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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

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50 character(s) maximum

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* Organisation name

50 character(s) maximum

Fundacion Alborada

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)

* 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 EDC-Free Europe coalition shares the views presented by leading scientific experts in the March 2019 European Parliament report “ED: from Scientific Evidence to Human Health Protection” (p. 80).

- Identification of EDCs must be based on a unique cross sectoral definition of EDCs, distinguishing known EDCs, presumed EDCs and suspected EDCs.
- In the case of sector-specific assessment and to avoid protection gaps and incoherence, the recognition of a substance as an ED in one sector must automatically entail its recognition as an ED with the same level of evidence in all other sectors.

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

A hazard category in CLP/GHS could be one way of achieving a more coherent identification system. However, improving EDC identification is the most urgent step for increased regulation and reduction of exposure. This can happen today without awaiting an agreement on a new category in the CLP and should not be blocked by its absence. A coherent cross-cutting identification system could also be achieved with a separate overarching umbrella identification system. An international agreement on a GHS category will take years and should not delay identification and regulation upgrades in the EU.
Re3) Introducing a hazard category in the CLP/GHS could help recognize that EDC hazard is at least equivalent to that of CMRs. The CLP should also be amended to include the environmental consideration of EDCs. Re 4) Improving the coherent risk management of EDCs across sectors also requires changes for better risk management decisions in the sectoral legislation.

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

EDC characterization should be done according to the 3 categories (known, presumed, suspected).This is coherent with current approaches to rank other chemicals, e.g. how cancer-causing chemicals are classified. It allows to provide transparent communication on a given chemical according to the level of scientific evidence available and given the current limitation of test methods. Several Member States (e.g. Denmark, France) are already taking initiatives to have a list of “suspected EDCs” and this should be the norm also at EU level with the aim to achieve a high level of health and environment protection and to implement the precautionary principle. Categorisation as suspected EDCs should result in a ban with possibility for specific derogations, in cases where essential uses can be demonstrated and no suitable alternatives exist. It should also lead to adequate information being communicated to the supply chain, workers, and consumers (through clear labelling). The system of three categories is very transparent and allows for an effective and efficient use of resources by focusing regulatory action in differentiated ways according to the categories. With more transparent information on the status of a given chemical companies can make smart choices, consider and invest into safer alternatives to drive sustainable innovation.

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

EDCs are identified and regulated across different EU legislative frameworks which vary very much in their approaches: in the context of pesticides and biocides regulations, EDCs are regulated based on hazard-based cut-offs while other frameworks such as cosmetics or toys regulate endocrine disruptors based on case-by-case risk assessment. Identification of EDCs under REACH does not result in automatic consequences for other regulations (for example BPA is restricted under REACH yet still allowed in food contact materials other than polycarbonate infant feeding bottles). Furthermore EDCs should be regulated by using group approaches based on similar structures and similar properties to avoid regrettable substitution. These differences give rise to inconsistencies in how endocrine disruptors are regulated and hinder adequate protection of people’s health, wildlife and the environment.

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

- EDCs identified under REACH do not trigger regulatory consequences under other EU legislation. In addition, the time lag between identification and regulation via authorisation takes years. In this transition time, identification of EDCs under REACH should lead to an automated restriction for use of these EDCs in consumer products such as toys, cosmetics and FCM and specific measures to urgently protect vulnerable groups across sectors.
- Where regulations technically allow for ED management, test requirements for EDCs are inadequate (including REACH, pesticides, biocides, and medical devices).
- To date, ED regulatory options have not allowed for the ban of any substance under either pesticide or biocide laws.
- EDCs should be regulated with the presumption that no safe threshold for exposure can be set with sufficient certainty.

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

- ( ) Yes
- (●) No

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

2000 character(s) maximum

The lack of coherence of EU legislation with regard to ED has repeatedly been pointed as a major issue to be addressed: see EDC-Free Europe “Our eight demands for an EU EDC strategy” May 2018; see European Parliament Resolution 19 April 2019, Environment Council conclusions June 2019, Study for the European Parliament “Endocrine Disruptors: from Scientific Evidence to Human Health Protection (March 2019) section 4.1.2 “The heterogeneous regulation of EDs in different sectors is hard to justify scientifically” section 4.1.3 “Even with specific sectors, management of EDs generally lacks coherence”, “There are surely historical or political reasons for this lack of coherence, but the situation seems hard to justify from scientific and public health standpoints, especially when considering the core principles of the EU such as the Precautionary principle and the 7th EAP”.

