



# 3 actions to protect people and wildlife from EDCs

An action plan for the EU institutions and States

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## Contents

Executive summary .....	2
<b>Part I. Fixing the EU EDC framework – a legal and moral obligation .....</b>	<b>3</b>
<b>1 The EU EDC framework is incomplete and inconsistent .....</b>	<b>3</b>
1.1 Not all known or presumed EDCs are restricted .....	3
1.2 A regulatory approach and concepts that reflect scientific findings are still missing....	4
1.3 Substances placed on the market are not screened for EDC properties.....	4
1.4 EU product, worker, industrial emissions, water and waste laws lack a reference to a continuously updated EDCs list.....	5
<b>2 The EU institutions and States have the obligation to create a complete and consistent framework .....</b>	<b>5</b>
<b>Part II. The way forward – three actions to reduce exposure to EDCs.....</b>	<b>7</b>
<b>1 Launch a REACH restriction for EDCs already identified .....</b>	<b>7</b>
1.1 Select the targeted substances using the existing lists of EDCs .....	7
The existing lists.....	7
The regulatory threshold of evidence .....	8
1.2 Prepare a REACH restriction fit to reduce exposure effectively .....	9
1.2.1 A group restriction .....	9
1.2.2 A horizontal restriction of non-essential uses .....	9
<b>2. Adopt implementing acts and guidance to update the existing screening systems .....</b>	<b>13</b>
<b>3. Adopt a legislative act for reform and gap filling .....</b>	<b>16</b>
3.1 To create an EU list of EDCs.....	16
3.1.1 Create an efficient identification system.....	16
3.1.2. Create an effective identification system.....	17
3.2 To reduce exposure to listed EDCs across all regulatory domains consistently .....	18
3.2.1 The legal consequences of an EU EDC list entry must be explicit .....	18
3.2.2 The legal consequences triggered .....	19
3.3 To put in place a specific, responsive EDC framework.....	20

## Executive summary

The President of the Commission has made a 'Green Deal' with the people of the European Union. That Green Deal promises policies that reflect the EU's values and way of life, and that create a new model of production, consumption and living where both people and the environment thrive. The EU has the opportunity to create a pioneering model whose promotion will form the basis for the EU's Green Diplomacy. But the EU's failure to ensure that people are protected from endocrine-disrupting chemicals (EDCs) made, used or present in the European Union puts this project at risk. EDCs interfere with hormone systems and have complex, serious, and irreversible effects on humans and wildlife.

EU law currently lags far behind the science on EDCs, and the first step towards improving the situation is to catch up. A restriction under REACH (the relevant EU legislation), minimising all sources of exposure to the substances already identified as EDCs by EU or national lists or regulations, is a tool fit for the task.

But structural changes are needed to make the EU EDC framework responsive to new knowledge. While the EU has tools to generate information about the hazardous properties of chemicals on the market, those tools are either fully incapable of capturing EDCs or have not yet been adapted in a way that will allow them to do so. The EU laws organising the screening of chemical properties to identify whether they are hazardous must be updated to eliminate this blind spot. Once updated they can feed a single list of EDCs that will become a common reference for separate pieces of legislation covering different sectors (products, workers, industrial emissions, water and waste).

Another key piece of the puzzle that is missing is the transition from a piecemeal, case-by-case determination of the regulatory consequences of an EDC identification to the automatic application of a regime addressing all sources of exposure in a coherent way. Placement on the EU EDC list must automatically trigger an obligation to minimise exposure under all relevant sectoral laws.

The EU institutions and States do not merely have the power to ensure people and wildlife are protected against EDC pollution. They have an obligation to prevent harm. There are three actions the EU institutions and States need to take to respect this obligation and minimise exposure to EDCs.

1. **Act now on already identified EDCs** – The European Commission or (a) Member State(s) must launch a REACH restriction process to reduce all sources of exposure to identified EDCs, in a consistent way.
2. **Fix existing EU chemical screening systems** – Most of those systems remain blind to endocrine disruptors' hazardous properties. But the European Commission and EU agencies have the power to fix those issues by adopting implementing acts and new guidance without delay.
3. **Fill the legislative gaps** – Existing sectoral laws need to be amended and new overarching provisions adopted to create a consistent and effective framework to deal with EDCs. The Commission must submit to the European Parliament and Council a legislative proposal to implement these much needed changes and, among other things, create a coordinated list of EDCs that will be continuously and easily updated. This list will increase the visibility of EDCs and trigger automatic regulatory consequences so that all sources of exposure are consistently addressed.

This paper sets out clearly what the problems are and how to solve them.

# Part I. Fixing the EU EDC framework – a legal and moral obligation

EU law already addresses some issues caused by endocrine disrupting chemicals (EDCs). In particular, there are legal tools that the EU institutions and States could already use to identify EDCs and control their use. But the tools that exist are not used efficiently nor to the full, and the tools that are missing are those that would enable the EU to protect people and environment from all sources of exposure in a quick, consistent and effective way (see section 1).

The EU institutions have a duty to prevent the harm caused by harmful chemicals, a duty rooted in international and European law. Considering the nature and irreversibility of EDCs' impacts, there is little doubt that preventing their emissions is a legal and moral obligation (section 2).

## 1 The EU EDC framework is incomplete and inconsistent

The EU EDC framework is currently neither consistent nor complete, for the following reasons.

### 1.1 Not all known or presumed EDCs are restricted

- The EU has regulated very few EDCs, despite existing scientific evidence identifying many substances which belong to this group. **A restriction on their manufacture, importation and use must be adopted as soon as possible for the EU EDC framework to catch up with existing knowledge** (see section 2).
- Only rarely does a full data set exist on the endocrine disrupting (ED) properties of chemical substances. The lack of such a data set has had a paralysing effect on the EU institutions and States, for example in the context of the REACH evaluation procedure or the Biocides Regulation. But EU law demands that decision-makers act when faced with a serious threat, even in the absence of full knowledge. That is the essence of the precautionary principle. As the Court of Justice has recently made clear,<sup>1</sup> Article 35 of the Charter of Fundamental Rights (high level of protection of human health) requires the EU institutions to comply with the precautionary principle when acting in areas such as chemicals regulation that have implications for human health. Article 37 of the Charter demands the same when it comes to environmental protection, and Article 38 of the Charter when it comes to consumer protection. So the EU institutions must adhere to the precautionary principle, particularly in REACH evaluation, identification and restriction processes, as well as in all pre-marketing authorisation processes.

