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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 (https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF) '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 (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-2470647_en).
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. (https://ec.europa.eu/eusurvey/runner/ED_FC_PublicConsultation)

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

Alicia

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*Organisation name

50 character(s) maximum

American Chamber of Commerce to the European Union

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)

*In which sector does you organisation operate?

Tick all that apply

- ☑ Plant Protection Products
- ☑ Biocidal products
- ☑ General chemicals
- ☑ Toys
- ☑ Detergents
- ☐ Fertilisers
- ☑ Electric and electronic equipment
- ☑ Food contact materials

- [x] Food additives
- [x] Cosmetics
- [x] Medical devices
- [x] Human and veterinary medicines
- [x] Water industry
- [ ] Waste/recycling industry

*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.

[x] 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 **identification** 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)

1,000 character(s) maximum

EU regulations such as REACH, Cosmetics Directive, Biocides, Plant Protection Products etc have demonstrated that substances which cause adverse effects in animal and ecotox studies and which act via an endocrine mechanism can be identified - so there is not a problem of incoherent identification today since the WHO IPCS definition and HR/MoA framework can be implemented utilizing robust weight of evidence science. However there is potential in the future for incoherence as more assessments of substances are conducted and by different EU Agencies for the different regulations. Horizontal criteria and/or guidance in line with the WHO definition for identification of EDs could then be helpful to avoid incoherence. Once an ED is identified risk assessment would be the important next step with risk management occurring at the sector/application level.

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.

1,000 character(s) maximum

CLP and GHS use identified adverse effects for hazard classification - so substances with adverse effects which may be caused by an endocrine mode of action are identified under CLP/GHS. Endocrine activity is a mode of action and GHS/CLP does not address mode of action at all and was never intended to do so. So it would then be redundant and duplicative to introduce a new ED classification since the adverse effects are already identified under GHS/CLP. REACH, Biocides, Crop Protection Agents can already identify EDs without the need for an ED CLP/GHS classification - indeed such identification of an ED already involves in several cases the existing CLP/GHS classification for the adverse effects. With respect to question 4. on risk management CLP/GHS involve hazard identification and communication and not risk management. REACH has already demonstrated the ability to identify EDs and to take risk management steps, without the need for CLP/GHS identification as an ED.

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 other approaches could be applied to the identification of endocrine disruptors under the CLP Regulation? What would be the consequences for protecting human health and the environment? What would be the economic consequences?

2,000 character(s) maximum

As already stated CLP is designed for hazard classification based on adverse effects - to introduce mode of action into a hazard classification and communication system would create potential complexity, duplication and confusion. Other regulations have shown that EDs can be identified, be risk assessed and subject to risk management without requiring a specific ED CLP classification. Including mode of action such as endocrine activity in the CLP/GHS would also lead to increased costs in implementing the regulation due to the additional complexity and bureaucracy that would be involved. Human health and the environment already have a very high level of protection based on regulation and risk assessment based on adverse effects. The previous major ED Options exercise conducted by the European Commission and JRC for criteria for Biocides and Crop Protection Agents reached this conclusion and rejected the three categories Option, and decided for identification of EDs of regulatory concern - there is no new information which would lead to the need to change this conclusion. The Commission concluded at the time that multiple categories could "lead to legal uncertainty, unpredictability and lack of operability because MS and stakeholders may interpret differently regulatory consequences", "may also reduce harmonisation in the single market", could be "expected to lead to additional animal testing", and "may lead to "black listing" of substances […] and may then impose additional burden to economic sectors".Including an additional category of "suspected" EDs would also likely lead to stigmatization of substances with potential market deselection - with substances beneficial for society being impacted with either no health or environmental benefit resulting or even negative consequences due to loss of substances which contribute to protecting health and the environment.

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.

2,000 character(s) maximum

Coformulants for biocides and crop protection agents may be assessed and controlled both under REACH and the BPR and PPP regulations, with the potential for different outcomes. REACH Authorisation allows a risk based approach (if a threshold can be established) - this is the preferred approach for the sustainable management of chemicals. Similarly medical devices and cosmetics regulations allow for a risk based approach - which again is the preferred approach to allow continued safe use of beneficial products/devices.

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.

