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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

Ninja

* Surname

50 character(s) maximum

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50 character(s) maximum

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* Organisation name

50 character(s) maximum

CHEM Trust Europe

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 absence of harmonized criteria is problematic for a coherent identification of EDs because:
- A substance may be identified as ED under one law and not an ED under another.
- EU laws have different data requirements, thus different amounts/quality of data is available for ED identification. The pesticides and biocides ED-criteria require a high burden of proof and many EDs will be left unidentified.
- While the basis usually is the WHO definition, the REACH ED identification requires an additional step: the demonstration of equivalent level of concern (irrelevant for the identification of the inherent property).
- What is needed is a horizontal approach to identify EDCs based on elements of adverse effect, endocrine activity and plausible link, reflecting the different levels of evidence and uncertainties (see JRC report 2013). Once a chemical is identified, the respective EU laws should be applied to act on the identified hazards, similar as they can act on PBTs, CMRs etc.

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

On Q 3) Introducing a hazard category in CLP/GHS could indeed be one way of achieving a more coherent identification system. However, a better option would be to establish a separate identification system which could function like an overarching umbrella and also embrace the current pesticides/biocides criteria. In any case it would need to include the reality of different data requirements from different sectors. In both cases the EU should develop its approach first and not wait until something has been agreed under GHS.

On Q 4) A crosscutting identification system for EDs could improve the coherence of risk management because it would establish the necessary base for identification. However, it will also be necessary to introduce new changes in the respective sector laws to include regulation of EDs. For example: The law on food contact materials would need to include a provision which bans use of EDs.

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

Chemicals can and should be identified as having endocrine disrupting properties with less evidence than currently required with the criteria for pesticides and biocides. CHEM Trust has argued for many years that in a similar way that CMRs are classified, a categorization system for endocrine disrupting chemicals (EDCs) would reflect the level of evidence for suggesting a chemical caused effects via an endocrine disrupting mechanism (https://www.chemtrust.org/wp-content/uploads/CHEM-Trust-WWF-EDC-Classification-Paper-Dec-2010.pdf). An additional category of `suspected ED`s should list those chemicals with substantial evidence on the elements needed to identify ED properties (adverse effect, endocrine activity and a plausible link), but where uncertainties or data gaps remain and prevent a final conclusion . Looking at the current list of chemicals dealt with by the ECHA ED group (https://echa.europa.eu/de/ed-assessment) it is obvious that many assessments cannot be concluded without asking for further data. This causes further unacceptable delays and slows the system down while exposure to humans and wildlife continues. Therefore, a category of suspected EDs should lead to stricter regulatory controls, e.g. in the form of restrictions with possibilities for derogations, more obligations for the supply chain and consumer communication. This will lead to huge benefits to environment and health and trigger innovation to safer solutions as currently, only few substances will be identified as EDs based on the available database. More precautionary regulatory control based on category 2 could also contribute to a decrease in animal studies as many of those substances that are not essential are likely to be substituted with less harmful substances.

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

There are many inconsistencies in the way how chemicals and EDs are identified and controlled across the EU, many have been described in the Chemicals Fitness Check published in June 2018. One example CHEM Trust highlighted is the fact that the REACH restriction of 4 phthalates for use in consumer products does not cover the use in food contact materials.
https://www.chemtrust.org/wp-content/uploads/chemtrust-fourphthalates-july18.pdf

EFSA has continued its work on further risk assessments of certain phthalates which is inconsistent and rather inefficient. It also illustrates that a generic risk assessment approach would have many advantages over the use of specific risk assessments which are often time-consuming and leave people exposed to EDCs. In CHEM Trust view the reform of the FCM laws are a real priority for tackling exposure from EDCs. One solution to addressing inconsistencies would be to establish an automatic trigger of control measures following the identification of an endocrine disrupting pesticide/biocide/industrial chemical under REACH. Another important example is the issue of thresholds. In the context of REACH authorization it is the responsibility of the applicant to demonstrate that a safe exposure level exists, in accordance with the Commission Communication on the REACH review in 2016 (https://ec.europa.eu/transparency/regdoc/rep/1/2016/EN/COM-2016-814-F1-EN-MAIN-PART-1.PDF)
This is not the case in other sectors such as cosmetics, toys or medical devices. In CHEM Trust view EDs should always be treated as non-threshold substances (https://www.chemtrust.org/wp-content/uploads/CHEM-Trust-Briefing-on-REACH-EDC-review-FINAL.pdf): There can be serious and irreversible effects even at very low doses and many uncertainties in the risk assessment, including the critical role of the timing of exposure, sensitive windows of development, NMDRs and the potential for mixture effects. https://chemtrust.org/edc-reports-regulatory-action/