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<sup>1</sup> Judgment of the Court of Justice (Grand Chamber) of 1 October 2019, *Blaise and others*, Case C-616/17, paras.41-42: “[W]hile Article 191(2) TFEU provides that the policy on the environment is to be based on, inter alia, the precautionary principle, that principle is also applicable in the context of other EU policies, in particular the policy on the protection of public health and where the EU institutions adopt, under the common agricultural policy or the policy on the internal market, measures for the protection of human health.... There is therefore an obligation on the EU legislature... to comply with the precautionary principle, in order to ensure, in particular, in accordance with Article 35 of the Charter of Fundamental Rights of the European Union and Article 9 and Article 168(1) TFEU, a high level of protection of human health”.

## 1.2 A regulatory approach and concepts that reflect scientific findings are still missing

- It is extremely difficult or impossible to determine safe thresholds for EDCs.<sup>2</sup> Most EU laws however, including regulations on toys and cosmetics, still apply a threshold approach to EDCs. **The regulation of EDCs must aim at the minimisation of all exposure, not at capping emissions.**
- The effects of EDCs are both very serious and irreversible.<sup>3</sup> They are also extremely costly to society.<sup>4</sup> However, EU law does not yet treat EDCs as a group of high concern across all regulatory domains, unlike carcinogenic, mutagenic, or reprotoxic substances (CMRs). **The identification of EDCs must automatically trigger regulatory consequences.**
- EDCs may have aggregated and combined effects. The existing piecemeal regulatory approach does not take this into account. Nor does it address all sources of contamination<sup>5</sup> or apply a consistent approach to the ones addressed<sup>6</sup>. **All sources of exposure must be addressed, and addressed in a consistent manner.**
- Exposure to EDCs during vulnerable periods of human and wildlife development raises particular concerns<sup>7</sup>. Nevertheless, EU laws targeting the universal sources of exposure (water, waste, industrial emissions, food contact materials and foodstuffs or additives) do not set explicit and tailored surveillance and control measures to EDCs as a group. In addition, regulations specifically targeting vulnerable populations (that is, regulations defining vulnerable populations and regulating pregnancy and childcare products) are missing. The ones that do exist do not set explicit and tailored surveillance and control measures for EDCs as a group (for example the Toy Regulation). **Regulatory gaps need to be filled.**
- EDCs are grouped into sub-families. The current substance-by-substance approach allows one harmful substance to be replaced by another of the same family (nonsensical substitution), making it ineffective. **A systematic group approach must apply to the identification and regulation of EDCs.**

## 1.3 Substances placed on the market are not screened for EDC properties

EU law uses three type of tools to develop knowledge on the hazardous properties of chemicals placed on the market. But those tools are either fully incapable of capturing EDCs or have not yet been adapted

<sup>2</sup> This is because of their “non-monotonic dose response” (i.e. lack of a simple relationship between dose and effect), their combined effects and the importance of vulnerable windows of exposure (i.e. periods when exposure poses a greater threat).

<sup>3</sup> WHO, 2012, ‘State of the Science of Endocrine Disrupting Chemicals - 2012: Summary for Decision-Makers’

<sup>4</sup> It has been estimated to be more than 1% of the EU GDP – see the studies referred to by The UN Global Chemicals Outlook II, 2019 p.172.

<sup>5</sup> For example contamination via food contact materials or electronic products is mainly ignored.

<sup>6</sup> For example the approach set for Pesticides and Biocides is more protective than the one applied under the Cosmetic Regulation, because of the lack of data and appropriate regulatory concept in the latter.

<sup>7</sup> See WHO, 2012, op.cit. above.

to be able to do so, even though the change is planned. The result is that the existing tools for systematic screening cannot today lead to the effective and continuous identification of EDCs (for full details see section 2 in Part II)

## 1.4 EU product, worker, industrial emissions, water and waste laws lack a reference to a continuously updated EDCs list

What are sometimes called the “downstream regulations” cover the manufacture and use of chemicals in industrial settings, their use for manufacturing products, their presence in final products as well as their presence in the environment and waste.

These regulations create a regulatory regime (restrictions or other risk management measures) that applies to dangerous substances. But they do not organise screening systems. Two tools are used to define which substances are dangerous and therefore controlled, often in combination:

i) a (generally very limited) list of individual substances, known to be dangerous at the time of the adoption of the law (“internal list”<sup>8</sup>);

ii) a reference to groups of hazardous substances as defined and listed under an EU Regulation organising the screening of chemical substances put on the market.

The first tool, the internal list, is limited and hard to update (because of the conditions triggering the update, the procedure to be followed and the use of a substance-by-substance approach). With this tool alone, the EU will not minimise exposure to EDCs from all sources in an effective and efficient way. The second tool relies in the vast majority of cases on harmonised classification under the Classification, Labelling, and Packaging Regulation (CLP) – generally the list of CMR substances for which a harmonised classification was adopted<sup>9</sup>. The REACH SVHC (substances of very high concern) list is used sometimes, but rarely<sup>10</sup>. Downstream regulations therefore still lack a reference to a list of substances that would include EDCs and be regularly and easily updated. Without such a list, EDCs will not be regulated as a group and only a few substances will be targeted.

## 2 The EU institutions and States have the obligation to create a complete and consistent framework

Under the European Treaties and legislation, the EU institutions and States have the power to restrict the manufacture, import and use of hazardous chemicals to protect human health and the environment. This power becomes an obligation when there is scientific evidence that not acting will or will probably lead to unacceptable consequences. The EU institutions and States have some, but not full, discretion in the definition of what amounts to “acceptable pollution” – they have to respect EU primary law, secondary law and their EU and international political commitments. These all point to an obligation to prevent irreversible harm (see box 1).

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<sup>8</sup> See for example the Toy Regulation, Drinking Water Directive, RoHS Regulation, etc.

<sup>9</sup> See the Toy Regulation and workers and waste laws, etc.

<sup>10</sup> For example, see the EU Ecolabel Regulation.

