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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

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50 character(s) maximum

Angeliki

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50 character(s) maximum

Lysimachou

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angeliki@pan-europe.info

*Organisation name

50 character(s) maximum

Pesticide Action Network Europe

Country of origin of your organisation

- ○ Austria
- ◉ Belgium
- ○ Bulgaria
- ○ Croatia
- ○ Cyprus
- ○ Czechia
- ○ Denmark

- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom
- Other (Please specify)

* Scope
  - International
  - National
  - Regional
  - Local

* Organisation size
  - Micro (1 to 9 employees)
  - Small (10 to 49 employees)
  - Medium (50 to 249 employees)
  - Large (250 or more)

* **Publication privacy settings**

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

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 Your personal details will not be published.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

- [x] I agree with the following personal data protection provisions

Personal data protection provisions

Privacy_statement.pdf

Survey

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

	Not at all familiar	A little familiar	Fairly familiar	Very familiar
Plant Protection Products Regulation (EC) 1107/2009	○	○	○	◉
Residues of Pesticides Regulation (EC) 396/2005	○	○	○	◉
Biocidal Products Regulation (EU) 2012/528	○	○	◉	○
REACH Regulation (EC) 1907/2006	○	○	◉	○
CLP: Classification, Labelling and Packaging of substances and mixtures (EC) 1272/2008	○	○	◉	○
Persistent Organic Pollutants Regulation (EC) 850/2004 and (EU) 2019/1021	○	◉	○	○
Food Contact Materials Regulation (EC) 1935/2004	◉	○	○	○
Contaminants in Food and Feed Regulation (EEC) 315/93 and Directive (EC) 32/2002	○	◉	○	○
Food Additives Regulation (EC) 1333/2008	◉	○	○	○
Cosmetic Products Regulation (EC) 1223/2009	◉	○	○	○
Medical Devices Regulation (EU) 2017/745	◉	○	○	○
In vitro Diagnostic Medical Devices Regulation (EU) 2017/746	◉	○	○	○
Toy Safety Directive 2009/48/EC	◉	○	○	○
Fertilisers Regulation (EC) 2003/2003 and Regulation (EU) 2019/1009	○	◉	○	○
Detergents Regulation (EC) 648/2004	◉	○	○	○
Medicinal Products for Humans Directive 2001/83/EC	◉	○	○	○
Veterinary Medicinal Products Regulation (EU) 2019/6	◉	○	○	○
General Product Safety Directive 2001/95/EC	◉	○	○	○
Water Framework Directive 2000/60/EC	○	○	○	◉
Priority Substances Directive 2013/39 EC	○	○	○	◉
Drinking Water Directive 98/83/EC	○	○	○	◉
Groundwater Directive 2006/118/EC	○	○	○	◉
Marine Strategy Framework Directive 2008/56/EC	○	○	◉	○

Urban Waste Water Directive 91/271/EEC	◉	○	○	○
Chemical Agents at Work Directive 98/24/EC	◉	○	○	○
Carcinogens and Mutagens at Work Directive 2004/37/EC	◉	○	○	○
Pregnant Workers Directive 92/85/EEC	◉	○	○	○
Young People at Work Directive 94/33/EC	◉	○	○	○
Waste Directive 2008/98/EC	◉	○	○	○
Restriction of the use of certain hazardous substances in Electrical and Electronic Equipment - Directive 2011/65/EU	◉	○	○	○
Industrial emissions Integrated Pollution Prevention and Control Directive 2010/75/EU	◉	○	○	○
Seveso-III-Directive 2012/18/EU	◉	○	○	○
Ambient Air Quality and Cleaner Air for Europe Directive 2008/50/EC	◉	○	○	○
Regulation (EC) 66/2010 on the EU Ecolabel	◉	○	○	○

Horizontal approach to the identification of endocrine disruptors

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

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

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

- ◉ It is an important problem, leading to incoherent identification of endocrine disruptors across sectors
- ○ It is not a problem, the criteria should be sector specific

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

1,000 character(s) maximum

So far, the number of substances identified as endocrine disruptors (EDs) is so small (16 under REACH, 2 under BPR, none under PPPR) that a comparison across sectors is impossible. However, the identification of a substance as an ED is a scientific process (hazard assessment) that depends on the properties of the substance and therefore an ED must be identified as such across all sectors irrespectively of its use. Then EDs can be regulated differently in each sector, based on their use and if they come in contact with humans, particularly the vulnerable groups of our society- the environment and its species. For the moment we've seen differences in the identification of pesticides, when different criteria had been used. E.g. 2,4-D was approved in 2015 for 15 yrs by SCoPAFF as a non-EDC based on interim criteria, but Commission's impact assessment exercise in 2016 using the JRC method identified it as an EDC. 2,4-D remains in the market, putting workers, consumers and citizens at risk.

