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

Fields marked with * are mandatory.

Introduction

Scope and objectives

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

The aims of this stakeholder survey are:

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

Target audience

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

Instructions

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

Information on respondent

* I am giving my contribution as:

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

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

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50 character(s) maximum

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* Organisation name

50 character(s) maximum

EurEau

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
- ☐ Food additives
- ☐ Cosmetics
- ☐ Medical devices
- ☐ Human and veterinary medicines
- ☑ 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.

☑ 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

EurEau, the water sector, favours a hazard based approach for all chemicals (including EDCs) entering the water cycle, which takes into consideration the risk of adverse impacts (the intrinsic harmful properties) to humans and environment without taking exposure into account. We insist that source control approach, the precautionary and polluter pays principles should be applied.
From our point of view the setting and implementation of harmonised criteria for the identification of EDCs in all relevant legislation is key to protect the environment and to prevent harmful EDCs to enter the water cycle.
The assessment of endocrine disrupting properties has to be implemented/established as a stringent cut-off criteria in all autorisation processes related to the placing of chemicals on the European market.

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

EurEau favours the control at source and polluter pays principles and supports any action for implementing /establishing the assessment of EDCs as a cut-off criteria in all relevant autorisation of chemicals (as done in the PPP and biocides regulations and REACH).
The lack of specific and clear hazard symbols for ED hinders the clear identification of a substance as ED for consumers/public. Despite possible controls may already be in place, this may lead to inadvertently disposal of EDCs into the water ways via inappropriate disposal / misuse. There is therefore a strong branding and communication piece required (potentially similar to WEE recycling) and where there are clear safe disposal receptacles for people to avail of. The inappropriate disposal of products may have potential downstream impacts on water quality. Increased awareness may reduce this risk.

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

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

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

> Substances with ED properties should be considererd and regulated in all relevant authorisation processes of chemicals which are placed on the European market (EDCs to be a cut-off criteria as been done under the PPP and biocides regulation)

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

> No direct examples available

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

2000 character(s) maximum

> There is a need for a common definition of EDC across all EU legislation that also addresses chemical substances. This is linked to the hazard-based approach that EurEau advocates also for EDCs. It will allow streamlining data and knowledge collected in the frame of other policies and will lead to the right measures and/or authorisation.

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

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

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

EurEau considers REACH as the key instrument to control hazardous substances entering the urban water cycle and to fulfil the requirements for good chemical status in the Water Framework Directive and the protection of drinking water resources. It is essential that the authorisation process of REACH is used much more, identifying more substances of very high concern for the candidate list and using the authorisation process in a strict way. As concerns EDC a uniform defintion is vital for carrying out the 'chemical safety assessment' and documenting the 'chemical safety report' (cf. annex I of REACH). Also safety assessments (for EDCs) should take into account emissions to waste water, the efficiency of waste water treatment, emissions to water bodies and the impact of sewage sludge utilisation.

Despite the significant progress achieved under REACH to protect human health and the environment, facilitate communication throughout the supply chain and enable traceability, additional measures/criteria could be further explored to more adequately address aspects such as ED, as well as the mobility of chemical substances.

The ECHA website is very user friendly and provides a wealth of information – it is an excellent resource and should be utilised in the tracking of Endocrine Disruptors and information on same.

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

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

[2] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

11.e) The regulatory process to identify and control substances with endocrine disrupting properties in **Medical Devices** [3] is effective in:

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

[3] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

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

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

Please explain your answers

2000 character(s) maximum

The control of chemical substances und WFD is confined to a substance by substance approach, translated in 45 PS/PHS and a varying number of RBSPs. Many of these substances have endocrine disrupting properties (cf. annex VIII), and ED is also considered in the proposals of substances for the watch lists. However, in absence of uniform criteria, it is not clear how EDCs are taken into account in the member states. Furthermore, there are many more not-regulated chemical/ED substances and the effect of mixtures is not considered.
As concerns environmental monitoring under WFD, existing data from MS on emissions to water, including diffuse emissions, do not deliver robust enough data to show trends in releases of PS to water, and as a consequence on whether control/priority measures are effective, also related to EDCs. Hence reporting requirements must be optimised/harmonised.

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

See also previous remark, the issue is the substance by substance and sectoral approach of chemical legislation and the many unknown substances that can not be tackled with this policies. Effect-based monitoring methods may add to the assessment of aggregated exposure and combined effects of EDCs.

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

Idem previous explanation.

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

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.

1000 character(s) maximum

REACH

18) Do you have any further comments on available regulatory test methods and data requirements under REACH, the Biocidal Products Regulation, the Plant Protection Products Regulation, and other sector specific legislation?

2000 character(s) maximum

Regulatory testing and animal welfare

Data generation according to standard information requirements is expensive, time consuming and requires the use of animals. The recently adopted criteria for identifying of endocrine disruptors require information on endocrine activity and adverse effects.

19) Do you agree with the following statement?
In vitro and/or *in silico* methods are not used systematically enough to prioritise further investigations.

- ○ Strongly agree
- ○ Moderately agree
- ○ Neither agree nor disagree
- ○ Moderately disagree
- ○ Strongly disagree
- ◉ Don't know

Please explain your answer.

1000 character(s) maximum

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

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

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

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?

- ☐ 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)	○	○	○	○	○	○	◉

Please explain your answers

1000 character(s) maximum

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

1000 character(s) maximum

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

The substance by substance approach is in contradiction to allowing applying more holistic methods on similar modes of action and or groups of chemicals.

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

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

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

- ○ Yes
- ○ No

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

1000 character(s) maximum

Useful links

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

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

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