Follow-up 2nd meeting of CASG-ED (2nd July 2020)

We would like to thank the Commission for providing the document ‘Options to include criteria for endocrine disruption in the CLP Regulation’ (CASG-ED/2020/06) which was discussed at the 2nd Meeting of Competent Authorities Sub-Group on Endocrine Disruptors (CASG-ED) on 2nd July 2020 and would like to make the following comments:

CHEM Trust is advocating for a more coherent, swift and precautionary way to address the harmful effects from endocrine disruptors and suspected endocrine disruptors in the EU. In the upcoming reflections on the way forward, the quickest way leading to the highest level of protection should be chosen.

We therefore welcome the paper as important input in this process and we strongly support Option 1 out of the presented options. However, we see the need to include the following prerequisites:

1) It is crucial to include a category of suspected EDs as part of a new ED hazard class in order to move forward with identification.

In order to address the different levels of information available on adverse effects, endocrine activity and a plausible link, a category is needed for those substances where there is substantive but not sufficient evidence to conclude their identification as ED. This is fully in line with the WHO definition that covers identified EDs and potential EDs. Further, it mirrors the CLP approach that allocates CMR substances to categories of either “known/presumed” or “suspected” according to the level of evidence for their hazardous effects.
2) One integrated class for ED identification should be established instead of two separate ones (one as ED for environment and one as ED for health).

Under the CLP the identification of adverse effects is currently carried out separately for human health and the environment. However, it is well-known that the hormonal system is well-conserved across vertebrate species and therefore, is very similar in many species. Also it is important to consider the results from mammal data for humans as well as animals. For example, rat data are used to predict effects in humans but these data are also relevant for mammals (including rats) living in the environment and vice versa. And there are many other examples of similar effects on the hormone system relevant for human health and environmental species. Consequently, an integrated approach for human health and the environment relating to endocrine disrupting effects should be established. This will enable a better use of the respective information in the assessment, take into account the relevance of cross-talk between endocrine systems and avoid duplication of regulatory processes.

3) It is likely that it will take several years until these policy decisions will be put in practice and thus intermediate protective measures must be set up to protect consumers and in particular, vulnerable groups such as pregnant women and children.

It has already taken many years of debate for the EU to agree on criteria for identifying endocrine disrupting pesticides and biocides as a first step for regulatory controls. However, implementation is slow and the exposure to EDs from many sources continues. We would urge the Commission and Member State to use existing knowledge about classification and strong suspicion on ED properties as basis for transition measures until all protective ED legislation is in place.

These ideas are further elaborated in our new CHEM Trust policy briefing ´A new path for EU control of Endocrine Disruptors´ attached to this submission which we would like to bring to the attention of the CASG-ED members.
A new path for EU control of Endocrine Disruptors

1 Executive Summary

The harmful impact that Endocrine Disruptors (EDs) have on health and environment has been known for more than 20 years. Despite the adoption of a Community Strategy for Endocrine Disrupters in 1999 and the 7th Environment Action Programme (7th EAP) in 2013 envisaging protective measures, very little progress has been made to protect European citizens and the environment from exposure to EDs.

Instead of adopting immediate measures to minimize exposures to EDs, the outgoing European Commission in 2019 started yet another review of the chemicals legislation as regards EDs – a ‘fitness check’. CHEM Trust provided an analysis of the existing gaps as part of the ED Fitness Check consultation and submitted some first ideas for a way forward on ED regulation in our comments to the CARACAL ED subgroup work.

Over the years CHEM Trust and the NGO coalition EDC-Free Europe have continuously called for preventive measures to protect against EDs. In this policy briefing, CHEM Trust maintains the call by proposing a new path for EU control of EDs focused on a horizontal approach for identification across regulatory sectors and strict control of these substances to protect citizens and the environment, and to facilitate innovation and ensure predictability for commercial operators.

