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

Fields marked with * are mandatory.

Introduction

Scope and objectives

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

The aims of this stakeholder survey are:

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

Target audience

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

Instructions

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

Information on respondent

* I am giving my contribution as:

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

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

* First name

50 character(s) maximum

Dolores

* Surname

50 character(s) maximum

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50 character(s) maximum

dolores.romano@eeb.org

* Organisation name

50 character(s) maximum

European Environmental Bureau

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 criteria established by the BPR, which is applied also for plant protection products, is based on a sectoral approach and cannot be applied directly to other sectors, for example to general consumer articles. Several substances have been identified as ED under REACH Regulation, however other laws do not contain provisions allowing for using this or a similar identification, resulting in a incoherent regulatory approach for the same chemicals. For example, NPE, DEHP or BPA have been identified as ED under REACH, with no consequences under food contact material, consumer products or worker protection regulations. We share the views presented by scientists in the EP report: “ED: from Scientific Evidence to Human Health Protection” that the identification of ED must be based on a unique cross sectoral definition of ED and that the identification of a substance as an ED in one sector, should automatically entails its recognition as an ED with the same level of evidence in all 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

Regulation to improve coherence across EU legislation and accelerate the regulation of ED across different sectors. By CLP Art. 53(1), the Commission has the task to up-date hazard categories (as set out in Annex I) to respond to scientific progress. For regulatory consistency, the update to Annex I should have been undertaken latest in 2017 when the scientific criteria for ED identification under PPPR and BPR were agreed at last. However, classification of chemicals as ED under CLP will likely take many years. Also many sectoral regulations will need to change to ensure that the ED categorization has regulatory consequences. Different umbrella identification systems can also be used to identify ED. These systems should be established already and should work in parallel to the inclusion of an ED category under CLP and the necessary changes to EU sectoral legislation are made. This would ensure that the identification and the regulation of ED across all relevant EU regulations is not f

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

Yes, ED should be classified, the same as CMR, depending on the level of evidence and include a category of suspected ED (cat. 2). This categorization enables authorities to prioritize regulatory action depending on the population to be protected. For example, CMR categories 1 and 2 are banned in toys in order to ensure the highest level of protection to children. However only CM category 1 is banned (unless no technically feasible substitute) for worker exposure under the CMD. This categorisation also gives an early warning to authorities, companies, trade unions and consumers that allows the adoption of preventive measures to avoid or reduce exposure and therefore better protects human health and the environment from the risks posed by these chemicals.

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

As the findings of the Fitness Check of the most relevant chemicals legislation read “inconsistencies have been identified regarding risk management decisions in the various pieces of legislation as regards endocrine disruptors...” and other chemicals.
Inconsistencies include lack of inclusion of ED under many/most sectoral regulations (Eg toys, waste, food contact materials); different identification approaches (Eg. biocides, REACH); different approaches to demonstration of safe thresholds under different regulations (Eg under REACH its up to the applicant of authorization while the Cosmetics Regulation does not require demonstration of safe thresholds) and different risk management options for ED substances under different regulations (Eg ED are generally not allowed under PPPR, however they may be authorized under REACH for industrial uses if socioeconomic benefits for the applicant outweigh risks for society).

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

ED are not regulated in many/most of relevant EU legislation. Even a horizontal regulatory framework such as REACH does not address all sectors. Gaps identified by the Fitness Check of the most relevant chemicals legislation also apply to ED including knowledge gaps regarding uses, releases and exposure data; lack of transparency on chemicals present in products; lack of adequate test and assessment methods that focus on long term, large scale and complex environmental effects of ED; lack of transparency in (eco) toxicological data in Reach-registered products; or lack of consideration of combined effects of exposure to several chemicals in established risk assessment processes.

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

- (●) Yes
- ( ) No

If yes, please provide examples and describe the consequences.

1000 character(s) maximum

Enforcement activities sucha as Safety Gate: the rapid alert system for dangerous non-food products show the high presence of ED that are banned in the EU (E.g. phthalates) in imported articles, in particular in toys. This shows the need to ban globally these toxic chemicals. https://eeb.org/flood-of-toxic-chinese-toys-threatens-childrens-health/
The EU should also stop the manufacture and export of chemicals that are not allowed in the EU in order to protect health and environment at a global scale.

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

2000 character(s) maximum

Unfortunately endocrine disrupters, as well as other chemicals of concern, are not covered by all EU chemicals, products or environmental legislation, allowing substances that have been regulated or restricted under one piece of legislation (Eg DEHP restricted under REACH for several uses) to be used in food contact materials, medical devices, building materials etc. All relevant pieces of chemical, products and environmental legislation should regulate all substances of concern. For example, waste, water, soil and air protection legislation should all regulate ED. Also ED identified through any of the existing legal frames should automatically be regulated under all other relevant pieces of chemical, products and environmental legislation.
Further, regulation of ED in Europe is coherent with international efforts such as the consideration of ED as an emerging issue of concern under SAICM.