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

On Q 7b: Setting safe levels for EDs may not be possible and therefore drawing conclusions in a risk assessment leads to unacceptable uncertainties. There are many problems with the current way risk assessments are often conducted resulting in the setting of safe levels by drawing overly firm conclusions on doubtful assumptions (without considering ED specific needs for sensitive test methods, low dose considerations of NMDRs, or also relying on unrealistic exposure assumptions).

On Q8Gaps: There are no regulatory consequences for identified EDCs used in consumer products in the same way as for CMR: i.e. REACH article 68.2 should be expanded to also cover EDCs. Equally, this approach needs to be applied for toys, FCM cosmetics, and medical devices. This is one important way of ensuring cleaner supply chains for a non-toxic circular economy.

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

- As shown in many product tests from national authorities or NGOs, consumer products still contain EDCs in other countries and are often imported to the EU despite being banned in EU (e.g. phthalates). The EU needs to step up enforcement in order to ensure public health and the environment are properly protected and also to reduce the threat of recycling contaminations into new products.

- The UNEP reports on EDCs https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/scientific-knowledge-endocrine-disrupting highlight the global importance of EDCs and their impacts on health and environment are for all countries.

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

2000 character(s) maximum

The results of the EU's general fitness check on relevant chemicals legislation already pointed out many gaps in protection in particular for pregnant workers and children. Also, the report `Endocrine disruptors: from scientific evidence to human health protection´commissioned by the EU Parliament’s petitions committee in 2019, summarised the latest science and exposed many regulatory gaps. Following that, in April 2019, the European Parliament made it very clear in its resolution on endocrine disrupters that they expect legislative proposals no later than June 2020 for specific provisions on EDs to be added to the

regulations for toys, cosmetics and food contact materials.

CHEM Trust has long advocated for a new approach for identifying and controlling EDs across all relevant laws, including detailed proposals for revisions or new legislation, with the aim of establishing coherent and effective protection. The best approach would be to have an identification system that will directly lead to regulatory consequences, in each of the specific legislative systems. It also needs to be ensured that suspected EDs – for which there is substantial information on such effects – are also captured, leading to regulatory consequences based on the precautionary principle.

A big obstacle for the current identification of EDs is the lack of adequate test methods; there is a need for further support of development of test methods. Meanwhile it is high time to extend the information requirements (in REACH, biocides and pesticides) so that ED properties are captured and EDs are identified. This is also needed to ensure companies are taking the responsibility for the safety of their chemicals. Another important element for a regulatory solution for better risk management is the use of grouping. This can avoid replacing a known ED with a similar chemical with similar properties, which CHEM Trust has highlighted in the case of the bisphenols (From BPA to BPZ - A Toxic soup).

Effectiveness in achieving policy objectives

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

11) Do you agree with the following statements?

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

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

Please explain your answers

2000 character(s) maximum

The main problems lie in the process of implementation of the BPR. There are too many delays in both the identification and control and the clear aim of minimization of exposures is far off. The process for identification is not effective as it takes very long time to identify substances as ED biocides (https://echa.europa.eu/de/ed-assessment). So far only 2 substances have been identified but none have been regulated so far. In contrast, there are many potential and suspected EDCs in consumer products (see PAN Germany publication: Endocrine disrupting biocides. Why highly hazardous biocides must be phased out, 2014). It should be a priority to finally improve the information requirements and ensure the relevant data for ED identification are generated. As this dilemma cannot be solved easily, the importance of creating a `suspected ED` category is once more obvious, also because the legal text of the BPR states `may cause adverse effects´. Full transparency of the outcome of all ED assessments is also important. Also, while the general approach of the BPR is supported even though the identification criteria requires a too high burden of proof only allowing identification of a limited number of active substances, the process for control is currently not effective due to the long time delays in decision making and further processes regarding potential derogations.