In the past four years, the EC worked on three major evaluations within the EU chemicals policy. All the results from these evaluations pointing at the gaps and actions needed are now available in addition to the studies and political requests listed above. In their letter of 8 November 2019 to EC President “A chemicals strategy as part of the European Green Deal: time to deliver”,24 leading environmental and health groups clearly exposed the follow up work urgently needed in order to develop a long-term overarching chemicals regulatory framework for 2030 and beyond, including as regard to coherence for EU legislation with regard to ED.

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

While in principle requisite tools are in place for the implementation of the Biocides Product Regulation (BPR), since the adoption of the criteria in June 2018, only two biocides active substances have been identified without leading to any ban. The work program is delayed by years.
There are little perspectives for improvements towards better health protection from biocides in the short term. The data sets are old and inadequate in the context of their implementation, and the EU EDC criteria require a high burden of proof. People are being exposed without having any knowledge about it.

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 criteria for the identification of EDCs under the Plant Protection Products regulation are too restrictive. They are limited to ED tests available and the most sensitive tests for EDs have not been delivered for pesticides. Furthermore, assessors are facing the problem of data gaps: and people continue to be exposed to such chemicals: according to EFSA, for 17 substances assessed since 2018 dossiers had data gaps and conclusions could not be drawn. This not only creates delays but also presents the risk of not identifying an EDC substance as such. Consequently, citizens and the environment continue to be exposed to such chemicals. Since their entry into force in November 2018, no pesticide active substance has been identified as an EDC. In the meantime, active substances that would be considered as typical endocrine disruptors by the scientific community such as chlorpyrifos (see Endocrine Society) are not considered as such by EFSA (see EFSA statement on chlorpyrifos, 2019). At the time of their adoption public health and scientific community had expressed strong concerns about the unfit character of the criteria to identify substances posing a threat to human health and the difficulty to use independent scientific evidence as a basis for identification in their implementation.

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 substance by substance assessment for the identification of EDCs under the REACH regulation is a long process and only 16 substances have been identified since December 2011, when octylphenol was identified as the first ED under REACH. However, the nonprofit research institute the Endocrine Disruption Exchange (TEDX) lists over 1,400 potential EDCs, the WHO mentions over 800 EDCs, and many more suspected EDCs still need to be investigated. The process places a high burden of proof on the authorities while it should be on industry (no data, no market). Bisphenol A, one of the world's most documented chemicals, was only identified as an EDC under REACH in 2017. The test requirements under REACH are not up to date to account for all the information relevant to ED properties.

As a data generation system, REACH still fails on EDCs: substances with low tonnage or intermediate use are not submitted to sufficient data requirements upon registration; current data requirements have limited to no capacity to provide assessors with data on ED properties; poor compliance with the obligation to provide and update data also creates obstacles to proper assessments.

SVHC identifications need to be quicker, which requires to use the category of ‘suspected EDCs’ in the evaluation and identification processes, to systematically apply grouping, as it should have been done for BPA/bisphenols, and the substances already on an EU or national EDC list or regulation should directly enter the candidate list. In addition Article 57(f) should be amended so that an equivalent level of concern (ELOC) does not have to be established for EDCs.

Furthermore, there is a large time lag between the identification of a substance of an ED and the risk assessment process leading to its regulation.

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) indicated concerns that EDCs in cosmetics will not be identified (June 2018) (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3295383 /feedback/F12858_en?p_id=255075), stressing that the “results obtained for a cosmetic ingredient using non-animal alternative methods (in silico, in vitro, ex vivo, omics technology, etc.) can only be indicative of endocrine activity and will not give information whether the substance can cause adverse effect(s) in an intact organism, thus whether it should be regarded as an endocrine disruptor or not. Indeed, it should be clearly noted that until today not a single validated non-animal alternative method exists for systemic toxicity”. The recent Commission review from December 2018 ignores this warning from SCCS . The Commission highlights in its review the ban on a number of parabens (cosmetic ingredients used as preservatives) as an example of risk identification and management of endocrine disruptors. However, five of the parabens that were banned in 2014 were banned because the industry chose not to defend the substances (limited or no data were submitted by industry to the SCCS which therefore could not evaluate their risk to human health – see Commission regulation point 7: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0358) EDCs should in any case be banned from cosmetics as no essential use can be justified.

