EDC-Free Europe's key recommendations for a reformed European regulatory framework on endocrine disrupting chemicals

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Introduction

The European Green Deal, published in December 2019, reinstates the need to *"ensure a toxic-free environment"* [1]. It commits to place action against our daily exposure to endocrine disrupting chemicals (EDCs) at the core of the EU policy agenda, with plans to rapidly make regulations on EDCs reflect scientific evidence. This commitment is coming after years of the European Commission delaying its delivery of an updated European strategy on EDCs.

In June 2019, the outgoing EU Commission launched a procedure to review current legislation as regard to EDCs and to prepare proposals to address current insufficiencies and incoherencies. Preliminary results of a 2020 EU Commission stakeholder survey [2] undertaken as part of this process, indicate that two-third of respondents consider the level of protection from EDCs by EU regulations to be insufficient for different groups of the population.

This EDC-Free Europe paper presents the key elements needed in the upcoming upgrade of the EU regulatory framework on endocrine disrupting chemicals. It builds on and complements the demands outlined in EDC-Free Europe's "Eight demands for an EU EDC strategy" [3], which were released in May 2018. It also takes stock of the conclusions of the numerous recent evaluations of EU regulations on chemicals as well as initiatives launched by EU Member states. **Our aim is to contribute to an effective reform of the EU regulatory framework in order to protect people and the environment against EDCs. We also stress the importance of adopting urgent measures in the transition period before the improved legislation is in place.**

Our recommendations address the identification of EDCs, the management and control of EDCs, and the measures to be taken in the transition towards the establishment of a robust and coherent regulatory system to deal with endocrine disruptors.

I. Identification of endocrine disrupting chemicals

In the context of the EU regulatory framework, substances can be formally identified as endocrine disrupting chemicals (EDCs) through the narrow scope of three regulations [4]:

- With the criteria for endocrine disrupting properties adopted under the Biocidal Products Regulation (BPR - herein referred to as biocides regulation);
- With the criteria for endocrine disrupting properties adopted under the Plant Protection Product Regulation (PPPR - herein referred to as pesticides regulation);
- In application of REACH on a case-by-case basis.

At the time of writing, only 19 chemical substances have been agreed upon to be strictly controlled for their endocrine disrupting properties in the framework of EU regulations [5]:

- Since December 2011, only 17 substances have been identified as substances of very high concern (SVHC) for their endocrine disrupting properties under the REACH regulation. The process is very slow and places an undue high burden of proof on the authorities (see text box 1).

- Since the criteria for the identification of endocrine disruptors under BPR entered into force in June 2018, only 2 biocides active substances have been identified as endocrine disruptors. However, this has not yet led to any removals from the EU market. This is one of the consequences of the unrealistic burden of proof requested, in particular considering the lack of data on endocrine disrupting properties.

- Since the criteria for the identification of endocrine disruptors under the PPPR entered into force in November 2018, just one substance, the fungicide Mancozeb [6], has been identified by the European Food and Safety Authority (EFSA) as meeting these criteria [7] and proposed for non-renewal by the European Commission. At the time of writing, no agreement has yet been reached between Member States to support this proposal.

At the time of the adoption of the pesticides and biocides endocrine disruptors criteria in 2017, environmental and health NGOs [8], the scientific community [9], the European Parliament [10] and the wider public expressed strong concerns about their unfit character to identify endocrine disrupting substances posing a threat to human health. There are concerns in particular about the high burden of proof needed and the insufficient use of scientific evidence from peer-reviewed literature [11]. These challenges will continue to severely slow down the identification of EDCs under this regulatory framework.

Text box 1 - Recent failure to identify Resorcinol as an endocrine disruptor: an illustration of the long and winding EDC identification process under the REACH regulation

Under the REACH regulation, substances can be identified for their endocrine disrupting properties through an identification as a substance of very high concern (SVHC) according to article 57(f): substances for which there is scientific evidence of probable serious effects to human health or the environment that give rise to an equivalent level of concern (ELoC) e.g. carcinogens, mutagens, reprotoxicants or persistent and bioaccumulative substances.

