Contribution ID: 22b2a34b-684b-4cf3-99f6-0931ad230e8a
Date: 31/01/2020 16:21:43

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

Fields marked with * are mandatory.

Introduction

Scope and objectives

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

The aims of this stakeholder survey are:

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

Target audience

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

Instructions

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

Information on respondent

* I am giving my contribution as:

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

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

* First name

50 character(s) maximum

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50 character(s) maximum

kit.bowerin@breastcanceruk.org.uk

* Organisation name

50 character(s) maximum

Breast Cancer UK

Country of origin of your organisation

- ○ Austria
- ○ Belgium
- ○ Bulgaria
- ○ Croatia
- ○ Cyprus
- ○ Czechia
- ○ Denmark
- ○ Estonia
- ○ Finland
- ○ France
- ○ Germany
- ○ Greece
- ○ Hungary
- ○ Ireland
- ○ Italy
- ○ Latvia
- ○ Lithuania
- ○ Luxembourg
- ○ Malta
- ○ Netherlands
- ○ Poland
- ○ Portugal
- ○ Romania
- ○ Slovak Republic
- ○ Slovenia
- ○ Spain
- ○ Sweden
- ◉ United Kingdom
- ○ Other (Please specify)

* Scope

- ○ International
- ◉ National
- ○ Regional
- ○ Local

* Organisation size

- ○ Micro (1 to 9 employees)
- ◉ Small (10 to 49 employees)
- ○ Medium (50 to 249 employees)
- ○ Large (250 or more)

* **Publication privacy settings**

The Commission will process the responses of this stakeholders survey for the purpose of the Fitness Check on the EU legislation on endocrine disruptors. This includes the publication of a summary report of the survey. You can choose to give your consent to publish your personal details, or to remain anonymous.

- ○ **Anonymous** - Only your stakeholder group, country of origin, sector, scope and size of your organisation may be published. Your personal details will not be published.
- ◉ **Public** - Your personal details may be published with your contribution.

☑ I agree with the following personal data protection provisions

Personal data protection provisions

Privacy_statement.pdf

Survey

1) How familiar are you with the following pieces of legislation?

	Not at all familiar	A little familiar	Fairly familiar	Very familiar
Plant Protection Products Regulation (EC) 1107/2009	○	○	◉	○
Residues of Pesticides Regulation (EC) 396/2005	○	◉	○	○
Biocidal Products Regulation (EU) 2012/528	○	○	◉	○
REACH Regulation (EC) 1907/2006	○	○	○	◉
CLP: Classification, Labelling and Packaging of substances and mixtures (EC) 1272/2008	○	○	◉	○
Persistent Organic Pollutants Regulation (EC) 850/2004 and (EU) 2019/1021	○	◉	○	○
Food Contact Materials Regulation (EC) 1935/2004	○	○	◉	○
Contaminants in Food and Feed Regulation (EEC) 315/93 and Directive (EC) 32/2002	○	◉	○	○
Food Additives Regulation (EC) 1333/2008	○	◉	○	○
Cosmetic Products Regulation (EC) 1223/2009	○	○	◉	○
Medical Devices Regulation (EU) 2017/745	○	◉	○	○
In vitro Diagnostic Medical Devices Regulation (EU) 2017/746	◉	○	○	○
Toy Safety Directive 2009/48/EC	○	◉	○	○
Fertilisers Regulation (EC) 2003/2003 and Regulation (EU) 2019/1009	◉	○	○	○
Detergents Regulation (EC) 648/2004	◉	○	○	○

Medicinal Products for Humans Directive 2001/83/EC	◉	○	○	○
Veterinary Medicinal Products Regulation (EU) 2019/6	◉	○	○	○
General Product Safety Directive 2001/95/EC	○	◉	○	○
Water Framework Directive 2000/60/EC	○	○	◉	○
Priority Substances Directive 2013/39 EC	○	◉	○	○
Drinking Water Directive 98/83/EC	○	◉	○	○
Groundwater Directive 2006/118/EC	◉	○	○	○
Marine Strategy Framework Directive 2008/56/EC	○	◉	○	○
Urban Waste Water Directive 91/271/EEC	○	◉	○	○
Chemical Agents at Work Directive 98/24/EC	◉	○	○	○
Carcinogens and Mutagens at Work Directive 2004/37/EC	○	◉	○	○
Pregnant Workers Directive 92/85/EEC	○	◉	○	○
Young People at Work Directive 94/33/EC	◉	○	○	○
Waste Directive 2008/98/EC	◉	○	○	○
Restriction of the use of certain hazardous substances in Electrical and Electronic Equipment - Directive 2011/65/EU	○	◉	○	○
Industrial emissions Integrated Pollution Prevention and Control Directive 2010/75/EU	◉	○	○	○
Seveso-III-Directive 2012/18/EU	◉	○	○	○
Ambient Air Quality and Cleaner Air for Europe Directive 2008/50/EC	○	◉	○	○
Regulation (EC) 66/2010 on the EU Ecolabel	○	◉	○	○