The proposal includes the following elements:

- New overarching ED legislation* for a horizontal approach on EDs across sectors
- ‘One’ ED identification system including a new category for Suspected EDs
- Improved identification of EDs through extended information/data requirements and screening
- Changes to existing legislation to ensure strict controls for sensitive uses of EDs
- A transition period with specific measures to ensure immediate protection from EDs
- Full transparency of ED assessments to facilitate substitution and informed choices

This proposal should lead to:

- Rapid and improved identification of substances with ED properties
- Strict control of substances with ED properties to avoid/minimize exposure
- Full transparency and easily accessible public information on EDs

* or clear political mandate ensuring equivalent control of EDs

2 https://ec.europa.eu/environment/action-programme/
The proposal is based on a precautionary approach, and is summarised here:

**Figure 1: A summary of CHEM Trust’s proposals**

**Regulation**
- New horizontal ED approach ensuring ED control measures included in all relevant EU legislation on chemical substances/products
- Risk management of EDs dependent on regulatory sector
- ED established as a hazard category under REACH and CLP
- Ban of substances with ED properties for sensitive uses
- REACH and CLP Regulation triggering downstream ED control measures
- Control based on grouping of substances with similar properties/effects
- EDs as default regarded as non-threshold substances and of particular concern

**Identification/Assessment**
- Horizontal approach for identification of EDs across all EU legislation
- Horizontal criteria embracing the current criteria for endocrine disrupting biocidal products and plant protection products
- ED criteria based on the full WHO definition and the CLP concept with 2 categories: ED (Known (1A) + Presumed (1B)), and Suspected ED (2), according to the level of evidence for ED
- Interim ED criteria addressing certain sensitive consumer uses until new legislation and data requirements are in place
- Hazard assessment addressing the specific uncertainties related to ED assessment
- One substance – one EU ED identification/hazard assessment as basis for all EU control of EDs

**Data requirements/Evidence**
- Information/data requirements including a systematic search for ED properties (also at low tonnage levels) based on a predefined minimum data search strategy
- Information/data requirements including all relevant OECD ED test methods
- In vitro testing of substances and use of QSARs to screen for ED activity, also in the context of the safety evaluation of cosmetics
- Acknowledging that absence of evidence of effects is not evidence of absence of effects

**Transparency/Information**
- Transparency of all regulatory ED assessments and decisions
- Easily accessible public information, i.e. official EU lists on EU identified EDs (cat. 1 ED) and Suspected EDs (cat. 2 ED)
- Supplementary labelling of chemical substances and products with ED properties
- Substitution of substances with ED properties

On this basis, a proposal for a new path for EU control of EDs is presented.

A transition period with swift identification and control of EDs based on interim ED criteria is proposed, in order to immediately remedy the lack of protection until adequate ED legislation and ED identification is in place. It is particularly important to address certain sensitive daily consumer uses in order to protect vulnerable groups, especially the unborn child and children.

This policy paper is part of CHEM Trust’s input to the EU processes on ED regulation, such as the announced EU Chemicals Strategy for Sustainability\(^5\) and the ED Fitness Check process.

\(^5\) www.europarl.europa.eu/legislative-train/theme-a-european-green-deal/file-chemicals-strategy
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2 Introduction

Back in the 1990’s the European Commission had already acknowledged that exposure to Endocrine Disruptors (EDs) may cause harm to human health and the environment, and a Community Strategy for EDs was launched in 1999 focusing on knowledge building, test method development and research, information and legislative actions.

The EU has worked on legislative controls for EDs for 20 years, with a range of delaying tactics from certain parts of industry successfully slowing down the processes at various stages. As a result, and despite some progress, such as adopting the world’s first regulatory criteria to identify endocrine disrupting Biocidal Products (BPs) and Plant Protection Products (PPPs) in 2018, the implementation is proceeding very slowly and the EU’s framework for controlling EDs remains patchy and lacks consistency.

Even now, the European Commission has not delivered the protective measures envisaged by the 7th EAP in terms of protecting human health and the environment from EDs by the minimisation of exposure. In particular, harmonised ED criteria are not developed, preventing that safety concerns related to EDs are effectively addressed in all relevant EU legislation. Furthermore, known EDs are still allowed for sensitive uses, such as in food contact materials.

This is particularly grave because EDs are especially harmful when foetuses are exposed and this can lead to serious and irreversible effects that appear at birth or later in life, or even appear in the next generation. Therefore, the results of a regulatory intervention today will only be fully achieved, after yet another generation.