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

Only a small limited number of EDs have been officially identified so far (16 under REACH, 2 under Biocides), this is not due to the lack of a hazard category in CLP Reg./GHS but due to: 1) the high level of evidence required to prove that a substance is an ED, for which there are always data gaps resulting in major delays and misclassification 2)lack of specific tests to identify EDs, e.g. for metabolic, behavioural and transgenerational effects 3)lack of ED provisions in other regulations 4)lack of subcategories.Since the identification of the EDs must be hazard-based and horizontal across sectors, a hazard category in CLP Reg/GHS, with subcategories would be useful in the long term but this should not block the implementation of sectorial ED policies. Following identification of EDs, each sector can proceed with risk management decisions independently based on whether the chemical comes in contact with humans, the vulnerable groups of our society, the environment and its species.

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?

2,000 character(s) maximum

WHO/IPCS introduces both endocrine disruptors and potential endocrine disruptors as chemicals of concern, recognizing our limited scientific knowledge and lack of testing to identify all such chemicals. It is pivotal to introduce a category for suspected endocrine disruptors (Cat 2) as well as Cat 3 (ED active) for regulatory purposes and provide the high level of protection from chemicals that EU law requires. At the moment, the level of proof under PPP and BP Reg. is too high (more like Cat 1A, rather than 1B) and adequate testing is missing, risking that several harmful chemicals will remain undetected and get approved for use for 10-15 years period, even though a level of concern has been detected (e.g. endocrine activity or/and adverse effects).
The use of suspected ED pesticides should also be restricted and such chemicals should be candidates for substitution that can only be authorised for 7 years maximum and national authorities have to carry out an assessment to establish whether safer alternatives exist, including non-chemical methods.
Cat 2 would also require a lower level of evidence which would be valuable for other pieces of legislation, where no tests are available and a potential harm is enough to trigger regulatory actions (e.g. cosmetics, toys).
The health and economic benefits for regulating all types of EDs have been addressed by scientific experts:
- Cost of inaction (Nordic Co-operation, 2014): costs related to effects of the current exposure to EDs on male reproductive health could amount to nearly EUR 600 million per year using the etiological fraction of 20% or EUR 1.2 billion per year using the etiological fraction of 40%
- Trasande et al 2016, Andrology 4(4):565-72. The estimated costs related to the effects of exposure to the considered EDs is likely to be €163 billion per year, with a 95% probability that costs were above €22 billion and a 25% probability of costs at least €196 billion/year

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

Although the PPPR and BPR set clear cut-off criteria for EDs (no contact with humans and environment), BPR allows a socioeconomic interest derogation. Further, other pieces of legislation (e.g. REACH, cosmetics) take into consideration the level of exposure (risk assessment) as well as socioeconomic interests. A risk assessment for EDs that come in contact with humans, animals, the environment and its species, is of concern as it assumes a safe level of exposure to EDs, for which there is no scientific consensus. PAN Europe highlights there is no safe exposure threshold for EDs. For pesticides not only the level of evidence to identify a substance as an ED is very high (leading to biased conclusions that a substance is safe), but also this identification is required only for active substances (AS) and not for the whole products. This means that products, containing co-formulants and adjuvants that enhance the product's effectiveness (toxicity), are never tested for ED properties. This is putting human health and the environment at great risk, since farmers, residents of agricultural areas and the environment are exposed to the whole product, not just the active ingredient.
Adjuvants and co-formulants are also not necessarily tested individually for ED-properties. For adjuvants, national provisions apply that do not contain ED testing, and the draft Reg. for co-formulants considers them unacceptable if assessed under BPR or REACH and identified as EDs. However, testing for EDs is not obligatory. MRLs Reg. 396/2005 also has a risk-based approach. Even for substances falling under the cut-off criteria and where the MRL is set below the LOQ, an import tolerance request can trigger a risk assessment, which could result increasing the MRL for imports. Therefore, even when a pesticide is identified as ED it can still be found as a residue in food consumed in EU, which could be of health concern since EDs may act at very low levels.