Horizontal approach to the identification of endocrine disruptors

Recently the European Commission published criteria for the identification of endocrine disruptors under both the Biocidal Products Regulation and the Plant Protection Products Regulation, which were very similar to each other and based on the WHO definition [1]. Other pieces of EU legislation related to human health and environmental protection from manufactured chemicals do not contain such criteria.

[1] "*An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations*."

2) To what extent does the absence of harmonised criteria pose a problem to a coherent approach for the **id entification** of endocrine disruptors?

- ◉ It is an important problem, leading to incoherent identification of endocrine disruptors across sectors

- ( ) It is not a problem, the criteria should be sector specific

Please explain your answer, indicating the sector(s) in which this problem occurs (max 1000 characters)

1000 character(s) maximum

Breast Cancer UK shares the views presented by leading scientific experts in the March 2019 European Parliament report “ED: from Scientific Evidence to Human Health Protection” (p. 80).

- Identification of EDCs must be based on a unique cross sectoral definition of EDCs, distinguishing known EDCs, presumed EDCs and suspected EDCs.

- In the case of sector-specific assessment and to avoid protection gaps and incoherence, the recognition of a substance as an EDC in one sector must automatically entail its recognition as an EDC in all other sectors.

Breast Cancer UK has long been concerned that exposures to oestrogenic EDCs is making us more vulnerable to breast cancer. Based on the sufficient scientific evidence of EDCs present in these items /products, we stress in particular the consequences of the current incoherence with regards to public exposure to EDCs via pesticides, cosmetics, toys, food contact materials, packaging, and in particular exposure of vulnerable groups.

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

A hazard category in CLP/GHS could be one way of achieving a more coherent identification system. However, improving EDC identification is a more urgent requirement for improving clarity and reducing EDC exposures. This can happen today without waiting for an agreement on a new category in the CLP, and should proceed without delay. A coherent cross-cutting identification system could also be achieved with a separate overarching umbrella identification system. An international agreement on a GHS category will take years and should not delay changes to identification and regulations in the EU.

We believe introducing a hazard category in the CLP/GHS could help recognise that EDC hazard is

equivalent to that of CMRs. The CLP should also be amended to include the environmental consideration of EDCs. Improving the coherent risk management of EDCs across sectors also requires changes for better risk management decisions in the sectoral legislation.

The CLP Regulation applies different approaches to categorise hazards depending on the endpoints, which may include aspects related to severity of effects or strength of evidence. Some stakeholders have suggested to classify endocrine disruptors in one of three categories based on the level of evidence: i.e. known, presumed or **suspected**.

5) Do you think that a category of **suspected** endocrine disruptor should be introduced?

- (●) Yes
- ( ) No

What should be the regulatory consequences of such a category? What would be the consequences for protecting human health and the environment? What would be the economic consequences?

2000 character(s) maximum

Breast Cancer UK supports calls for EDC characterisation to be done according to the 3 categories (known, presumed, suspected). This is coherent with current approaches to rank other chemicals, e.g. how cancer-causing chemicals are classified. It enables transparent communication on a given chemical according to the level of scientific evidence available and recognises the limitation of test methods currently available. Several Member States are already taking initiatives to have a list of “suspected EDCs” and this should be introduced at an EU level to ensure EU legislation delivers the highest levels of public health and environmental protection. In the first instance this list could comprise the EU’s own category 1 priority list of suspected EDCs. Categorisation of suspected EDCs should result in a ban with possibility for specific derogations, in cases where essential uses can be demonstrated, and no suitable alternatives exist. It should also lead to adequate information being communicated across the supply chain through clear product labelling.

