Disrupted Criteria

The criteria to identify endocrine disruptors: implications beyond pesticides and biocides

CIEL Center for International Environmental Law

ClientEarth

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Executive Summary

Endocrine Disrupting Chemicals (EDCs) are chemicals that interfere with the natural hormones in our bodies. EDCs are very likely to be contributing to serious health disorders such as cancer, fertility problems, obesity, and other debilitating diseases.

EDCs are used in a wide variety of products. They are present in our food, cosmetics, clothes, cleaning products, and plastics.

The growing scientific evidence of their negative impacts and the wide exposure to them has led the EU legislator to mention, identify, and manage the risks from EDCs despite the lack of internationally harmonised criteria.

For the first time under EU law, the pesticides and biocides regulations both require the European Commission (the Commission) to determine the scientific criteria necessary to identify EDCs. These two regulations also provide for measure to control the risks from EDCs once identified.

Other regulations similarly contain provisions restricting the use of EDCs but have yet to provide identification criteria (e.g. the proposed regulations regarding medical devices). Still other regulations, such as the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), regulate EDCs as "substances of very high concern" on a case-by-case basis. In some cases, the law mentions EDCs without regulating their use, such as the Cosmetics Regulation or the Water Framework Directive.

In June 2016, the European Commission proposed criteria for the identification of EDCs.

However, despite the variety of sources of exposure to EDCs, a mandate given to the Commission by the 7th Environmental Action Programme (7th EAP) to draft harmonised hazard-based criteria for EDCs, and seven years of work to establish these criteria, the European Commission chose a very narrow approach. It decided to set scientific criteria exclusive for relevant chemicals in pesticides and biocides.

The following report demonstrates that the Commission's proposal is problematic and could:

- Further delay the identification of EDCs and their proper regulation. Until horizontal criteria are developed as stipulated in the 7th EAP, EDCs cannot be regulated under other legislation. This is also at odds with the founding principles of Better Regulation, which aim at ensuring that the EU delivers high quality legislation.
- Lower the level of protection from EDCs due to the misapplication of criteria relevant for biocides and pesticides to other regulatory frameworks. Applying sector-specific criteria to non-pesticides and biocides creates a risk that certain chemicals will not be identified as EDCs.
- Lead to inconsistencies between the EDCs identified under the Pesticides and Biocides Regulations and those identified under other regulatory frameworks. The consequences of such approach may lead to a lower level of protection from EDCs, particularly for uses in consumer products (e.g. cosmetics, food contact materials, and toys).
- Create an unclear, unstable, and unpredictable regulatory framework for businesses, workers, and citizens for as long as the scientific criteria are not applicable to chemicals under all regulatory frameworks.

In light of these concerns, CIEL and ClientEarth recommend:

- The Commission should amend its proposed draft criteria to ensure they are applicable across all relevant EU law. The new criteria must be designed to identify EDCs in whatever product they are used, irrespective of the sector. This means that no sector-specific notions such as "non-target organisms" should be used. It should also follow the methodology of hazard identification under the United Nations Globally Harmonised System of Classification and Labelling of Chemicals and the Classification, Labelling and Packaging Regulation by providing three hazard categories based on the differing strength of evidence: "known" (category 1A), "presumed" (category 1B), and "suspected" EDCs (category 2).
- If the Commission refuses to change its approach and adopts the proposals, the European Parliament and the Council should reject them, in compliance with the regulatory procedure with scrutiny and the procedure applicable to delegated acts under Article 290(2) TFEU, respectively.
- If the current sector-specific scientific criteria are nonetheless approved, the Commission must immediately begin review of the criteria to comply with the objective of setting harmonised EDC criteria by 2020, as provided by the 7th EAP.

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Introduction[1]

Since June 2016, the European Commission (the Commission) has proposed four different versions of the scientific criteria to identify endocrine disrupting chemicals (EDCs). These criteria are necessary to identify chemicals that will undergo risk management measures under the Biocides[2] and Pesticides[3] Regulations.

As of February 2017, these criteria have still not been adopted. Until their adoption, the Commission will continue to be in breach of the Biocides Regulation, which required the Commission to act before December 2013, as affirmed by the Court of Justice of the European Union (CJEU) in 2015.[4] This report aims to highlight the consequences of the Commission's failure to propose "horizontal" criteria, applicable beyond pesticides and biocides.

When the Commission started an impact assessment to determine the criteria for EDCs, it aimed to determine criteria applicable to all sectors.[5] After the CJEU decision however, the Commission decided to propose criteria applicable only to biocides and pesticides, choosing a "sector-specific" approach rather than a horizontal one. The Commission then alleged that these criteria would "not have any direct legal consequence for other areas of EU law."[6] This statement is misleading. As detailed in this report, even though intended and designed for pesticides and biocides only, the criteria will have a direct impact on the way EDCs will be identified under other pieces of EU legislation and thus whether, when, and how they will be regulated.

This report begins with an explanation of how the draft criteria are "sector-specific" (1). It then assesses the potential impact of the draft criteria on the regulation of EDCs beyond pesticides and biocides (2). It argues that this sector-specific approach breaches the principles of "Better Law Making" (3) and runs contrary to the EU priority objectives for 2020 set by the European Parliament and the Council (4). The report concludes with recommendations addressed to the Commission, the European Parliament, and the Council (5).