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

Several gaps are identified in the way endocrine disruptors are regulated in EU:
1) Pesticide Active Substances have to be assessed for ED properties but not pesticide products. However, for biocides both active substances and products have to be assessed for ED properties. Farmers, workers, residents, visitors of agricultural fields and the environment are exposed to the whole product not just the active ingredient.
2) Mixtures of EDs or pesticides/biocides are not addressed, despite the Reg. 396/2005, 1107/2009 and 528/2012 requirements. These chemicals may act additively or synergistically, enhancing or adding to individual substance's toxicity.
3) An identification of a substance as an ED under REACH will not trigger automatically the ban of all products in the market containing this substance, across sectors (e.g. non active ingredients of pesticide products).
4) Commission so far has not insisted for dossiers to have all the ED data requirements.

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

- ◉ Yes
- ○ No

If yes, please provide examples and describe the consequences.

1,000 character(s) maximum

A number of WTO countries repeatedly attack the EU for the pesticide hazard-based criteria for EDs in relation to food residues and impact on the trade of imported food products. These countries, and certain policy-makers insist to follow the traditional risk assessment to set MRLs, even for hazard cut-off substances, for which the MRL should be set at the limit of quantification. However, cut-off criteria were established by the co-legislators as an acknowledgment that no risk assessment would need to be performed on such substances which are, based upon their classification, deemed too dangerous to be used on food. Therefore, WTO countries should respect this decision. Moreover, when ED pesticide substances are finally identified, European companies are still allowed to sale their banned products outside Europe overlooking the harm these chemicals cause over there. Banning these substances in EU imported products is the least Europe can do.

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

2,000 character(s) maximum

EU must ensure the incorporation of ED provisions across all regulatory sectors related to chemicals – using a hazard-based approach when EDs come directly in contact with humans, animals or the environment- but must also focus on the effective implementation of the EU law to identify EDs and remove them from the market without further delays. Chemicals should be assessed for ED properties based on recent scientific tests and scientific knowledge, using all available literature, including peer reviewed academic literature. Potential and suspected EDs should be flagged. In case of uncertainty, regulators must apply the precautionary principle and favor the removal, restriction and/or substitution of the substance in question.
With pesticides we've seen that although provisions to regulate EDs are in place, pesticides for which there is evidence of having ED activity and/or causing possibly endocrine related adverse effects in animal studies, were repeatedly approved without requesting ED-specific testing- although ED tests were part of Reg 283/2013 on pesticide data requirements (see PAN report trapped in vicious cycle "shorturl.at/cuyGZ"). The interim criteria were also never implemented to ban a substance. As a result, even pesticides that were identified as known EDs using JRC methodology in 2016 (Cat 1, EU Impact assessment study) have been approved. We also found that since the implementation of the criteria in Nov 2018, pesticides were approved with data gaps and testing was not requested at all or it was requested after authorisation approval and not delivered. Decisions were taken based on non ED-specific animal testing leading to potential misidentification. Hence, despite the EU law enforcement since 2011 to ban ED pesticides, still zero pesticides have been banned. These pesticides must now be revised, a process that takes several years. In the meantime, humans, animals and the environment keep being exposed to these dangerous chemicals.

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

In theory, the Biocide regulation should had been very effective in protecting the health of citizens, workers, and environment from EDs and stimulating innovation for safer alternatives but unfortunately it is not implemented in practice. EDs are considered hazards and have to be removed from the market without risk assessment to evaluate a safe level of exposure. However, despite the provisions to identify and regulate EDs since 2012, no biocide substance has been banned based on the interim criteria and only 2 biocides have been identified based on ED criteria (in force since Jun 2018) but remain to be regulated. Therefore, the identification and control of these dangerous substances has hardly been effective, and the EU law provisions to provide a high level of protection for human, animals and the environment remain to be fulfilled. The ED criteria require a high level of proof that is very difficult to identify a substance as an ED. Further, applicants submit the dossiers with data gaps and these tests are only requested at the end of the evaluation, creating substantial delays. Even when identified then the different derogation processes are evaluated separately for each AS/product combination, creating even more delays. In the meantime, these substances remain in the market posing a health risk to humans, animals and the environment. According to ECHA, under the 8 substances discussed in the BPC, 4 had missing data to conclude on ED properties, which blocks decisions. As ED-tests are included in the data requirements since 2013, dossiers should not be considered “admissible” without specific tests to address EDs. Further, derogations shouldn’t be assessed for different products separately. Since no biocide substance has been banned, the law hasn’t had an impact yet to improve market or enhance innovation by promoting safer alternatives or practices.

