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

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Introduction

Scope and objectives

In its <u>Communication</u> '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,

The aims of this stakeholder survey are:

efficiency, relevance and EU added value.

- 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 <u>public survey</u>.

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**.

Allowers 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
Alexandra
Surname
50 character(s) maximum
Caterbow
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50 character(s) maximum
alexandra.caterbow@hej-support.org
Organisation name
50 character(s) maximum
ou character(s) maximum
Health and Environment Justice Support

Count	ry of origin of your organisation
0	Austria
0	Belgium
0	Bulgaria
0	Croatia
0	Cyprus
	Czechia
	Denmark
	Estonia
	Finland
	France
0	Germany
	Greece
	Hungary
	Ireland
	Italy
	Latvia
	Lithuania
	Luxembourg
	Malta
	Netherlands
	Poland
	Portugal
	Romania
	Slovak Republic
	Slovenia
	Spain
	Sweden
	United Kingdom
0	Other (Please specify)
* Scope	
<u> </u>	International
0	National
	Regional
	Local
* Organ	isation size
0	Micro (1 to 9 employees)
	1 7 /
	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	0	0	•	0
Residues of Pesticides Regulation (EC) 396/2005	0	•	0	0
Biocidal Products Regulation (EU) 2012/528	0	0	•	0
REACH Regulation (EC) 1907/2006	0	0	•	0
CLP: Classification, Labelling and Packaging of substances and mixtures (EC) 1272/2008	0	0	•	0
Persistent Organic Pollutants Regulation (EC) 850/2004 and (EU) 2019/1021	0	0	0	•
Food Contact Materials Regulation (EC) 1935/2004	0	0	•	0
Contaminants in Food and Feed Regulation (EEC) 315/93 and Directive (EC) 32/2002	0	•	0	0
Food Additives Regulation (EC) 1333/2008	0	•	0	0
Cosmetic Products Regulation (EC) 1223/2009	0	0	0	•
Medical Devices Regulation (EU) 2017/745	0	•	0	0
<i>In vitro</i> Diagnostic Medical Devices Regulation (EU) 2017 /746	•	0	0	0
Toy Safety Directive 2009/48/EC	0	0	0	•
Fertilisers Regulation (EC) 2003/2003 and Regulation (EU) 2019/1009	0	•	0	0
Detergents Regulation (EC) 648/2004	0	©	•	0

Medicinal Products for Humans Directive 2001/83/EC	0	•	0	0
Veterinary Medicinal Products Regulation (EU) 2019/6	•	0	0	0
General Product Safety Directive 2001/95/EC	0	0	•	0
Water Framework Directive 2000/60/EC	0	0	•	0
Priority Substances Directive 2013/39 EC	0	0	•	0
Drinking Water Directive 98/83/EC	0	•	0	0
Groundwater Directive 2006/118/EC	0	•	0	0
Marine Strategy Framework Directive 2008/56/EC	0	•	0	0
Urban Waste Water Directive 91/271/EEC	•	0	0	0
Chemical Agents at Work Directive 98/24/EC	0	•	0	0
Carcinogens and Mutagens at Work Directive 2004/37/EC	0	0	•	0
Pregnant Workers Directive 92/85/EEC	0	0	•	0
Young People at Work Directive 94/33/EC	0	0	•	0
Waste Directive 2008/98/EC	0	0	•	0
Restriction of the use of certain hazardous substances in Electrical and Electronic Equipment - Directive 2011/65/EU	0	0	•	0
Industrial emissions Integrated Pollution Prevention and Control Directive 2010/75/EU	0	0	•	0
Seveso-III-Directive 2012/18/EU	0	0	•	0
Ambient Air Quality and Cleaner Air for Europe Directive 2008/50/EC	•	0	0	0
Regulation (EC) 66/2010 on the EU Ecolabel	0	0	•	0

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 absence of harmonized criteria for EDs is a sever problem to a coherent approach for identification.

- Currently different EU laws and regulations require different levels and ways of identification, which lead to incoherences in the level of protection of human health and the environment.
- Identification gaps and therefore insufficient regulation include many consumer products, such as toys, cosmetics, food contact materials, which can contain numerous EDs, but also the safety at the workplace, especially for pregnant women.
- A horizontal approach to identify EDs is needed, based on a unique cross sectoral definition of EDs, distinguishing known EDs, presumed EDs and suspected EDs, as mentioned in the European Parliament report from March 2019. Once this identification scheme is in place, the identified substances can be regulated on the identified hazards in all respective EU laws, similar to PBTs or CMRs.