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1 This report is authored by Giulia Carlini at the Center for International Environmental Law (CIEL) and Vito Buonsante and Alice Bernard at ClientEarth.

2 Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1–123 ("Biocides Regulation").

3 Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, 2009 OJ L 309/ 1 ("Pesticides Regulation").

4 Focusing on the Biocides Regulation: Judgment of the General Court of 16 December 2015 - Sweden v. Commission (Case T-521/14), EU:T:2015:976.

5 Commission Roadmap 06/2014, Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation, available at http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf ("EDC Roadmap"), p. 2-3.

6 Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products, 15 June 2016, COM(2016) 350 final, available at http://ec.europa.eu/health//sites/health/files/endocrine_disruptors/docs/com_2016_350_en.pdf ("Commission Communication on the draft EDC criteria") p. 8.

1 The Commission's draft criteria to identify EDCs: intended and designed for pesticides and biocides only

What does "identification" of EDCs mean?

Identifying EDCs is different from deciding what regulatory actions should be taken to protect humans and the environment from EDCs.

According to the International Programme on Chemical Safety (IPCS) of the World Health Organisation, a risk assessment begins with the identification of a "hazard," which is an "Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent."[7]

Thus, identifying EDCs is only a preliminary step in assessing the potential of a chemical to cause harm.[8] Following identification, various elements of risk are considered, and finally, under "risk management" other factors are considered in a political decision-making process to determine under which circumstances the use of EDCs should be permitted.[9]

Understanding the difference between the notions of "hazard" and "risk" is key to avoiding confusion about the purpose of the draft criteria to identify EDCs. Understanding this distinction also makes it clear that the use of horizontal criteria does not preclude the imposition of different "risk management" for different sectors.

For example, carcinogens, which are another type of hazard, are identified following the same scientific criteria under EU law, irrespective of the sector. Different risk management measures have however been adopted for different sectors (and expected level of exposure): carcinogens in cosmetics are not subject to the same restrictions as carcinogens in pesticides.

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7 International Programme on Chemical Safety (IPCS), IPCS Risk Assessment Terminology, 2004, available at http://apps.who.int/iris/bitstream/10665/42908/1/9241562676.pdf, p. 12.

8 Idem, p. 14: "The risk assessment process includes four steps: hazard identification, hazard characterization (related term: Dose–response assessment), exposure assessment, and risk characterization." See also EDC Roadmap p. 6 (distinguishing hazard identification from other elements of risk assessment).

9 Ibidem: "Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard".

1.1. Sector-specific criteria by design

When the Commission decided in 2014 to conduct an impact assessment for establishing scientific criteria for endocrine disruptors, the Commission explained that one of the main problems it was planning to address was the need for horizontal legislation. According to the Roadmap, "since ED[Cs] are referred to in numerous legislation, *these criteria should be developed with the aim of enabling their 'horizontal' application* in the wider legislation covering the regulation of ED[Cs] in different regulatory settings" (emphasis added).[10]

The draft criteria however, only apply to biocides and pesticides.[11] According to the Commission, this sector-specific approach is justified by the fact that in pesticides and biocides, "there exists a *legal obligation* to define the criteria to determine what is an endocrine disruptor" (emphasis added).[12] However, this legal obligation does not prevent the Commission from adopting criteria that would be applicable to all sectors. Yet, as discussed below, the draft criteria cannot be used in other sectors.

1.2. Sector-specific criteria *by their features*

Two main features of the draft criteria, for both the Pesticides and Biocides Regulations, make any horizontal application problematic.[13] First, the draft criteria deviate from the method applied under the Classification, Labelling and Packaging Regulation[14] (CLP Regulation), an internationally agreed methodology and one of the pillars of chemicals legislation in the EU. Second, they use a notion only relevant to pesticides and biocides (non-target organisms).

10 EDC Roadmap, p. 4.

11 Commission Communication on the draft EDC criteria, p 8. The Explanatory Memorandum of the draft proposals references this Communication. Draft Commission Delegated Regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012, C(2016) 3752, Explanatory Memorandum, Context of the delegated act, available at: https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/201702_bp_criteria_en.pdf, p. 2.

12 Commission Communication on the draft EDC criteria, p. 9. The impact assessment echoes this view. Commission Staff Working Document, Impact Assessment, of 15 June 2016 (SWD(2016) 211 final), available at https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf p. 15.

13 Draft Commission Regulation amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties C(2016) 3751, available at https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/201702_ppp_criteria_en.pdf; Commission Delegated Regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012, C(2016) 3752, available at: https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/201702_bp_criteria_en.pdf

14 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, ("CLP Regulation").