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

Since the applicability of the criteria in June 2018, only two biocidal active substances have been identified, without leading to any ban yet. The work program is advancing extremely slowly allowing people and the environment to be exposed to endocrine disrupters.

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

Since the PPP Regulation entered into force in 2011 no active substance has been banned due to its ED properties, allowing farmers, consumers and the environment to be exposed to these toxic chemicals (Eg chlorpyrifos). As already stated by academia (https://www.endocrine.org/news-and-advocacy/news-room/2018/eu-criteria-fall-short-of-protecting-public-from-endocrine-disrupting-chemicals) and NGO (https://www.pan-europe.info/resources/briefings/2016/07/pan-europes-response-coms-edc-criteria-feedback-mechanism), the criteria to identify ED under the BPR and PPPR are not adequate to protect people and the environment. Further, taking into account that plant protection active substances are evaluated only after their authorization period has expired (10-15 years), the assessment of the substances allowed to be used as pesticides in the EU will take decades.
https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/PAN%20report%20testing%20endocrines-%20a%20vicious%20circle%20-%20Nov%202019.pdf

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 lack of proper information requirements for ED properties and the lack of control and enforcement of the registration process under REACH has resulted in lack of proper information on ED properties of registered chemicals. The process to identify ED under REACH is a long process that requires an agreement by consensus of ECHA's MSC. If no unanimous agreement is reached by MSC, the decision is forwarded to the REACH Committee, which leads to further delays.

Since 2011, agreement has been reached for the identification as ED for only 16 substances, mainly chemicals with ED effects for the environment despite the strong existing evidence on endocrine disruption effects on human health (E.g. this has been the case for DEHP, DBP, BBP, DIBP). The lack of a grouping approach is also limiting and delaying the identification of ED under REACH. Once identified as ED, the RAC still applies a threshold approach when assessing the risks of ED for restriction. The most protective measure so far has been to apply an assessment factor to take into account ED properties. The choice of the AF is not well justified in most cases. Also the specific properties of ED are not taken into account by RAC opinions on risk assessments, such as low dose effects, non monotonic dose response curves, synergistic effects, etc. This has resulted in ECHA opinions and COM decisions to likely underestimate the risks to human health (both of workers and general population) and the environment (Eg, restriction of BPA in thermal paper, restriction of reprotoxic substances with ED effects in tattoos, restriction of NPE, etc.). Also the ECHA guidance to assess risk does not take into account adequately the gender differences in exposure to chemicals, which are of great relevance in the case of ED.

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

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

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

As data from academic studies and official monitoring programs show, ED are frequently found in EU river basins, groundwater and marine waters. The European environment —state and outlook 2020 shows that Europe is not on track to meet the objective to minimize the release of hazardous chemicals to air, water and land, given the lack of information about emissions of thousands of persistent chemicals.
The lack of adequate regulation of ED in all sectors results in releases of ED to the environment and their presence in continental and marine waters.
Further, there is a lack of responsiveness between regulations on chemicals, pesticides, pharmaceuticals, biocides, cosmetics, etc. and the water framework directive. For example, the identification of a substance as of high concern under REACH should trigger its immediate regulation and monitoring under the WFD. Water quality standards need to be updated through update of the EQS Directive to existing scientific knowledge on hazardous properties of ED and take into account mixture toxicity. Monitoring programs by river basin authorities need to be aligned with the actual chemicals used and released by farms and industries in the area. Finally, the lack of proper implementation and enforcement of the WFD adds to ineffectiveness of the WFD to protect people and the environment from EDS.
Ríos hormonados https://www.ecologistasenaccion.org/35829/informe-rios-hormonados/
The European environment —state and outlook 2020 https://www.eea.europa.eu/soer-2020/intro

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 regulatory frameworks for chemicals works in silos, addressing sector by sector and therefore not considering aggregated exposure from different exposure sources. Only REACH Restriction process covers different sources of exposure to the same chemical (although only the sources under the scope of REACH). As the SWD REACH Refit points out: " In order to improve the consistency on the exchange of information and the risk assessment between REACH and other Union legislation, when an Annex XV dossier for restriction, addresses the cumulative exposure of humans and emissions to the environment from different sources also in areas not covered by REACH, the specific Union legislation could use the information included in the Annex XV dossier as a basis for further regulatory actions. The Annex XV dossier could indeed be used as an important source of information for other Union legislation."

13) Do you agree with the following statements?

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

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

Please explain your answers and provide examples

1000 character(s) maximum

As the results of the chemicals Refit highlight: “Risk assessment processes implemented within the EU chemicals legislation are not expressly designed to identify and assess potential human health and environmental risks of different hazardous chemicals acting in combination". Progress has been made with regard to knowledge building and the development of risk assessment methodologies in the context of plant protection products and in the broader context of the food chain. Nevertheless, a workable methodological framework for all chemicals has not been agreed upon. Requirements to ensure the risk assessment of combination effects exist only in some pieces of legislation (e.g. in the area of pesticides) while other relevant pieces of legislation do not contain legal provisions that cater for such an assessment.”
It should be noted that although the pesticides regulation obliges to assess the risk of combined exposure to pesticides, this has not done so far.