Current product labelling requirements also remain inadequate. Manufacturers are only obliged to reveal whether their products contain EDCs which are substances of very high concern (SVHC) and the substance is present in an article above 0.1% concentration. If a consumer writes to the manufacturer to request that information, they then have to wait over 45 days to get that information. More stringent measures are required to ensure manufacturers and producers are required to label their products if they contain chemicals of concern e.g. EDCs.

The system of three categories is very transparent and allows for an effective and efficient use of resources by focusing regulatory action in differentiated ways according to the categories. With more transparent information on the status of a given chemical companies can make smart choices and invest into safer alternatives to drive sustainable innovation.

Rationale and consequences of different regulatory approaches

Under some pieces of legislation, endocrine disruptors are regulated based on their hazardous properties, whereas under others they are regulated on the basis of risk.

6) Are you aware of any inconsistencies in the way chemicals are **identified and controlled** with regard to endocrine disrupting properties across regulated areas in the EU?

- (●) Yes
- ( ) No

Please provide examples and describe the consequences.

2000 character(s) maximum

EDCs are identified and regulated across different EU legislative frameworks which vary very much in their approaches: in the context of pesticides and biocides regulations, EDCs are regulated based on hazard-based cut-offs while other frameworks such as food contact materials, cosmetics or toys regulate EDCs based on a case-by-case risk assessment. Identification of EDCs under REACH does not result in automatic consequences for other regulations (for example BPA was identified as a substance of very high concern in 2017 and is restricted under REACH, yet it is still allowed in food contact materials other than baby bottles). Furthermore, EDCs should be regulated by using grouping approaches, where possible, based on similar structures and similar properties to avoid instances of regrettable substitution. It is also important to consider the “cocktail effect” of exposure to multiple chemicals. Differences in identification and control give rise to the array of inconsistencies and regulatory gaps contained within the EU’s legislative framework for EDCs, which negatively impact public health and environmental protections.

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

EDCs identified under REACH do not trigger the necessary regulatory consequences under other pieces of EU legislation. In addition, the time lag between identification and regulation via authorisation takes years. We believe that during this transition period, identification of EDCs under REACH should lead to an automated restriction for use of these EDCs in consumer products such as toys, cosmetics and FCM where well known regulatory loopholes exist.

Where regulations technically allow for ED management, test requirements for EDCs are inadequate (including within REACH, pesticides and biocides). To date, EDC regulatory options do not allow for the banning of any substance under either pesticide or biocide laws. Breast Cancer UK believes that EDCs should be regulated with the presumption that no safe threshold for exposure can be set with sufficient certainty. Regulators must adopt a precautionary interpretation of scientific knowledge in order to best protect public health.

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

The WHO has warned that EDCs are “a global threat that needs to be resolved” (State of the Science Report, 2012). As the UK leaves the EU on January 31st, Breast Cancer UK is calling on the UK Government to retain the closest possible relationship with REACH and ECHA to ensure Brexit does not weaken environmental protections from EDCs. We believe that allowing the UK to remain within (and bound by) REACH and participating in ECHA (in a non-voting capacity) remains the best solution, so long as the UK accepts the conditions set by the EU 27.

Should the UK set up its own chemicals regime, we are calling for such a regime to incorporate the precautionary principle, feature a hazard-based approach and adopt criteria for identifying EDCs which includes regulation of substances that ‘may’ cause adverse health effects. The consequences of failing to retain alignment with EU chemical laws will be divergence and less robust regulations which could enable more EDCs to enter the UK market.

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

2000 character(s) maximum

The lack of coherence across EU legislation is a major issue that's needs to be urgently addressed: see EDC-Free Europe "Our eight demands for an EU EDC strategy" May 2018 which Breast Cancer UK co-signed.
The Commission must also take account of the following developments:

Environment Council Conclusions on chemicals June 2019 – which urged the commission to ensure a high level of protection of human health and the environment by minimising exposures to endocrine disruptors, and by stimulating substitution by safer chemicals.

European Parliament resolution on endocrine disruptors April 2019 – MEPs called on the Commission to swiftly take all necessary action to ensure a high level of protection of human health and the environment against EDCs.

Study for the European Parliament "Endocrine Disruptors: from Scientific Evidence to Human Health Protection March 2019 "The heterogeneous regulation of EDCs in different sectors is hard to justify scientifically" section 4.1.3 "Even with specific sectors, management of EDCs generally lacks coherence", "There are surely historical or political reasons for this lack of coherence, but the situation seems hard to justify from scientific and public health standpoints, especially when considering the core principles of the EU such as the Precautionary principle and the 7th EAP".