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

Currently, vulnerable populations (in particular premature babies and patients undergoing haemodialysis) are often highly exposed to EDCs (above safe levels) in intensive care situations, notably to DEHP and BPA, even if in many cases the safer alternatives exist. On the European market, several manufacturers offer EDC-free (phthalate and/or BPA-free) medical devices for nearly all product categories. Still, phasing out EDs in medical devices is so far driven by commitment and demand from individual hospitals and NOT by existing regulations (with French law being an exception in the case of one phthalate: since 1 July 2015 tubing/pipes containing DEHP have been banned for use in paediatric, neonatal, and maternity departments in hospitals in France).
The identification of EDs in medical devices refers to the ED criteria specified as part of the biocidal products regulation, with the test requirements related to REACH regulation - these are too limited to allow proper identification of EDs in those devices. The use of substances identified as EDs for humans in medical devices is not efficiently controlled because:
1) The existence of general exemption from REACH - an application for authorisation is not required for an ED substance used in a medical device.
2) The new medical devices regulation (MDR) requires a justification of the presence of EDs (above a concentration of 0.1% weight by weight) ONLY in some (i.e. invasive) medical devices - and even then manufacturers need to perform a benefit-risk assessment (BRA) which may result in justification for continued use of the endocrine disruptor OR its substitution.
We are currently facing delays in implementation of the MDR and lack transparency for how many medical devices such BRA will effectively result in substitution of EDs when safer alternatives are available and technically feasible.
3) If an ED compound has a history of use, then its ongoing use is often assured.

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 Water Framework Directive (WFD) is not effective in protecting citizens from exposure to endocrine disruptors. The recent REFIT exercise pointed to a lack of coordination observed between the measures

taken under the WFD and those resulting from the chemicals regulations such as REACH, hindering the control of the pollution at the source and limiting the effectiveness of the WFD.
Only the drinking water directive now sets a limit value for bisphenol A, reduces the limit values for essential parameters (eg lead), introduces limit values for a number of PFAS. This is not enough to quantify or efficiently limit the impact of ED from drinking water exposure. The new watchlist for a number of substances (including EDCs beta-estradiol and nonylphenol) doesn't trigger automatic policy action to reduce their presence. Overall this is way too weak to protect humans and the environment, especially considering that detection of EDCs in the water means emissions have already occurred and large parts of the population are widely exposed on a daily basis. Finally, the burden of monitoring and follow up action weighs mostly on public authorities and the taxpayers instead of being on the companies which are releasing the chemicals into the environment. These have virtually no obligation regarding ED assessment. This is a striking breach of the polluter pays principle.
See Report from Generations Futures (April 2019) regarding the presence in the "French departements studied" of an average of 41 active substances potentially ED .
Options to limit the source of contamination in drinking water by ED and other hazardous chemicals , including from drugs should be outlined and and considered (Treatment of water, specific collection and treatment of the urine of patients using specific drugs, of effluents from hospitals…)

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 limitations and gaps of the current EU regulatory framework to assess EDCs and protect humans and wildlife from daily exposure to mixtures of chemicals from multiple sources, including food are widely exposed and acknowledged (see results of tests on children and adults hair - KEMI 2015, Generation Futures Jan 2019- 40 to 62 chemical substances found including EDCs, cancer causing chemicals etc - to be considered in combination with the known low dose effect of EDCs); see results of tests on plastic dishes and plates used everyday in primary school restaurants in French schools (Cantines sans plastique France), analysis of dusts analysis of official monitoring of freshwater contamination (Generations futures), results of biomonitoring programs. This has been highlighted in the Commission's own studies and reviews (supporting study on a non-toxic environment, chemicals fitness check, EU H2020 research programs). June 2019, Environment Council conclusions called on the Commission "to