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 categ	ory covering endocrine	disrupting properties	in the CLP
Regulation and/or GHS	poses a problem for th	ne coherent identificati	on of endocrine disru	ptors?

- 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

Highest priority for regulators and policy makers should be to improve the EU regulatory framework by developing a unique cross-cutting horizontal identification scheme, being applied to all relevant regulations and laws in the EU to reduce exposure significantly. This should happen immediately without waiting for a lengthy negotiation process in CLP or GHS to come to an agreement. In general, a hazard category in CLP /GHS is something that can be very useful, showing that EDC hazard is at least equivalent to that of CMRs. A hazard category in GHS is important, especially to advance the regulation of EDs in non-EU countries. The CLP should be amended to include environmental considerations of EDs, to be best equipped to address them.

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

O 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

Similar to CMR substances, an identification system that includes known EDCs, presumed EDCs and suspected EDCs is urgently needed. This will help policy makers and risk managers to prioritize their actions, and provides early warnings for producers, users and regulators about substances that might be known or presumed EDs if more data is available. It also gives direction for further research. The concept of three categories, where the degree of concern is based on available evidence works very well with e.g. CMRs. Several EU Member States like Denmark and France already started initiatives listing suspected EDCs, and the EU should take on this concept as well. EDCs categorized as "suspected" should result in a ban with the 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 whole supply chain, workers, and consumers (through clear and meaningful labelling). To achieve a non-toxic circular economy forward thinking and transparency is key.

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

O No

Please provide examples and describe the consequences.

2000 character(s) maximum

There are inconsistencies in the EU legislative frameworks regarding EDs, and some of them also have been described in the Chemicals Fitness Check (2018):

- in the biocides and pesticides context EDs are being regulated based on hazard-based cut-offs, whereas in e.g. the cosmetics or toys directives EDs are being regulated on a case-by-case risk assessment. In HEJSupport view, EDs should be treated as non-threshold substances. Therefore, a case-by-case risk assessment does not guarantee a high level of protection, given the many uncertainties exist in risk assessment of EDs, especially for vulnerable groups such as children and pregnant women.
- The case of substitution of BPA with other harmful bisphenols, demonstrates that regulation applying a group approach, based on similar structures and properties, is urgently needed to avoid regrettable substitution.
- Identification of a substance or a group of substances as EDCs (pesticides/biocides/industrial chemicals)

under REACH should automatically trigger restrictions or bans in other regulation, such as for e.g. toys, cosmetics, food contact materials. Currently this is not the case, e.g. BPA is restricted under REACH, but still allowed in food contact materials.

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	0	0	0	0	•	0
Environmental protection	0	0	0	0	•	0
Functioning of the internal market	0	0	0	0	•	0
Competitiveness and innovation	0	0	0	•	0	0

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	0	•	0	0	0	0
Environmental protection	0	•	0	0	0	0
Functioning of the internal market	0	•	0	0	0	0
Competitiveness and innovation	0	0	•	0	0	0

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
 - O No

Please provide examples and describe the consequences.

1000 character(s) maximum

On 7b) It is questionable and probably not possible to set safe levels of EDs, therefore risk assessment includes too many uncertainties.

Gaps:

- EDs should be treated and regulated as non-threshold substances (see above)
- EDs should be regulated using a group approach, where possible (see above)
- EDs identified under REACH should automatically trigger regulatory consequences under other EU legislation, especially automated restrictions and ban in consumer products and in regulating protection of workers and vulnerable groups. There is a long time lag between EDs identified under REACH and their regulation via authorization. During that time the automated restriction should come into effect.
- 9) Have you experienced issues or problems because endocrine disruptors are regulated differently in the EU compared with non-EU countries?
 - Yes
 - O No

If yes, please provide examples and describe the consequences.

1000 character(s) maximum

As EDs are mostly unregulated in many non-EU countries (with some exceptions such as the better regulation of BPA in children's products e.g. sippy cups in India) the EU plays a frontrunner role in the identification and regulation of EDs. In HEJSupport view this should lead to strong support by the EU and its MS for EDC exposure reduction and capacity building Imported products often contain restricted or banned EDs, such as phthalates. Information on EDs in products is provided randomly to consumers via official or NGO reports on product testing. There is a lack of adequate information, surveillance, enforcement and regulation (only REACH restriction regulate imports) in the EU.

EU based companies export chemicals and pesticides, which are restricted or banned in the EU to non-EU countries (see pic report 2018). This has severe negative consequences for the environment and people's health in countries that mostly do not have effective chemicals management and regulation in place.