1,000 character(s) maximum

As already stated there is a potential need for horizontal criteria and/or guidance to avoid incoherence between different evaluations by different EU agencies / stakeholders under different regulations. While this is not an issue today it is a potential issue for the future as more assessments are conducted. There is a potential overlap with biocidal inert ingredients which may be evaluated for ED properties under both the Biocides Regulation and REACH for example. Once a substance is identified as an ED using the common criteria (using the WHO definition) and with a robust weight of evidence expert assessment then risk assessment can be conducted based on the uses and potential exposure and with risk management at the sector level. A hazard based approach does not provide a sustainable and predictable environment since it means that many beneficial substances could be restricted based on hazard alone, when in practice they may well be able to be used safely based on RA

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.

1,000 character(s) maximum

As yet major issues or problems have not been experienced but the potential certainly exists for the future. Many other countries and regions of the world are working on the assessment and identification of EDs. They primarily include the Americas and Asia, specifically the United States, Canada, Brazil,
China and Japan, all key EU trading partners. An approach to ED identification not based on
internationally-recognised scientific principles, such as the definition issued by the WHO/International
Programme on Chemical Safety (IPCS) in 2002, and testing methods based on international standards,
such as the Organisation for Economic Cooperation and Development (OECD) framework for testing
and evaluating ED (revised in 2012)5, as well very importantly as the use of robust weight of evidence expert hazard AND risk assessment, will inevitably lead to the creation of trade barriers between these trading partners.

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

2,000 character(s) maximum

It is crucial that robust scientific evidence, fundamental principles of toxicology, and hazard characterisation be incorporated into the criteria for ED identification as well then as allowing for sectorial or multi-sectorial (where multiple different uses) risk assessment and risk management of substances identified as EDs. If not, many substances will be identified as ED and potentially restricted/banned/deselected even though they present no risk in current uses. This could have potentially major unintended consequences for health, agriculture, trade, industry and the economy across Europe.
AmCham EU calls on EU policy-makers to work with other governments, and to base its proposal on existing work by the OECD and the WHO, to develop robust scientific criteria for identifying ED that fully take into account the internationally-recognised principles of toxicology, associated definitions and frameworks which include:

- Adverse effects and their severity and reversibility;
- Dose response;
- Endocrine mode of action and causality;
- WHO definition of EDs;
- OECD Framework for the Assessment and Testing of Endocrine Disruptors.

A full risk assessment must also be applied to identify endocrine disrupting substances which are of concern to human health and the environment. Substances identified as presenting an unacceptable risk should be subject to the appropriate regulatory action. Not following the above path will lead to impacts on competitiveness, innovation and investment within the EU and also lead to trade barriers.

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

2,000 character(s) maximum

While the criteria adopted under the Biocides regulation if implemented as written are robust and involve weight of evidence, the approach under the Biocides regulation is to a very large degree driven by hazard only - leading to not approving substances for biocidal use based on ED properties alone. This then results in products with benefits for human health (protection from bacterial disease) being restricted where risk assessment may show safe use, and therefore restriction of use brings no added value. This illustrates the importance of the risk based approach versus hazard only approach. Public health and public hygiene: guaranteeing the highest level of public health in Europe
Biocidal substances are critical to both our public and private health systems. Biocidal products serve as disinfectants for human, surface, equipment, veterinary, food and feed, as well as preservative and pest control uses. They prevent the spreading of infections by harmful micro-organisms in places where hygiene is critical, such as hospitals, dining areas and swimming pools. (In-can) preservatives not only protect the shelf life of products, but they also prevent bacterial contamination or mould development, which may lead to human infections.
Rodenticides are also essential for the protection of human and animal health and food stocks, as well as the prevention of all other damages caused by rodents. Insecticides meanwhile prevent insect-borne diseases such as malaria. Biocides are essential in our everyday lives for the purposes of prevention and protection.
Under the BPR, biocidal substances identified as EDs will be automatically prohibited with no further evaluation or assessment. This will be the case unless a specific exemption for public health reasons is granted, which has thus far never occurred. Even if an exemption was granted, such a substance would nevertheless be a candidate for substitution.