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

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

Please explain your answers

2000 character(s) maximum

The biggest challenges can be found in the process of the implementation of the PPPR rather than the regulation itself, even though the identification criteria do require a too high burden of proof. There are too many procedural delays in both the identification and subsequent controls and the regulatory process to identify and control pesticide substances with ED properties has not been effective until now. So far not one pesticide has been identified as an endocrine disrupter and banned although several active substances on the market are known to be EDs.
One of the real missing links are the data requirements: There is a need for a systematic ED screening procedure, including testing with in vitro batteries, and the EOGRTS (OECD TG 443) should be mandatory requirement. Too many studies are outdated and the results from old 2 generation studies are not sensitive enough for ED endpoints. If they have been used there is often a need for supplementary studies with ED relevant endpoints.
In order to get a better overview of the gaps and limitations there is a clear need for full transparency of the outcome of all ED assessments to be able to understand the conclusions and outcomes.
It would also be very important to establish a category for `suspected EDs` to better reflect the level of scientific knowledge available, and also because the legal text of the PPPR states: `may cause adverse effects´.

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

Even if the main elements are in the legislation and REACH has successfully identified some substances as EDCs under 57(f) or 57(c), the overall regulatory process for identification takes too much time and subsequent control measures are taken too slowly. The data provided by companies rarely include the relevant ED endpoints and sensitivities and therefore the task of identification is mainly left to MSCAs. It is therefore long overdue to enhance the data requirements to also include specific requirement as regards ED-properties. Those few substances that have been identified as EDs so far based on the WHO/IPCS definition were only identified following additional justification for why the substance is of equivalent concern. This additional requirement should be removed. One proposal would be to establish that the new horizontal criteria should automatically fulfill Art. 57(f) or another option would be to create a separate category in REACH as 57(g).

Some examples for long delays in the process are the octylphenol ethoxylates which were included in the candidate list as EDs in 2012 and the sunset date was set for 2021! Another example is BPS: RAC had already highlighted in 2015 that BPS has similar properties to BPA. Subsequently, ECHA found evidence of BPA being replaced with BPS (https://echa.europa.eu/de/-/bpa-being-replaced-by-bps-in-thermal-paper-echa-survey-finds). In 2019 Belgium started the classification procedure to identify BPS as a compound toxic to reproduction and controls are still not in place.

As highlighted by the second REACH review, it will be important to increase activities to promote substitution of SVHCs, including EDCs.

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

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

[2] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

The provisions for reducing consumer exposure from known and suspected EDCs used in cosmetics need to be strengthened. There needs to be coherence in EU legislations that EDCs/suspected EDCs should not be allowed for consumer use. The SCCS is currently risk assessing EDCs without taking all the uncertainties in relation to assessment of EDCs into account; low dose effects, NMDR, non-threshold issue, lack of knowledge, lack of adequate test methods etc.

The COM review from December 2018 ignored several important points, such as: The Commission highlights the ban on a number of parabens (cosmetic ingredients used as preservatives) as an example of risk identification and management of endocrine disruptors. Five of the parabens that were banned in 2014 were, however, banned because the industry chose not to defend the substances (limited or no data were submitted by industry to the SCCS which therefore could not evaluate their risk to human health – see Commission regulation point 7: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0358

The need for implementing regulatory consequences for a category of suspected EDCs is also supported by the concern of SCCS that EDCs is cosmetic will not be identified in the current situation (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3295383/feedback/F12858_en?p_id=255075). In June 2018 it stated that the “results obtained for a cosmetic ingredient using non-animal alternative methods (in silico, in vitro, ex vivo, omics technology, etc.), can only be indicative of endocrine activity and will not give information whether the substance can cause adverse effect(s) in an intact organism, thus whether it should be regarded as an endocrine disruptor or not. Indeed, it should be clearly noted that until today not a single validated non-animal alternative method exists for systemic toxicity”.