## Box 1: The primary and international law provisions creating an obligation to prevent harm

- Article 9 TFEU states that: “In defining and implementing its policies and activities, the Union **shall take into account** requirements linked to the... **protection of human health**”.
- Article 168(1) TFEU states that: “A **high level of human health** protection shall be ensured in the definition and implementation of all Union policies and activities”.
- Article 191(1) TFEU states that: “Union policy on the environment shall contribute to pursuit of the following objectives: **preserving, protecting and improving the quality of the environment, protecting human health** [...]”.
- Article 191(2) TFEU states that: “Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay”.
- Article 31(1) of the EU Charter of Fundamental rights states that: “Every worker has the right to working conditions which **respect his or her health, safety and dignity**”.
- Article 35 of the Charter adds that “(...) A **high level of human health** protection shall be ensured in the definition and implementation of all the Union's policies and activities”.
- Article 37 of the Charter: “A **high level of environmental protection** and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development”.
- Article 38 of the Charter: “Union policies shall ensure a high level of consumer protection”.
- Table 10.1 of the European Environment Agency 2020 State of the Environment Outlook<sup>11</sup> summarises the long list of the EU institutions and States’ political commitments and legal obligations on chemical management. All promise to **minimise exposure** to harmful chemicals including EDCs and ensure a high level of environmental and health protection. It also found that the EU current framework and actions are unlikely to achieve these goals.
- Article 68(1) REACH affirms that REACH restrictions **shall be adopted** “when there is an **unacceptable risk** to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis”.
- The EU’s values require **extra-protection for the most vulnerable groups**, something which is reflected in the many secondary laws that already implement such an approach<sup>12</sup>, as well as by the Human Rights recognised by the EU and/or States.<sup>13</sup> States have for example “a duty to ensure the social determinants of health, including safe food, water, and housing, as well as healthy occupational and environmental conditions, for children”<sup>14</sup>.
- Finally, UN Sustainable Development Goals 3, 6 and 12 call directly for minimising the manufacture and use of harmful chemicals which end up as pollution and create barriers to the circular economy.

<sup>11</sup> See <https://www.eea.europa.eu/soer/2020> P.237

<sup>12</sup> See the summary by the sub-study c: Protection of children and vulnerable groups from harmful exposure to chemicals in the “Study for the strategy for a non-toxic environment of the 7<sup>th</sup> EAP”, 2017.

<sup>13</sup> For example the Convention on the Rights of the Child – see Report of the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes, 2016.

<sup>14</sup> Committee on Economic, Social and Cultural Rights, general comment No. 14 (2000) on the right to the highest attainable standard of health, para. 11.

The nature of EDCs' effects (for example type-2 diabetes, thyroid disorder, reduced anogenital distance, reduced semen quality, cognitive deficits and attention-deficit disorder) and their irreversibility make EDCs a matter of very high concern. The fact that the most vulnerable populations, such as children, are the most affected makes their effects that much more unacceptable. As mentioned above, the cost to society of EDC pollution is extremely high. There is no doubt that EDC pollution leads to effects that are unacceptable both in absolute and relative terms. This triggers the EU institutions' and States' duty to prevent harm, anchored in EU law, Human Rights Law and international commitments.<sup>15</sup>

## Part II. The way forward – three actions to reduce exposure to EDCs

### 1 Launch a REACH restriction for EDCs already identified

Much progress has been made since the first Wingspread Consensus Statement on EDCs in 1991, so much so that the science on endocrine disruption has outpaced existing regulations. This was the conclusion of the August 2020 editorial in the *Lancet Diabetes & Endocrinology Review*, which also affirms that “the growing evidence implicating EDCs as human health hazards supports urgent action to reduce exposure to EDCs and this can be best achieved through regulation”.<sup>16</sup> The EU framework must be amended to become capable of responding to new knowledge on EDCs, but such reform will take time. In the meantime, the EU must act to restrict the use of the ones already identified by the most recent and independent scientific research. A REACH restriction is the perfect tool to do so (1.2), after selecting the targeted substances already listed at EU or national level (1.1).

#### 1.1 Select the targeted substances using the existing lists of EDCs

##### The existing lists

International, national and EU institutions, in addition to researchers and NGOs, have established many EDC lists in the last 10 years. The EU institutions and States could use this wealth of knowledge as the basis for a REACH restriction, starting with the substances that are on all or on most of these lists:

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<sup>15</sup> See the Report of the Special Rapporteurs on the Duty to prevent - Report of the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes, 2019.

<sup>16</sup> [https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(20\)30242-4/fulltext?dgcid=raven\\_jbs\\_etoc\\_email](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(20)30242-4/fulltext?dgcid=raven_jbs_etoc_email).



<b>EU lists</b>	<ul style="list-style-type: none"> <li>- The substances identified as known or suspected EDCs in the EU already<sup>17</sup> but that are not subject to a consistent and horizontal regime, or to a regime using regulatory concepts able to tackle EDCs exposure appropriately;</li> <li>- The EU EASIS database 2.0 on endocrine-active substances, when released;</li> <li>- Suspected EDCs in the 2011 State of the Art assessment of EDCs prepared for the Commission in 2011<sup>18</sup>;</li> <li>- The identified known or suspected EDCs in the EDC screening study prepared for the EU Commission under option III<sup>19</sup>;</li> <li>- As a complement, the substances included in the Community Rolling Action Plan list<sup>20</sup> as a potential EDCs could also be considered for inclusion.</li> </ul>
<b>EU States lists</b>	<ul style="list-style-type: none"> <li>- The joint “<a href="#">list III</a>” consolidated by Belgium, Denmark, France, the Netherlands and Sweden<sup>21</sup>;</li> <li>- Substances considered as EDCs in the other EU Member States.</li> </ul>
<b>International list</b>	<ul style="list-style-type: none"> <li>- The 2017 UNEP list<sup>22</sup>.</li> </ul>
<b>NGOs’ and researchers’ lists</b>	<ul style="list-style-type: none"> <li>- The study done for the PETI Committee of the European Parliament entitled “Endocrine Disruptors: from scientific evidence to human health”<sup>23</sup>, see also the latest EDC series of the Lancet Diabetes &amp; Endocrinology Review<sup>24</sup>;</li> <li>The ChemSec SIN list<sup>25</sup>;</li> <li>- The TedX list<sup>26</sup>.</li> </ul>

## The regulatory threshold of evidence

One or several Member States or the Commission (asking the European Chemicals Agency – ECHA) may start a REACH restriction process. Whoever is in charge has to build an “Annex XV dossier” compiling the evidence available on the substances targeted. The reluctance to act before a full data set exists on a specific issue has slowed down the EU regulatory process. For EDCs, the issue is acute as the level of evidence available on different substances and sub-groups varies immensely. But scientific uncertainty must not bar the EU authorities from acting when needed.