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 EDs causes an insufficient level of protection for human health and the environment, especially for vulnerable groups. The delay in implementing stricter regulation, foremost in legal frameworks that should protect consumers/citizens and workers contradicts the precautionary principle. The European Parliament, the Endocrine Society, FIGO, and the EDC-free Coalition

have called repeatedly on the EU Commission to address this lack of coherence. Additionally, the European Commission has worked on three major evaluations of the EU chemicals policy in the last three years. Their results point at the existing gaps and actions needed. For the EU Commission it is time to deliver now.

- Double standards exist for virgin and recycled products (e.g. lead or DEHP in recycled PVC). For both materials the same standards and level of regulation should apply to avoid toxic recycling.
- Supply chains are often global and therefore transparency regarding hazardous chemicals and full disclosure of ingredients in products and materials along the whole supply chain should be mandatory, to enable informed choices for consumers, downstream producers and investors.
- Chemical pollution of air, soil and water should be addressed also by upstream regulation (REACH, product related directives)
- The protection of vulnerable groups must have a high priority in regard to EDs. EDs should be banned / severely restricted in environments where pregnant women live and work and where children live and play.

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	0	0	0	0	•	0
Protecting workers by minimising exposure to endocrine disruptors	0	0	0	0	•	0
Protecting citizens by minimising exposure to endocrine disruptors via the environment	0	0	0	0	•	0
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	0	0	0	0	•	0
Improving the functioning of the internal market	0	0	•	0	0	0
Enhancing competitiveness and innovation	0	0	•	0	0	0
Promoting alternatives to animal testing	0	0	•	0	0	0

Please explain your answers

2000 character(s) maximum

The implementation of the BPR is not sufficiently working. The identification process is not effective and takes too long. Since the adoption of the BPR in 2018 only two substances have been identified as ED, but none of them have been banned, yet. The EU EDC criteria in place for the BPR require a very high burden of proof, which leads to biocide products containing EDs still being on the market exposing people. Still there are many products on the market containing EDs (see PAN Germany: Endocrine disrupting biocides. Why highly hazardous biocides must be phased out, 2014)

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	0	0	0	0	•	0
Protecting workers by minimising exposure to endocrine disruptors	0	0	0	0	•	0
Protecting citizens by minimising exposure to endocrine disruptors via the environment	0	0	0	0	•	0
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	0	0	0	0	•	0
Improving the functioning of the internal market	0	0	•	0	0	0
Enhancing competitiveness and innovation	0	0	•	0	0	0
Promoting alternatives to animal testing	0	0	0	0	0	0

Please explain your answers

2000 character(s) maximum

Similar to the BPR in the PPPR the identification criteria are a too high burden of proof and not fit for purpose. This leaves too many pesticides containing EDs on the market. Up to now not one pesticide has been identified as an endocrine disruptor, although several active substances are on the market, which are known to be endocrine disruptors, e.g. chlorpyrifos (identified as endocrine disruptor by the Endocrine Society but not by EFSA (2019)).

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	©	0	0	0	•	0
Protecting workers by minimising exposure to endocrine disruptors	0	0	0	0	•	0
Protecting citizens by minimising exposure to endocrine disruptors via the environment	0	0	0	0	•	0
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	©	0	0	0	•	0
Improving the functioning of the internal market	0	0	•	0	0	0
Enhancing competitiveness and innovation	0	0	0	0	•	0
Promoting alternatives to animal testing	0	0	•	0	0	0

Please explain your answers

2000 character(s) maximum

Since December 2011 only 16 substances have been identified as EDCs under REACH. The substance by substance assessment process takes too long and therefore control measures are not being applied. Compared to the 16 identified EDCs under REACH, the non-profit research institute Endocrine Disruption Exchange (TEDX) lists more than 1400 potential EDCs, and the WHO mentions over 800 EDCs. This shows that REACH has to speed up and enhance identification of EDCs, and apply a grouping approach. Data generation in REACH fails on EDs as substances with low tonnage or intermediate use are not submitted to sufficient data requirements upon registration. The data requirements are not fit to provide adequate data on ED properties.

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	0	0	0	0	•	0
Protecting workers by minimising exposure to endocrine disruptors	0	0	0	0	•	0
Improving the functioning of the internal market	0	0	•	0	0	0
Enhancing competitiveness and innovation	0	0	•	0	0	0
Promoting alternatives to animal testing	0	0	•	0	0	0

[2] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

The current system does not provide for identification of ingredients with ED properties by the SCCS. This has been raised as a concern by the SCCS as well (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3295383/feedback/F12858_en?p_id=255075)

The decision by SCCS to presume that safe dose can be identified is of severe concern, as current science indicates. Therefore, EDs should be treated as non-threshold substances. In the view of HEJSupport there are no safe thresholds for EDs, especially when they are ingredients in products used by pregnant women and children.

