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Fitness Check of the EU legislation with regard to Endocrine Disruptors - Stakeholders Survey

Fields marked with * are mandatory.

Introduction

Scope and objectives

In its Communication 'Towards a comprehensive European Union framework on endocrine disruptors', adopted on 7 November 2018, the Commission confirmed its commitment to protect EU citizens and the environment from endocrine disruptors by minimising human and wildlife exposure to these substances. The Communication outlines a comprehensive set of actions including a cross-cutting Fitness Check of the relevant legislation.
The Fitness Check aims at analysing the coherence of the different regulatory approaches to the assessment and management of endocrine disruptors and at assessing whether legislation delivers on its objectives to protect humans and the environment.
The legislative measures constituting the EU legal framework regulating chemicals have been developed at different points in time and have, in certain cases, different objectives. This has resulted in different approaches to regulating endocrine disruptors, depending on the sector, and has raised questions as to whether the EU legal framework regulating endocrine disruptors is sufficiently coherent. The Fitness Check aims to assess specifically the consequences of the absence of common criteria to identify endocrine disruptors across the different legal frameworks, and different regulatory approaches for managing substances identified as endocrine disruptors. More information is available in the published Roadmap.
Stakeholder consultation is an essential step to collect evidence for the Fitness Check. It aims at gathering inputs from a broad range of stakeholder groups as well as citizens to ensure that relevant evidence and views from all interested parties are considered in the evaluation. The consultation activities solicit input to the analysis of the coherence of the EU framework, as well as, to the extent possible, its effectiveness, efficiency, relevance and EU added value.

The aims of this stakeholder survey are:

- To collect views on possible legislative inconsistencies and to assess their impact on stakeholders;
- To collect information from stakeholders on the effectiveness of the current EU legislation for the identification and risk management of endocrine disruptors;
- To collect information on the efficiency of procedures for the identification and risk management of endocrine disruptors (e.g. duplication of efforts) and to identify opportunities for improvement.

Target audience

This survey is addressed to **stakeholder organisations** such as businesses, public authorities, academia research and NGOs, and to **experts** working in such areas responding in their professional capacity. If you would like to comment in your personal capacity from a citizen's perspective, please respond to the public survey.

Instructions

Respondents are encouraged to explain their answers providing examples and data in the open fields provided. However, there is no mandatory field in the main survey section.
Answers should be in **English**.

Information on respondent

* I am giving my contribution as:

Some questions are specific to certain stakeholders group(s) and will be visible according to your answer to this question

- ( ) Academic/research institution
- ( ) Business association
- ( ) Company/business organisation
- (•) Civil society organisations
- ( ) Public authority
- ( ) Trade union
- ( ) Other

* First name

50 character(s) maximum

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50 character(s) maximum

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* Organisation name

50 character(s) maximum

Center for International Environmental Law (CIEL)

Country of origin of your organisation

- ○ Austria
- ○ Belgium
- ○ Bulgaria
- ○ Croatia
- ○ Cyprus
- ○ Czechia
- ○ Denmark
- ○ Estonia
- ○ Finland
- ○ France
- ○ Germany
- ○ Greece
- ○ Hungary
- ○ Ireland
- ○ Italy
- ○ Latvia
- ○ Lithuania
- ○ Luxembourg
- ○ Malta
- ○ Netherlands
- ○ Poland
- ○ Portugal
- ○ Romania
- ○ Slovak Republic
- ○ Slovenia
- ○ Spain
- ○ Sweden
- ○ United Kingdom
- ◉ Other (Please specify)

Specify country

Switzerland

* Scope

- ◉ International
- ○ National
- ○ Regional
- ○ Local

* Organisation size

- ○ Micro (1 to 9 employees)
- ◉ Small (10 to 49 employees)
- ○ Medium (50 to 249 employees)
- ○ Large (250 or more)

* **Publication privacy settings**

The Commission will process the responses of this stakeholders survey for the purpose of the Fitness Check on the EU legislation on endocrine disruptors. This includes the publication of a summary report of the survey. You can choose to give your consent to publish your personal details, or to remain anonymous.

- ○ **Anonymous** - Only your stakeholder group, country of origin, sector, scope and size of your organisation may be published. Your personal details will not be published.
- ◉ **Public** - Your personal details may be published with your contribution.

☑ I agree with the following personal data protection provisions

Personal data protection provisions

Privacy_statement.pdf

Survey

1) How familiar are you with the following pieces of legislation?