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

In theory, Reg 1107/2009 should had been effective in protecting the health of citizens (including vulnerable groups, consumers, residents of agricultural zones), workers, and environment from EDs and stimulating innovation for safer alternatives and sustainable agricultural methods: EDs are considered hazards and must be removed from the market without delay. Unfortunately, this has not been the case.
The regulatory process to identify and control pesticide substances with ED properties has not been effective so far because:
1) zero pesticides have been banned as EDs since 2011 when PPPR entered officially into force.
2) the ED interim criteria were never implemented to ban a pesticide
3) ED-specific tests were part of the data requirements since 2013 and although these were not included in the pesticide dossiers, the dossiers were accepted as admissible by EU institutions. In many cases pesticides were approved and ED testing was requested as confirmatory information to be delivered later and sometimes never provided. In the meantime, exposure to these chemicals continues.
4) Commission's 2016 screening screening (impact assessment, based on JRC method) found 32 pesticides that are EDs. A few (7) were banned but due to other toxicity (e.g. reprotoxic or PBT); the rest remain in the market. According to PAN report (trapped in vicious cycle shorturl.at/cuyGZ) 7 such pesticides have been approved under PPPR. A review of these substances is urgent.
5) A substance is evaluated only at the end of its 10-15 yrs authorization period, thus it will take years to evaluate all substances currently in the market and misidentification causes more delays
6) The process of reviewing the health impact of a substance once its approved takes too long, resulting in known hazardous substances remaining for years in the market (e.g. chlorpyrifos, thiacloprid)
7) MRLs Reg. is still risk-based, meaning that import tolerance may permit ED pesticide residues in imported food.

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

In REACH, the identification of a chemical as an ED is also a very long process, and so far, only 16 chemicals have been identified as EDs. This is a very small number compared to the over 800 EDCs mentioned by WHO and more than 1,400 potential EDCs included in the Endocrine Disruption Exchange (TEDX) lists. The data requirements are also limited and insufficient to address ED properties. Further, not all chemicals are tested for ED properties or adverse effects since this depends on the volume of the substances. Therefore, the Regulation is far from being effective.

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

PAN Europe doesn't work on Cosmetics

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

PAN Europe does not work on Medical Devises legilsation

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

The WFD is a good piece of European Legislation that aims to bring all EU waters to good chemical and ecological status. The WFD fitness check concluded in December 2019 that the Directive is indeed fit for purpose and has generally lead to a higher level of protection than would be expected without it. However, although the directive has been successful in setting river basin management plans and bringing policy actors together, its implementation has been significantly delayed and therefore its objectives remain to be reached since less than half of the EU waters are in good status (see Pan Europe/PAN Germany briefing on WFD implementation). In the case of endocrine disruptors, when we focus on pesticides we see that several such chemicals are detected in EU rivers (see Ecologistas en Accion and PAN E report "Rios hormonados") and yet no policy action has been taken to prevent river contamination from these agricultural chemicals. Agricultural practices in proximity to rivers and lakes must change, synthetic pesticides should be replaced with non-chemical practices and farmers should receive financial support for such transition.

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

For pesticide and biocide active substances, if in the future they are identified as EDs they should be banned (cut off) and therefore in theory there should be no human and wildlife exposure. However, as mentioned before no ED pesticides have been identified so far and for biocides, the 2 ED substances have not been regulated yet and therefore their use continues. If in the future a category for potential and suspected EDCs is provided, then the exposure to both biocide and pesticide substances should be taken into account.

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

Mixtures of chemicals can cause additive or synergistic adverse effects at exposures below the NOAEL of individual chemicals. This was shown at Horizon2020 project EDC-MixRisk and at Hass et al. 2018 Danish EPA for pesticides. Right now, only drinking water and groundwater directive have a threshold for sum of pesticides, but not for EDCs. Setting specific measures to address pesticide mixtures (Reg. 396/2005, 1107/2009, 528/2012) or mixtures of other chemicals is urgent. PAN Europe 2017 report (ED pesticides in EU food shorturl.at/admM4) showed that about 50% of fruits consumed in EU contain multiple pesticide residues and 24% are EDs, up to 8 ED pesticides were detected in one sample. This is worrying considering that fruits are the main diet of babies and young children. Moreover, EFSA's 2019 CRA pilot study for chronic thyroid effects was based on old non-ED studies and the conclusion that no additional action is necessary is concerning. Adequate assessment of mixtures is urgent.