A further challenge is that many EDs cause effects at very low doses. At the same time, these substances are ubiquitous in our daily life and in the environment resulting in exposure to EDs from multiple sources, leading to mixture effects. CHEM Trust has published several briefings and reports highlighting these concerns⁶⁻⁹.

After continued pressure from the European Parliament and Member States, the European Commission in November 2018 released a Communication ‘Towards a comprehensive European Union Framework on endocrine disruptors’¹⁰. CHEM Trust has welcomed the aim to minimise the exposure to EDs but has criticised the complete lack of concrete actions or measures¹¹.

CHEM Trust is also a member of the NGO coalition EDC-Free Europe that since 2013 has advocated for more protection from EDs, and back in May 2018 published 8 demands for an EU ED strategy¹². A lot of the reflections presented here are also a result of discussion with coalition partners.

After the European Parliament’s heavy criticism of the framework’s low ambition, in July 2019, the European Commission launched a public consultation on a roadmap for an ED Fitness Check. The fitness check is supposed to investigate the coherence of different regulatory approaches to the assessment and management of EDs and scrutinise whether the current legislation delivers its objectives to protect human health and the environment against the hazards from EDs. The ED Fitness Check was the subject of a public consultation until the end of January 2020 (see the CHEM Trust response¹³) and a report by the European Commission Joint Research Centre (JRC)

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⁹ https://chemtrust.org/chemical-mixture-effects/
¹¹ https://chemtrust.org/eu-edc-strategy/
EDC Policy - 2020

provides a factual summary of the submissions received. The final report of the ED Fitness Check is now expected in the autumn of 2020.

2.1 CHEM Trust view on the ED Fitness Check

By delivering a thorough and comprehensive fitness check solely directed towards EDs, the European Commission may live up to the promises to “protect citizen’s health from environmental degradation and pollution addressing (...) EDs” given by the new European Commission President-elect and reinstated by commitments in December 2019 to ensure a toxic-free environment by the European Green Deal, and in line with Council Conclusions on the 8th EAP. It is, therefore, extremely important to ensure that the ED Fitness Check report delivers a thorough analysis of all relevant EU legislation, including for all types of consumer products, and of whether these deliver to meet the objective of protecting human health and the environment by minimising the overall exposure to EDs.

In CHEM Trust’s view a new horizontal approach for identifying and controlling EDs across all relevant legislation should be proposed by the conclusions of the ED Fitness Check, including detailed proposals for revision of provisions or of new legislation. Such an approach should be based on full enforcement of the precautionary principle. It should take account of the critical windows of susceptibility, the limited data available, and should ensure fully transparent processes to ensure clarity as to which substances have been assessed and what the outcome of these assessments are.

CHEM Trust outlined our main priorities for a way forward for Endocrine Disrupting Chemicals (EDCs) in an article for Chemical Watch in December 2019:

1. The need for a cross-cutting regulatory framework for EDCs

A new approach for identifying and controlling EDCs across all relevant laws must be proposed, including detailed proposals for revisions or for new legislation, aiming at establishing a coherent and effective protection. For example, EDCs should not be allowed in consumer products for daily use e.g. food contact materials, toys, cosmetics. Ideally, these substances should be removed from the market and substituted with safer alternatives. The best approach would be to have an identification system for EDCs that will lead to regulatory consequences in each of the specific legislative systems.

2. The need to capture and act on ‘suspected EDCs’

Although the EU has finally established criteria for endocrine disrupting pesticides and biocides, we cannot just directly reapply them in the context of other legislation due to the lack of safety data available for other chemicals. The current identification criteria for pesticides and biocides require the demonstration of an adverse effect in an intact organism, endocrine activity and a plausible link between the two. This is a high burden of proof, so we need to ensure that suspected EDCs for which there is substantial information on ED effects are also captured and lead to regulatory consequences based on the precautionary principle.

3. The need for extending information requirements to ensure sufficient information is available for identifying EDCs

ED identification is difficult as in many cases the necessary information to make a clear conclusion is missing. CHEM Trust therefore welcomes the planned EU discussions under the Competent Authorities for REACH and CLP (CARACAL) on an update of the REACH annexes to include new standard information requirements for ED properties including updated test methods. This is also needed in other sectors.