	Not at all familiar	A little familiar	Fairly familiar	Very familiar
Plant Protection Products Regulation (EC) 1107/2009	○	○	○	◉
Residues of Pesticides Regulation (EC) 396/2005	○	◉	○	○
Biocidal Products Regulation (EU) 2012/528	○	○	○	◉
REACH Regulation (EC) 1907/2006	○	○	◉	○
CLP: Classification, Labelling and Packaging of substances and mixtures (EC) 1272/2008	○	○	◉	○
Persistent Organic Pollutants Regulation (EC) 850/2004 and (EU) 2019/1021	○	○	○	◉
Food Contact Materials Regulation (EC) 1935/2004	○	○	◉	○
Contaminants in Food and Feed Regulation (EEC) 315/93 and Directive (EC) 32/2002	◉	○	○	○
Food Additives Regulation (EC) 1333/2008	◉	○	○	○
Cosmetic Products Regulation (EC) 1223/2009	○	○	◉	○
Medical Devices Regulation (EU) 2017/745	○	○	◉	○
In vitro Diagnostic Medical Devices Regulation (EU) 2017/746	○	○	◉	○
Toy Safety Directive 2009/48/EC	○	○	◉	○
Fertilisers Regulation (EC) 2003/2003 and Regulation (EU) 2019/1009	◉	○	○	○

Detergents Regulation (EC) 648/2004	◉	○	○	○
Medicinal Products for Humans Directive 2001/83/EC	◉	○	○	○
Veterinary Medicinal Products Regulation (EU) 2019/6	◉	○	○	○
General Product Safety Directive 2001/95/EC	◉	○	○	○
Water Framework Directive 2000/60/EC	○	◉	○	○
Priority Substances Directive 2013/39 EC	◉	○	○	○
Drinking Water Directive 98/83/EC	○	◉	○	○
Groundwater Directive 2006/118/EC	◉	○	○	○
Marine Strategy Framework Directive 2008/56/EC	○	◉	○	○
Urban Waste Water Directive 91/271/EEC	◉	○	○	○
Chemical Agents at Work Directive 98/24/EC	◉	○	○	○
Carcinogens and Mutagens at Work Directive 2004/37/EC	○	◉	○	○
Pregnant Workers Directive 92/85/EEC	◉	○	○	○
Young People at Work Directive 94/33/EC	◉	○	○	○
Waste Directive 2008/98/EC	○	◉	○	○
Restriction of the use of certain hazardous substances in Electrical and Electronic Equipment - Directive 2011/65/EU	○	◉	○	○
Industrial emissions Integrated Pollution Prevention and Control Directive 2010/75/EU	◉	○	○	○
Seveso-III-Directive 2012/18/EU	◉	○	○	○
Ambient Air Quality and Cleaner Air for Europe Directive 2008/50/EC	◉	○	○	○
Regulation (EC) 66/2010 on the EU Ecolabel	○	◉	○	○

Horizontal approach to the identification of endocrine disruptors

Recently the European Commission published criteria for the identification of endocrine disruptors under both the Biocidal Products Regulation and the Plant Protection Products Regulation, which were very similar to each other and based on the WHO definition [1]. Other pieces of EU legislation related to human health and environmental protection from manufactured chemicals do not contain such criteria.

[1] "*An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations*."

2) To what extent does the absence of harmonised criteria pose a problem to a coherent approach for the **id entification** of endocrine disruptors?

- (●) It is an important problem, leading to incoherent identification of endocrine disruptors across sectors
- ( ) It is not a problem, the criteria should be sector specific

Please explain your answer, indicating the sector(s) in which this problem occurs (max 1000 characters)

1000 character(s) maximum

The EU was mandated to "develop harmonised hazard-based criteria for the identification of endocrine disruptors" by the 7th EAP. However, only sectoral identification criteria have been developed, leaving inconsistencies and gaps in both the identification and the data requirements in different pieces of the EU legislation. Applying those sector-specific criteria to non-pesticides and biocides creates a risk that certain substances will not be identified as EDCs. This can turn into a lower level of protection from EDCs, in particular, in the case of uses in consumer products such as cosmetics, toys, and food contact materials.

The Regulation on Classification, Labelling and Packaging (CLP) of substances and mixtures and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) set rules for the classification and labelling of hazardous substances, based on their physical, health or environmental hazards.

3) Do you think that the lack of a hazard category covering endocrine disrupting properties in the CLP Regulation and/or GHS poses a problem for the coherent **identification** of endocrine disruptors?

- ( ) Yes
- (●) No

4) Do you think that the lack of a hazard category covering endocrine disrupting properties in the CLP Regulation and/or GHS poses a problem for the coherent **risk management** of endocrine disruptors?

- ( ) Yes
- (●) No

Please explain your answers to questions 3 and 4, if possible indicating the sector(s) in which this problem occurs.