(i) Deviating from international classification methodology based on categories

Before 2002, a number of different classification and labeling systems for chemicals coexisted in the world, until the creation of the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The Strategic Approach to International Chemicals Management (SAICM) adopted by the International Conference for Chemicals Management in Dubai in 2006 set as an objective the promotion of the implementation of the common definitions and criteria contained in GHS. In that context, the EU CLP Regulation was adopted to implement the GHS. The CLP Regulation is a horizontal legislation, i.e. applicable to all types of chemicals.[15]

The EU's previous approach to classification did not differ significantly from the GHS. For example, under the previous framework,[16] carcinogens were classified in three categories depending on the level of evidence available. The GHS incorporated the use of categories and provided for a similar classification of carcinogens specifying the strength of evidence required under each category:

(i) Category 1A: *known* carcinogens (based largely on human evidence);
(ii) Category 1B: *presumed* carcinogens (based largely on human evidence); and
(iii) Category 2: *suspected* carcinogens (evidence not sufficiently convincing to class in the other categories).

The purpose of classifying chemicals not only on the basis of their "hazard class" (e.g. carcinogenicity), but also on the basis of the strength of available evidence (hazard category) was to facilitate harmonization of classification between countries and between sectors. This would enable legislators to define different levels of protection according to their local preferences and to the vulnerability of different portions of the population.[17] This is called the "building blocks approach." Thus, setting categories was a harmonization tool allowing legislators to regulate different chemicals that are *known, presumed, or suspected* to cause harm.

Endocrine disruption is not yet listed as a "hazard class" under the GHS or the CLP Regulation, and the Commission has declined to follow the building blocks approach. As a result, EDCs are not classified differently depending on the strength of evidence,

15 Idem, recital 11; except those listed under Art. 1(5) CLP Regulation.
16 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 1–98.
17 Commission Explanatory Memorandum to the Proposal to implement GHS with the CLP Regulation, available at: http://ec.europa.eu/environment/chemicals/labelling/pdf/ghs_sc_volume1.pdf

and the draft criteria do not distinguish between known, presumed, and suspected EDCs.

This deviation for the GHS methodology not only creates an incoherent system of identification, but also will make the criteria for identification difficult to apply across sectors. It deprives the legislator of the flexibility to adjust regulatory responses depending on the level of evidence and the particularities of a use (e.g. exposure to children and pregnant women). This is a barrier to the proper horizontal application of the criteria and thus the proper identification of all EDCs.

The Commission's reasons for not setting out categories for EDCs are both generic and misleading. The Commission stated that it "considers that establishing different categories of what *may be* an endocrine disruptor does not help to define what *is* an endocrine disruptor in the pesticides" (emphasis added).[18]

In light of the GHS and CLP Regulation, the question underlying the classification of a chemical under a "hazard class" for example a carcinogen, is not only "what is a carcinogen" but also "what level of evidence is required" to identify a carcinogen. The explicit acknowledgement of the degree of uncertainty related to the identification of a hazard can encourage new studies that aim to clarify these uncertainties.

The Commission's approach fails to appreciate the degree of uncertainty involved in identifying the hazardous properties of a substance. Substances are rarely *known* to cause harm with certainty. For example, only about 25% of all Category 1 carcinogens listed in the harmonised classification under CLP are *known* carcinogens (Category 1A).[19]

The Commission asserts without explanation that "such categorisation for pesticides and biocides *would decrease legal* certainty for regulators and stakeholders, without established benefits in terms of protection of health and the environment."[20] It is unclear why categories would create legal uncertainty, when the reality is quite the opposite. Categories would clarify what type and level of evidence is required to identify EDCs. It would also help economic operators plan and prioritise research and development for substitution.

In any event, the failure to use categories creates an obstacle to the horizontal application of the criteria across sectors. While a legislator may want to ban *suspected* EDCs only in childcare products or in cosmetics, he or she will not be able to do so if the criteria to identify EDCs do not include such a category.

18 Commission Communication on the draft EDC criteria, p. 5.
19 CLP Regulation, Annex VI.
20 Commission Communication on the draft EDC criteria, p. 5-6.

(ii) Using a notion relevant only to pesticides and biocides

The draft criteria make a distinction between EDCs with respect to humans and to "non-target organisms." This notion of "non-target organism" is specific to pesticides and biocides. It covers animals or plants that are collateral damage to the use of pesticides or biocides, as opposed to organisms that the product aims at damaging. There are a number of problems with this approach.

First, EDCs that only have an impact on "target organisms" will not be classified as EDCs, even though in fact they are EDCs. Excluding the identification of substances as EDCs because they are *intended* to cause such harm on certain organisms confuses the identification of a hazard with the regulatory response (see 'What does "identification" of EDCs mean?' page 6). The political decision to allow EDCs in pesticides is an entirely separate question from whether the substance is, in fact, an EDC.

Second, the same chemical may be used both in biocides and pesticides and may target different organisms.[21] There is a risk, therefore, of inconsistencies between the identification of an EDC when it is used as a biocide or a pesticide.

Third, only pesticides and biocides are produced and designed with the intent to damage certain organisms. Thus, the notion of "non-target organisms" is not relevant under the rest of the EU legislation,[22] and the draft criteria are even more problematic if this terms is applied in other sectors.

21 Opinion of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) on "the definition of scientific criteria for defining endocrine disruptors", 19 July 2016, p 6-7, available at https://www.anses.fr/en/system/files/SUBCHIM2016SA0133EN.pdf.