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.

2,000 character(s) maximum

The Pesticides and biocides Regulations clearly state to protect the vulnerable from EDs. However, substances that are EDs remain to be regulated (despite the hazard based criteria), since the criteria appear to be too strict to capture EDs with current dossier data and the process is slow, also they are no measures for mixtures of pesticides/biocides nor official human or environmental biomonitoring to know the extent to which we're exposed to. Scientific evidence shows that we're all exposed to these chemicals, even new born babies who are exposed through their mother. In theory, the cut-off should provide a higher level of protection for vulnerable groups but the regulation should be implemented properly, and the Commission should seek ways to accelerate the efficient ED identification. For example, all the pesticides identified as EDs (Cat I and II) by Commission's Impact Assessment Screening, should be immediately reviewed to withdraw their authorisation or request additional data. We cannot wait for 10 to 15 years until the authorisation of each pesticides AS expires to assess them for ED properties. These chemicals are in the market even end up in our food putting the vulnerable groups of the population at risk.

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

Currently the EFSA/ECHA guidance document (GD) focuses only on EATS modalities, although there are 48 nuclear receptors in humans. Other modalities have been already investigated and protocols have been established in academic literature, for example PPARs, RXRs and metabolic disorders, brain receptors and neurotoxicity or behavioural changes, as well as vitamin D and vitamin A receptors. Further, the current EATS tests are not necessarily the most sensitive ones or most robust (e.g. aromatase assay), and further tests to assess alterations in hormone synthesis and metabolism are missing, as the interaction with the receptor is not the only way hormone function is affected. The impact of thyroid alterations on brain development has also not been investigated thoroughly. Other tests should focus on epigenetic and transgenerational effects, effects on microbiome. Further with the current GD invertebrates are not taken into account since they don't have vertebrate-like hormones.

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

- [x] No

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

1,000 character(s) maximum

Data requirements for PPP/BP are currently being updated to include all tests under OECD 150 GD. These tests however, are not complete, only focus on EATS and do not even cover EATS modalities fully. Nevertheless, PAN Europe survey showed that even though certain ED related tests are included in the data requirements since 2013 [Reg (EU) No 283/2013], these are not provided by the applicant, even when there are indications for endocrine disruption from other animal experiments. The regulators must ensure first that all data requirements are regularly updated with the newest established test protocols and then that all the data have been delivered when they check the admissibility of the dossier. Academic scientific literature must always be taken into account since further evidence on EATS or non EATS modalities could be available.

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

PAN Europe does not follow closely ED authorization under REACH regulation, and since no substance has been identified as ED (no EFSA opinion) under the pesticides law a comparison at this stage would be incorrect

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

What we have observed with the (lack of) implementation of the pesticide regulation in relation to endocrine disruptors is that when evidence on ED effects appears in studies (e.g. extended 2 gen) the applicant is arguing that these effects are not relevant to endocrine disruption without providing additional scientific information. In some cases, this information (additional data) is requested by the Commission as confirmatory information but after the approval had been granted. We observed that often the tests were not delivered and the issue remained unresolved. For older substances, applicants and regulators should always consult and rely on the academic peer reviewed literature. We expect the regulators to apply the precautionary principle in cases of uncertainty rather than approving the authorisation of a potentially dangerous substance.
Further, substances are evaluated every 10-15 years, which is a long period to wait while humans and the environment are exposed to potentially dangerous EDs. Regulators should develop a screening system to assess all pesticides currently on the market, and immediately review the ones already identified as EDs in Commission Impact Assessment Screening.

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

In the PAN Europe survey on testing (See PAN E report, vicious circle) OECD level 2/3 tests were not systematically performed, which raises questions on the reasoning. Have they been performed but have not been included in the dossiers on purpose? PAN Europe supports a screening to flag potentially dangerous pesticides and withdraw them from the market without further testing. However, in cases where in vitro tests show no adverse effects, the toxicity of these chemicals should be further tested, as at this stage absence of effects in vitro does not indicate that no effects will be observed in vivo since the alteration may be via another pathway.