1000 character(s) maximum

EU legislators have consistently attributed an equivalent level of concern to CMRs and EDCs, therefore EDCs should be classified accordingly. The Cosmetics Regulation, for instance, prohibits the use of known, presumed, and suspected CMRs. Setting categories is a harmonization tool that can allow regulating different chemicals that are known, presumed, or suspected EDCs.
The classification of chemicals not only on the basis of their hazard class but also on the basis of their hazard category facilitates the harmonization of cross-sectoral classification and helps the harmonization across countries. While the creation of a hazard category in the CLP Regulation and/or GHS could be beneficial for a coherent identification of EDCs, it should not come at the cost of further delaying the identification of EDCs.

Risk management decisions will need to be addressed by amending the different pieces of sectoral legislation, e.g. including provisions that prohibit the use of EDCs in FCM.

The CLP Regulation applies different approaches to categorise hazards depending on the endpoints, which may include aspects related to severity of effects or strength of evidence. Some stakeholders have suggested to classify endocrine disruptors in one of three categories based on the level of evidence: i.e. known, presumed or **suspected**.

5) Do you think that a category of **suspected** endocrine disruptor should be introduced?

- (●) Yes
- ( ) No

What should be the regulatory consequences of such a category? What would be the consequences for protecting human health and the environment? What would be the economic consequences?

2000 character(s) maximum

EDCs should be classified on the basis of the strength of available evidence. The WHO/IPCS definition of EDCs also includes the definition of "potential" EDCs. The use of categories of known, presumed, and suspected EDCs will enable the horizontal application of the criteria across sectors and will be coherent with EU legislation, which has consistently attributed an equivalent level of concern to CMRs and EDCs. The legislator will also obtain more flexibility to adjust regulatory responses according to not only the level of evidence but also to the particularities of the uses of the substances (e.g. in the case of exposure to vulnerable populations). According to the objectives of the protection of human health and the environment, and the necessity to reduce exposure, the use of suspected EDCs should be prohibited, with the possibility to include sector-specific derogations for essential uses with minimized exposure or for controlled used with negligible exposure. This approach will increase the level of protection and boost competitiveness and innovation: for example, in response to stricter laws to protect people and the environment from phthalates, international patent filings shows acceleration in the invention of alternative chemicals and products (CIEL report "Driving Innovation": https://www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf). Failure to do so, will maintain a high cost of inaction (see for instance Trasande et al., 2016, Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis) and high health costs for the EU population.
Adequate information and labeling should be communicated acrss the supply chain, including to workers and consumers.

Rationale and consequences of different regulatory approaches

Under some pieces of legislation, endocrine disruptors are regulated based on their hazardous properties, whereas under others they are regulated on the basis of risk.

6) Are you aware of any inconsistencies in the way chemicals are **identified and controlled** with regard to endocrine disrupting properties across regulated areas in the EU?

- (●) Yes
- ( ) No

Please provide examples and describe the consequences.

2000 character(s) maximum

CIEL warned about the upcoming inconsistencies of identifying EDCs in a narrow and sectoral way in our 2017 report "Disrupted Criteria - The criteria to identify endocrine disruptors: implications beyond pesticides and biocides" (https://www.ciel.org/wp-content/uploads/2017/02/Disrupted-Criteria_EDCs_Final_14feb2017.pdf). The current identification criteria for EDCs were developed with a sectoral approach (for biocides and

pesticides), and their application to other regulations creates the risk that certain chemicals will not be identified as EDCs.
Legislative gaps affecting the effectiveness of the EU regulations on EDCs were also included in the June 2018 Fitness Check on chemicals legislation. An example of inconsistency is the difference between the BPR and PPPR regulation using hazard-based cut-offs while other pieces of legislation such as Cosmetics and Toys use a case-by-case risk assessment. The latter approach wrongly assumes a safe level of exposure to EDCs: the EU legislation will be in line with the precautionary principle and achieve consistency when EDCs will be treated as non-threshold substances.

EDCs should also be regulated following a grouping approach or the consequence be the use of regrettable substitutions, like it is occurring in the case of bisphenols.
The use of the precautionary principle and the consequences for EDCs identification are also inconsistent: for instance, bisphenol A was banned from infant feeding bottles but is still used in other products or packaging-containing foods that are used for feeding babies. Whether there is a sectoral identification of an EDC, this should trigger automatic consequences across the EU legislation to bring consistency in EU law and human and environmental protection.

7.a) In your opinion, how do **hazard-based criteria for identifying** endocrine disruptors in combination with a **hazard-based approach to decision-making** affect the following objectives?

	Very negatively	Negatively	No effect	Positively	Very positively	Don't know
Human health protection	○	○	○	○	◉	○
Environmental protection	○	○	○	○	◉	○
Functioning of the internal market	○	○	○	○	◉	○
Competitiveness and innovation	○	○	○	◉	○	○

7.b) In your opinion, how do **hazard-based criteria for identifying** endocrine disruptors in combination with a **risk-based approach to decision-making** affect the following objectives?