The Cosmetic Regulation should recognize and apply the category of suspected EDCs, consider EDCs as non-threshold substances, ban all known and suspected EDCs automatically, address possible cocktail effects and the migration of EDCs from packaging into the cosmetics.

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	0	0	0	0	•	0
Protecting workers by minimising exposure to endocrine disruptors	0	0	0	0	•	0
Improving the functioning of the internal market	0	0	•	0	0	0
Enhancing competitiveness and innovation	0	0	•	0	0	0
Promoting alternatives to animal testing	0	0	•	0	0	0

[3] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

EDCs like BPA and DEHP still are being used in medical devices in the EU. Therefore often vulnerable groups, like premature babies and people with diseases, are being exposed to EDs. In the European market safer alternatives for most of the product categories exist, but still the medical devices regulation is not sufficiently protecting human health. The new medical devices regulation requires a justification of the presence of EDs (above a concentration of 0,1% weight by weight) in only some 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.

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	0	0	•	0	•	0
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	0	0	0	0	•	0

Please explain your answers

2000 character(s) maximum

Citizens are not being protected sufficiently from EDs by the Water Framework Directive. In the recent REFIT process a lack of coordination as been identified between the measures taken under the Water Framework Directive and the ones under chemicals regulations and REACH. Detection of EDs in waterways is a result of immense exposure of humans, wildlife and nature. Currently the burden of monitoring, which is anyway too little, and follow up actions lies with public authorities and taxpayers, instead of the polluters. The polluter pays principle should be included in the regulation and applied accordingly.

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 current EU regulatory framework has gaps in addressing mixtures/cocktail effects, although this has been highlighted in studies and reviews of the EU Commission itself (supporting study on a non-toxic environment, chemicals fitness check, EU H2020 research programs). In June 2019 the Environment Council conclusions called on the Commission "to present options to introduce requirements in the relevant pieces of EU chemicals legislation to ensure that the combination effects of chemicals (cocktail effects) and the combined exposure of humans and the environment from all relevant sources are properly and consistently addressed in the risk assessment and risk management processes".

Aggregated exposure is ignored by the sector specific regulation of products and REACH (registration dossiers focus on uses by the applicant). A trigger mechanism for automated regulatory consequences in the whole regulatory framework should be implemented, once a substance is identified as ED.

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)	©	©	©		•	0	
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

See also answer 12)

Human biomonitoring studies show that humans are highly exposed to EDs, even babies are being born prepolluted. BPA alone can be detected in about 90-99% of the population (Vandenberg LN. Exposure to bisphenol A in Canada: invoking the precautionary principle. CMAJ 2011; online Feb 22:doi:10.1503/cmaj. 101408).). 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.

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	0	•	0
newborn up to the age of 3	0	•	0
children until puberty	0	•	0
young persons around the age of puberty	0	•	0
pregnant women	0	•	0
adults in general	0	•	0
people at work	0	•	0
elderly	0	•	0

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

In all regulatory sectors vulnerable groups lack sufficient protection from exposure to EDs. The Chemicals Fitness Check and the sub-study on vulnerable population of NTES demonstrate that vulnerable groups are not consistently and sufficiently protected. Products that are being used by children and pregnant women or that they are surrounded with, like toys, cosmetics, food, furniture, indoor air, contain EDs. Protection of pregnant women at the workplace is not sufficient either, as EDs are not fully banned in the directive. The lack of coherence and ambition in the EU regulatory framework on EDs hits the most vulnerable groups the hardest.

The average adult (mainly male adult) is still the common point of reference to estimate exposure and safe dose. This should change and the most vulnerable group should be taken as main reference. The EU chemical regulations and laws do often not specify and define vulnerable groups.

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) A	Are available r	egulatory	tests sufficient	to identify	endocrine	disruptors f	for humans	(including
vulne	erable groups)	as well a	s wildlife?					

Yes

No

Which tests should be developed?

1000 character(s) maximum

There is a need to accelerate test development and validation, as being stated by 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"

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

Tests required under REACH do not include all relevant endpoints. There is no mandatory screening for ED
properties for low volume substances. Industry should be obliged to provide data supporting the identification
of EDs category 1 and 2. This can be achieved by updating REACH annexes.