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

Under the MDR regulation that applies from 26 May 2020, endocrine disruptors will only be restricted at concentrations above 0.1 % and only in particular sensitive uses e.g. invasive devices. The use of EDs may be justified based on an analysis of several parameters: analysis of potential patients or user exposure, analysis of possible alternatives, and consideration of use of the device in treatment of vulnerable groups as children, pregnant women or breastfeeding women. In general, endocrine disruptors are still allowed in medical devices and for sensitive uses also in amounts below 0.1%. In the MDR endocrine disruptors are defined as substances identified as SVHC and included in the REACH candidate list as set out in REACH Art. 59 or if identified as a substance with endocrine disrupting properties under the Biocidal Products Regulation 528/2012. As both these regulations do not include the necessary data requirements and do not identify those substances for which there are substantial data on their endocrine disrupting properties, they are inadequate to properly identify all substances with endocrine disrupting properties and thereby protecting consumers and workers by minimizing exposure to endocrine disruptors from medical devices. CHEM Trust finds that endocrine disruptors in general should be banned for use in medical devices, however, with a possibility for derogation for life-saving devices when there is a lack of safer alternatives. Endocrine disruptors should be identified based on a horizontal EU approach that also includes identification of suspected endocrine disruptors. EU identified endocrine disruptors and suspected endocrine disruptors should in general be banned for use in medical devices.

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

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

Please explain your answers

2000 character(s) maximum

- The possibilities for controlling harmful substances under the WFD are very limited and the situation for surface and drinking water is rather concerning. Studies frequently find pesticides, pharmaceuticals and industrial chemicals in EU surface water https://www.sciencedirect.com/science/article/pii/S0048969719311969?via%3Dihub
- The EEA recently warned about PFAS contamination in drinking water and that these substances, many of them having endocrine disrupting properties, need to be controlled as a group https://www.eea.europa.eu/themes/human/chemicals/emerging-chemical-risks-in-europe

- EU Water suppliers have recently highlighted in a position paper on persistent and mobile substances that ´Control-at-source measures are crucial to mitigating preventable emissions of hazardous chemicals into the environment. The burden placed on the drinking water industry – and consequently on the consumer' s water bill – to remove these substances is unviable.´
- http://www.eureau.org/resources/briefing-notes/3934-briefing-note-on-moving-forward-on-pmt-and-vpvm-substances/file
- The WFD implementation at EU level suffers from a lack of emission controls for priority substances causing failure across the EU in achieving good status of water bodies. The EU has to respond and make use of its legislation to control chemicals at the source like REACH, Waste and IED.
- Moreover, the process of updating the WFD's list of priority substances, for setting EQS, emission controls and monitoring has been too slow in particular for substances with (suspected) ED properties. Identified EDs should automatically be listed as priority hazardous substances for substitution and suspected EDs should be listed on the watch list.
- Also the polluter pays principle needs to be strengthened, currently there is a lot of burden on the authorities (and eventually the consumer via the water bills) to try and solve the problem instead of putting the responsibility back to the producers.

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

CHEM Trust advocated for many years to improve protection of humans and wildlife from the risks to one substance from several sources (aggregate exposures). Due to the different assessments in several legislative silos the risk of exposure to the same substance from various exposure pathways is not properly accounted for and therefore the overall risk is underestimated. A solution would be to allocate only a fraction of the risk quotient to a particular source, otherwise aggregated exposure may lead to exceedance of the risk level.
One example CHEM Trust often highlights, is the continued use of EDCs such as BPA in FCM, e.g. in our submission on the EC draft regulation "on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials". https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4140854/feedback/F6902_en?p_id=10

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

In CHEM Trust`s view there is a high urgency to address the risks from combined exposures to different EDs https://www.chemtrust.org/wp-content/uploads/CHEMTrust_response_EFSA_MIXTOX_Guidance_2018.pdf A Danish report highlighted the concern about current exposure levels of antiandrogenic substances and the resulting risks for children and unborn children from the combined effects (Danish Environmental protection Agency, 2017 ISBN: 978-87-93529-84-7). The EU Human Biomonitoring project HBM4EU investigates the body burden of the population at a European scale.

