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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

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Organisation name

50 character(s) maximum

KTF Organisation AB

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

- [x] Plant Protection Products
- [x] Biocidal products
- [ ] General chemicals
- [ ] Toys
- [x] 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 **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

The identification of endocrine disruptors should be done by harmonised criteria, it should not matter in what product category the substance is used. The identification should be kept at substance level. However, the risk management can differ in the different sector specific legislations. Companies often operate in different sectors and it would be most confusing if the identification process of an ED is different in each sector.

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 already captures the different hazard categories that are needed. CLP does not focus on the mode of action but on the actual hazard of the substance, which is sufficient also for ED substances. There is a process running within REACH that can identify and assess possible ED substances. There is no need for a hazard category regarding EDs since the focus should be on the effect of the substance rather than the ED mechanism itself.

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

We believe there is no added value if a category for "suspected endocrine disruptor" should be introduced. We see an obvious risk in a black-listing effect that would lead to significant economic consequences for industry. We favor harmonized scientific criteria for identifying the ED substances as well as harmonized categorization. To introduce a category for "suspected" ED would need a thorough socio-economic consequence analysis.

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

EDs are treated differenly in the biocide, plant protection and REACH regulation. The identification of an ED should be consistent between different legislations, but the risk management would need to be adapted to the different exposures/uses.

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

There is a lack in common criteria between the different pieces of legislation to identify ED. If EDs are identified through the different sector legislations there is an increased risk of overlaps in the outcome.

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

- ○ Yes
- ◉ No

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

2,000 character(s) maximum

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

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The identification of an ED needs to be linked to a risk assessment to have
an effect regarding for instance exposure etc..
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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

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

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 Cosmetic Products Regulation stipulates that cosmetic products are safe for humans with regards to exposure. The possible environmental effects of substances used in cosmetic products are taken care of by REACH. Both regulations allow the regulation of EDs. Again there is a need for a horizontal definition for EDs that allow the identification of EDs regardless of sector of use. However, risk management should be handled by each specific sector of use.

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

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

REACH already has some safety factors included in the regulation. The Cosmetic Regulation takes aggregated exposure into consideration in the SCCS recommendations, for instance regarding preservatives.

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

REACH focuses on evaluations of individual substances. The current approach has a large margin of safety that takes care of the risk for combined exposure of substances in a reasonable way. We believe the current approach is sufficient in the REACH regulation. Further scietific research might indicate otherwise in the future, but aggregated exposure should not be included in REACH at this point.

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

Which tests should be developed?

1,000 character(s) maximum

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There are not enough tests to identify EDs without animals for cosmetic
products. Animal testing is banned in the Cosmetic Products Regulation. It
is problematic that the definition of EDs rely on animal data.
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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.

1,000 character(s) maximum

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There is not enough data on the substances in the lowest tonnage range of
REACH.
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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

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There is much more data requried for approval in the Biocide and Plant
Protection regulations than in REACH. The cost and time to reach an approval
for Biocide or Plant protection would indicate that it is not possible to
copy the requirements into REACH and more than 20000 substances.
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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

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

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

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?

- ☐ 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

Please explain your answers

1,000 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

1,000 character(s) maximum

We are very worried that there will not be any preservatives (regulated by the BPR) available in the future, partly due to the implementation of the ED exclusion criteria in the BPR.

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

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

All regulations should be based on scientific risk assessments.

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.

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

- Yes
- No

Please provide examples and details

1,000 character(s) maximum

The French ban on BPA in food contact materials and the Danish ban on some parabens in cosmetic products for children under three years.

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

1,000 character(s) maximum

All regulations should be based on scientific risk assessments, not on a mode of action of a substance.

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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