Over the past four years, the Commission has worked on three major evaluations within the EU chemicals policy. All the results from these evaluations have illustrated the array of legislative gaps and actions required in addition to the studies and political requests listed above. Therefore, the Commission must deliver proposals this year which:

- Close loopholes which allow EDCs to enter toys, food contact materials and cosmetics.
- Establish an EU list of the most problematic and suspected groups of EDCs.
- Ensure legislative safety nets to build a clean circular economy and a non-toxic environment.

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

While in principle requisite tools are in place for the implementation of the Biocides Product Regulation (BPR), since the adoption of the criteria in June 2018, only two biocides active substances have been identified without leading to any ban. The work program is delayed by years. There are little perspectives for improvements towards better health protection from biocides in the short term. The data sets are old and inadequate in the context of their implementation, and the EU EDC criteria require a high burden of proof. People are being exposed without having any knowledge about it.

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

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

Please explain your answers

2000 character(s) maximum

The criteria for the identification of EDCs under the Plant Protection Products regulation is too restrictive and therefore inadequate. They are limited to ED tests available and the most sensitive tests for EDCs have not been delivered for pesticides. Furthermore, assessors are facing the problem of data gaps: and people continue to be exposed to such chemicals: according to EFSA, for 17 substances assessed since 2018 dossiers had data gaps and conclusions could not be drawn. This not only creates delays but also presents the risk of not identifying an EDC substance as such. Consequently, the current identification criteria is not sufficient to adequately protect EU citizens and the environment from continued exposure to EDCs and must be addressed.

11.c) The regulatory process to identify and control substances with endocrine disrupting properties under **REACH** is effective in:

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

Please explain your answers

2000 character(s) maximum

The substance by substance assessment for the identification of EDCs under the REACH regulation is a long process and only 16 substances have been identified since December 2011. However, the Endocrine Disruption Exchange (TEDX) lists over 1,400 potential EDCs, the WHO mentions over 800 EDCs, and many more suspected EDCs still need to be investigated. The identification process currently places a high burden of proof on authorities while it should be on industry (no data, no market). Bisphenol A, one of the world's most documented chemicals, was only identified as an EDC under REACH in 2017. To date, the testing requirements under REACH are not up to date to account for all the information relevant to ED properties.

As a data generation system, REACH still fails on EDCs: substances with low tonnage or intermediate use are not submitted to sufficient data requirements upon registration; current data requirements have limited capacity to provide assessors with data on ED properties; poor compliance with the obligation to provide and update data also creates obstacles to robust assessments. SVHC identifications therefore need to be much quicker, which requires the introduction of the category of ‘suspected EDCs’ into evaluation and identification processes, to systematically apply grouping, as it should have been done for BPA/bisphenols. Substances already on an EU or national EDC list or regulation should directly enter the EU’s candidate list. Furthermore, Article 57(f) should be amended so that an equivalent level of concern (ELOC) does not have to be established for EDCs.

There remains an excessive time lag between the identification of a substance as an EDC and the risk assessment process leading to its regulation. This needs to be addressed to ensure EU legislation is fit for purpose.

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

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

[2] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

The Scientific Committee on Consumer Safety (SCCS) indicated concerns that EDCs in cosmetics will not be identified (June 2018) (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3295383/feedback/F12858_en?p_id=255075), stressing that the “results obtained for a cosmetic ingredient using non-animal alternative methods (in silico, in vitro, ex vivo, omics technology, etc.) can only be indicative of endocrine activity and will not give information whether the substance can cause adverse effect(s) in an intact organism, thus whether it should be regarded as an endocrine disruptor or not. Indeed, it should be clearly noted that until today not a single validated non-animal alternative method exists for systemic toxicity”.

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

It is imperative that the Fitness check compensates for these shortcomings when assessing whether the Cosmetics Regulation is fit to protect consumers against endocrine disruptors. Breast Cancer UK believes that EDCs should in any case be banned from cosmetics as no essential use can be justified.

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

N/A - Breast Cancer UK is not in a position to answer.

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

N/A - Breast Cancer UK not in a position to answer.