22 Idem, p. 8.

2 Potential impact of the sector-specific criteria on the regulation of EDCs beyond pesticides and biocides

Despite their sector-specific features, the draft criteria will have an impact on the identification and regulation of EDCs under other legislation. The Commission notes that "the EU regulatory framework is already working with the notion of 'endocrine disruptors' (albeit without criteria set in EU legislation to define what is an endocrine disruptor)."[23] The Biocides expert group highlighted the importance of identifying how the criteria may apply in these other contexts, notwithstanding the fact that they are intended to apply only to biocides and pesticides.[24]

The following section explores this question. First, it addresses the potential impact of the draft criteria under legislation applicable to all sectors (horizontal legislation) and second, under sector-specific legislation.

1.1 Potential impact of the draft criteria under horizontal legislation

(i) Potential impact under the GHS

As explained previously, the current proposal for sector-specific draft criteria does not follow the GHS approach and CLP Regulation implementation, and this makes the criteria difficult to apply beyond pesticides and biocides (see section 1.2.).

In addition, the failure to use categories could also prevent harmonisation of the identification of EDCs under the GHS. The EU's failure to propose criteria that are suitable for harmonisation could delay the adoption of criteria at the United Nations level. It could also lead to the adoption of different criteria under the GHS, creating a potential conflict with EU law and legal uncertainty.

23 Commission Communication on the draft EDC criteria, p 8.
24 Draft Minutes, 68th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, 21 December 2016, available at https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/ev_20161221_mi_en.pdf.

(ii) Potential impact on the implementation of the REACH Regulation

The Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[25] applies to all chemical substances manufactured and used in the EU.[26] The REACH Regulation aims, *inter alia*, to replace the most hazardous substances, so-called "substances of very high concern" (SVHC), with safer alternatives. After being added to REACH Annex XV (the Candidate List), a chemical may then proceed to REACH Annex XIV (the Authorisation List) and become subject to authorisation.

In 2013, the Commission published a Roadmap for the inclusion of all currently known SVHCs to be included in the candidate list by 2020.[27] For EDCs, the Roadmap proposes that the EU database (Endocrine Active Substances Information System) be screened once the EDC criteria are available (starting in 2014 for screening and in 2015 for assessment of the fulfilment of the criteria).

Among other things, a chemical can be listed as an SVHC under REACH[28] if it is classified as Category 1A or 1B carcinogenic, mutagenic, or toxic for reproduction (CMRs) under the CLP Regulation.[29]

Endocrine disruptors not identified as carcinogenic, however, are identified as a SVHC if "there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent concern" to those of known or presumed CMRs.[30]

This assessment is carried out on a case-by-case basis by the Member State Committee (MSC) assigned by the European Chemical Agency (ECHA).[31] Thus, despite the absence of harmonised criteria to identify EDCs, MSCs have already been identifying EDCs as SVHCs.

25 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, OJ L 396 30.12.2006, p. 1. ("REACH Regulation").
26 Except those excluded from its scope under Art. 2.
27 European Commission Roadmap on Substances of Very High Concern, 6 February 2013, available at http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT.
28 Candidate List of substances of very high concern for Authorisation (published in accordance with Art. 59(10) of the REACH Regulation), ("Candidate List"), available at https://echa.europa.eu/candidate-list-table.
29 REACH Regulation, Art. 57.
30 Ibidem, Art. 57(f).
31 Members are appointed by the Member States (one each), and they must reach a unanimous decision. If they do not, the Commission has to decide. ECHA, Rules of Procedure for the Member State Committee, MB/14/2013, available at https://echa.europa.eu/documents/10162/13578/msc_procedure_rules_en.pdf/03e16e67-d1c2-4f58-9ceb-74fd1e099e9f, Artt. 3, 19.

What would be the impact of the draft sector-specific criteria on the way EDCs are currently identified as SVHCs?

The consequence of proposing sector-specific criteria by the Commission on ECHA's work under REACH may be the following if ECHA were to apply the sector-specific criteria:

- **Lower levels of protection**, i.e. failure to identify certain chemicals as EDCs and thus as SVHC. Since the draft criteria are not designed to catch EDCs beyond pesticides and biocides, there is a risk that chemicals used in other sectors may not be identified as EDCs. This means that consumers products could end up containing EDCs;
- **More difficult assessment of "equivalent level of concern."** The lack of categories makes it harder to compare a Category 1 CMR with a Category 1 EDC;
- **Delayed implementation** of the Roadmap for identification of EDCs as SVHCs;

If ECHA were to ignore the sector-specific criteria, this may lead to:

- **Inconsistencies** between the EDCs on the SVHC list and the EDCs identified under the Pesticides and Biocides Regulations due to the use of different methodologies;
- **Inconsistencies** between the methodologies used by the MSCs and those used under the draft criteria.