It is essential to make full use of the precautionary principle. This principle is enshrined in the European Treaties precisely to enable the EU to handle situations of data scarcity, variability and other source of scientific uncertainties. “The absence of scientific proof of the existence of a cause-effect relationship, a

<sup>17</sup> See “List I” consolidated by Belgium, Denmark, France, the Netherlands and Sweden

<sup>18</sup> [https://ec.europa.eu/environment/chemicals/endocrine/pdf/sota\\_edc\\_final\\_report.pdf](https://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf).

<sup>19</sup> [https://ec.europa.eu/health/sites/health/files/endocrine\\_disruptors/docs/2016\\_impact\\_assessment\\_study\\_en.pdf](https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_study_en.pdf)

<sup>20</sup> <https://echa.europa.eu/da/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances>.

<sup>21</sup> As stated on the website, “This list contains substances that are considered as endocrine disruptors at the national level in one of the participating Member States, due to e.g. ED properties or structural similarities with known EDs”.

<sup>22</sup> Overview Report II: An overview of current scientific knowledge on the life cycles, environmental exposures, and environmental effects of select endocrine disrupting chemicals (EDCs) and potential EDCs

[https://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc\\_report2.pdf?sequence=1&isAllowed=n](https://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=n)

<sup>23</sup> [https://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL\\_STU\(2019\)608866\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL_STU(2019)608866_EN.pdf).

<sup>24</sup> August 2020 – in particular the article “Endocrine-disrupting chemicals: implications for human health” by Author links open overlay panelLinda GKahnPhD°ClairePhilippatPhD°Nakayama S. Slama, R. Trasande, L.

<sup>25</sup> See the [32 EDCs](#) identified.

<sup>26</sup> <https://endocrinedisruption.org/interactive-tools/tedx-list-of-potential-endocrine-disruptors/search-the-tedx-list>.

quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure should not be used to justify inaction. Even if scientific advice is supported only by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognised”.<sup>27</sup>

The precautionary principle requires the EU institutions and States to restrict the use of a product when uncertainties remain about its environmental or health impact and if such a restriction is needed to prevent unacceptable serious consequences.

It does not mean that no conditions apply – the action has to rely on a scientific and socio-economic evaluation, which REACH restrictions do. It also has to be proportionate, non-discriminatory, consistent and responsive. However, the EU institutions and States have the obligation to restrict activities exposing people and wildlife to known or presumed EDCs, even if uncertainties remain. REACH restrictions must be adopted “when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis” (REACH, Article 68(1)). The consequences of EDCs, because of their nature and irreversibility, are unacceptable. The fact that the precautionary principle explicitly underpins the REACH Regulation – as stated in its first Article – is just another reminder of the obligation to act.

## 1.2 Prepare a REACH restriction fit to reduce exposure effectively

REACH restrictions are the fittest tool for EU law to catch up with science on EDCs. The regulatory processes are already in place to restrict a large number of chemicals with a complex informational basis, and REACH restrictions are a tool able to cover nearly all regulatory domains that are relevant for EDCs.

### 1.2.1 A group restriction

The EU institutions and States now have experience in restrictions of broad chemical groups under REACH (e.g. tattoo inks: over 4000 substances; skin sensitisers in textile: 1000 substances) and in targeting a broad set of uses (e.g. microplastic).

In order to be effective, the restriction must cover the substances selected from the lists mentioned above, but also consider the other substances belonging to their sub-groups to avoid nonsensical substitution – which happened for example with Bisphenol A<sup>28</sup>.

### 1.2.2 A horizontal restriction of non-essential uses

REACH restrictions are a versatile regulatory tool. They are the only non-legislative EU act that the EU institutions and States may use to restrict EDC pollution horizontally, targeting nearly all sources of exposure at the same time.

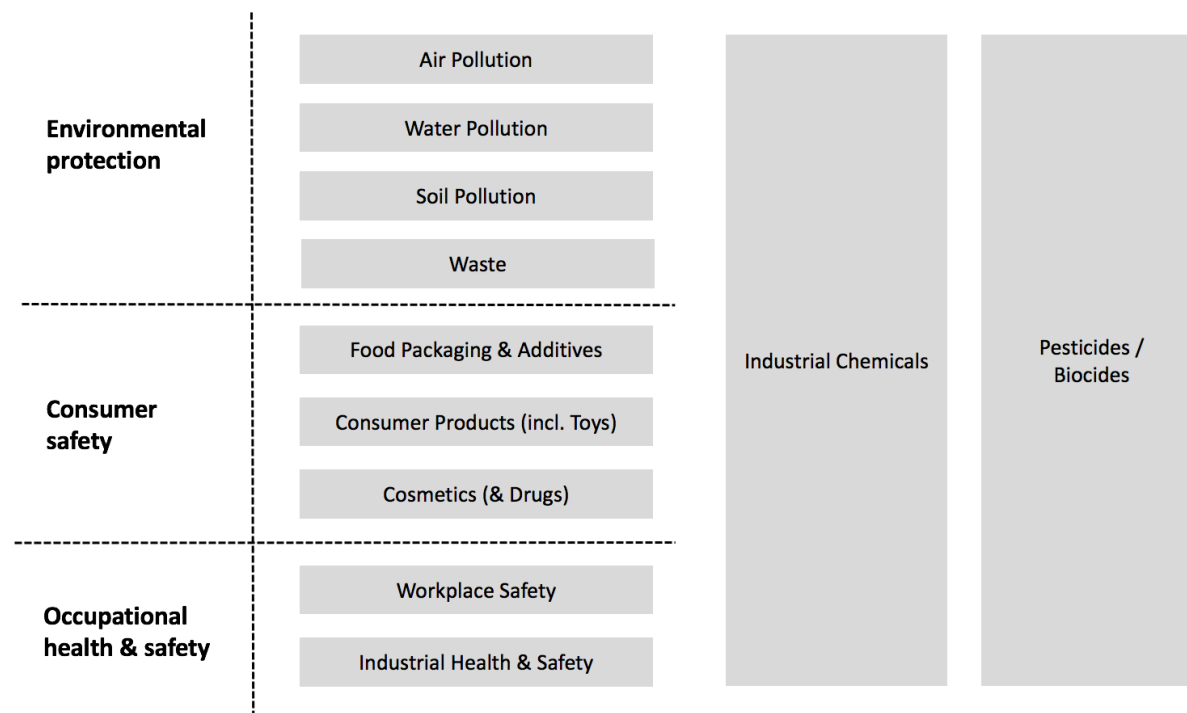
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<sup>27</sup> See Communication from the Commission on the precautionary principle, COM(2000)1 final.