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17 https://chemtrust.org/eu-fitness-check-on-edcs/

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3 Background and proposal for a new path for EU control of EDs

3.1 The current situation

The existing EU laws on different kinds of chemical substances and products are not consistent when it comes to protection from exposure to EDs; for some uses EDs are strictly regulated, for others only to a minor extent, and for many there are no regulation at all. EDs are covered by legislation on plant protection products, biocidal products, industrial chemicals, cosmetics, medical devices, and the Water Framework Directive.

Within the EU, the horizontal chemicals legislations (REACH\textsuperscript{19} and the Classification, Labelling and Packaging (CLP\textsuperscript{20}) regulations), as well as regulations on biocidal products (BPR\textsuperscript{21}) and plant protection products (PPPR\textsuperscript{22}), provide baseline protection for human health and the environment. Criteria for the identification of endocrine disrupting BP and PPP have been established, however, these criteria cannot easily be applied to substances in other regulatory sectors (horizontal approach) as they are specifically directed at BPs and PPPs for which comprehensive data are required.

Under REACH there are no specific information requirements directed at ED properties but EDs are identified based on the information requirements for other endpoints e.g. reproductive toxicity. However, these information requirements only apply to substances produced in amounts above 100 tonnes per year. An update of the REACH standard information requirements with regard to ED properties is currently under discussion\textsuperscript{23} as well as updates of the data requirements are taking place in the context of the BPR and PPPR. CLP is not specifically addressing EDs.

However, although ED criteria now in force and being applied under the BPR and PPPR and although a few substances have been identified as EDs under REACH, none of these different pieces of legislation can currently effectively identify substances with ED properties. Neither do they address substances for which there are substantial data on ED properties, however, not sufficient to fulfil the ED criteria. In fact, no PPPs, only two biocides, and seventeen substances under REACH have so far been identified as EDs.

Currently, many ED assessments under REACH, PPPR and BPR end up being inconclusive, as can be seen for example in the assessment list of the ECHA ED Expert Group\textsuperscript{24} that provides scientific advice on the identification of EDs under REACH and BPR. Due to the existing gaps of knowledge and the lack of adequate test methods, it could be expected that this will be the exact situation for most of the EDs/potential EDs that we know of today. In addition, none of these different pieces of legislation would on their own be able to cover all aspects necessary to ensure minimisation of exposure to EDs.

Recently, a process of risk assessment of cosmetic ingredients\textsuperscript{25}, based on a list of 28 prioritised potential EDs, has been initiated under the Cosmetic Products Regulation, however, this work is focusing on the traditional approach for safety evaluation and not identification and control as EDs.

\textsuperscript{19} https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20200428&from=EN
\textsuperscript{22} https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1107-20191214&from=EN
\textsuperscript{24} https://echa.europa.eu/ed-assessment
\textsuperscript{25} https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en
As there is no horizontal identification and too little information on which substances are suspected of having ED properties, producers and the downstream users are hindered in their possibility to substitute to safer alternatives and consumers are not able to make informed choices in their daily life.

Hence, there is a need for a new way forward to protect EU citizens and the environment from exposure to EDs. The following sections address the elements needed for a new horizontal approach which will ensure necessary protection from exposure to EDs, which are:

1) overarching ED legislation to ensure ED control across EU legislation, see 2.2.1
2) ‘one’ horizontal identification of EDs and Suspected EDs, see 2.2.2
3) improved ED identification based on extended information/data requirements and screening, see 2.2.3
4) changes to existing legislation for strict control of sensitive uses of EDs, see 2.2.4
5) transition measures for immediate protection from EDs, see 2.2.5, and
6) full transparency on assessments and easily accessible public information on EDs, see 2.2.6

3.2 The challenges and what is needed – CHEM Trust’s proposal

The European Commission ED Fitness Check will analyse potential gaps in the current legislation with regard to protection against effects from EDs. The outcome of this analysis and recommendations are expected to be presented together with the EU Chemicals Strategy for Sustainability by the autumn of 2020.