	Very negatively	Negatively	No effect	Positively	Very positively	Don't know
Human health protection	○	◉	○	○	○	○
Environmental protection	○	◉	○	○	○	○
Functioning of the internal market	○	◉	○	○	○	○
Competitiveness and innovation	○	○	◉	○	○	○

Chemicals are managed under different EU regulations according to their uses and the environmental media into which they are released during their life cycle (production, use, recycling/disposal).

8) Are you aware of any gaps or overlaps in the way endocrine disruptors are regulated in the EU?

- (●) Yes
- ( ) No

Please provide examples and describe the consequences.

1000 character(s) maximum

Identified EDCs (e.g. under REACH) do not automatically entail regulatory consequences across other pieces of EU legislation, and despite the equivalent level of concern, there are still big differences between the way CMRs and EDCs are regulated. The category of suspected EDCs is not used. There is still slow progress in identifying EDCs under the BPR and PPPR and most consumer product legislation doesn't even have robust provisions that regulate EDCs. The combined effects of exposure are also not addressed, as showed in the Fitness Check of chemicals legislation.
As a consequence, there is ongoing widespread exposure to EDCs, a lack of transparency and information on EDCs in products, and the real risk that EDCs remain in the loop when products are recycled. The EU population is still exposed to EDCs with high health and societal costs.

9) Have you experienced issues or problems because endocrine disruptors are regulated differently in the EU compared with non-EU countries?

- (●) Yes
- ( ) No

If yes, please provide examples and describe the consequences.

1000 character(s) maximum

There is no level playing field. No harmonized criteria for the identification of EDCs or EDC-specific data requirements are available across jurisdictions, and there's often no information regarding EDCs regulation in developing countries (UNEP "Overview Report III: Existing national, regional and global regulatory frameworks addressing EDCs"). There are still double standards, e.g. pesticides with ED properties that are prohibited in the EU but are still produced in the EU and exported to non-EU countries. EDCs that are banned in the EU can still be found in imported articles, such as toys (e.g. EEB: "'Flood' of toxic Chinese toys threatens children's health"), and regulatory loopholes, exemptions, and high content levels of EDC-POPs under the Stockholm Convention lead in practice to the recycling of POPs into new products (e.g. DecaBDE) (see e.g. Arnika, IPEN, HEAL: "Toxic loophole" and "Toxic Toy or Toxic Waste").

10) Do you have any further comments on the coherence of EU legislation with regard to endocrine disruptors?

2000 character(s) maximum

A failure to address the interface between chemicals (including EDCs), products, and waste will compromise the EU's transition to a circular economy, cause widespread contamination and exposure, and undermine the reputation of the recycling sector.

A clear and predictable regulatory framework that effectively and coherently regulates and reduces exposure to EDCs will be in line with the Better Regulation and be beneficial to businesses, workers, and citizens. It

will also position the EU as a global leader in EDCs regulation and bring coherence between the circular economy, the plastic strategy, and chemicals strategy for a toxic-free environment.

Effectiveness in achieving policy objectives

A common goal of EU chemicals legislation is the protection of human and environmental health, by minimising exposure to hazardous chemicals, while at the same time improving the functioning of the internal market, enhancing competitiveness and innovation, and minimising animal testing. Some regulations have specific provisions for the identification and control of endocrine disruptors.

11) Do you agree with the following statements?

11.a) The regulatory process to identify and control substances with endocrine disrupting properties in **Biocidal Products** is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting citizens by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○
Improving the functioning of the internal market	○	○	○	○	○	◉
Enhancing competitiveness and innovation	○	○	○	○	◉	○
Promoting alternatives to animal testing	○	○	○	○	○	◉

Please explain your answers

2000 character(s) maximum

The EDC identification criteria for biocidal products entered into force more than one year and a half ago, and the regulatory provisions on EDCs are part of the regulation since 2012. However, only 2 EDCs have been identified, with no regulatory consequence yet. The burden of proof in the EDCs identification criteria is too high, as anticipated by scientists during the development of the criteria. The direct consequence is a continued exposure to EDCs and no incentives to develop safer alternatives.

In the BPR regulation, the EU legislator decided to refer to EDCs as substances "having endocrine-disrupting properties that MAY cause adverse effects". The establishment of a category for "suspected" EDCs would better reflect the available level of scientific knowledge and give full effect to the precautionary principle, that underpins the regulation. The use of independent scientific research and the need to have better data requirements with relevant endpoints would also help to improve the identification of EDCs.

