ClientEarth's contribution to the Public consultation on the Roadmap 'Towards a more comprehensive EU framework on endocrine disruptors'

July 2018

We welcome the Roadmap as a recognition that the Commission needs to propose a strategy and new regulatory action on endocrine disruptors. We also welcome the recognition, in the roadmap, of the existence of critical windows of exposure for endocrine disrupting chemicals (EDCs) and of the need to manage cocktail effects, considering that both will require an adaptation of EU chemicals regulations.

However, we are concerned both by the celebratory tone employed by the Commission to describe the existing regulatory framework's capacity to address the challenge of EDCs and, correlatively, by the absence of real commitments to fill the current gaps in environmental and health protection.

We invite the Commission to seize the opportunity of the Roadmap and the Communication which will follow to adopt the indispensable and long awaited updated EU strategy on EDC. The strategy needs to contain commitments going beyond what is already done or planned, in line with what is required by the 2013 EP resolution, the 2016 Council conclusion and the EDC-free coalition's 8 demands for an EU strategy.

The Commission should not adopt a celebratory tone to describe its scorecard

The Commission presents a glowing picture of its scorecard. In doing so it seems to forget several significant mistakes and failures from the Commission in the last years, such as:

- the excessive delay in adopting the EDC criteria under the pesticides and biocides Regulation, sanctioned by the Court;[1]
- the addition of an illegal provision to the EDC criteria, sanctioned by the EP[2] as going beyond the Commission's mandate;
- a more recent attempt of the Commission to adopt, beyond its mandate, via comitology, a change of an essential element of the PPPR in relation to EDC as it appeared from the agenda of the ScoPAFF[3] and;

[1] General Court, T-521/14, Sweden v. Commission, 16 December 2015, ECLI:EU:T:2015:976.
[2] See the analysis done by ClientEarth available on https://www.clientearth.org/analysis-reveals-unlawful-action-eu-commission-hormone-disrupting-chemicals/
[3] See item A.18.2 on the ScoPAFF agenda for the 19-20 July 2018 meeting available at https://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals_en

- the violation of the January 2015 deadline set by the Cosmetic Regulation for its review to better address the risks of EDC.[4]

The Commission wrongly affirms that the EU regulatory framework offers a 'comprehensive' protection against EDCs

We are also concerned that the Roadmap repeatedly affirms that the regulatory framework is 'comprehensive' and therefore already provides a high level of protection from risks caused by exposure to EDCs. The Commission appears to have already reached a positive evaluation of the regulatory framework before having done the state of the art it is planning to do, before having received comments from stakeholders or completed the chemical regulations REFIT. The Commission's evaluation also ignores the patent gaps in the regulation of EDCs already identified by stakeholders[5], the co-legislators[6] and studies funded by the Commission itself.[7]

EDCs are a category of chemicals which, because of their specificities, **need to be made an independent regulatory class** such as carcinogenic, mutagenic and reprotoxic substances – as required by the European Parliament from the Commission in 2013.[8] The fact that they are not yet recognised as such across the chemical, product and process regulations in EU law leads to several gaps.

- **Gap in the identification of EDCs**

For the risks of chemicals with endocrine properties to be handled, those substances need first to be identified as such – which cannot be done without testing the substances currently on the market to learn whether they may have EDC properties, in application of criteria agreed upon beforehand and using tests able to detect EDC effects.

After many years of delay, such criteria and obligation to test exist under the Pesticide and the Biocide Regulations. The Medical Devices Regulation is connected to this effort as it refers to the EDC criteria set in the Biocide Regulation, but without detailing how they ought to be applied.

One can hope that these new provisions will ensure that pesticides and biocides with ED properties are identified as such and not approved for marketing. This will depend on the proper implementation of these provisions. But the EU regulatory framework still does not guarantee that the substances used for other applications do not have ED properties.

[4] Clearly set in its Article 15.4 '4. When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties'.
[5] See EDC-free Europe 8 demands - http://www.edc-free-europe.org/wp-content/uploads/2018/05/EDC-Free-statement-on-EU-EDC-Strategy-final-EN1.pdf
[6] Council conclusions on the protection of human health and the environment through the sound management of chemicals, 6 December 2016, 15046/16 and European Parliament resolution of 14 March 2013 on the protection of public health from endocrine disrupters (2012/2066(INI)), P7_TA(2013)0091.
[7] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme http://ec.europa.eu/environment/chemicals/non-toxic/pdf/NTE%20main%20report%20final.pdf
[8] European Parliament resolution of 14 March 2013 on the protection of public health from endocrine disrupters (2012/2066(INI)), P7_TA(2013)0091.