<sup>28</sup> See CHEM Trust report ‘Toxic soup’ that documents the issue: <https://www.chemtrust.org/wp-content/uploads/chemtrust-toxicsoup-mar-18.pdf>.

The scope – nearly all regulatory domains

Figure 1. Regulatory domains of relevance for EDCs<sup>29</sup>



Nearly all regulatory domains relevant to EDCs (see figure 1 above) may be targeted by a REACH restriction. The only exceptions are waste<sup>30</sup> and the human health aspects of substances used in cosmetics<sup>31</sup>. The EDC restriction must be as wide as possible to create a consistent regulatory regime (see below). The REACH restriction needs to be complemented by actions in the regulatory domains that it cannot, or better not, cover:

- The REACH restriction cannot cover uses of substances in cosmetics, but a restriction may be adopted under the **Cosmetics Regulation**, and must be launched in parallel, making full use of the precautionary principle and considering both known and suspected EDCs;
- The chemical provisions of **EU waste and water laws** attempt to manage the risk of legacy substances (already banned) or the residual presence of legally used hazardous substances. The substances covered by the REACH restriction should trigger actions under the waste and water regulations, for example the application of their most protective provisions.
- **Biocides and Pesticides Products** are submitted to a specific system of pre-marketing authorisations. For the EDCs integrated to the REACH restriction, the Commission shall under

<sup>29</sup> Adapted from UNEP Overview Report III, Existing national, regional, and global regulatory frameworks addressing Endocrine Disrupting Chemicals (EDCs), June 2017.

[https://wedocs.unep.org/bitstream/handle/20.500.11822/25636/edc\\_report3.pdf?sequence=1&isAllowed=y](https://wedocs.unep.org/bitstream/handle/20.500.11822/25636/edc_report3.pdf?sequence=1&isAllowed=y)

<sup>30</sup> Article 2.2 REACH.

<sup>31</sup> Article 67.2 REACH.

the Pesticides or Biocides Regulations trigger a review of the existing authorisations, making full use of the precautionary principle and considering both known and suspected EDCs.

## The scope – ban with derogations for essential uses only

It has been a full seven years since a consensus was reached on the definition of EDCs, on the existence of “non-monotonic dose responses”, and on the difficulties for EDCs of determining thresholds of exposure below which safety is assumed<sup>32</sup>, including because exposure to EDCs raises particular concerns when it happens during vulnerable periods of human and wildlife development. It is paramount that the new model takes into account this scientific consensus<sup>33</sup>.

Because of the irreversibility of EDCs’ impact and because of the difficulties in determining thresholds, the REACH restriction of EDCs must treat them as persistent bioaccumulative toxics (PBTs). In other words, the determination of thresholds (DNELs, PNECs) should not be attempted and any exposure must be treated as a proxy for risk<sup>34</sup>. The goal must be to minimise all emissions from all sources as much as possible<sup>35</sup>.

The regulation of persistent chemicals also gave birth to the concept of “essential use”, a concept that could be of great use to EDC regulation. It is used under the Montreal Protocol and promoted by a group of PFAS experts as a tool to manage this group of chemicals.<sup>36</sup> It is increasingly used under REACH (see microplastic and PFHxA restrictions, as well as the broad PFAS restrictions considered by Germany, the Netherlands, Norway, Sweden and Denmark<sup>37</sup>).

The concept of essential uses offers a key tool to public authority when they determine whether derogations, or transition periods, may be allowed to soften the ban on substances with irreversible effects.

The restriction of known and presumed EDCs should follow this approach. This would mean in practice that:

- Preferably one or several Member State(s) would launch a REACH restriction proposal for several sub-groups of EDCs, identified on the basis of the existing EDC lists. If no Member State volunteers, the

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<sup>32</sup> Zoeller, RT., Bergman, A., Becher, G., Bjerregaard, P., Bomman, R., Brandt, I., et al. (2016) '[The Path Forward on Endocrine Disruptors Requires Focus on the Basics](#)'. *Toxicological sciences*, 149 (2). pp. 272 - 272. ISSN: 1096-6080, referring to the European Commission 2013 [Minutes of the expert meeting on endocrine disruptors](#). Date 24/10/2013, 14:00-17:00. Venue: Office of the Chief Scientific Adviser, European Commission, Berlaymont Building, Brussels.

<sup>33</sup> Bergman, Å., Heindel, JJ., Kasten, T., Byléhn, AS., Kidd, KA., Jobling, S., et al. (2013) '[The impact of endocrine disruption: A consensus statement on the state of the science](#)'. *Environmental Health Perspectives*, 121 (4). pp. a104 - a106. ISSN: 0091-6765.

<sup>34</sup> The burden must be on the industry and not the public authority to bring evidence that a threshold may be set with sufficient uncertainty – which is the approach adopted today for EDCs under the authorisation provisions. See <https://ec.europa.eu/transparency/regdoc/rep/1/2016/EN/COM-2016-814-F1-EN-MAIN-PART-1.PDF>.

<sup>35</sup> See Annex I section 6.4.

<sup>36</sup> See Ian T. Cousins, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Carla A. Ng, Sharyle Patton, Martin Scheringer, Xenia Trier, Lena Vierke, Zhanyun Wang, and Jamie C. DeWitt, 'The concept of essential use for determining when uses of PFASs can be phased out', *Environ. Sci.: Processes Impacts*, 2019, 21, 1803-1815.

<sup>37</sup> See <https://echa.europa.eu/de/-/five-european-states-call-for-evidence-on-broad-pfas-restriction>.

Commission must mandate ECHA to start the process. The project should start with a public consultation calling for information on the substances uses and alternatives.

- The restriction must ban the manufacture, use, import and export of the ED substances targeted, and ban their use or importation in article or mixtures.
- Derogations must be considered only for “essential uses”, and be subject to a revision clause, to the obligation to plan substitution, and to the application of the best available technique or other emission reduction obligation when relevant. Derogations must be considered only for uses reported during the first consultation. Members of the CARACAL (the EU’s chemicals expert group) could be given an opportunity to comment on which uses they consider essential before the submission of the restriction dossier.
- The determination of the “essentialness” of a given use needs to be guided by clear criteria. The criteria set under the Montreal Protocol by [Decision MOP IV/25](#) are an excellent starting point:

That a use of a controlled substance should qualify as “essential” only if:

- (i) It is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and
- (ii) There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;

Production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

- (i) All economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and
- (ii) The controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries’ need for controlled substances;

In application of those criteria, for example the use of Chemical A to manufacture a plastic doll, is not an essential use. If playing is essential to humans, there are many ways to play that do not involve plastic dolls and a doll can in any case be manufactured without using plastic, or maybe plastic made without using Chemical A.