Aggregated exposure and combined effects

Humans and wildlife can be exposed to the same endocrine disruptor via various sources (**aggregate exposure**) if this substance is present in different types of products.
Humans and wildlife can also be exposed to a combination of multiple endocrine disruptors from one or multiple sources, which may lead to combined effects (**mixture**/**cocktail effect**). Such effects may include additive and synergistic effects.

12) Do you agree with the following statements?

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Humans are protected by the current regulatory framework from the risks associated with the aggregated exposure to	○	○	○	○	◉	○

one substance with endocrine disrupting properties from all exposure sources						
Wildlife is protected by the current regulatory framework from the risks associated with the aggregated exposure to one substance with endocrine disrupting properties from all exposure sources	○	○	○	○	◉	○

Please explain your answers and provide examples

1000 character(s) maximum

The limitations and gaps of the current EU regulatory framework to assess EDCs and protect humans and wildlife from daily exposure to mixtures of chemicals from multiple sources, including food are widely exposed and acknowledged. This has been highlighted in the Commission's own studies and reviews (supporting study on a non-toxic environment, chemicals fitness check, EU H2020 research programs). June 2019, Environment Council conclusions called on the Commission "to present options to introduce requirements in the relevant pieces of EU chemicals legislation to ensure that the combination effects of chemicals (cocktail effects) and the combined exposure of humans and the environment from all relevant sources are properly and consistently addressed in the risk assessment and risk management processes".

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

According to the UN's Global Chemicals Outlook, hazardous chemicals such as EDCs are now "ubiquitous in humans and the environment". EDCs end up in all of us – contaminating our bodies without our consent or knowledge.

Human biomonitoring samples of urine, hair and blood across Europe have demonstrated the extent of that internal pollution. In France, over 20 EDCs were found in women tested for the presence of these chemicals in 2015. The scientific community has made proposals to address the challenge of mixtures and start adapting risk assessments accordingly (See reports from 2009 onwards). According to recent findings from the EU funded EDC MixRisk project, health risks associated with combined EDC exposures are currently systematically underestimated. Exposure to mixtures of EDCs at the prenatal stage has been associated with adverse health and development effects of children in three domains: sexual development, neurodevelopment and metabolism and growth.

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

Breast Cancer UK has long been concerned that exposure to EDCs is increasing our vulnerability to breast cancer and is contributing to a significant rise incidence rates of many public health conditions across Europe. Scientists have repeatedly warned that exposure to EDCs, even at low concentrations, can trigger chemical reactions in the body that increase the chances of suffering from lethal diseases and health disorders. These include hormonal dependent cancers, obesity, diabetes, cardiovascular disease, reproductive problems and neuro-behavioural and cognitive difficulties.

Recent biomonitoring studies from across Europe have shown that people in the general population are typically contaminated with several chemicals including EDCs. Evidence suggests that the critical windows of sensitivity are during development in the womb, early infancy, childhood and into puberty. Prenatal exposures are believed to the most harmful. Baskut Tuncak, UN special rapporteur on toxins has warned that children are being born pre-polluted, as studies have discovered banned flame retardants in the umbilical cord of new-borns and breast milk. Special care should be taken to reduce exposures before and during pregnancy, in early childhood, and during puberty. Most vulnerable groups to the effects of EDCs include pregnant women, babies in utero, children under 3 and teenagers.

See briefings and reports from Breast Cancer UK, ChemTrust, HEAL, Study for the European Parliament... etc. Former Environment Commissioner Vellas acknowledged in his speech at the 1st EC Stakeholder forum on EDC on 8 November that EDCs are of special concern as they “affect people, and animals, when the body is particularly vulnerable, such as during conception, embryonic and foetal development, early childhood, or puberty” and that “the effects are permanent and they can sometimes be observed even in the next generation”.

Data requirements and available regulatory test methods

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

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

- ○ Yes
- ◉ No

Which tests should be developed?

1000 character(s) maximum

Please refer to results of EC REACH Review & Study for the European Parliament “Endocrine Disruptors: from Scientific Evidence to Human Health Protection”, March 2019, sections 4.4 and 4.5 - p.86 “ There is an urgent need, not only to accelerate test development and validation, especially in areas beyond E, A, T, S (which are currently insufficiently covered, in particular for the thyroid axis), but also for regulators to use academic publications when assessing ED properties as clearly stated in the ECHA-EFSA Guidance document”.

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

- ○ Yes
- ◉ No

Please specify what requirements you would add or modify in each piece of legislation.