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

2,000 character(s) maximum

While the criteria adopted under the Plant Protection Products regulation if implemented as written are robust and involve weight of evidence, the approach under the regulation is to a very large degree driven by hazard only - leading to not approving substances for plant protection use based on ED properties alone. This then results in products with benefits for plant protection and food production being restricted where risk assessment may show safe use, and therefore restriction of use brings no added value.
Agriculture and food production and supply: securing a future for European farming
The use of crop protection agents is essential in ensuring sustainable food production. If many are banned due to a hazard only approach rather than using risk assessment, then this could have major adverse impacts on food production and price, with associated negative consequences on health, the environment and society as a whole.
This risk is very high and has been assessed in a study2 carried out in the UK. This study has shown that if dose response is not considered when determining whether a substance is an ED, then the number of crop protection agents available could be reduced by as much as 40%. This would have enormous implications for the availability and supply of essential foods and their prices.
The example of azole fungicides is illustrative. Azoles are the backbone of crop protection in a number of key crops like cereals and cannot be easily substituted. After decades of use, they continue to protect wheat from a damaging disease called Septoria. While azole fungicides are known to affect endocrine activity, risk assessments have shown they can be used safely.

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

2,000 character(s) maximum

There is a high level of protection of consumers, workers, citizen (environment) under REACH on the basis of the identification of the adverse endocrine effects of substances - the additional understanding on mode of action and the link with the adverse effect does not necessarily bring significant additional protection. This will depend on other factors such as relevance of animal findings to humans. The additional requirements to understand mode of action and the link with the adverse effects mean additional resource and cost requirements compared to non-EU competitors which can undermine competitiveness of EU producers. The additional requirements will also mean potentially more animal studies or in vitro studies which also require animals to some degree. It is in principle possible under Authorisation (REACH) to have an ED authorized based on risk assessment - however the hurdle seems to be very high to do this re: demonstration of a threshold - this is the reason for the strongly disagree for enhancing competitiveness.Also under REACH we see rejection of proportionate testing with read across when it comes to testing requirements - hence moderately disagree on alternatives to animal testing.

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

2,000 character(s) maximum

The Cosmetics regulation has a robust risk assessment process as described by the Vice Chair of the Scientific Committee on Consumer Safety (SCCS) at the November 8 Commission Annual Endocrine Forum. This process leads to the identification of EDs and their safe use in cosmetics or restricted use as appropriate based on the risk assessment. This is achieved through risk assessment and NOT by minimizing exposure per se. This robust risk assessment process can then lead to improved competitiveness and innovation.

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

2,000 character(s) maximum

The Medical Devices regulation allows for the continued use of EDs based on a risk assessment process. This process leads to the identification of EDs and their safe use in Medical Devices or restricted use as appropriate based on the risk assessment. This is achieved through risk assessment and NOT by minimizing exposure per se. This robust risk assessment process can then lead to improved competitiveness and innovation.

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

2,000 character(s) maximum

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

1,000 character(s) maximum

A high level of protection is provided by extensive regulations based on the identification of adverse effects including those which are occurring via an endocrine mode of action. Risk assessments take into account aggregated exposure to the same substance from all exposure sources with assessment versus tolerable/acceptable intakes / DNELs, enabling a determination of safe use or risk with the requirement to regulate or not as the case may be.

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

1,000 character(s) maximum

Combined exposures to different substances can often still be within tolerable/acceptable intakes/DNELs which always include large safety factors applied to no adverse effect levels in animal studies. This then means that there are often large margins of safety between exposures and tolerable limits. Further in-depth evaluation of combined exposures should certainly be considered where there is potential for significant exposure to substances which act in a similar producing similar adverse effects. This has been done for example by ECHA for the four classified low molecular weight phthalates: DEHP, DBP, DIBP and BBP - although it should be noted that very conservative assumptions were made on DNELs for these substances. Restrictions have now been proposed for flexible vinyl articles made with these substances by ECHA on the basis of combined exposure and identified risk - Commission has accepted the proposed restrictions and they come into force in July 2020.

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	◉	○	○

Data requirements and available regulatory test methods

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

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

- ◉ Yes
- ○ No

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

- ◉ Yes
- ○ No

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

- ○ Yes
- ◉ No

Please explain your answer and provide examples.