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

Due to the lack of identification and regulation the whole EU population is daily exposed to EDs.

As the Non-toxic environment study (NTES)shows, there is no common definition of vulnerable groups across the EU legislative framework. There are special life stages where exposure to ED is of higher significance, such as during development in the womb, childhood, adolescence. https://ec.europa.eu/environment/chemicals/non-toxic/pdf/NTE%20main%20report%20final.pdf

However, people with illnesses should also be considered a vulnerable group. Some treatments (E.g. premature babies, dialysis, blood transfusions, etc.) expose patients to high levels of ED (phtalates, BPA). Presence of Bisphenol A and Parabens in a Neonatal Intensive Care Unit: An Exploratory Study of Potential Sources of Exposure. https://ehp.niehs.nih.gov/doi/10.1289/EHP5564

At workplaces, young people, elderly, and immigrants are considered vulnerable groups to chemical exposures.

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

See the report: “ED: from Scientific Evidence to Human Health Protection” https://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL_STU(2019)608866_EN.pdf

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

REACH registration requirements should be updated as they have limited capacity to provide data on ED properties. There are obligations to provide data on ED properties only for high volume chemicals, and as stated by the second REACH review, several REACH annexes need to be updated to ensure industry provides adequate data for the identification of ED. REACH should include data requirements on ED properties of all chemicals, low volume chemicals and polymers who are exempted from registration. REACH implementation also needs to improve to better use of independent academic studies. Under BPR, data requirements under Annex II would have to be updated to reflect the ED assessment guidance for biocides and plant protection products. Also data requirements under PPPR are not adequate as a recent report from PAN has highlighted. Most pesticides examined by the report were approved without any scientific test on their impact on the hormonal system of humans. (see answer to 11.b).

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

Information requirements are not adequate under all existing frameworks .
It is difficult to compare processes as REACH is not systematic and a case by case approach, requiring demonstration of equivalent level of concern, while BPR is a structured and systematic approach.
Identification is extremely slow and not working properly in any of the processes.

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

The data requirements under REACH need to be updated with respect to endocrine disruption. New standard information requirements for endocrine disrupting properties, including updated test methods should be introduced. Inclusion of DNT and DIT cohorts in EOGRT studies should be addressed. Information requirements for lower tonnage substances need further consideration regarding endocrine activity. In this respect a standard batch of in vitro and in silico methods would be useful as standard data requirement in the Annex for low tonnage substances. OECD updates of test methods on endocrine effects should be implemented immediately under REACH after endorsement by OECD.

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 are particularly useful in the evaluation of substances with lower tonnage data requirements under REACH. Existing information from other sources should be taken into account when evaluating ED properties in addition to the results of in silico and in-vitro methods, such as non-standard in-vivo information (eg from scientific papers) and information from structural analogues. These tools should also be used much more systematically in the work for grouping of substances: to evaluate endocrine activity, to reduce animal testing and to prevent regrettable substitution by other substances with ED properties.

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

To establish a centralized system that provides safety testing of chemicals by independent laboratories, with the process being paid for by an industry-supplied fund that is managed by public authorities.This would ensure the necessary coordination and help avoiding repetition of tests and better sharing of data results, as well as increasing 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

The lack of provisions for identifying and regulating endocrine disrupters in all relevant legislation widespread use of these chemicals and lack of protection of citizens and the environment.

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

See answers to question 6

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

Insufficient role of independent epidemiological and biomonitoring data, and insufficient use of independent academic studies as preference is generally given to standard test results.

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

2000 character(s) maximum

The legislative framework is not providing adequate information on the risks of ED and how to avoid them. Neither authorities, citizens, downstream users, workers, or even health profesionals have information on which substances have ED properties, where they can be found, exposure routes or recommendations to

avoid or reduce exposure.
Authorities should be obliged by law to publish updated lists of known or suspected ED, similar to the list published by TEDX: https://endocrinedisruption.org/interactive-tools/tedx-list-of-potential-endocrine-disruptors/search-the-tedx-list
Also transparency on chemicals present in products and articles needs to by guaranteed by law.

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

Given the delay of the EU to take action on the risks posed by ED, National authorities have the legal and moral obligation to take all measures in their realm to protect people population and the environment.

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

1000 character(s) maximum

Further added value of regulating ED include among others:

Setting a global example and encouraging action at a global level.
Contributing to the achievement of the Sustainable Development Goals.
Contributing to the success of the Green Deal in general and of the Circular economy, Biodiversity, Farm to Fork and zero pollution strategies in particular.
Promoting safer alternatives and safer practices.

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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