In practice, an EU Member State prepares an identification dossier (as specified under REACH Annex XV) and presents it for discussion in the Member States' Committee. A consensus must be reached between Member States to agree on the "identification" of the substance as an EDC in application of these provisions. It is up to the Member State presenting the identification dossier to build up its own justification for meeting the ELoC condition and to muster consensus amongst the committee for the identification to be successful. The process can often take years, or fail.

The recent failure to identify Resorcinol as an EDC under REACH provides an excellent yet worrying illustration of the limits of the system and the very high burden of proof put on the authority presenting the identification dossier. In the case of Resorcinol, whereas a majority of Member States supported that the substance meets the WHO definition of an endocrine disruptor, they failed to agree that the evidence provided also meets the condition of EloC [12]. This outcome is far from citizens' expressed demands to increase European action to identify all EDCs, according to current levels of scientific evidence available. The dossier will now be forwarded to the REACH committee - which is chaired by the European Commission and composed of Member States representatives - for further discussion and vote.

In comparison to these 19 substances officially recognised as endocrine disrupting chemicals under EU regulatory frameworks, the non-profit research institute The Endocrine Disruption Exchange (TEDX) lists over 1,400 potential EDCs [13], while the World Health Organization (WHO) compilation of national and NGO initiatives to identify chemicals as EDCs or potential EDCs points at several hundreds of chemicals as endocrine disruptors [14]. The European Commission's impact assessment for BPR & PPPR EDC criteria also showed that 281 substances were identified as EDCs or suspected EDCs, when a selection of 600 chemical substances were screened in the context of this process [15].

It is obvious that these EDC identification provisions under current EU regulations are extremely limited, when compared to the wide range of products in which these substances are used, and the known and potential exposure of people and the environment to endocrine disruptors.

These three frameworks for the identification of EDCs are the basis for some control and management measures in other EU regulations, albeit with a very limited extent:

- The legislation on medical devices refers to REACH and BPR;
- The legislation on the EU ecolabel refers to the REACH SVHC candidate list, and;
- The cosmetics regulation provides that it is to be reviewed when horizontal criteria for endocrine disruptors have been established.

EDC-Free Europe recommendations

A protective and coherent EDC identification framework at the European level must be built on the following principles:

- The establishment of horizontal criteria based on the full WHO definition, to allow for identification of EDCs across sectors, uses and regulations.

- These horizontal criteria should include a category for suspected endocrine disruptors, in line with the existing categories for carcinogenic, mutagenic and reproductive (CMR) substances in EU legislation and the WHO definition. This additional category would also permit the reflection of varying levels of evidence available and the current limitations in test methods.

- When selecting the risk management measures, the specificity of the hazards posed by EDCs must be recognised: exposure during critical windows of development may lead to severe and irreversible effects, including at very low doses, and they may manifest themselves later in life or even in the next generations.

- An update of current information requirements for endocrine disrupting properties in EU regulations - e.g. REACH - so that adequate data is requested from applicants and provided for assessments. Information requirements should regularly be updated so as to be in line with the development and validation of new and more sensitive test methods for EDCs.

- An absolute guarantee of independence, objectivity and transparency of the assessment process and experts involved. There must be recognised expertise in the field of endocrine science [16] and no conflict of interest [17].

II. Management and control of endocrine disrupting chemicals

Although endocrine disrupting chemicals (EDCs) are found in a wide diversity of products and materials, only the Biocidal Products Regulation (BPR), the Plant Protection Product Regulation (PPPR - herein referred to as pesticides regulation) and REACH provide for an identification procedure of substances with endocrine disrupting properties. But none of these regulations lead to systematic recognition nor appropriate control measures in the other relevant pieces of EU legislation.

The PPPR and BPR provide for strict control of endocrine disrupting pesticides and biocides, and EDCs identified as SVHC under REACH are to some extent under strict control via restriction and authorisation. EDCs identified under the BPR and under REACH art. 57(f) are also restricted under the new Medical Device Regulation [18]. In other product regulations - such as the Cosmetics Product Regulation, the Toys Safety Directive, or the Drinking Water Directive, and regulations for workers protection - there is no explicit risk management regime to deal with a substance identified as an EDC. These sectoral differences lead to repeated assessments of the same substance and often inconsistent risk management.