On the opposite end of the spectrum, the use of Chemical A to manufacture plastic feeding tubes needed for neonatal care may be considered essential, but only if there is no other way to manufacture plastic tubes, or no safer techniques to feed premature or sick babies.

EU law needs to catch up with EDC science through such a REACH restriction. But that action will not fix the structural gaps in the EU framework that, for now, make it incapable of being responsive to new science. Fixing the EU systems that screen the substances on the market to identify their hazards is the first action needed to make EU law responsive, and therefore protective enough.

## 2. Adopt implementing acts and guidance to update the existing screening systems

EU chemical laws require chemical manufacturers or importers, and sometimes EU institutions and States, to assess the properties of the chemicals placed on the market in order to identify which ones are hazardous. But these “screening systems” are either fully incapable of capturing EDCs (colour coded red in the table below) or have not yet been adapted to be able to do so, even though the change is planned (orange).

Fortunately, the European Commission has the power to fill most of these gaps by proposing the adoption of a non-legislative act – see table below.

Nature of the screening tool	Regulatory domain & substances concerned	What is not working	Action needed
<b>Tool 1</b> <b>Pre-marketing, self-assessment &amp; notification</b>	REACH for substances over 1 tonne with information requirements that increase with quantity and hazard	Information requirements not yet able to capture EDC properties  Discussion on the adoption of new information requirements started in CARACAL ED special group	The Commission needs to propose and adopt an Implementing Act under Article 131 REACH to reform REACH Annexes in a way that would, at a minimum, allow a practical translation of the OECD Guidance Document (GD 150) into the information requirements.
	CLP for all substances placed on the market	No classification criteria for EDCs, existing criteria not able to capture all EDCs' effects	The Commission needs to propose and adopt a Delegated Act to create a hazard class for EDCs, with hazard categories for known, presumed and suspected EDCs.
	Cosmetics ingredients - except colourants, UV filters and preservatives	Limitations of non-animal testing methods prevent the creation of adequate data	The Commission needs to adopt a guidance under the Cosmetics Regulation to ease the threshold of evidence required to identify EDCs, to take into account the impact of the restriction on animal testing on the availability of relevant data.
<b>Tool 2</b> <b>Pre-marketing authorisation</b>	Pesticides and biocides	Criteria are adopted, testing obligations exist, but the data-requirements regulations still need to be updated	The Commission needs to finish updating all the non-legislative acts containing information requirements to align them with the ECHA-EFSA EDC guidance.
	Chemicals added in food and feed <sup>38</sup>	Information requirements not yet able to capture EDC properties	The Commission needs to update the non-legislative act setting the endpoints to be considered. EFSA and the Commission need to update the connected guidance on the relevant scientific evidence - using OECD Guidance Document (GD 150) as a basis.

<sup>38</sup> Additives, flavouring, enzyme.

	Substances intentionally used in plastic food contact material <sup>39</sup>	Information requirements not yet able to capture EDC properties	EFSA needs to update the endpoints to be considered during the assessment of the plastic food contact materials monomers, other starting substances and polymer production aids as well as related guidance on the relevant scientific evidence – using OECD Guidance Document (GD 150) as a basis OR broader change in the reform of the Regulation (Q1 2022).
	Surfactants and detergent containing surfactants that do not comply with the biodegradation criteria set in EU law	Endocrine disrupting properties are required to be considered but guidance/tests are missing	The Commission needs to adopt guidance to indicate clearly the needed testing scheme, as called for the Detergent Regulation Annex 4.2.3, using OECD Guidance Document (GD 150) as a basis.
	Cosmetics for CMRs, UV filter, colourants and preservatives	Limitations of non-animal testing methods prevent the creation of adequate data	The Commission needs to adopt guidance under the Cosmetics Regulation to ease the threshold of evidence required to identify an EDC, to take into account the impact of the restriction on animal testing on the availability of relevant data.
<b>Tool 3 Punctual binding classification</b>	REACH SVHC identification	EDCs exist as a group of high concern to identify but Article 57 (f) requires evidence of “equivalent level of concern”, which is an extra hurdle for the Member States/ECHA	Would require a legislative amendment (see below section 3)
		The adequate-information requirements are still missing from registration obligation (on-going work)	The Commission needs to propose and adopt an Implementing Act under Article 131 REACH to reform REACH Annexes in a way that would, at a minimum, allow a practical translation of the OECD Guidance Document (GD 150) into the information requirements.
	Harmonised classification under CLP	No classification criteria for EDCs, existing criteria not able to capture all EDCs effects	The Commission needs to propose and adopt a Delegated Act to create a hazard class for EDCs, with hazard categories for known, presumed and suspected EDCs.

<sup>39</sup> Monomers, other starting substances and polymer production aids.



## 3. Adopt a legislative act for reform and gap filling

Taking the actions recommended in section 2 will cure the current EDC-blindness of the EU's systems for screening chemicals placed on the market for hazardous properties. They will not however be sufficient to create an effective and efficient EU EDC identification system – which needs the actions described in section 3.1 below. They will also not automatically ensure that the risk-management measures triggered by the identification are fit to address EDCs' effects and mode of action – a problem solved by the actions proposed in section 3.2. Finally, adopting the legislation proposed below could be an opportunity to fix barriers to efficient and effective regulatory processes. Those barriers are not necessarily unique to problems with EDCs but are nevertheless a big obstacle to dealing with them, as seen in section 3.3.

### 3.1 To create an EU list of EDCs

In order to create a better identification system, the EU legislator would need to set the basis for new mechanisms and partially amend the existing screening systems in the following manner.

#### 3.1.1 Create an efficient identification system

**The identification system we have today is not efficient:**

- We have multiple screening systems that will identify EDCs if the changes described in section 2 are implemented, but that leads to repeated evaluations of the same substance.
- The product, worker, industrial emissions, water and waste laws lack a list of EDCs to refer to in order to trigger the application of protective measures.
- The REACH SVHC list is used as such by the Medical Devices Law and the EU Ecolabel Regulation, but this is the exception.

**The proposal to amend currently under discussion is needed but not sufficient:**

There is an on-going proposal to create an EDC hazard class under the CLP Regulation, with the idea of creating an EDC list under CLP, via harmonised classification, that could become the reference list for downstream regulations. Such a change would definitely help, but would not be sufficient:

- It would not put an end to wasting resources by unnecessarily repeating the evaluation under the different screening systems.
- First the creation of the hazard class, then the population of the EDC list with a critical mass of harmonised classifications will take so long that it will be at least several decades before the EU EDC framework becomes effective (the CLP procedure takes seven years on average to be concluded). There is a limit to the number of substances that can be processed through the CLP's procedures, and this limit has already been reached today without the existence of an EDC hazard class.