1000 character(s) maximum

EU Commission support study on the non-toxic environment and the REACH review acknowledge the inadequacy of data requirements for the identification of EDCs. Tests required under REACH do not include all relevant endpoints and there is no mandatory screening for ED properties for “low volume chemicals”. Breast Cancer UK welcomes the recent process to update REACH test requirements. We call on the EC to pursue these processes without further delay. The minimum step would be to bring the requirements of all regulations at least in line with the OECD guidance document 150, although it is still far from covering all relevant ED endpoints. In addition, it is essential that independent peer-reviewed scientific literature is taken into account to feed into identification.

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

N/A - Breast Cancer UK not in a position to answer.

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

N/A - Breast Cancer UK not in a position to answer.

Regulatory testing and animal welfare

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

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

- ○ Strongly agree
- ◉ Moderately agree
- ○ Neither agree nor disagree
- ○

Moderately disagree
- Strongly disagree
- Don't know

Please explain your answer.

1000 character(s) maximum

All provisions for data requirements should include a systematic screening for ED-properties as a first step to inform, support and prioritise further testing/investigations. These tools should also be used much more systematically in the work for grouping of substances: grouping substances for regulation, to group substances and subsequently avoid unnecessary testing of similar chemicals and to group chemicals with the aim of initiating supportive testing.

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

The current incoherence of the regulatory framework leads to re-testing chemicals under many frameworks - incoherence leads to many unnecessary animal tests.

A system of centralised testing - “joint/common testing centre” financed by industry and staffed by public authorities would provide the necessary coordination and help avoiding repetition of tests and better sharing of data results, as well as increase the public’s confidence regarding conflicts of interests and independence of testing results.

Effectiveness of regulatory procedures

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

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

	Yes	No
Workers protection	(•)	○

Toys	◉	○
Detergents	◉	○
Fertilisers	◉	○
Electrical and electronic equipment	◉	○
Food contact materials	◉	○
Food additives	◉	○
Cosmetics	◉	○
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	◉	○
Human and veterinary pharmaceuticals (only for effects on the environment)	◉	○
Water	◉	○
Waste/recycling	◉	○
Other (please specify)	◉	○

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

1000 character(s) maximum

EDCs are everywhere in our daily lives: examples includes parabens used as preservatives in food and cosmetics: restricted phthalates that are still found in one out of five toys: BPA and bisphenol substitutes used in plastics production, pesticides sprayed on and ending up in our food and toxic flame retardants in upholstery, soft furnishings and electronics. EDCs are routinely found in our environment, in rivers, soil, drinking water and air. We ingest them though food and drink, inhale them in the air we breathe and absorb them through our skin via exposure to soil and dust.

These situations result from the lack of adequate provisions to effectively identify EDCs across sectors and to take the necessary risk management measures in each relevant law and sector.

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

Covered in answers above

24) In your view, on which areas should market surveillance authorities focus their activities to effectively enforce chemical safety of products as regards endocrine disruptors?

	Yes	No	Don't know
Plant Protection Products	◉	○	○
Biocidal products	◉	○	○
General chemicals	◉	○	○
Toys	◉	○	○
Detergents	○	◉	○
Fertilisers	○	◉	○
Electrical and electronic equipment	◉	○	○
Food contact materials	◉	○	○
Food additives	◉	○	○
Cosmetics	◉	○	○
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	○	○	◉
Human and veterinary pharmaceuticals (only for effects on the environment)	○	○	◉
Waste/recycling	◉	○	○
Other (please specify)	○	○	◉

Adequacy of legislation to address needs and concerns on endocrine disruptors

In 1999 the European Commission published a Community strategy on endocrine disruptors, reflecting

public concerns that these substances might cause diseases/disorders in humans and affect wildlife populations and biodiversity. Diseases/disorders in humans that are endocrine-related (i.e. via effect on the endocrine system) might result from a combination of factors such as genetic origin, diet, lifestyle, exposure to endocrine disruptors and other chemical stressors. Effects on wildlife populations and biodiversity might be caused by a combination of factors such as habitat loss, climate change, exposure to endocrine disruptors and other chemical stressors.

30) To what extent do you think exposure to endocrine disruptors is contributing to the **increase in endocrine-related human diseases/disorders**, in the EU, in comparison with other factors?