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

In pesticides, testing is confidential and each company carries out its own tests. As a result the same exact test, without additional endpoints, is done 2 or more times. Furthermore, often we have seen misconduct in the preparation of the dossiers or study reports. The Pesticide dossiers can be of 1000 pages and RMS do not often go through them in detail, let lone comparing the results with raw data. Since PPPR calls that pesticides should cause no adverse effects to human and animals, if an effect is observed in animal studies this should lead to regulatory ban, rather than the applicant trying to prove that it's not ED related. In case of doubt the precautionary principle should apply. A solution to decrease animal testing is to centralise the testing in specific facilities. A public authority (e.g. EFSA or ECHA) could commission the testing and the private sector would cover the costs (via a fund). The number of tests would be minimized and scientific misconduct reduced.

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)	○	○	○

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

In theory Reg 1107/2009 and Reg 528/2012 ask to include "all relevant scientific evidence" in assessment of ED properties, nevertheless from past experience we see that this has rarely been the case (see PAN E report missed & dissmised). Non-industry sponsored studies from academic literature are repeatedly dismissed from the assessment as non-relevant using the outdated Klimisch score. This is important for EDs already in the market, since a lot of information comes for peer-reviewed scientific literature. With the current gaps in the data requirements, dismissing such information from the academic literature risks to misclassify a dangerous substance as a non-ED and grant a 10 or 15 years authorisation. Epidemiology studies although included are given little weight of evidence in the final decision. Also currently non-official monitoring has never triggered the revision of the authorisation of pesticide substances, even though this is under the provisions of the Regulation

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

PAN Europe highlights that we should not wait any further to incorporate and implement effective measures across all EU legislative sectors to protect humans, animals and the environment from protection to EDs. Europe should adopt the zero-exposure policy to EDs, which means that these chemicals should not come in contact with humans or the environment and its species. There are already persistent ED chemicals in our environment and our bodies, and therefore no additional exposure should be permitted. We should not wait to identify substance by substance in each piece of legislation and we should not carry a full risk assessment when the EU policy is clear that exposure to EDs is undesirable. If there is any evidence on endocrine-related adverse effects, this should be enough to trigger legislative measures in certain sectors (where there is contact with humans), without arguing on a plausible link between adverse effect and endocrine mode of action. The precautionary principle is a tool that could be used in such cases. We also need to keep in mind that this is the way to push for the development of alternatives, including non-chemical agricultural methods that protect rather than destroy biodiversity, including soil health, resulting in abundance of ecosystem services that are extremely valuable for agriculture. A different agricultural model is urgent.

Added value of EU level intervention

There have been instances where Member State authorities have taken unilateral action on endocrine disruptors before a decision has been taken at the EU level. For example, in October 2012, the French authorities introduced a ban of Bisphenol A in all Food Contact Materials (http://www.senat.fr/petite-loi-ameli/2012-2013/9.html), applicable from July 2015.

34) Do you think:

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

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

1,000 character(s) maximum

For pesticides, although the authorisation of an active substance takes place at EU level, for pesticide products it takes place at Member State level, where the producer wants to sell its products. There are cases where Member States may refuse an authorisation of product due to national policies. E.g. Denmark, has a very strict policy when it comes to groundwater contamination from pesticides, as they use it untreated for drinking water. According to PPPR Member States can apply the precautionary principle and refuse the authorisation of a product in their territory (Art 1.4). But we see that this isn't always the case since Member States are challenged in court by companies. This is unacceptable, countries should be allowed to provide a higher level of protection if they wish to do. Pesticides after all, are designed to be toxic & safety assessment does not take into account quantities of pesticides used from all farmers and the magnitude of applications across agricultural fields.

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

1,000 character(s) maximum

It's been just over 20 years since endocrine disruptors entered the Commission's agenda as a serious health issue that needed to be addressed (1999). Yet very few substances have even been identified and even less regulated, while hundreds of substances have entered the market and their use has spread. Such a delay to establish coherent ED provisions and implement them to prevent exposure to EDs is unacceptable and utterly concerning. Evidence shows that endocrine-related cancers are on the rise and so are genital malformation, infertility, metabolic disorders as well as neurobehavioural and learning disorders associated with thyroid disruption. A coherent, regulatory action to remove these chemicals from our lives is urgent. We have the tools; we now need their coherent implementation.

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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