**The way forward – coordination and mutual recognition**

Repeating the evaluation of a substance's hazardous properties might be useful, but only if new information comes to light or the previous evaluation has been found erroneous or insufficient. ECHA

and the European Food Safety Authority (EFSA), and potentially the European Medicines Agency (EMA), could ensure that there is no unnecessary repetition of a substance's hazard assessment across the EU's screening systems. This coordination could take the form of i) an adequate share/allocation of the work that has to be done – with the support of ECHA's ED expert group – in order to ensure that endocrinologists have been involved; and ii) a mutual recognition of the validity of the analysis.

The mutual recognition would be operationalised through the automatic addition of any EU act identifying an EDC-containing substance, whatever that act's source, to the EU EDC list. National acts would not lead to automatic addition, but would be automatically sent to ECHA to consider for placement on the EU EDC list. The placement on the EU EDC list would trigger measures in each regulatory domain for managing the risks of EDCs. Such a system would give horizontal effect to any identification while allowing the identification of a substance to trigger responses adapted to the specificities of each regulatory domain.

### 3.1.2. Create an effective identification system

#### **Consolidate an adequate informational basis**

In order to provide experts with the informational basis they need to determine whether a substance is an EDC, the following changes are needed:

- Ensure that data are developed when not available:
  - Oblige chemical manufacturers, importers or users to test their substances or analyse existing data (which will be done by implementing the actions listed in section 2).
  - Confirm the obligation for industry and public authorities to take into account all available evidence, and therefore to give appropriate consideration and weight to independent literature.
  - Support the development of new scientific methods, particularly for non-EATS<sup>40</sup> modalities (e.g. financial support via EU research funds).
  - Support and organise biomonitoring and ecosystem monitoring campaigns.
- Ensure the existing data is accessible and published in a user-friendly way:
  - Prioritise and organise the creation of a chemical data space where all data submitted by the industry or produced by the EU institutions are shared among all EU institutions and national authorities (in compliance with the EU Digital Strategy).
  - Create an early warning mechanism: a system that would allow independent researchers and other whistle blowers to send data to ECHA/EFSA for consideration.
- Ensure that supplementary data are not required when existing data are enough:

The EU EDC framework must remind risk assessors and managers of the obligation to avoid 'paralysis by analysis' and to use the precautionary principle fully.

#### **Ensure that endocrinologists are involved**

The support of endocrinologists is needed to assess and reach conclusions on ED properties. The already-existing ECHA ED expert group could play a support role across regulatory domain, either

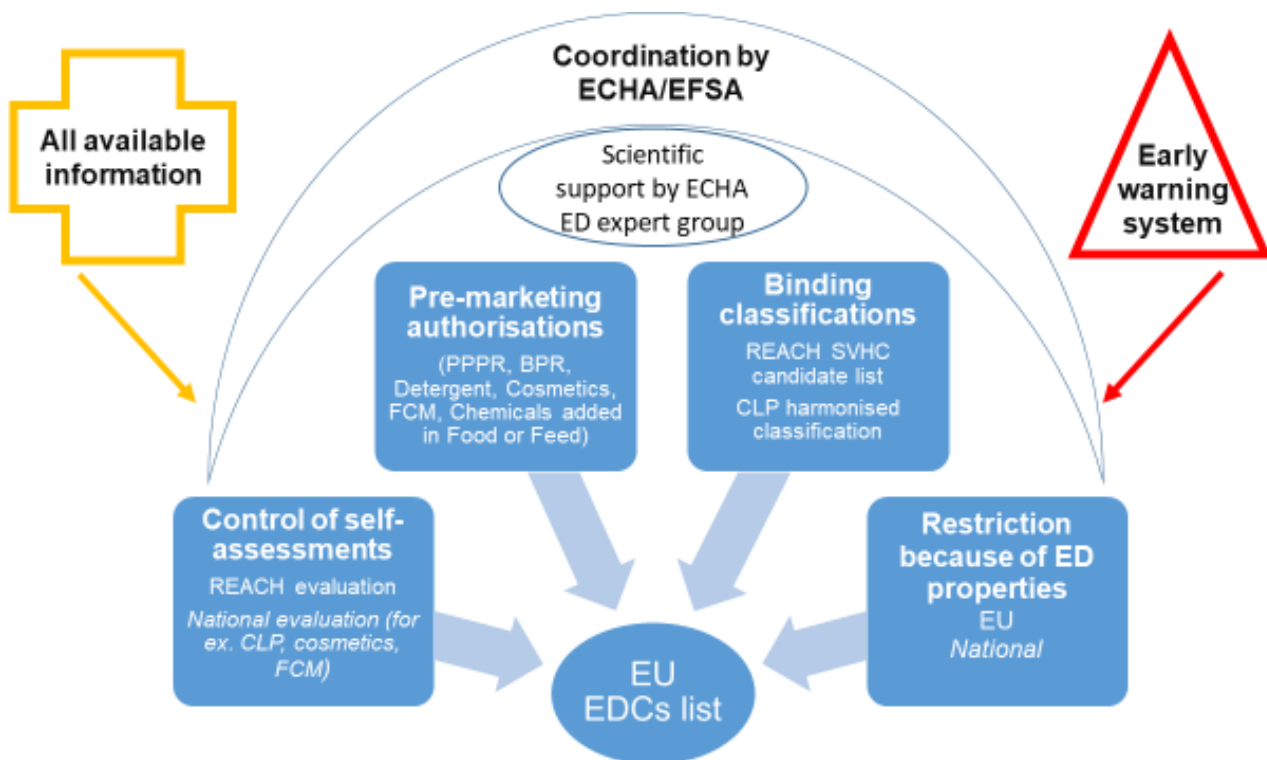
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<sup>40</sup> "EATS" refers to oestrogen, androgen, thyroid and steroidogenic. EDCs operating through non-EATS modalities operate through other endocrine systems.

through systematic inclusion or upon receiving a request for ad hoc support from the groups tasked with assessing ED properties.