11.b) The regulatory process to identify and control substances with endocrine disrupting properties in **Plant Protection Products** is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting citizens by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○
Improving the functioning of the internal market	○	○	○	○	○	◉
Enhancing competitiveness and innovation	○	○	○	○	◉	○
Promoting alternatives to animal testing	○	○	○	○	○	◉

Please explain your answers

2000 character(s) maximum

The EDC identification criteria for plant protection products entered into force more than one year and a half ago, and the regulatory provisions on EDCs have been part of the regulation for almost a decade. However, no EDC has been identified. The burden of proof in the EDC identification criteria is too high, as anticipated by scientists during the development of the criteria. The direct consequence is a continued exposure to EDCs and no incentives to develop safer alternatives.

In the PP regulation, the EU legislator decided to refer to EDCs as substances "having endocrine-disrupting properties that MAY cause adverse effects". The establishment of a category for "suspected" EDCs would better reflect the available level of scientific knowledge and give full effect to the precautionary principle, that underpins the regulation. The use of independent scientific research and the need to have better data requirements with relevant endpoints would also help to improve the identification of EDCs.

11.c) The regulatory process to identify and control substances with endocrine disrupting properties under **REACH** is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting citizens by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○
Improving the functioning of the internal market	○	○	○	○	○	◉
Enhancing competitiveness and innovation	○	○	○	○	◉	○
Promoting alternatives to animal testing	○	○	○	○	○	◉

Please explain your answers

2000 character(s) maximum

The identification of EDCs is too slow, with less than 20 substances identified under REACH, while there could be hundreds of EDCs in use (see e.g. UNEP Overview Report I: Worldwide initiatives to identify endocrine disrupting chemicals (EDCs) and potential EDCs as of July 2017). The data that companies provide is often lacking the relevant EDCs' endpoints and sensitivities, and there is poor compliance with the obligations of providing and updating data. Therefore, the burden is mainly left to Member States Competent Authorities, while it should fall on the companies instead.
To improve the process, the systematic use of chemical grouping to avoid regrettable substitutions (as in the case of BPA-BPS) and the full use of the precautionary principle should be implemented.

11.d) The regulatory process to identify and control substances with endocrine disrupting properties in **Cosmetics** [2] is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Improving the functioning of the internal market	○	○	○	○	◉	○
Enhancing competitiveness and innovation	○	○	○	○	○	◉
Promoting alternatives to animal testing	○	○	○	○	○	◉

[2] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

The Scientific Committee on Consumer Safety (SCCS) has explicitly warned that the current definition of EDCs "is in sharp contradiction with the actual stringent ban on animal testing, making it almost impossible to identify ingredients of cosmetics and personal care products as having endocrine disrupting activity", and stated that "not a single validated non-animal alternative method exists for systemic toxicity"(https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3295383/feedback/F12858_en?p_id=255075). This remains a crucial issue.
The regulation could be improved also by strengthening and implementing regulatory consequences for the category of suspected EDCs, prohibiting suspected EDC ingredients, and addressing the issue of combined exposures. These issues were not addressed in the Commission review report (COM(2018) 739 final) and should be now included in this Fitness Check on EDCs.

11.e) The regulatory process to identify and control substances with endocrine disrupting properties in **Medical Devices** [3] is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Improving the functioning of the internal market	○	○	○	○	○	◉
Enhancing competitiveness and innovation	○	○	○	◉	○	○
Promoting alternatives to animal testing	○	○	○	○	○	◉

[3] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

The new Medical Devices Regulation will be fully applicable only in May 2020, and the new regulation on in vitro diagnostic medical devices will be fully applicable only in May 2022. Therefore it's difficult to understand how to respond to this question and to what it refers to.

On EDCs, the MDR makes a cross-reference to the EDC identification processes under REACH Art 59 or under the BPR. As previously mentioned, both REACH and BPR fail to properly and swiftly identify EDCs, and do not include the necessary data requirements that would be needed for effective identification. Therefore the MDR is not going to adequately protect patients or users from the exposure to EDCs.

Additionally, EDCs in the MDR will be controlled only for specific concentrations (above 0.1 % and in particular uses). A more protective approach would be to prohibit the use of known and suspected EDCs in medical devices, allowing exemptions only for essential uses (e.g. life-saving medical devices).

11.f) The regulatory process to control substances with endocrine disrupting properties under the **Water Framework Directive** is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting citizens by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○

Please explain your answers

2000 character(s) maximum

The EEA 2019 state of the environment report identified Europe as "not on track to meet the objective of minimising risks to health from hazardous chemicals by 2020". An example is the case of human and wildlife contamination from PFAS, identified as one of the emerging chemical risks in Europe, with legacy and new PFAS contaminating rivers (see for instance the recent case of cC6O4 contamination in the main Italian river https://www.arpa.veneto.it/arpav/pagine-generiche/il-composto-cc604-nel-po).
Health and societal costs fall merely on private citizens or single municipalities or member states, with a lack of coherent action and a lack of application of the polluter-pays principle.

