences, training courses and publications, by raising public awareness, liaison with national and international legislators, and by any other appropriate means. It is ESE’s vision to shape the future of endocrinology to improve science, knowledge and health.

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- ⁱ Endocrine Society (2020). Estimated Costs of Endocrine-Disrupting Chemical Exposure Exceed €150 Billion Annually in EU. Available at: <https://www.endocrine.org/news-and-advocacy/news-room/2015/estimated-costs-of-endocrine-disrupting-chemical-exposure-exceed-150-billion-annually-in-eu> - date accessed: 01/02/2020
- ⁱⁱ European Parliament (2019). Endocrine Disruptors: From Scientific Evidence to Human Health Protection. https://www.europarl.europa.eu/thinktank/fr/document.html?reference=IPOP_STU%282019%29608866 – date accessed: 27/04/2020
- ⁱⁱⁱ United Institute for Training and Research (2020). Technical Expert Workshop on Criteria for Substances of International Concern Beyond 2020. <https://www.unitar.org/technical-expert-workshop-criteria-substances-international-concern-beyond-2020> - date accessed: 27/04/2020
- ^{iv} European Chemicals Agency (2019). Mapping the chemical universe to address substances of concern. <https://www.echa.europa.eu/-/mapping-the-chemical-universe-list-of-substances-by-regulatory-action-published> - date accessed: 21/02/2020
- ^v European Food Safety Authority (2018). Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. <https://www.efsa.europa.eu/en/efsajournal/pub/5311> - date accessed: 26/04/2020
- ^{vi} European Commission. Eurobarometer 2016: Chemical Safety. Available at: <https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2111> - date accessed: 09/02/2020