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

EDCs end up in all of us – children and adults alike – contaminating our bodies without our consent or knowledge. Human biomonitoring samples of urine, hair and blood across Europe are starting to demonstrate the extent of that internal pollution. In France, over 20 EDCs were found in women tested for

the presence of these chemicals in 2015. The scientific community has made proposals since to address the challenge of mixtures and start adapting risk assessments accordingly (See reports from 2009 onwards). According to recent findings from the EU funded EDC MixRisk project, health risks associated with combined EDC exposures are currently systematically underestimated, leaving people unprotected. Exposure to mixtures of EDCs at the prenatal stage has been associated with adverse health and development effects of children in three domains: sexual development, neurodevelopment and metabolism and growth.

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

Scientists have repeatedly voiced concerns about EDCs as they are contributing to the dramatic increases of serious diseases and health disorders, such as reproductive and fertility problems, breast, prostate and testicular cancers, effects on brain development and nervous system problems, and obesity and diabetes. Recent biomonitoring studies from across Europe have shown that people in the general population are typically contaminated with several chemicals including EDCs. Special care should be taken to reduce exposures before and during pregnancy, in early childhood, and during puberty. Many people come into contact with EDCs on a daily basis including from consumer products, indoor air, water, food or from the workplace. See reports from Women in Europe for a Common Future on pregnancy and exposure to chemicals including EDCs, reports from ChemTrust, HEAL, Study for the European Parliament... etc. Former Environment Commissioner Vellas acknowledged in his speech for 1st EC Stakeholder forum on EDC on 8 November that endocrine disrupting chemicals are of special concern as they “affect people, and animals,

when the body is particularly vulnerable, such as during conception, embryonic and foetal development, early childhood, or puberty" and that "the effects are permanent and they can sometimes be observed even in the next generation".

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

Which tests should be developed?

1000 character(s) maximum

Please refer to results of EC REACH Review & Study for the European Parliament "Endocrine Disruptors: from Scientific Evidence to Human Health Protection", March 2019, sections 4.4 and 4.5 - p.86 " There is an urgent need, not only to accelerate test development and validation, especially in areas beyond E, A, T, S (which are currently insufficiently covered, in particular for the thyroid axis), but also for regulators to use academic publications when assessing ED properties as clearly stated in the ECHA-EFSA Guidance document".

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

Please specify what requirements you would add or modify in each piece of legislation.

1000 character(s) maximum

EU Commission support study on the non-toxic environment and the REACH review acknowledge the inadequacy of data requirements for the identification of EDCs. Tests required under REACH do not include all relevant endpoints and there is no mandatory screening for ED properties for "low volume chemicals". EDC-Free Europe welcomes the recent process to update REACH test requirements and ongoing one to adapt those of the pesticides and biocides legislations following the adoption of the EFSA/ECHA guidance. We call on the EC to pursue these processes without further delay. The minimum step would be to bring the requirements of all regulations at least in line with the OECD guidance document 150, although it is still far from covering all relevant ED endpoints. In addition it is essential that independent peer-reviewed scientific literature is taken into account to feed into identification.

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

All provisions for data requirements should include a systematic screening for ED-properties as a first step to inform, support and prioritize further testing/investigations. These tools should also be used much more systematically in the work for grouping of substances: grouping substances for regulation, to group substances and subsequently avoid unnecessary testing of similar chemicals and to group chemicals with the aim of initiating supportive testing.

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

The current incoherence of the regulatory framework leads to re-testing chemicals under many frameworks - incoherence leads to many unnecessary animal tests.
A system of centralised testing - “joint/common testing center” financed by industry and staffed by public authorities would provide the necessary coordination and help avoiding repetition of tests and better sharing of data results, as well as increase the public’s confidence regarding conflicts of interests and independence of testing results.

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

EDCs are nearly everywhere, both at home and in the workplace: from high-profile substances, such as the bisphenols used in the making of certain plastic bottles and can linings, and restricted phthalates that are still found in one out of five toys; the flame retardants used in sofas; the pesticides sprayed on and ending up in our food; and the antimicrobial biocides found in cleaning products. These situations result from the lack of adequate provisions to effectively identify EDCs across sectors (see response to question 2) and to take the necessary risk management measures in each relevant law and sector (see answers to questions above).