1,000 character(s) maximum

For EATS (Estrogen, Androgen, Testosterone and Steroidogenesis endpoints) regulatory tests are considered sufficient (See OECD Guidance Document 15). For wildlife there is potential for further improvement - although testing should be proportionate to tonnages, uses and potential exposure. It is not possible to test every substance for every endpoint nor is it necessary. Where there is potential concern then a tiered approach is appropriate (see OECD Conceptual Framework).

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?

2,000 character(s) maximum

Under all these regulations it is of fundamental importance to start an ED assessment by focusing on adverse effects or apical endpoints from mammalian studies – only once a robust weight of evidence assessment has been completed for adverse effects then the other aspects of ED re: mode of action and biologically plausible link can be addressed. These aspects also need to be addressed with a robust weight of evidence expert assessment including use of the IPCS Mode of Action/Human Relevance Framework for determining whether or not there is a biologically plausible link between the proposed mode of action and the adverse effect. It should also though be noted that mode of action assessment is research work – where assays and methods are often geared to the type of substance and the nature of the adverse effect – it is not possible nor appropriate to have a tandardized / tick box approach to mode of action. Assessment under REACH can potentially be further improved through use of horizontal criteria – these should be the same as for Crop Protection Agents and Biocides while recognizing that REACH chemicals are not designed for biological activity and that lower testing and data requirements should therefore apply. Under REACH it may also be possible to consider an ED assessment (akin to the PBT assessment required at >10 tonnes per year).

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.

1,000 character(s) maximum

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There are examples were such tests can be used systematically. It shoul
d though be noted that mode of action is research work where methods of
ten need to be geared to the substance and type of effect and potential
mode of action. Therefore it is not possible to have a tick box approac
h to mode of action.
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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?

1,000 character(s) maximum

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Build on the existing historical databases which have led to knowledge,
understanding and expertise relevant to substances and their uses. In p
articular balanced proportionate testing with read across should be use
d. This is not happening in practice in particular under the REACH regu
lation where it seems every box has to be ticked with an actual test on
the substance and where read across is often being rejected. This is fa
r from an efficient use of human and financial resources and appears to
be a pursuit of data for the sake of data with the associated implicati
ons for the extensive and disproportionate use of animals and impact on
animal welfare. In the ECHA Expert Group frequently proposals are made
for more animal and fish testing which are often not appropriate nor ju
stified.
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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)	○	○

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)	○	○

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)	○	○	○

Efficiency of regulatory provisions for endocrine disruptors

Benefits of regulatory intervention include human health and environmental protection, smooth functioning of the internal market, innovation and competitiveness. Costs can be economic (time, resources) as well as ethical (e.g. use of laboratory animals for testing). Efficiency considers the benefits in relation to costs.

25) Has the implementation of regulatory requirements for endocrine disruptors increased your total operating costs?

- ☑ Yes, to a significant extent
- ☐ Yes, but not to a significant extent

- [ ] No
- [ ] Not applicable

26) Has the assessment of substances for endocrine disrupting properties delayed your assessment work in other areas of human health or environmental protection?

- [x] Yes, to a significant extent
- [ ] Yes, but not to a significant extent
- [ ] No
- [ ] Not applicable

27) What is the cost increase for your company (companies your association is representing) to comply with the regulatory requirements (e.g. testing, restriction or ban) specifically related to endocrine disruptors?

	More than 10%	Between 5 and 10%	Between 1 and 5%	Below 1%	Don't know	Not applicable
Investment in the development of new testing methodologies for endocrine disrupting properties	○	◉	○	○	○	○
Costs related to the provision of test data on endocrine disrupting properties	○	◉	○	○	○	○
Costs related to the preparation of registration or authorisation dossiers covering endocrine disrupting properties	○	◉	○	○	○	○
Cost to replace substances due to endocrine disrupting properties (e.g. as a producer or user)	○	◉	○	○	○	○

28) What has been the impact of the provisions for endocrine disruptors on the sector you represent?