Companies placing chemicals on the market have some obligations to test the potential adverse effects of their substances, under the REACH[9] and CLP Regulations[10]. However, the endpoints considered in the tests prescribed are not fit to detect all EDCs' potential adverse effects. The ED properties of these substances can therefore go undetected. The cosmetic Regulation does foresee the possibility of tests on ED properties but those tests are not systematic and the Regulation does not set a coherent and systematic approach to EDCs. There is no test of ED properties required for chemicals used in food contact materials, toys, childcare products and other daily consumer goods.

The REACH regulation provides for a mechanism to identify chemicals with ED properties irrespective of their purpose (e.g. pesticide or else). However, this mechanism in practice has been quite slow and difficult, considering that the information submitted by companies when they place a substance on the market is not enough to pick up ED properties. It has led to the identification of only 12 EDCs so far- compared to the 123 EDCs identified in the SINlist.[11]

Workers, consumers, and the population in general, as well as the environment are exposed to these chemicals through production processes (of the chemicals themselves, of materials or products) and through the lifetime of products in which they are present, including when they become waste.[12]

- **Gap in the prevention of adverse effects of EDCs**

The second gap relates to a lack of prevention as even when an EDC is identified as such, the EU regulatory framework does not fully ensure that the adverse effects of EDCs are prevented, for three reasons.

Firstly, there is no legal mechanism to guarantee that the identification of an EDC under one legislation (for example, REACH) leads to risk management measures notably under other relevant sectoral legislations (for example, Toys, Cosmetics, etc.). This means that even if a chemical is identified officially for example under REACH, as an endocrine disruptor shown to have serious adverse effects,[13] it may still be legally used by companies and present in everyday products. The current EU framework needs to be amended so that when a chemical is identified as an EDC under a sectoral legislation, this identification triggers risk management measures in each relevant laws and sectors.

Secondly, only the Pesticides, the Biocides, the Medical Devices Regulations and to a more limited degree REACH give a clear indication of what should be the risk management measure adopted when a substance is identified as an EDC, by treating them as a regulatory class

[9] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1–849.

[10] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, *OJ L 353, 31.12.2008, p. 1–1355.*

[11] http://sinlist.chemsec.org/search/search?query=&healthenvironmentconcerns=1

[12] Chemicals can be found for example in the dust of homes, leaching from materials that were not intended to leach any chemicals. For more information on this see: https://youtu.be/E4WPTRiXGf8 (Video from the Green Science Institute)

[13] See the adverse effects identified by the Member State Committee of ECHA, regarding the endocrine disrupting properties of Bisphenol A: https://echa.europa.eu/documents/10162/908badc9-e65d-3bae-933a-3512a9262e59 : affect the reproductive function, mammary gland development, cognitive function or metabolism, and thus associated with serious health conditions such as neurobehavioural disorders and diabetes.

equivalent to CMRs. The other relevant regulations such as the Cosmetics, Toys and Food Contact Material Regulations do not, even when they recognise the need to give a specific and stringent treatment to CMRs. The identification of a substance as a CMR, in this situation, therefore leads to a higher level of protection than the identification of a chemical as an EDC. This is for example the case of the Cosmetics or Toys Regulation, which exclude CMRs from being present as a matter of principle but not EDCs. Products such as childcare products, or the packaging of cosmetics are also not addressing directly the potential risks arising from the (even small) exposure to EDCs.[14] The Food Contact Materials regulation is in a similar situation. Some EDCs have been regulated under the plastic Food Contact Material Regulation, but those provisions are inadequate to ensure a high level of protection. Indeed, the presence of the chemical in the material is still allowed under a certain threshold. This decision was taken on the basis of the assumption that a safe level of exposure can be set with sufficient certainty, and assuming that a product - not intentionally designed for a child - will not end up in the hands and mouth of a child.

It is true that those regulations contain a general provision requiring that products can only be placed in the EU market if safe. The competent authority may in that case rely on such provision, if it wants to regulate the presence in products of a substance identified beforehand as an EDC. But the notion of safety in that context is too general to ensure that risks arising from the exposure to EDCs is minimised to a satisfactory level. It also leaves to the competent authority a margin of discretion which does not guarantee a coherent and systematic management of the risks of EDCs. This gap ignores the complexity of the risk arising from the exposure to chemicals, and even more so the specificity of the risk arising from the exposure to EDCs. It also ignores the need to adopt a coherent approach as the one that the EU decided to adopt for CMRs.