Here CHEM Trust proposes a way forward for EU control of EDs which complements our earlier submission to the ED Fitness Check consultation.

The aim of this proposal is to ensure that control measures for EDs are included in all relevant EU legislation on chemical substances and products, and to ensure consistent and swift identification of substances with ED properties.

This proposed overall set-up for a consistent and coherent EU regulatory framework for EDs is based on a horizontal approach for the ED identification that builds on the full WHO definition,\(^{26}\), the principle of one substance - one identification/hazard assessment, extended information requirements, the criteria for endocrine disrupting BPs and PPPs and the CLP concept, including 2 categories to reflect the level of evidence for ED properties.

Furthermore, it is based on a PBT-like approach acknowledging EDs as of particular concern, a concept of strict regulation of sensitive uses, and a transition period with immediate regulation of certain sensitive consumer uses to protect vulnerable groups.

In each of the following sections, we highlight the current status, the challenges and needs, together with CHEM Trust recommendation for the way forward.

3.2.1 New overarching ED legislation - ED control across legislation

The EU legislation for the protection of human health and the environment from EDs is currently incoherent, inconsistent, inadequate, and is even lacking for some regulatory sectors/uses as recently confirmed by the extensive European Commission’s assessments of its chemicals regulations.\(^{27,28}\). Currently, EDs can only be identified on the basis of ED criteria under the BPR and PPPR which are specifically developed for these regulations. Under REACH substances are identified as EDs on a case-by-case basis (cf. Art. 57(f)). Legislation on medical devices refers to

\(^{26}\) https://www.who.int/ipcs/publications/en/ch1.pdf?ua=1  
\(^{27}\) https://ec.europa.eu/docsroom/documents/36085  
\(^{28}\) https://ec.europa.eu/growth/sectors/chemicals/reach/review_en
REACH and the BPR, while the Cosmetic Products Regulation\textsuperscript{29} mentions horizontal criteria to be considered. Regulatory consequences, if any, differ across pieces of legislation.

Legislation is an important and strong tool to ensure minimisation of exposure to EDs, thus the challenge is to set up a cross-cutting regulatory framework for EDs that covers all relevant regulations and uses, while at the same time respecting already functioning legislation on EDs.

Ideally, all legislation should be thoroughly scrutinised, revised, and harmonised in order to ensure that EDs are identified and controlled consistently in all regulatory sectors. However, acknowledging that this will be a huge challenge, a more feasible and straightforward way will be to establish a horizontal approach that ensures that EDs will be adequately addressed by all relevant EU legislation referring to chemical substances and products. This approach makes use of the well-functioning parts of the existing pieces of legislation and combines these with a new overarching ED legislation (or clear political mandate ensuring equivalent control of EDs), followed by the necessary revisions/adaptations of the existing legislation.

A new overarching ED legislation, building on and integrated with REACH, CLP, BPR and PPPR, including horizontal criteria for identification based on the full WHO definition of EDs, could ensure that EDs are treated and controlled in a coherent and consistent way in the EU even though risk management may differ across regulatory sectors.

\textbf{CHEM Trust proposal:}

\begin{itemize}
  \item \textbf{1. New overarching ED legislation for a horizontal ED approach across sectors}
    \begin{itemize}
      \item \textit{New overarching ED legislation} should ensure coherent and consistent identification, assessment, and risk management of EDs across all EU legislation. The overarching ED legislation interacting with REACH, CLP, BPR and PPPR should \textit{lay down a horizontal approach for ED identification and control}. This should include \textit{horizontal criteria for ED identification} that can be applied across different pieces of legislation building on and integrating the criteria for endocrine disrupting BPs and PPPs and \textit{include a category for Suspected EDs}. The interaction with REACH, BPR and PPPR will have to ensure requirements for standard information/data, and the interaction with CLP will have to introduce consistent requirements for a hazard assessment for ED properties for all substances, independent of tonnage levels (including hazard categorisation and labelling).
      \item Further, it should \textit{lay down requirements for transparency of assessments, horizontal information on EDs and general principles for regulatory consequences} as soon as \textit{substances are} being identified by the horizontal criteria. This should ensure publication of official lists of the status for ED assessments and consistent and coherent risk management in different regulatory sectors.
      \item The overarching ED legislation should also \textit{lay down} that \textit{all relevant legislation on chemical substances and products should be revised/adapted as necessary}. This should ensure that ED control measures are included in all relevant EU legislation by referring to this new overarching ED legislation and/or other regulatory frameworks such as REACH or CLP which will be triggering downstream control measures for EDs in many other pieces of legislation.
      \item The legislation should also \textit{lay down transitional measures} for the swift identification and control of EDs for certain sensitive consumer uses based on \textit{interim criteria} for identification of EDs to ensure immediate protection of vulnerable groups, especially the unborn child and children.
    \end{itemize}
\end{itemize}