Aggregated exposure and combined effects

Humans and wildlife can be exposed to the same endocrine disruptor via various sources (**aggregate exposure**) if this substance is present in different types of products.
Humans and wildlife can also be exposed to a combination of multiple endocrine disruptors from one or multiple sources, which may lead to combined effects (**mixture/cocktail effect**). Such effects may include additive and synergistic effects.

12) Do you agree with the following statements?

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Humans are protected by the current regulatory framework from the risks associated with the aggregated exposure to one substance with endocrine disrupting properties from all exposure sources	○	○	○	○	◉	○
Wildlife is protected by the current regulatory framework from the risks associated with the aggregated exposure to one substance with endocrine disrupting properties from all exposure sources	○	○	○	○	◉	○

Please explain your answers and provide examples

1000 character(s) maximum

The EU regulatory framework has been failing to address aggregated exposure, due to its general focus on sectoral uses of the substances and the "lack of a consistent approach across product/risk/sector-specific legislation" (see for instance the fitness check on chemicals legislation). REACH addresses aggregated exposure only partially, within the limits of its scope.

Protection could be improved if the identification of (known/presumed/suspected) EDCs in one sector/piece of legislation could trigger automatic consequences across EU law.

13) Do you agree with the following statements?

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know

Humans are protected by the current regulatory framework from the risks associated with the combined exposure to different substances with endocrine disrupting properties (combined effects)	○	○	○	○	◉	○
Wildlife is protected by the current regulatory framework from the risks associated with the combined exposure to different substances with endocrine disrupting properties (combined effects)	○	○	○	○	◉	○

Please explain your answers and provide examples

1000 character(s) maximum

As noted by the Fitness check on chemicals legislation, "Risk assessment processes...are not expressly designed to identify and assess potential human health and environmental risks of different hazardous chemicals acting in combination"; "a workable methodological framework for all chemicals has not been agreed upon. Requirements to ensure the risk assessment of combination effects exist only in some pieces of legislation...while other relevant pieces of legislation do not contain legal provisions that cater for such an assessment." The EU Horizon 2020 EDC-MixRisk project recently showed that health risks associated with combined exposures to EDCs or potential EDCs are systematically underestimated. (https://edcmixrisk.ki.se/2019/03/26/press-release-health-risks-associated-with-mixtures-of-man-made-chemicals-are-underestimated/).

Vulnerable groups

The endocrine system controls a large number of processes in the body throughout life from early stages such as embryonic development, to later ones such as puberty, reproductive life and old age. It controls formation and functions of tissues and organs, as well as homeostasis of physiological processes.

14) Do you think that the following groups are sufficiently protected from exposure to substances with endocrine disrupting properties?

	Yes	No	Don't know
unborn through exposure during pregnancy	○	◉	○
newborn up to the age of 3	○	◉	○
children until puberty	○	◉	○
young persons around the age of puberty	○	◉	○

pregnant women	○	◉	○
adults in general	○	◉	○
people at work	○	◉	○
elderly	○	◉	○
people with illnesses	○	◉	○

Please give examples of regulatory sectors in which a group is not sufficiently protected from exposure to endocrine disruptors and explain why.

2000 character(s) maximum

While there can be periods of life of particular vulnerability, exposure to EDCs is widespread and can occur on a daily basis, from multiple sources, and without people's knowledge. No group can be deemed "sufficiently" protected.
The identification of vulnerable groups is not systematically addressed across EU legislation and can create inconsistencies (see the results of the fitness check of chemicals legislation). e.g. Bisphenol A is banned in baby bottles but not in other children's products, posing children at risk to be exposed to this same substance in other products.

Data requirements and available regulatory test methods

Several EU regulations require registrants or applicants to perform some tests on the toxicity of their substance. These tests should be run according to validated test methods that are accepted by the authorities (Test Guidelines adopted at international level such as the OECD, or methods laid down in the Commission Regulation (EC) 440/2008 on test methods). Several of these tests can be used to identify endocrine disruptors.

15) Are available regulatory **tests** sufficient **to identify endocrine disruptors** for humans (including vulnerable groups) as well as wildlife?

- ○ Yes
- ○ No

16) Are current provisions for **data requirements** laid down in relevant legislation (REACH, Biocidal Products Regulation, Plant Protection Products Regulation) sufficient **to identify endocrine disruptors** for humans (including vulnerable groups) as well as wildlife?