ECHA itself acknowledged the issues raised by sector-specific criteria:

> it should be considered that the criteria in practice will inevitably impact the discussions within other legal frameworks dealing with endocrine disruptors, such as for example the REACH, Cosmetics and Medicinal Products Regulations. Therefore, in order to ensure good administrative practice and to avoid situations where it could happen that under one(/some) of the different legal frameworks the same substance would be identified as endocrine disruptor whereas under the other ones it would not, it is necessary to ensure coherence across the different legal frameworks with regard to the criteria and assessment methodologies leading to the identification of endocrine disruptors.[32]

32 ECHA comments on the draft COM proposal for scientific ED-criteria in the context of the biocides and pesticides legal frameworks of 6 July 2016, available at http://files.chemicalwatch.com/EchacommentsEDC%20criteria.pdf, p. 1.

The lack of legal certainty and undue complexity brought by the sector-specific approach would also delay the process of identification of EDCs as SVHCs. As highlighted by the Council, "[a]chieving the objective to list all relevant SVHC [including EDCs] in the REACH candidate list by 2020 is at risk."[33] When the Commission committed to achieve this objective, it assumed that horizontal criteria for EDCs would be adopted.[34] Having sector-specific criteria will likely further slow down the process.

1.2 Potential impact of the draft criteria under other sector-specific legislation

(i) Potential impact of the draft criteria under the Cosmetics Regulation

The Cosmetics Regulation establishes the safety requirements for cosmetic products and aims, inter alia, to ensure a high level of protection for human health.[35] To that end, the regulation prohibits the use of substances in cosmetics that are classified under the CLP Regulation as known, presumed, and suspected CMRs.[36]

Currently the use of EDCs in cosmetic products is not regulated under the Cosmetics Regulation. However, the Commission is required to review the regulation "when Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015."[37]

What would be the impact of the draft sector-specific criteria on the way EDCs will be regulated under the Cosmetics Regulation?

If the draft criteria are used to identify EDCs in cosmetics, the criteria's sector-specific features may lead to:

33 Council Conclusions of 19 December 2016, n°15673/16, Protection of human health and the environment through the sound management of chemicals, available at http://data.consilium.europa.eu/doc/document/ST-15673-2016-INIT/en/pdf.
34 Commission Roadmap on Substances of Very High Concern, n°5867/13, 6 February 2013, available at http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT, p. 15.
35 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p 59. ("Cosmetics Regulation"), art. 1.
36 Cosmetics Regulation, Art. 15; Under certain conditions set out at Art. 15, CMRs can be used in cosmetics.
37 Ibidem, Art. 15(4).

- **The failure to identify certain chemicals as EDCs.** Since the draft criteria are not designed to include EDCs beyond pesticides and biocides, there is a risk that chemicals used in cosmetics may not be identified as EDCs. This means that cosmetic products could contain EDCs;
- **Lower levels of protection.** Because the draft criteria do not provide for categories, legislators will not be able to use the criteria to identify suspected EDCs, even though suspected CMRs are banned in cosmetics. As a result, the rules on EDCs will be more lenient than the rules on CMRs. This would be problematic because EU legislators have consistently attributed an equivalent level of concern to CMRs and EDCs.[38] This will lead to a lower level of protection for human health and the environment, contrary to the objective of the Cosmetics Regulation;
- **Inconsistency** between the EDCs identified under the Cosmetics Regulation and the EDCs identified under the Pesticides and Biocides Regulations, if the draft criteria are not used and other sector-specific criteria are adopted specifically applicable to cosmetics.

If the Commission was to adopt sector-specific criteria for cosmetics, this will lead to *further delay* in regulating EDCs in cosmetics. The Commission has already failed to comply with the requirement to review the Cosmetics Regulation regarding EDCs no later than 11 January 2015.[39]

(ii) Potential impact of the draft criteria under the Water Framework Directive

The Water Framework Directive (WFD) establishes the framework for Member States to protect all forms of water (inland surface, transitional, coastal, and ground water) against pollution.[40]

For chemical pollution, the WFD provides that Member States are required to identify chemical pollutants of significance, to set quality standards for the water, and to establish emission control measures. To assist Member States, the WFD provides

38 See, Legal opinion of Sonderforschungsgruppe Institutionenanalyse, on behalf of ClientEarth, The European Commission Proposals and Legal Requirements Concerning the Determination of Scientific Criteria to Identify Endocrine Disruptive Properties of Active Substances, June 2016, p. 21; available at http://www.documents.clientearth.org/library/download-info/summary-of-analysis-of-european-commission-proposals-and-legal-requirements-concerning-the-determination-of-scientific-criteria-to-identify-endocrine-disruptive-properties-of-active-substances/.

39 Cosmetics Regulation, Art. 15(4).

40 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1–73) ("WFD"), Art. 1.

for an "indicative list of the main pollutants."[41] This list includes substances "which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment."[42]

What would be the impact of the draft sector-specific criteria on the way EDCs are considered as "main pollutants" under the WFD?