\textsuperscript{29} https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&from=EN
3.2.2 ‘One’ ED identification system - horizontal identification of EDs and Suspected EDs

A prerequisite for control of EDs is that substances with ED properties can be identified. Accordingly, there is a need to define what an ED is. Furthermore, criteria are needed to decide which level of evidence is required to designate a substance as an ED in a regulatory context.

The criteria for endocrine disrupting BPs\textsuperscript{30} and PPPs\textsuperscript{31} in the BPR and PPPR are based on the WHO definition of an ED. However, the level of evidence required for the ED properties, as laid down by the criteria and the accompanying ECHA/EFSA guidance\textsuperscript{32}, has been criticised by several Member States, NGOs and scientists for being too high to ensure sufficient protection of human health and the environment. The high level of evidence required also makes it difficult to apply the criteria to other legislation on chemical substances. This difficulty arises from the large differences in toxicity data for substances that are required under the different pieces of legislation. Furthermore, the current interpretation of REACH article 57(f) to require an additional ‘equivalent level of concern’ (ELOC) justification to class substances as EDs hampers their identification under REACH.

Thus, the challenge is to establish horizontal criteria when criteria for BPs and PPPs are already in force and there is a need for one single ED identification system that ensures substances are identified as EDs based on their intrinsic properties and not according to peculiarities of specific EU chemical regulations, their use, exposure, or regulatory sectors.

CHEM Trust proposes to use the current criteria for endocrine disrupting BPs and PPPs and the accompanying guidance document as the basis for setting up the horizontal criteria.

It should, however, be emphasised that this approach still has some limitations, e.g. it is not covering all hormonal axes and endocrine mechanisms and thus, all aspects of endocrine

\textsuperscript{30} https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2100&from=EN
disruption. Therefore, such information, if available, should always be taken into account by ED identification. In particular, attention should be paid to indications of effects on the thyroid and developmental neurotoxic and immunotoxic effects. Advances in science should also continuously be taken into account.

It is, however, quite clear that BPs and PPPs are a special case; they are covered by an authorisation scheme to approve their use because they are intended to control (kill and inhibit) living organisms and therefore, considerable information on their hazardous properties are required before they can be authorised. This is not the case for chemicals in other regulatory sectors. There will often be a lack of data and especially on their ED properties. If data are available, they are usually not sufficiently comprehensive to meet the BPR/PPPR ED criteria – and this is even the case for many BPs and PPPs themselves. Therefore, CHEM Trust advocates for the establishment of a new ED category to identify and control substances suspected to have ED properties based on substantial evidence, however, not sufficient to meet the criteria for an ED.

By applying the full WHO definition, including the definition of a potential ED: "A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations", in the horizontal ED criteria, the complications that arise from the need for additional data can be overcome. Such horizontal ED criteria should encompass both the strict criteria for identification of endocrine disrupting BPs and PPPs as EDs, as well as criteria for Suspected EDs for which a lower level of evidence would be sufficient.

The concept of identification of Suspected EDs is not a new invention but is entirely in line with the Global Harmonised System (GHS)/EU CLP Regulation on CMR substances that includes a category 1 (1A and 1B) and 2 according to the level of evidence for the effect. It is logical to follow this concept as many EDs are also identified as Toxic to Reproduction or as Carcinogenic (see CHEM Trust’s comments on initial ideas in the context of the CARACAL discussions33).