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

Please see the response to question N°6. Some of these regulations do not mention EDCs at all. Others do but without making a link to an identification process or to clear regulatory actions as a consequence to the identification as EDC (or future category of “suspected EDC”). EDC identification under one regulation such as REACH should automatically trigger risk management measures for the same substance under all the other relevant regulations. Please also see Study for the European Parliament, “Endocrine Disruptors: from Scientific Evidence to Human Health Protection’, European Parliament, March 2019, p. 91.

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

EDC-Free Europe stressed in May 2018 “Eight demands for an EU EDC Strategy” the need to respond more swiftly to early warning signals from new scientific findings about potential health or environmental damages in re-approvals and authorisations of substances, or in emergency cases. This is in line with the precautionary principle embedded in the EU Treaty.
The current regulatory framework is often referring to specific tests in the EU test method regulation which is not systematically updated when new OECD tests have been agreed upon. There is therefore a time lag between the adoption of a test method and the practical implementation and use in the EU. Likewise, many EU guidance documents are not systematically updated when new test methods, assessment methods or new sorts of data are available. The regulatory framework should be constructed in a way that immediately allows for including new scientific data and methodologies.

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

Avoiding EDCs is not a choice that a person can make anymore. EDCs are found everywhere in our daily lives: from high-profile substances, such as the bisphenols used in the making of certain plastic bottles and can linings, and restricted phthalates that are still found in one out of five toys; the flame retardants used in sofas; the pesticides sprayed on and ending up in our food; and the antimicrobial biocides found in cleaning products. They are nearly everywhere, both at home and in the workplace. WHO/UNEP refers to EDCs as a “global threat that needs to be resolved”. The unanymous call from the scientific community (see The Endocrine Society, Position Statement: Endocrine Disrupting Chemicals in the European Union 1st May 2018) the 2019 European Parliament Resolution on EDCs as well as June 2019 Council Conclusions and Opinion of the European Committee of the Region in response to the delay of the European Commission Strategy on EDC clearly reflect the consensus on the urgency to act to upgrade EU legislative and policy framework on EDCs without further delay.
Furthermore, the available estimates of the burden of diseases of EDCs all point to the huge economic opportunity of prevention through increased regulation. The best conservative estimate of health costs arising from EDC exposure is of 163 billion euros/year in Europe (Trasande et al., 2016). The Commission’s own support study on the Non-Toxic Environment highlights an annual €1.5 billion for female reproductive disorders and diseases in the EU as a result of exposure to EDCs. With current trends, those figures are

expected to keep increasing until regulation is substantially improved with full implementation of the precautionary and the polluter pays principles.

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

Ideally, all measures taken to protect people and the environment should cover the entire EU. However, given the delay exposed to take action at EU level and the gaps of the EU regulatory framework, when there are new evidence or a reassessment of existing information indicating an unacceptable danger to human health or the environment and a need to avoid postponing protection, action of national authorities is to be justified when EU wide measures are uncertain or delayed.
In the past, single action by individual member states has often led to EU action and positively contributed to the protection goals as well as societal costs.

- In general the benefits of EU chemicals legislation (hugely) outweighs the costs (ref: Fitness check)
- The second REACH review reached the same conclusion
- Scientist estimates that the annual cost to the EU of ED exposures is 163 bn

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

1000 character(s) maximum

Building on the results of the extensive assessments of its chemical regulations carried out over the last few years but also on the comprehensive scientific expertise developed through the different EU national and international research programs, the European Union is in a unique position to effectively address the shortcoming of its regulatory framework on EDCs and respond to the tremendous societal, health and environment challenges that EDCs are posing, thus contributing to the key component of the European Green Deal: sustainable chemicals strategy, circular economy action plan, farm to fork strategy, and the EU' s action plan on cancer.
The initiatives taken by some member states in the absence of an updated EU strategy on EDCs and given the growing scientific concerns and citizens awareness demonstrate the urgency to act at EU level to ensure a high level of health and environment protection throughout the EU and in particular for vulnerable groups.

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/initiati/ares-2019-2470647_en)

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