If the draft criteria are used to identify EDCs as "main pollutants," their sector-specific features may lead to lower levels of protection as a result of a failure to identify certain chemicals as EDCs. Since the draft criteria are not designed to catch EDCs beyond pesticides and biocides, there is a risk that chemicals which are present in water but not used as pesticides or biocides (such as those released from a landfill, consumer products, or a manufacturing plant) may not be identified as EDCs and thus as a "main pollutant" by Member States. This would be contrary to the objectives of the WFD and notably "prevents further deterioration and protects and enhances the status of aquatic ecosystems."[43]

In effect, contrary to the Pesticides and Biocides Regulations, the WFD does not require the proof of "adverse effects" for a chemical to be listed as a main pollutant. It only refers to "properties which may affect [...] endocrine-related functions,"[44] while the Pesticides and Biocides Regulations refer to EDCs that "may cause adverse effects"[45]. Applying the draft criteria would likely limit the identification of EDCs as main pollutants under the WFD.

(iii) Potential impact of the draft criteria under the draft Medical Devices Regulations

Medical devices are currently regulated in the EU under three directives.[46] These directives do not refer to EDCs. In 2012, the Commission proposed replacing these

41 WFD, Annex VIII.
42 WFD, Annex VIII, Point 4.
43 WFD, Art. 1.
44 WFD, Annex VIII, Point 4.
45 Pesticides Regulation, Annex II, Art. 3.6.5; Biocides Regulation Art. 5.1(d).
46 Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p.17); Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p.1); Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

directives with two regulations, which include EDC-specific provisions.[47] In June 2016, Council of Ministers' Permanent Representatives Committee and the European Parliament's Environment Committee endorsed the proposals.[48] The new regulations are expected to be adopted in April 2017.[49]

The objective of these regulations is to ensure high standards of quality and safety for medical devices and in vitro diagnostic medical devices, "thus ensuring a high level of protection of health and safety of patients, users and other persons." [50] The regulations set rules for the design and manufacture of devices, clinical testing, authorization, and post-market surveillance.

Regarding EDCs, the proposed regulation on implantable medical devices sets a maximum concentration limit for EDCs in certain types of devices. EDCs under this restriction "are identified either in accordance with the procedure set out in Article 59 of [REACH] or in accordance with those criteria that are relevant to human health of the criteria established in the delegated act adopted by the Commission [under the Biocides Regulation]."[51] In other words, if a chemical is identified as an EDC under REACH or under the Biocides Regulation, its presence in the implantable medical device will be restricted.

> What would be the impact of the draft sector-specific criteria on the way EDCs are restricted under the proposed Regulation on Medical Devices?

The co-legislators attempted to reduce legal uncertainty by referring to the identification of EDCs under REACH and the criteria set under the Biocides Regulation. However, the co-legislators apparently assumed that the draft criteria under the Biocides Regulation would be horizontal. The fact that the draft criteria are actually sector-specific and will be used to identify EDCs in medical devices raises issues:

- **Legal uncertainty**: for example, debates may emerge as to the relevance of "non-target organism" in medical devices;

47 Commission Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (COM(2012) 541 final); Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012) 542 final).
48 Council Press release n°330/16, 15 June 2016, Medical devices: Council confirms deal with EP.
49 Chemical Watch, 11 January 2017, EU to adopt medical devices Regulations in May, available at https://chemicalwatch.com/52039/eu-to-adopt-medical-devices-regulations-in-may .
50 Council Note n° 9364/3/16, Interinstitutional File n°2012/0267 (COD), Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices ("IVD Regulation") recital 67; Council Note n° 9364/3/16, Interinstitutional File n°2012/0266 (COD), Proposal for a Regulation of the European Parliament and of the Council on medical devices, ("MDR") recital 71.
51 MDR, Annex I, Art. 7.4.1.

- **Lower levels of protection**: i.e. failure to identify certain chemicals as EDCs. Since the draft criteria are not designed to catch EDCs beyond biocides, there is a risk that chemicals present in medical devices may not be identified as EDCs. This means that products such as devices used for small children, pregnant women, and medical patients could end up containing EDCs.

In addition, the proposal for a regulation on in vitro diagnostic medical devices covers only EDCs identified in accordance with the SVHC procedure under REACH.[52] The draft criteria (under the Biocides Regulation) are not mentioned in this second proposed regulation. This lack of coherence with the proposed regulation on implantable medical devices creates additional legal uncertainty.

In light of this, the sector-specific nature of the draft criteria raises many issues: legal uncertainty, risk of inconsistencies, lower level of protection, and further delay in the regulatory response to protect human health and the environment from EDCs. This approach also runs contrary to the Better Law Making principles and the priority objectives of the EU set by the European Parliament and the Council.

3 Sector-specific criteria: breach of Better Law Making principles

The sector-specific nature of the draft criteria runs contrary to the Inter-institutional Agreement on Better Law Making and the Commission's Better Regulation Guidelines. The Better Regulation program aims to create a simple, clear, stable, and predictable regulatory framework for businesses, workers, and citizens. The Better Regulation program is thus designed to ensure that Commission proposals meet policy goals at minimum cost and deliver maximum benefits to citizens, businesses, and workers while avoiding unnecessary regulatory burdens.