Text box 2 - The case of bisphenol A (BPA)

In addition to its classification as 'toxic for reproduction' under the Classification, Labelling and Packaging (CLP) regulation, bisphenol A (BPA) has been identified, in application of REACH, as an EDC for human health and the environment of equivalent level of concern (ELoC). As a consequence, in 2016, Members States have agreed on a restriction of its use in thermal paper. This came into force in January 2020.

Furthermore, in application of EU Directive (2011/8/EU), BPA is forbidden in baby bottles since 2011 [19]. However, BPA is still tolerated in many food contact materials and is found in items such as cans coating [20], pizza boxes [20] and polycarbonate water bottles [22].

BPA is a prime example of why there is a need to control entire groups/families of endocrine disrupting substances, in order to avoid regrettable substitutions [23]. ECHA has reported that many manufacturers have just switched to using bisphenol S, following the recent ban on bisphenol A, in till receipts [24]. This is really problematic as bisphenol S seems to have similar endocrine disrupting properties which have not yet been officially identified.

The case of BPA is a striking illustration of the incoherence and insufficiencies of the current system, leaving people and the environment unprotected for years until appropriate measures are taken.

EDC-Free Europe recommendations

The EDC-Free Europe coalition calls for a protective, consistent and coherent EDC management framework at the European level, based on the following principles:

- The goal of regulatory control of EDCs must be to prevent/minimise exposure of humans and the environment to EDCs across all sectors and uses in a consistent and coherent way.

- Identification of a substance as an EDC under one piece of EU legislation must have automatic effects under all other relevant pieces of EU legislation on chemical substances and products, and trigger risk management actions (such as restrictions and bans) across all the sectors using the substance.

- A 'one substance - one hazard assessment' principle should ensure the basis for consistent and coherent risk management through an improved coordination between the responsible agencies, and with the aim to also fasten decisions on identification and restriction measures.

- Identification as a suspected endocrine disruptor should lead to regulatory consequences, on the basis of the precautionary principle.

- Control measures for EDCs should be included in all relevant EU legislation on chemical substances and products. In particular, strict control measures for EDCs are needed in legislation on food contact materials, toys, cosmetics and textiles, as well as for other sensitive uses such as devices for drinking water.

- Existing scientific knowledge about the specificities of EDCs must be reflected, including potential irreversible health effects and even with exposure at very low-doses, non-monotonic dose responses, possible large time lags between exposure and the materialisation of the effect (sometimes generations). Therefore, EDCs should by default be considered as non-threshold chemicals and of particular concern [25], and under REACH by default be regarded as ELoC and treated in line with persistent bioaccumulative and toxic substances (PBTs).

- All uses of EDCs should be strictly controlled and in particular, all uses of EDCs in consumer products should be prohibited.

- Derogations and exemptions should be granted only for "essential use" following the existing approach described in the Montreal Protocol, and proposed for phasing out of PFAS [26].

- No derogation should be granted for the use of EDCs in certain types of products such as toys and childcare articles, food contact materials and cosmetics.

- The impacts on vulnerable groups exposed must be fully accounted for and provisions for protection clearly outlined, including regular biomonitoring where relevant. Costs for systematic environmental and human biomonitoring could be part of industry's application fees for the authorisation of EDCs.

- A coherent and comprehensive system of restriction for the use and release of substances identified as EDCs during their entire life-cycle must be secured - for example, through the entire cycle of food processing and packaging (pesticides in food, packaging, and food contact material).

- EU official lists of EDCs and suspected EDCs should be made publicly available to facilitate prioritisation of work, research and development, substitution to safer alternatives, and to inform the public, enabling them to make informed choices. This cannot be limited to the initiative of few members states [27].

- Effective protection of workers against exposure to EDCs in professional activities to prevent workers' and environmental exposure must be ensured [28].

Text box 3 – Ongoing discussions to include hazard categories for EDCs under the Regulation on Classification, Labelling and Packaging of substances and mixtures

EDC-Free Europe coalition welcomes the ongoing work of the European Commission and Member States to consider the development of hazard class(es) for endocrine disrupting chemicals (EDCs) as part of the Regulation on Classification, Labelling and Packaging (CLP) of substances and mixtures. This could be one way of achieving a more coherent system and would help recognize that the hazard of EDCs is at least equivalent to that of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMRs). It is essential however that the ED hazard class includes several categories, as it is the case for CMRs, and therefore includes one for suspected EDCs [29]. Finally, the following complementary improvement are essential to make this new set up effective:

- Addressing the current issues with the CLP itself and with harmonised classification.