	Very negative	Negative	No impact	Positive	Very positive	Don't know	Not applicable

Innovation	○	◉	○	○	○	○	○
Productivity	○	◉	○	○	○	○	○
Profitability	○	◉	○	○	○	○	○
International trade	○	◉	○	○	○	○	○
Other (please specify)	○	◉	○	○	○	○	○

Other:

100 character(s) maximum

Investment in existing and new substances - uncertainty and lack of any regulatory predictability

Please explain your answers

1,000 character(s) maximum

The extension from adverse effects to include modes of action which can then potentially stigmatize substances unjustifiably and based on effects or hazard alone leads to significant uncertainty and lack of regulatory predictability. This applies also for CLP proposals for CMR for endocrine related adverse effects where such proposals are sometimes not justified by the science - this again leads to significant uncertainty in the market place with associated negative implications for innovation, productivity, profitability, international trade and investment.

29) Are the costs of the provisions for endocrine disruptor identification and management, for the sector(s) you operate in, justified and proportionate to the benefits accrued for society and the environment?

- ◉ Not at all
- ○ To some extent
- ○ Fully
- ○ Don't know

Please explain your answer

1,000 character(s) maximum

The large majority of the benefits accrued for society and the environment come from identifying adverse effects of substances and not modes of action. Risk assessment based on the adverse effects of substances provides a very high level of protection. In 2016 the European Commission did a survey on the "cumulative cost assessment for the EU chemical industry" - the conclusions was "When all legislation relevant to chemical companies is cumulated, the estimated average annual total direct cost borne by the subsectors covered by the study during the period 2004-2014 approaches €9.5 billion, representing around 2% of their turnover and 12% of the value added. Comparing cost with Gross Operating Surplus (GOS), which can be used as a proxy for profit, the cost represents as much as 30% of this value, indicating that legislation cost is among the important factors shaping the profitability of the EU chemical industry." This information illustrates the major cost impact of EU legislation.

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.

1,000 character(s) maximum

Modified tests, research methodologies, biomonitoring data, epidemiology data are all being used to a significant degree in the assessment of chemical substances. Majority of epidemiology studies are however not robust enough to make any firm conclusions - typically only that certain associations need further research. An in-depth robust weight of evidence assessment will aim to look at all relevant studies and integrate epidemiological findings with animal study findings, taking into account the quality, consistency and coherence of findings with appropriate expert assessments and conclusions being made (as opposed to picking isolated findings and non-robust studies to support conclusions)

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

2,000 character(s) maximum

The EU already has extensive regulations on chemical substances which ensure a high level of protection of human health and the environment. The topic of endocrine disruption can be addressed via the development of horizontal criteria to support consistent and coherent identification of EDs, With the application of risk assessment and risk management ED substances can continue to be used where risk assessment shows safe use or be restricted where risks are identified. The use of a hazard only based approach will not be sustainable in the long term since substances bringing significant health, environmental and sustainability benefits may be restricted based on hazard alone, when they may well in practice be able to be used safely. Many foodstuffs also contain naturally occurring endocrine disrupting substances.

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 (http://www.senat.fr/petite-loi-ameli/2012-2013/9.html), 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?

1,000 character(s) maximum

Under the TFEU (article 34 and 36)

35) Has your organisation been impacted by unilateral actions at national level?

◉ Yes
○ No

Please provide examples and details

1,000 character(s) maximum

Proposals to include certain plasticisers on the French National Endocrine Program/Strategy when these substances have already been extensively assessed. This then requires extensive discussions and communications usually in a very compressed timeframe. Any proposal from an authority can have a significant impact on the reputation of a substance - so it is important to have upfront dialogue before substance proposals also appear. Similar comments apply to Denmark.

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

1,000 character(s) maximum

In the EU we have the extensive regulatory framework including REACH, CLP, Biocides Regulation, Plant Protection Products, Medical Devices etc which is able to identify, risk assess and manage endocrine disruptors. This is particularly because the tests and data requirements in these regulations support the identification of adverse effects and which then enable further work to be conducted to identify the endocrine mode of action and the link with the adverse effects (or not as the case may be). Horizontal criteria can then support consistent and coherent identification of EDs, although it is critical that the implementation of the criteria is done via robust expert weight of evidence assessments, followed by risk assessment and risk management at the sector level.

Useful links

European Commission central information portal on endocrine disruptors (https://ec.europa.eu/info/policies/endocrine-disruptors_en) (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) (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-2470647_en)

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