EU researchers such as from the EDCMixRisk project have repeatedly warned that health risks from mad-made chemicals are underestimated even at current exposure levels. Others have shown a concern for PBDE exposure and neurobehavioral outcomes. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5783671/ A systematic approach is needed to properly protect citizens, see: https://chemtrust.org/chemical-cocktail-mixture-effects/

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

In general, no one is currently sufficiently protected from exposure to endocrine disruptors. Vulnerability is not officially defined and different EU legislations include different levels of protections as also stated by the recent EU chemical fitness check. Exposure to EDs may affect people in all ages, however, there are especially vulnerable periods of life where it is crucial for important developments or functions that hormones in the right amounts are well-functioning in the right place and in particular, the pregnant woman/unborn child, neonates and young children, and in general children until fully developed and elderly, are especially vulnerable. There is a general lack of knowledge about endocrine disruptors, a lack of adequate test methods and only few substances have been assessed for their ED-properties. At the same time humans are daily exposed to a plethora of different chemicals from e.g. pesticides, consumer products, cosmetics, toys, food contact materials, medical devices and the environment, and many known/suspected EDs are ubiquitous in the environment as e.g. bisphenols and phthalates. Biomonitoring studies show that many of these chemicals are present in human bodies, i.e. a study from 2015 detected BPA in over 90% of people from six EU Member States, including in 100% of Swedish mothers and children (https://www.chemtrust.org/wp-content/uploads/chemtrust-toxicsoup-mar-18.pdf). Daily exposure of consumers and workers to known

and presumed endocrine disruptors is in particularly worrying because of the serious consequences this exposure may have on the unborn child. Scientific research has shown associations/possible associations between prenatal exposure to EDCs and serious health disorders even later in life, including developmental, reproductive and neurodevelopmental disorders, endocrine-related cancers and metabolic diseases (Swan, S.H. Environ. Res. (2008), doi:10.1016/j.envres.2008.08.007).

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

Endocrine disruption may lead to many different adverse effects. CHEM Trust proposes these priorities: There is a need for new test methods:
- to identify endocrine disrupting effect in various species in the environment
- to predict thyroid disruptive effects both in humans and in the environment, as well as
- test methods to reflect the existence of low dose effects e.g. by enhancing existing test methods to cover much broader dose ranges by including dose groups with very low exposure levels. In order to keep use of resources and use of experimental animals as low as possible the enhancement could be to include more dose groups with fewer animals reflecting a broad dose range, however, still in compliance with statistical needs.
- test methods covering effects during senescence, and including more endpoints relevant to predict effects in females,
- in general test methods covering the whole life cycle of organisms and non-EATS modalities

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

CHEM Trust proposes to include a systematic screening for ED-properties both with non-test methods and in-vitro test batteries in all provisions for data requirements as a first step to inform and prioritize further testing. All OECD ED relevant test methods should also be included and until test methods to identify all ED-

properties (see point 15) have been developed, special attention should be given to these shortcomings when evaluating data.
The requirement to use the latest OECD test method should be included or old studies should be supplemented (e.g. always EORGTS and with cohorts and old 2-gen. studies need supplemented studies with relevant ED-endpoints). The current approach in REACH is not sufficient to protect humans and wildlife against adverse effects from EDs as EDs may cause serious effects even at very low doses and in next generations. Therefore, there is a need for establishing a screening procedure even for low tonnages, followed by more data requirements.

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

Data requirements under BPR and PPPR cover all substances whereas under REACH is dependent on tonnage level with no specific data requirements for ED, so the likelihood of identifying EDs under REACH seems lower when looking at data requirements, only. However, use of EOGTRS (currently the most definitive test method for detection of human ED effects) is mandatory for the highest tonnage level in REACH and further, ECHA has developed tools for screening of potential ED-substances which can be used to increase ED-identification under different regulatory procedures. In practice, most EDs have been identified under REACH.
All provisions on data requirements are insufficient to properly identify EDs due to a lack of: systematic screening for ED-properties both by non-test and by in-vitro test methods, comprehensive and relevant test methods to identify all ED-properties (see also point 15)) as well as general requirement for using the latest and most comprehensive OECD test methods.