- ○ Yes
- ○ No

17) Considering the information requirements of REACH, the Biocidal Products Regulation and the Plant Protection Products Regulation, do you think the likelihood of identifying a substance as an endocrine disruptor is lower under one of these regulations compared to the others?

- ○ Yes
- ○ No

Please explain your answer and provide examples.

1000 character(s) maximum

18) Do you have any further comments on available regulatory test methods and data requirements under REACH, the Biocidal Products Regulation, the Plant Protection Products Regulation, and other sector specific legislation?

2000 character(s) maximum

Regulatory testing and animal welfare

Data generation according to standard information requirements is expensive, time consuming and requires the use of animals. The recently adopted criteria for identifying of endocrine disruptors require information on endocrine activity and adverse effects.

19) Do you agree with the following statement?
In vitro and/or *in silico* methods are not used systematically enough to prioritise further investigations.

- Strongly agree
- Moderately agree
- Neither agree nor disagree
- Moderately disagree
- Strongly disagree
- Don't know

Please explain your answer.

1000 character(s) maximum

Regulations requiring testing for endocrine disrupting properties of a substance (Biocidal Products Regulation, Plant Protection Products Regulation, REACH) specifically require the use of vertebrate animals to be minimised, in accordance with Directive 2010/63/EU on the protection of animals used for scientific purposes.

20) In your opinion, is the impact of assessing chemicals for endocrine disrupting properties on animal welfare minimised in the EU?

- Not at all
- Insufficiently minimised
- Minimised to the extent possible
- Don't know

21) Do you have recommendations on how to further minimise the impact of assessing chemicals for endocrine disrupting properties on animal welfare?

1000 character(s) maximum

Effectiveness of regulatory procedures

The following sectors are regulated via sector-specific legislation as well as by horizontal/other legislation (e. g. REACH, Biocidal Products Regulation, CLP Regulation).

22) Are you aware of issues that result from the lack of specific provisions for **identifying** endocrine disruptors in sector-specific legislation for the following areas:

	Yes	No
Workers protection	◉	○
Toys	◉	○
Detergents	◉	○
Fertilisers	◉	○
Electrical and electronic equipment	◉	○
Food contact materials	◉	○
Food additives	◉	○
Cosmetics	◉	○
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	◉	○
Human and veterinary pharmaceuticals (only for effects on the environment)	◉	○
Water	◉	○
Waste/recycling	◉	○
Other (please specify)	○	○

Please explain your answers, including the consideration of sector-specific interconnections with horizontal legislation (e.g. REACH).

1000 character(s) maximum

There's a lack of a coherent, harmonized, hazard-based identification system for EDCs. Identification criteria should be applicable across all relevant EU law and identify EDCs in whatever product they are used, irrespective of the sector. This new horizontal identification system should use three hazard categories based on the differing strength of evidence: “known”, “presumed”, and “suspected” EDCs. The current BPR identification criteria are designed in a sectoral and narrow way, therefore should not be used across EU law.

23) Are you aware of issues that result from the lack of specific provisions for **managing** endocrine disruptors in sector-specific legislation for the following areas:

	Yes	No
Workers protection	◉	○
Toys	◉	○

Detergents	◉	○
Fertilisers	◉	○
Electrical and electronic equipment	◉	○
Food contact materials	◉	○
Food additives	◉	○
Cosmetics	◉	○
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	◉	○
Human and veterinary pharmaceuticals (only for effects on the environment)	◉	○
Water	◉	○
Waste/recycling	◉	○
Other (please specify)	○	○

Please explain your answers, including the consideration of sector-specific interconnections with horizontal legislation (e.g. REACH).

1000 character(s) maximum

Some regulations do not contain EDCs-specific provisions or specific regulatory consequences. EDCs should be prohibited, and the use of derogations be allowed only for essential uses with minimized exposure. For example, identified EDCs under REACH or BPR should be automatically prohibited in toys, FCM...
See the section "Management of EDs across sectors to protect health" from the “European Parliament - Endocrine Disruptors: from Scientific Evidence to Human Health Protection’.

24) In your view, on which areas should market surveillance authorities focus their activities to effectively enforce chemical safety of products as regards endocrine disruptors?