Figure 2: Functioning of a coordinated multi-source EU EDC list

This figure shows the basis of the system the EDC framework legislation should create:



## 3.2 To reduce exposure to listed EDCs across all regulatory domains consistently

The EU's ED political goal, as promised by the Commission and required by the EU co-legislators, is to minimise of human and wildlife exposure. To reach that goal, the EU institutions and States must address the different sources of exposure consistently and simultaneously.

In legal terms, this means that EU law must foresee explicit, pre-determined regulatory consequences in all relevant regulatory domains for the identification of an EDC.

### 3.2.1 The legal consequences of an EU EDC list entry must be explicit

Under EU law, CMR substances are regulated as a group. The classification of a substance as C, M or R under CLP triggers the application of the strictest restriction provisions in most downstream

regulations. Such an approach remains the exception for EDCs.<sup>41</sup> Most EU sectoral laws ignore EDCs altogether. Some show awareness that EDCs might pose a problem but do not prescribe adapted risk management measures if one were to be identified.<sup>42</sup> EDCs might be regulated as any hazardous substances under EU law – and some have been<sup>43</sup> – but public authorities had, every time, to start from scratch when determining the type of regulatory consequences that are appropriate.

There is a need for an explicit and coherent regime for EDCs, which a piece of EU EDC framework legislation could set according to the principles below.

### 3.2.2 The legal consequences triggered

The ultimate goal of EU law must be to end the manufacture, use, import and export of EDCs as well as the good management of legacy EDCs already in waste, water or soil. The details of how this goal is reached, including which activities may justify derogations or delays, will necessarily vary depending on the regulatory domain. They must however be guided by common principles in order to create a coherent EDC regime.

**Placement on the EU ED list must automatically trigger legal consequences** – the automatic application of pre-set regulatory consequences will save considerable public and private resources.

**The goal is to minimise the exposure to EDCs, not cap it.** EDCs have a non-monotonic dose response as well as aggregated and combined effects. Because setting a threshold is difficult or impossible, EU law must not attempt to regulate on the basis of a safe level, but must aim at minimising all sources of exposure, starting by phasing out EDCs with exceptions allowed for essential uses only.

The approach set under the Montreal Protocol as described in section 1.2.2 must be followed. The adoption of the EDC framework legislation must be an opportunity to debate what is considered, under EU law, as an essential use (Green), a non-essential use (Red) and uses that may be both and require a contextual analysis (Orange).

The Green uses are for example the exceptions to the EDC ban already listed in the Pesticides, Biocides and Medical Devices Regulation. Toys and Cosmetics are manifest red uses. The uses covered by the Detergent Regulations or the Food Contact Regulations belong to the orange categories, and will require criteria specific to the area to determine what may be considered as “essential”.

**The priority must be on reducing exposure of the most vulnerable.** Vulnerable populations and children in particular are the most impacted by EDCs. Efforts to minimise exposure must therefore prioritise minimising universal sources of exposure (indoor air, water, food) and specific sources of exposure (pregnancy-related products, childcare and child-targeted products).

**Substituting an EDC for another chemical of the same group is not acceptable.** To avoid endless displacement of hazardous practices, each sectoral legislation must prioritise group restrictions. REACH restrictions must be used when a restriction applicable across all regulatory domains is more appropriate.

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<sup>41</sup> It can be found only in the Plant Protection Products Regulation, Biocidal Products Regulation, Medical Devices Regulation, and REACH SVHC identification.

<sup>42</sup> Which is the case for example for the Cosmetic or Detergent Regulations.

<sup>43</sup> See for example the REACH phthalate restriction, BPA Regulation, drinking water monitoring for some ED substances.

To bring these principles to life, the EU EDC framework legislation must amend existing EU laws, and set deadlines for the adoption of laws currently missing, so as to cover the whole life-cycle of EDCs.

## **Management of the presence in waste/water/soil/air**

- Waste: the law must apply its strictest provisions – such as the ones applied to CMRs – to EDCs.
- Water: the law must expand monitoring obligations and review the drinking water standards.
- Soil/air: the law must ensure EU institutions and States promote monitoring campaigns.

## **3.3 To put in place a specific, responsive EDC framework**

### **Barriers in REACH**

REACH contains provisions that aim at simplifying some decision-making processes for the most dangerous group of substances, CMRs, PBTs, and very persistent, very bioaccumulative substances (vPvBs). The EU EDC framework legislation could amend REACH to:

- Expand the simplified restriction process set in Article 68 (2) to EDCs.
- Extend the presumption that some hazardous properties are of very high concern – today limited by Article 57 (a) to (e) to CMRs and PBTs/vPvBs –to EDCs in an Article 57 (e) (bis), ending the necessity to prove an equivalent level of concern to list EDCs as SVHCs.
- Ensure, as for PBTs/vPvBs, because of the difficulty to identify a threshold, that when EDCs are listed as SVHCs, authorisations may only be granted if the conditions of the “socio-economic route” (Article 60(4)) are met.

### **Barriers in CLP**

Currently CLP does not fully perform as a screening system as it relies on Member States to launch harmonised classifications and relies on the industry for accurately and appropriately self-classifying their substance. The EU EDC framework legislation could be an opportunity to follow the non-REACH REFIT recommendations and:

- Grant to ECHA (upon request by the Commission) the power to propose harmonised classifications.
- Amend CLP to grant new authority to ECHA to control self-classifications, promote and make mandatory the coordination of self-classifications – similar to the REACH “one substance, one registration” principle – and enforce the rules on self-classifications.
- Amend CLP to grant ECHA the power to publish and share the identity of registrants in order to avoid duplications and divergences in the classification of the same substance.

Dr. Apolline Roger  
Legal and Policy Advisor  
Chemicals Programme Lead  
020 7749 5975  
aroger@clientearth.org  
[www.clientearth.org](http://www.clientearth.org)

Alice Bernard  
Legal and Policy Advisor  
020 7749 5975  
abernard@clientearth.org  
[www.clientearth.org](http://www.clientearth.org)



**Brussels**  
60 Rue du Trône (3ème étage)  
Box 11, Ixelles, 1050 Bruxelles  
Belgique

**Berlin**  
Albrechtstraße 22  
10117 Berlin  
Germany

**Warsaw**  
ul. Mokotowska 33/35  
00-560 Warszawa  
Polska

**Beijing**  
1950 Sunflower Tower  
No. 37 Maizidianjie  
Chaoyang District  
Beijing 100026  
China

**London**  
Fieldworks  
274 Richmond Road  
Martello St. Entrance  
E8 3QW  
United Kingdom

**Madrid**  
García de Paredes  
76 duplicado  
1º Dcha  
28010 Madrid  
Spain