Thirdly, when the EU has regulated EDCs, it has generally done so substance by substance. For example, Bisphenol A was banned for some of its uses without considering other bisphenols, chemicals sharing obvious structural similarities. Bisphenol S,[15] in particular is not banned, despite the fact that ECHA risk assessment committee, already in 2015, considered this chemical as ‘the most likely substitute [to BPA] according to the Dossier Submitter, may have a toxicological profile similar to BPA’, it even added, ‘the RAC advises against substitution with BPS’.[16] In that case, the gigantic effort needed to obtain regulatory action to protect people’s health and the environment from one chemical quickly has to start all over again, with a chemical which, on the basis of the current information, could have been banned at the same time following a grouping approach. The EU regulatory framework therefore needs to be implemented - and amended when necessary - in a way which would prevent such problematic substitution from happening and therefore encourage companies to invest in truly innovative and safer alternative solutions.[17] It would also benefit public authorities as they would escape their difficult 'Sisyphus' position, condemned to push the same rock eternally up the mountain.

[14] For more information on the potential risks of exposure from EDCs and the question whether, for EDCs, a safe dose can be relied on, see A. C. Gore, V. A. Chappell, S. E. Fenton, J. A. Flaws, A. Nadal, G. S. Prins, J. Toppari, and R. T. Zoeller, EDC-2: The Endocrine Society’s Second Scientific Statement on Endocrine-Disrupting Chemicals (available at: https://academic.oup.com/edrv/article/36/6/E1/2354691) page E11.
[15] See the detailed report of ChemTrust describing in detail the phenomenon ‘From BPA to BPA: a toxic soup’ available at http://www.chemtrust.org/wp-content/uploads/chemtrust-toxicsoup-mar-18.pdf .
[16] https://echa.europa.eu/documents/10162/209030fc-ca4b-4745-97b6-98bfc4d6bdd3
[17] Thermal paper used for receipts could be replaced for example by electronic receipts.

The actions planned in the Roadmap do not suffice to reduce the exposure to EDCs

We call on the Commission to commit to actions going, contrary to those announced in the Roadmap, beyond business as usual. The Commission has indeed committed to securing budget for research and to cooperating at international level – both actions are needed but do not go beyond what was already planned and done. The Commission then committed to 'link science and regulation' 'by ensuring that the EU legislative framework is adequately implemented and remains fit for purpose'. We must remind the Commission that ensuring that EU law is adequately implemented cannot be seen as a new commitment – it is the main and permanent duty of the Commission as guardian of the Treaty. Finally, ensuring that the EU legislative framework 'remains fit for purpose' is also not a satisfactory commitment: as explained above, the framework is not fit for purpose regarding the identification of ED and the management of the risk, arising from exposure to EDCs.

The gaps of the current regulatory framework must be acknowledged by the Commission, and acted upon for the EU to truly become leader in the protection of the risks caused by EDCs. We categorically disagree with the Commission when it calls the current framework 'comprehensive' and call on the Commission to find inspiration in the EU 2013 resolution, the 2016 Council Conclusions[18] and the EDC-free Europe's 8 demands for an EU EDC strategy[19] to adopt an ambitious EU strategy.

The Commission needs to fix both the acute gaps in some sectoral legislations (i.e. toys, cosmetics) and the lack of coherent and systematic approach to the risk management of EDCs. The first step will be to recognise EDCs as **independent regulatory class across EU legislations to guarantee their systematic identification and the appropriate management of their adverse effects.**

[18] Council conclusions on the protection of human health and the environment through the sound management of chemicals, 6 December 2016, 15046/16.
[19] May 2018, Available at http://www.edc-free-europe.org/wp-content/uploads/2018/05/EDC-Free-statement-on-EU-EDC-Strategy-final-EN1.pdf

Dr. Apolline Roger
Law and Policy Advisor, Chemicals Project Lead

60 Rue du Trône (Box 11), Brussels, 1050
020 7749 5975
aroger@clientearth.org
www.clientearth.org

Alice Bernard
Lawyer/ Juriste, Chemicals

60 Rue du Trône (Box 11), Brussels, 1050
020 7749 5975
abernard@clientearth.org
www.clientearth.org

ClientEarth is a non-profit environmental law organisation based in London, Brussels and Warsaw. We are activist lawyers working at the interface of law, science and policy. Using the power of the law, we develop legal strategies and tools to address major environmental issues.

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Brussels
Rue du Trône 60
5ème étage
1050 Bruxelles
Belgique

London
274 Richmond Road
London
E8 3QW
UK

Warsaw
ul. Żurawia 45
00-680 Warszawa
Polska