	Yes	No	Don't know
Plant Protection Products	◉	○	○
Biocidal products	◉	○	○
General chemicals	◉	○	○
Toys	◉	○	○
Detergents	◉	○	○
Fertilisers	◉	○	○
Electrical and electronic equipment	◉	○	○
Food contact materials	◉	○	○
Food additives	◉	○	○

Cosmetics	◉	○	○
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	◉	○	○
Human and veterinary pharmaceuticals (only for effects on the environment)	◉	○	○
Waste/recycling	◉	○	○
Other (please specify)	○	○	○

Adequacy of legislation to address needs and concerns on endocrine disruptors

In 1999 the European Commission published a Community strategy on endocrine disruptors, reflecting public concerns that these substances might cause diseases/disorders in humans and affect wildlife populations and biodiversity. Diseases/disorders in humans that are endocrine-related (i.e. via effect on the endocrine system) might result from a combination of factors such as genetic origin, diet, lifestyle, exposure to endocrine disruptors and other chemical stressors. Effects on wildlife populations and biodiversity might be caused by a combination of factors such as habitat loss, climate change, exposure to endocrine disruptors and other chemical stressors.

30) To what extent do you think exposure to endocrine disruptors is contributing to the **increase in endocrine-related human diseases/disorders**, in the EU, in comparison with other factors?

- ◉ To a significant extent
- ○ Not to a significant extent
- ○ Not at all
- ○ Don't know

31) To what extent do you think exposure to endocrine disruptors is contributing to the **decrease in aquatic and terrestrial biodiversity** in the EU, in comparison with other factors?

- ◉ To a significant extent
- ○ Not to a significant extent
- ○ Not at all
- ○ Don't know

The 1999 Community strategy highlighted the need for research and development of new tools to understand the mechanisms of endocrine disruption.

32) Is the regulatory framework flexible enough to take into account new scientific information and methods in the assessment of endocrine disrupting properties (e.g. new toxicological tests, (bio)monitoring data, (eco)epidemiology)?

- ○ Yes
- ◉ No

Please explain your answer with examples for specific regulated areas.

1000 character(s) maximum

33) Do you have any further comments on the adequacy of legislation to address societal needs and concerns on endocrine disruptors?

2000 character(s) maximum

The lack of transparency and information on EDCs hinders informed consumer choices and needs to be implemented. However, information on EDCs must follow their presence across the value chain and needs to come hand in hand with regulatory consequences, such as the prohibitions of the use of EDCs in certain products in the first place. EU legislation is the most adequate tool to address this need. The reduction of exposure to EDCs cannot be a personal choice but must be fulfilled through the implementation of adequate legislation that protects human health and the environment.

The elimination of exposure to EDCs must be achieved through legislation, and adequate regulations can also help promoting and respecting human rights, such as the right to information, workers' rights, the right to a healthy and sustainable environment, women rights, children's rights, rights to food and water (see e.g. UN Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes, e.g. the latest Report on the Duty to Prevent Exposure).

Added value of EU level intervention

There have been instances where Member State authorities have taken unilateral action on endocrine disruptors before a decision has been taken at the EU level. For example, in October 2012, the French authorities introduced a ban of Bisphenol A in all Food Contact Materials, applicable from July 2015.

34) Do you think:

- ○ This is not justifiable – decisions should be taken at EU level and all citizens of the EU should be protected in an equal way, while preserving the integrity of the single market.
- ○ This is justifiable, but it should be followed by an EU wide action to preserve the integrity of the single market.
- ◉ This is justifiable in some cases – protection of human health or the environment is more important than preserving the integrity of the single market.
- ○ This is justifiable – endocrine disruptors should not be regulated at EU level.

Under which circumstances do you think that a decision at national level would be justifiable?

1000 character(s) maximum

Member States authorities should be allowed to take unilateral action and protect the health of their population and environment in case of EU inaction. While harmonization must be reached to ensure the same level of protection across the EU, it should not be used as an excuse to apply only the common lower denominator. Unilateral actions from Member States could also be beneficial for the whole EU leading the EU to adopt a common and higher level of protection.
In case of unilateral action from Member State, it would be beneficial to trigger a system of automatic review /assessment by the EU Commission or relevant scientific body, in a short timeframe, in order to ensure the extension of harmonized protective measures across the EU.

36) Do you have any further comments on the added value of regulating endocrine disruptors at EU level?

1000 character(s) maximum

The regulation of EDCs at the EU level can set an example for the rest of the world. The EU would drive the leading regulatory framework in international chemicals fora such as SAICM ICCM5 and the future

international framework on chemicals and waste beyond 2020. It would also contribute to achieving the SDGs. There would also be health benefits for future generations (e.g. on neurodevelopment, fertility, and overall hormone-related diseases). In the internal market, EU regulation can build consumer trust, boost innovation for safer chemicals and non-chemical alternatives, and increase competitiveness; it would also be a prerequisite to the EU Green Deal strategies, creating a true transition to a "toxic-free" circular economy and to an agricultural system based on agroecology.

Useful links

European Commission central information portal on endocrine disruptors (https://ec.europa.eu/info/policies/endocrine-disruptors_en)

Harmful chemicals endocrine disruptors, review of EU rules (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-2470647_en)

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