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

Data requirements under BPR, PPPR and REACH and the existing regulatory test methods are not sufficient to properly detect substances with ED properties. Currently, there are no specific ED data requirements in REACH and whereas the requirements for biocides and pesticides do, these are not reflecting latest scientific developments i.e. requesting a systematic screening for ED properties in scientific literature and by using non-test methodologies and in-vitro test batteries. There is also a lack of adequate test methods to properly detect EDs, and in addition, the existing test methods are not utilized optimally e.g. it is still allowed to use the 2-gen reproduction toxicity assay instead of the EORGTS with cohorts in the PPPR/ BPR and in REACH, the cohorts for DNT and IT are not a mandatory part of the EOGRTS. Data requirements as regards effects on the environment are limited/ inadequate. Data requirements under all legislation should reflect that EDCs have the potential to lead to serious and irreversible effects in current and future generations – effects that can be seen after exposure to very low doses and where the timing of exposure is critical. Therefore, an approach for data requirements based on quantities may be questionable as well as a very rigid approach. Use of existing information, QSARs and in vitro test batteries for identification of EDCs should be compulsory parts of all standard information requirements (even at lowest tonnage levels) as well as use of information from academic publications and mutual reference to available knowledge from human

health and environment and vice versa should be standard for deciding upon the further information and testing requirements. If concern about ED-properties is raised based on either QSARS or in vitro tests this should lead to direct requirements of definitive tests, see also report from Centre on Endocrine Disruptors (http://www.cend.dk/files/EDtestingstrategy.pdf).

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

Systematic screening for ED-properties both by non-test methods such as QSARs or read-across and by in-vitro test methods should be included in all provisions for data requirements as a first step to inform, support and prioritize further testing/investigations. These tools can be used to screen for certain ED-properties that needs to be further investigated, they can be used to support results from in vivo testing and they can be used to prioritize further testing, e.g. indications of ED-properties may lead directly to more definitive tests. These tools should also be used much more systematically in the work with grouping of substances. Can be used for grouping substances for regulation, to group substances and subsequently avoid unnecessary testing of similar chemicals and to group chemicals with the aim of initiating supportive testing. Thus priorities can be set and more transparency will be achieved.

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

Systematic screening for ED-properties as proposed above under 19) will lead to more sensible and effective testing, avoiding unnecessary testing. Using a grouping approach for similar substances will also help. New provisions for sensitive uses, i.e. regulations that prohibit endocrine disruptors and suspected endocrine disruptors for consumer use will also lead to less testing and thereby improve animal welfare. This could be achieved by establishing a cat 2 for suspected EDCs. Using this approach will lead to minimization of exposures and less use of animal tests. Today many tests are carried out to defend continued use of a chemical.

Another way forward to minimize animal testing and increase coherence in data generation is to establish a central and independent testing entity that is entitled to conduct chemical testing for EU-regulatory purposes. Industry can then apply and pay for the testing necessary for the approval or registration of chemicals.

Effectiveness of regulatory procedures

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

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

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

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

1000 character(s) maximum

EDCs are used in many sectors and they can be found at home and in the workplace, in the manufacture of plastics as well as in the food (from pesticide residues or biocides found in various consumer products). The problem is not necessarily that many of the mentioned sectors do not have a specific identification system by themselves. They should rather all refer to a main identification system for EDCs (either in CLP or a separate horizontal identification scheme, or also in REACH). The main issue therefore is to create this identification system and ensure the other laws refer it so that controls can be established to reach the goal of minimizing exposures. Thus, a horizontal identification can be ensured and the respective regulatory consequences (use restrictions with potential derogations) can be sector specific.