- Deleting the ELoC requirement for EDCs in REACH and creating an Art 57(e) bis for EDCs with new info requirements.

- Establishing a restriction of the non-essential uses of currently known and suspected EDCs under REACH.

- Modifying at the same time the relevant downstream and associated regulations - for example: cosmetics, toys, food contact materials but also the Restriction of Hazardous Substances (RoHS) and Ecodesign directive - to give effects to the classification beyond the CLP.

For detailed recommendations on these elements and beyond, see the ClientEarth's paper "3 actions to protect people and wildlife from endocrine disrupting substances - An action plan for the EU institutions and Member States", and the CHEM Trust policy paper "A new path for EU control of Endocrine Disruptors".

III. Transition measures to ensure protection of vulnerable groups without further delay

EU measures to strengthen protection against endocrine disrupting chemicals (EDCs) were expected to deliver by 2020, according to 7th Environment Action program [30]. Unfortunately, previous attempts to update the 1999 EU Community Strategy on EDCs were seriously derailed [31], leaving people exposed to these chemicals in every part of their daily life [32].

This inaction persisted despite repeated calls from the scientific community to take action [33]. For example, recent results of biomonitoring studies show that babies in Europe are born pre-polluted with a cocktail of chemicals [34], including EDCs and suspected EDCs affecting the development of and health of children. This is a fundamental breach of children's rights [35].

Amendments to the various pieces of EU legislation will take time to adopt and bear results. Interim transition protection measures must be put in place with ambitious implementation of current tools, increased transparency and determination to take precautionary approaches. Current information on EDCs and vulnerable groups calls for enhanced protection mechanisms to be implemented without further delay. Specific parts of the population are particularly vulnerable to EDCs and other hazardous chemicals. This is especially the case for these groups in the EU and beyond:

- Pregnant women and the unborn child; young children and teenagers; and the elderly.
- Workers exposed to chemical products.
- Those already affected by non-communicable diseases such as cancer.
- People of low socio-economic background, because they might not have the information they need to protect themselves against harmful substances or simply the financial means to make those choices.

Protection for the most vulnerable and at critical times of life cannot wait for another three to five years. This is especially true when considering scientists have been ringing the alarm bell for over two decades.

EDC-Free Europe recommendations:

EDC-Free Europe calls for:

- Ambitious implementation of current provisions addressing endocrine disruptors in existing legislation - in particular in REACH, the Pesticides and Biocides Regulations and the Cosmetics Regulation - giving full force to the precautionary principle and using all available information and data to prioritise decisions under current legislation. Specific measures should minimise exposure to known and suspected EDCs, in particular in consumer products.

- Full transparency of EDC assessments undertaken in the framework of existing legislation, in order to facilitate substitution and informed choices.

For more details on the specific measures to be taken, see: CHEM Trust Policy paper: "A new path for EU control of Endocrine Disruptors" and ClientEARTH report "3 actions to protect people and wildlife from EDCs - An action plan for the EU institutions and Member States" [36].

In addition, EDC-Free Europe calls for a Europe-wide campaign to raise awareness on EDCs, in particular towards vulnerable groups. Specific focuses of such a campaign should include:

- The introduction of information channels for parents before and during pregnancy, and families in general, about ways to minimise exposures in everyday life [36].

- The dissemination of good practices for exposure reductions and health advice connected to grassroots and local agendas, and the creation of a bank of success stories to show how the EU is making a difference.

- Information and training materials for medical, health and educational professionals and multiplier groups so that they can advise the public on reducing their exposures.

- A response to consumers' concerns and the provision of tools for traceability and the right to know for chemicals in products.

EDC-Free Europe is a coalition of public interest groups representing more than 70 environmental, health, women's and consumer groups across Europe who share a concern about hormone disrupting chemicals (EDCs) and their impact on our health and wildlife. Campaign partners include trade unions, consumers, public health and healthcare professionals, advocates for cancer prevention, environmentalists and women's groups.

The EDC-Free Europe secretariat is hosted by the Health and Environment Alliance (HEAL). HEAL's EU transparency register number: 00723343929-96

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