52 IVD Regulation, Annex I, Art. 7.3.

1.3 Contrary to the Inter-institutional Agreement on Better Law Making

According to the Inter-institutional Agreement of 13 April 2016, the Commission, the European Parliament, and the Council, all agreed to pursue "Better Law-Making."[53] The Agreement stipulates that:

> [t]he three Institutions recognise their joint responsibility in delivering high-quality Union legislation and in ensuring that such legislation […] is as efficient and effective as possible in delivering the common policy objectives of the Union, is as simple and as clear as possible, […] and is designed with a view to facilitating its transposition and practical application and to strengthening the competitiveness and sustainability of the Union economy.[54]

The sector-specific nature of the draft criteria runs contrary to these "Better Law Making" principles. As explained above, the practical application of the criteria beyond pesticides and biocides raises many issues. The sector-specific approach creates unnecessary complexity and lack of legal certainty. It may cause the need for several repeated assessments to verify if the same chemical fulfills criteria to be considered an EDC under various regulatory frameworks. This uncertainty may cause a chilling effect for business investments where the risk of unpredictable regulatory consequences may be very high.

The sector-specific criteria do not appear efficient and effective in delivering a high level of protection of human health and the environment, and the Commission is thus in breach of this inter-institutional agreement.

1.4 Contrary to the Better Regulation Guidelines

In 2015, the Commission adopted guidelines defining "Better Regulation" and how it should be applied in the day-to-day practices of Commission officials preparing new initiatives and proposals or managing existing policies and legislation.[55] According to the Better Regulation Guidelines, an existing piece of legislation must be evaluated on

53 Interinstitutional Agreement Between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making Interinstitutional Agreement of 13 April 2016 on Better Law-Making, (OJ L 123, 12.5.2016, p 1-14) (the "Inter-institutional Agreement").
54 Inter-institutional Agreement, Recital 2.
55 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, "Better Regulation for Better Results - An EU Agenda" (COM(2015) 215 Final) (the "Better Regulation Guidelines").

six questions, including: "How coherent is the EU intervention internally and with other (EU) actions?"[56] As explained below, the proposed criteria are both internally and externally incoherent.

i) Lack of coherence within the same initiative

As explained previously (Section 1.1), the initial intent of the Commission was to adopt criteria "with the aim of enabling their 'horizontal' application in the wider legislation covering the regulation of [endocrine disruptors] in different regulatory settings."[57] The objectives of the regulatory action were clearly identified:

- Providing for legal clarity, predictability, and coherence in the identification of EDCs;
- Providing for scientific criteria that are operational in terms of regulatory decision-making;
- Ensuring the possibility that these criteria could apply across all relevant Union legislation.[58]

Nevertheless, the report on the impact assessment published in 2016 reveals that the Commission's objective changed after the CJEU condemnation for failure to act under the Biocides Regulation to focus only on pesticides and biocides.[59]

This lack of internal consistency within the same initiative is in breach of the Commission's Guidelines on Better Regulation.

ii) Lack of coherence with other EU actions

As discussed above, the inconsistencies that result from sector-specific criteria under the Biocides and Pesticides Regulations result in significant incoherence with other EU actions related to EDCs.

56 Better Regulation Guidelines, p. 59.
57 EDCs Roadmap, p. 4.
58 Ibidem.
59 Commission Staff Working Document, Impact Assessment, of 15 June 2016 (SWD(2016) 211 final), p. 15, available at https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf

The draft criteria also lack coherence with other EU laws, such as the REACH and non-REACH fitness checks. The purpose of the fitness check on "the most relevant chemicals legislation (excluding REACH)" (non-REACH REFIT), as specified in the Roadmap, is to "assess the overall effectiveness, efficiency, relevance, coherence, and EU added value" of the legislative framework and to "identify possible excessive regulatory burdens, overlaps, inconsistencies, obsolete measures and gaps."[60]

In particular, the non-REACH REFIT aims at analysing the coherence of the legislative approach and procedures regarding hazard identification. "This will include an analysis of the manner in which a given chemical is treated throughout the EU chemicals legislation and whether the various provisions applying to it provide for consistent definitions and coherent measures (i.e. measures adapted to the substance and the context)."[61] The non-REACH REFIT will cover, for example, the CLP Regulation, the Pesticides Regulation, and the Biocides Regulation.

The REACH Regulation is currently going through a separate evaluation and fitness check (REACH REFIT), which will assess, amongst other issues: "to what extent have inconsistencies, contradictions or missing links with other EU chemical legislation been addressed through REACH implementation after 2013?"[62] It will also "assess whether REACH is fit to tackle evolving issues such as [...] endocrine disruptors."[63]

The Commission is, on the one hand, with these REFITs, checking if the identification of the hazardous properties of a given chemical is coherent throughout EU legislation, and on the other, proposing sector-specific criteria for the identification of EDCs for pesticides and biocides, hereby creating a risk of inconsistency in the identification of EDCs in chemicals legislation.

As a result, the draft criteria, due to their sector-specific nature, defeat the purpose of both the REACH and non-REACH REFIT evaluations and breach the Guidelines of Better Regulation.

60 Commission Roadmap Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, 18 May 2016 ("non-REACH REFIT Roadmap").
61 Idem, p. 6.
62 Commission Roadmap, REFIT evaluation in view of the obligation stemming from Art. 117(4) of Regulation (EC) No 1907/2006 for the Commission to report by 1 June 2017 on the implementation of the REACH Regulation, 18 May 2016 ("REACH REFIT Roadmap"), p. 5.
63 Idem, p. 1.