- (●) To a significant extent
- ( ) Not to a significant extent
- ( ) Not at all
- ( ) Don't know

31) To what extent do you think exposure to endocrine disruptors is contributing to the **decrease in aquatic and terrestrial biodiversity** in the EU, in comparison with other factors?

- (●) To a significant extent
- ( ) Not to a significant extent
- ( ) Not at all
- ( ) Don't know

The 1999 Community strategy highlighted the need for research and development of new tools to understand the mechanisms of endocrine disruption.

32) Is the regulatory framework flexible enough to take into account new scientific information and methods in the assessment of endocrine disrupting properties (e.g. new toxicological tests, (bio)monitoring data, (eco)epidemiology)?

- ( ) Yes
- (●) No

Please explain your answer with examples for specific regulated areas.

1000 character(s) maximum

Breast Cancer UK as a member of the EDC-Free Europe coalition stressed in May 2018 “Eight demands for an EU EDC Strategy” the need to respond more swiftly to early warning signals from new scientific findings about potential health or environmental damages in re-approvals and authorisations of substances, or in emergency cases. This is in line with the precautionary principle embedded in EU Treaties.

The current regulatory framework is often referring to specific tests in the EU test method regulation which is not systematically updated when new OECD tests have been agreed upon. There is therefore a time lag between the adoption of a test method and the practical implementation and use in the EU. Likewise, many EU guidance documents are not systematically updated when new test methods, assessment methods or new sorts of data are available. The regulatory framework should be constructed in a way that immediately allows for including new scientific data and methodologies.

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

2000 character(s) maximum

Avoiding EDCs is not a choice that a person can make anymore. EDCs are found everywhere in our daily lives: from high-profile substances, such as the bisphenols used in the making of certain plastic bottles, restricted phthalates that are still found in one out of five toys; the flame retardants used in sofas and the pesticides ending up in our food. The unanimous call from the scientific community, the 2019 European Parliament Resolution on EDCs as well as June 2019 Council Conclusions and Opinion of the European Committee of the Region in response to the delay of the European Commission Strategy on EDC clearly reflect the consensus on the urgency to act to upgrade EU legislative and policy framework on EDCs without further delay. Calls which Breast Cancer UK fully supports.

The available estimates of the burden of diseases of EDCs all point to the huge economic opportunity of prevention through increased regulation. The Commission's own support study on the Non-Toxic Environment highlights an annual €1.5 billion for female reproductive disorders and diseases in the EU as a result of exposure to EDCs. With current trends, those figures are expected to keep increasing until regulation is substantially improved with full implementation of the precautionary and the polluter pays principles.

It's vital the New Commission, responds to citizens demands for improved public health protection from EDCs and delivers a comprehensive action plan that prevents further impacts on health and the environment associated with EDCs. Such a plan must set out legally binding targets for eliminating exposures and reflect the 2030 commitments set out in the UN sustainable development goals to "substantially reduce the number of deaths and illnesses from hazardous chemicals".

Added value of EU level intervention

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

34) Do you think:

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

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

1000 character(s) maximum

Ideally, all measures taken to protect people and the environment should cover the entire EU. However, given the delay exposed to take action at EU level and the gaps of the EU regulatory framework, when there are new evidence or a reassessment of existing information indicating an unacceptable danger to human health or the environment and a need to avoid postponing protection, action of national authorities is completely justified when EU wide measures are uncertain or delayed.

In the past, single action by individual member states has often led to EU action and positively contributed to the protection goals as well as societal costs.

- In general the benefits of EU chemicals legislation (hugely) outweighs the costs (ref: Fitness check)
- The second REACH review reached the same conclusion
- Scientists estimates that the annual cost to the EU of ED exposures is €163 billion

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

1000 character(s) maximum

Building on the results of the extensive assessments of its chemical regulations, the EU is in a unique position to address the shortcomings of its regulatory framework on EDCs, thus contributing to the key components of the European Green Deal: sustainable chemicals strategy, and the EU's action plan on cancer.

The update of the EU's EDC strategy and the upgrading of regulation is an absolute prerequisite to the new Commission's commitment to a Zero Pollution Objective. By boosting EU rules to protect the population from the effects of EDCs, prevent diseases and health costs flowing from EDC exposure and stimulate innovation for safer alternatives and safer products. Breast Cancer UK will continue to monitor developments closely to ensure the European Green Deal leads to a non-toxic environment which reduces EU citizens exposure to EDCs linked to breast cancer.

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)

Contact

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