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?
YesNo
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
O 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.

	are minimised in the EU?		
	Not at all		
	Insufficiently minimised		
	Minimised to the extent possible		
	Don't know		
end	Do you have recommendations on how to further minimise the impact of assessing chemic ocrine disrupting properties on animal welfare? On character(s) maximum	cals for	
	The current incoherence of the EU regulatory framework on EDs results in several testing under regulations, which leads to many unnecessary animal tests. Centralising independent testing by authorities and financed by industry would lead to a minimization of tests and better coordination	public	t
Effe	ctiveness of regulatory procedures		
	following sectors are regulated via sector-specific legislation as well as by horizontal/othe EACH, Biocidal Products Regulation, CLP Regulation).	r legisla	tion (e.
22)	Are you aware of issues that result from the lack of specific provisions for identifying end	ocrine	
,	Are you aware of issues that result from the lack of specific provisions for identifying enduptors in sector-specific legislation for the following areas:	ocrine	
,		ocrine Yes	No
,			No O
,	uptors in sector-specific legislation for the following areas:	Yes	
,	uptors in sector-specific legislation for the following areas: Workers protection	Yes	0
,	uptors in sector-specific legislation for the following areas: Workers protection Toys	Yes o	0
,	Workers protection Toys Detergents	Yes o o	0
,	Workers protection Toys Detergents Fertilisers	Yes O O O	0
,	Workers protection Toys Detergents Fertilisers Electrical and electronic equipment	Yes O O O	
,	Workers protection Toys Detergents Fertilisers Electrical and electronic equipment Food contact materials	Yes O O O O O	

20) In your opinion, is the impact of assessing chemicals for endocrine disrupting properties on animal

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

Human and veterinary pharmaceuticals (only for effects on the environment)

Water

Waste/recycling

Other (please specify)

0

0

The main problem is that there is no main ED identification system in place, which identifies EDs for once and then triggers regulation measures in all cross-sector regulations and laws.

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	0	0
Toys	•	0
Detergents	0	0
Fertilisers	•	0
Electrical and electronic equipment	•	0
Food contact materials	•	0
Food additives	•	0
Cosmetics	0	0
Medical devices and <i>in vitro</i> diagnostic medical devices (only for effects on the environment)	0	0
Human and veterinary pharmaceuticals (only for effects on the environment)	•	0
Water	0	0
Waste/recycling	•	0
Other (please specify)	0	0

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

1000 character(s) maximum

Some of the mentioned legislations do not mention EDs at all or address them sufficiently. ED 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	•	0	0
Biocidal products	•	0	0

General chemicals	•	0	0
Toys	•	0	0
Detergents	•	0	0
Fertilisers	•	0	0
Electrical and electronic equipment	•	0	0
Food contact materials	•	0	0
Food additives	•	0	0
Cosmetics	•	0	0
Medical devices and <i>in vitro</i> diagnostic medical devices (only for effects on the environment)	•	0	0
Human and veterinary pharmaceuticals (only for effects on the environment)	•	0	0
Waste/recycling	0	0	0
Other (please specify)	0	0	0

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 met	hods
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

Independent data and academic studies are not being included sufficiently. EU guidances are not being systematically updated when new test and assessment methods are available. New scientific data and methodologies should be included immediately in the regulatory framework.

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

There is no full transparency about EDCs in products, which makes it impossible for consumers and also often downstream users to make informed decisions. As we are exposed to EDCs everywhere, in the products we use, the food we eat, the air we breathe, citizens have no choice and no control over their exposure and therefore are unable to control it. Therefore we urgently need strong protection (bans and phase outs, safe alternatives) by regulation and laws, as this is the only sufficient way to minimize exposure. WHO/UNEP refers to EDCs as a "global threat that needs to be resolved". Policy makers and regulators have to act fast now, without any further delays. The burden for citizens and the environment is huge, in terms of suffering from various diseases, biodiversity loss and huge cost for the society. 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

Preferably protection measures should cover the entire EU, so that all EU citizens and the environment in the region can benefit. However, it should be allowed to take national action, where new evidence or a reassessment of existing information indicates an unacceptable danger to human health or the environment and national authorities conclude that this is an unacceptable danger, and the European political bodies and authorities are not moving fast enough in terms of regulation or not moving ahead at all.

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

1000 character(s) maximum

The swift identification and strict regulation of EDCs in the EU regulatory framework will benefit the following processes and issues:

- implementation of SDGs
- achieving a clean and non-toxic circular economy
- health and well being of EU citizens
- clean and healthy environment, biodiversity, clean rivers and oceans
- economy (reduction of health cost, reduction of productivity loss, incentive for begning products)
- implementation of core principles: precautionary principle, right to know, polluter pays
- fork to farm
- zero pollution strategy
- promotion of safe alternatives
- new green deal

The EU should be a global frontrunner again, promoting EDC-free policies globally.

Useful links

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

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

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