4 Sector-specific criteria: breach of the priority objectives of the EU

In addition to breaching the principles of Better Regulation, the proposal of sector-specific criteria is contrary to the priority objectives of the EU.

The Seventh Environment Action Programme (7th EAP) adopted by the Parliament and the Council under Article 192(2) TFEU[64] set the priority objectives of the EU in the environmental field until 2020.

Regarding EDCs, the 7th EAP is very clear:

> The Union will further develop and implement approaches to address combination effects of chemicals and safety concerns related to endocrine disruptors in all relevant Union legislation. In particular, the Union will develop *harmonised* hazard-based criteria for the identification of endocrine disruptors.[65]

By proposing criteria applicable only to biocides and pesticides, the Commission is ignoring the objectives of the EU set forth in the 7th EAP to safeguard EU citizens from environment-related pressures and risks to health and well-being.

In 2013, the European Parliament, also stressed that the EDC identification criteria "must be scientifically based and horizontal."[66] In December 2016, the Council similarly "CALL[ED] UPON the Commission to comply with the relevant 7th EAP provisions,"[67] referring to the EU's priority objective to develop harmonised criteria.

The Commission itself acknowledged that

> [t]he development of criteria that will be used to identify substances with endocrine disrupting properties under the Biocides Regulation and the [Pesticides] Regulation is related to the general calls on the Commission to establish horizontal hazard-based scientific criteria to identify endocrine disruptors by both the Council and the European Parliament, in the form of Council conclusions and an own initiative report, respectively.[68]

64 Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013, on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet', OJ L 354, 28.12.2013, ("7th EAP") p. 171–200.
65 Idem, para. 50.
66 European Parliament Resolution of 14 March 2013 on the protection of public health from endocrine disrupters (2012/2066(INI)), Recital 9.
67 Council Conclusions n°15673/16 of 19 December 2016, Protection of human health and the environment through the sound management of chemicals, Recital 7.
68 EDCs Roadmap, p 1-2, section A.

The Commission is therefore knowingly ignoring one of the EU priority objectives for 2020 and proposes identification criteria for EDCs solely applicable to pesticides and biocides.

Finally, the 7th EAP requires that EDCs be identified on the basis of a hazard-based approach.[69] Since the criteria include derogations based on exposure (i.e. excluding substances that are meant to be endocrine disruptors for target organisms from identification), they further fail to comply with the 7th EAP.

5 Conclusion and Recommendations

By proposing criteria designed to identify EDCs in pesticides and biocides only, the Commission is ignoring the priority objectives that the European Parliament and the Council set for the EU in the 7th EAP. The Commission is also breaching its own Guidelines on Better Regulation as well as the Inter-institutional Agreement on Better Law Making.

This silo approach raises complex questions and legal uncertainty, creates a risk of inconsistencies in the identification of EDCs between sectors and a risk that certain EDCs will escape identification, and threatens to delay the identification of EDCs and the adoption or implementation of the rules necessary to protect EU citizens and the environment from these chemicals.

CIEL and ClientEarth recommend that the February draft proposal be amended as follows:

- The criteria must be redesigned to identify EDCs wherever they are located, irrespective of the sector. No sector-specific notions such as "non-target organisms" should be used. The criteria should also follow the methodology of hazard identification under the GHS and the CLP Regulation by providing three hazard categories based on different strength of evidence: known (Category1A), presumed (Category 1B), and suspected (Category 2) EDCs; and,
- The scope of application of the criteria must be clearly defined as horizontal.

69 7th EAP, recital 50.

Horizontal criteria would ensure clarity and legal certainty, reduce the risk of inconsistencies between legal frameworks and sectors, and limit the risk that some EDCs go unregulated. Horizontal criteria would also fulfil the principles of Better Regulation and contribute to the achievement of the EU's priority objectives set out in the 7th EAP.

CIEL and ClientEarth call on the Commission to amend its draft proposals as described above, before putting it to vote in the Standing Committees.

Should the Commission refuse to change its approach, CIEL and ClientEarth call on the European Parliament and the Council to veto the current proposals in compliance with the regulatory procedure with scrutiny (applicable to the proposal under the Pesticides Regulation) and the procedure applicable to delegated acts under Article 290(2) TFEU (applicable to the proposal under the Biocides Regulation).[70]

Finally, once EDCs are finally identified, CIEL and ClientEarth call for expanding the protection of human health and the environment from these chemicals. For example, the Commission should propose restrictions to EDCs in other products such as toys or food packaging materials.

70 For more details on the European Parliament and the Council's rights, see Legal opinion of Sonderforschungsgruppe Institutionenanalyse, on behalf of ClientEarth, The European Commission Proposals and Legal Requirements Concerning the Determination of Scientific Criteria to Identify Endocrine Disruptive Properties of Active Substances, June 2016, available at http://www.documents.clientearth.org/library/download-info/summary-of-analysis-of-european-commission-proposals-and-legal-requirements-concerning-the-determination-of-scientific-criteria-to-identify-endocrine-disruptive-properties-of-active-substances/, p. 42-43.