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

- Most of these laws do not mention EDs as potential problem chemical and have no mechanism to address regulatory consequences. EDC identification under one regulation such as REACH should automatically trigger risk management measures for the same substance under all the other relevant regulations.
- As an example: the cosmetics law should be amended to say that all EDs/suspected EDs identified under REACH and biocides should automatically be restricted (listed in Annex II).
- The same applies to toys, medical devices, and to food contact materials (FCM): currently 4 reprotoxic phthalates are restricted in consumer products but allowed and widely used in FCM.
- For the WFD: identified EDCs should automatically be listed as priority hazardous substances (and treated as non-threshold chemicals),

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)	◉	○	○

Other:

50 character(s) maximum

Drinking water directive

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

It is positive that many EU laws refer to regular scientific updates and that new information can trigger reviews or further investigation. However, there is a need to act more quickly on early warning signals from new scientific findings about potential health or environmental damages as highlighted in the EDC Free coalition paper (CHEM Trust is a member).
Moreover, there is often a delay in acting on new science and clear procedures and deadlines are missing. One example is the EU test method regulation which is not systematically updated when new OECD tests have been agreed upon. There is an enormous time lag between the adoption of a test method and the practical implementation and use in the EU. Likewise, many EU guidance documents are not systematically updated when new test methods, assessment methods or data have become available. Therefore, the regulatory framework should be constructed in a way that swiftly allows for including new scientific data and methodologies.

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

2000 character(s) maximum

Identification of EDCs under REACH, PPPR and BPR is excruciating slow - in practice only a few steps have been taken in order to minimize exposure to EDCs despite public and political concern and the maturity of knowledge to support regulatory action. This is extra worrying as full effect of subsequent regulatory interventions will only take place after a generation of time. This has huge impact on EU citizens and environment, e.g. suffering due to diseases, decrease in biodiversity and enormous annual societal costs e. g. 163 billion € as estimated by Trasande et al 2016. A new horizontal and precautionary approach to identify and control EDCs across all relevant laws should reflect EDC-properties such as; serious and irreversible effects even a very low doses, effects later in life/next generations, occurrence of NMDR, critical role of time of exposure, many uncertainties, incl. non-threshold, related to their risk assessment, and combination effects. Suspected EDCs should also be identified. All data requirements should include systematic screening for ED-properties guiding further testing and new relevant ED test methods should be

developed. The best approach should include one EU identification leading to regulatory consequences in each of the specific legislative systems. Substances with similar properties should be grouped for regulatory action to avoid regrettable substitution. Seriousness of effects, ubiquitous exposure, limitations of adequate test methods and knowledge call for implementation of the precautionary principle - it should not be left to consumers to protect themselves; EDCs/suspected EDCs should not be allowed for all sensitive uses such as FCM, toys, cosmetics and medical devices. Full transparency of all ED assessments and official EU-lists of EDCs and suspected EDCs will allow responsible companies to substitute EDCs with less harmful substances and consumers will be able to take informed choices on chemicals/products to avoid.

Added value of EU level intervention

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

34) Do you think:

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

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

1000 character(s) maximum

Ideally, all measures taken to protect humans and environment should cover the entire EU. However, in cases 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 danger will be unacceptably compounded by postponing mitigation until EU has responded with an EU wide action, it should be allowed to take national action. In the past, single action by individual member States has often led to EU action and positively contributed to the protection goals as well as societal costs. The recent Fitness Check of Chemical Regulation has shown that the benefits of EU chemicals legislation significantly outweigh the costs.

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

1000 character(s) maximum

A new and improved cross-sectoral identification and regulation of EDCs at EU level will first of all lead to an enormous increase in protection of health and the environment. Moreover, it will also lead to innovation and more sustainable solutions, thus increasing the competitiveness of European industry and contributing to the key components of the European Green Deal. The huge impact of EDCs on the environment and on human health, including from substances that affect neurodevelopment effects, cannot be emphasized enough – it is the reproduction and brain development of future generations that is at stake.
Therefore it will be imperative to act on substantial evidence rather than absolute proof (see No Brainer report CHEM Trust https://chemtrust.org/brain-policy-recommendations/) Moreover, allowing only essential uses of EDCs could also be a helpful concept to steer towards a more sustainable use of chemicals.

Useful links

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

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

Contact

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