A horizontal approach that also includes ‘one substance – one identification/hazard assessment’ could help ensure consistent, faster, and more transparent EU assessments of EDs to assure efficient and effective management of EDs. However, as pointed out in our comments to the European Commission’s roadmap for a Chemical Strategy for Sustainability34, it is a prerequisite that this leads to faster decision making and not become an obstacle in case of disagreement between too many parties. It should also not exclude a grouping approach.

A ‘one substance – one assessment’ principle ensures that the identification/hazard assessment is the same for a substance regardless of the regulatory sector in question, whereas the regulatory consequences may vary. When a substance has been identified as an ED or a Suspected ED, this assessment is applicable across all legislation.

The assessment should take into account uncertainties related to assessment of EDs, e.g., critical windows of effects, low dose effects, non-monotonic dose responses, and the lack of relevant ED endpoints in old and current test methods.

In CHEM Trust’s view, it is preferable to have only one EU ED assessment body with specific expertise in the assessment of EDs as this will make it easier to ensure consistency and efficiency in the expert assessments, and ensure that all evidence for ED properties and all uncertainties related to assessment of EDs are taken into account.

It is well-known that the hormonal system is well-conserved across vertebrate species with little variation. Therefore, evidence from human and animal data may also be relevant for the evaluation of environmental effects and vice versa. Consequently, horizontal ED criteria based on an integrated approach for human health and the environment should be established.

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CHEM Trust proposal:

2. ‘One’ ED identification system, including a new category for Suspected EDs

- The horizontal approach for criteria for ED identification across legislation should build on the full WHO definition for an ED and a potential ED, the criteria and guidance document for endocrine disrupting BPs and PPPs, and the CLP concept including two categories depending on the level of evidence. To reflect the current lack of knowledge and the different levels of evidence for ED properties, substances for which there are substantial data on ED properties, but not sufficiently to meet the criteria as an ED, will also be identified, i.e. as Suspected EDs.

- New horizontal ED criteria integrating the assessment for human health and environment, will identify substances as an ED (Category 1, including Known (cat. 1A) and Presumed (cat. 1B)) or as a Suspected ED (Category 2) according to the level of evidence for the ED properties, see fig. 3.

- Identification should be based on all available data, including peer-reviewed academic studies, taking account of particularly ‘sensitive’ studies, and be conducted by experts in ED assessment.

- The level of evidence for identification as Suspected ED should be based on expert judgement of all information, including QSAR, read across to other substances and grouping of substances.

Figure 3: ED hazard categories

ED hazard categories

- **Cat. 1: ED**
  - 1A: Known ED + 1B: Presumed ED
  - Using wording of BPR and PPPR criteria
  - + integration of environment

([Cat. 1A: ED confirmed for human health/environment from epidemiological/case/field studies
Cat. 1B: ED confirmed for human health/environment from animal studies]

- **Cat. 2: Suspected ED**
  - Substantial evidence but not sufficient to conclude on one or several of the following:
    - adverse effect
    - endocrine mode of action
    - plausible link

3.2.3 Improved identification of EDs - through extended information/data requirements and screening

Currently, only very few substances have been identified as EDs or investigated for their potential ED properties. This is even the case for BPs and PPPs. Although, the BPR, PPPR and REACH include standard information/data requirements, these are insufficient for the
identification of ED properties. There is no systematic search for information and screening for ED properties, and even adopted OECD ED test methods are not implemented. Further, in REACH these requirements vary with the tonnage level and are not specifically directed at endocrine disruption.

**Relevant test methods** that specifically detect ED properties are either **lacking or have only become available in recent years**. To fill this gap the EU has started funding the EU research cluster, EURION, to improve identification of EDs but it will take years until the new test methods are fit for regulatory use.\(^{35}\) However, adopted and relevant OECD test methods for identification of ED properties should immediately be implemented in the EU legislation and be part of the standard information/data requirements. In addition, a wide range of *in vitro* tests covering all ED modalities should be requested.

Identification of substances as ED rely as much as possible on existing toxicity data but all too often existing data are old and were obtained by using test methods without relevant ED endpoints or even outdated test methods. Especially, this is the case for reproductive toxicity, a type of toxicity highly relevant to endocrine disruption. Therefore, **many substances, including those suspected of being EDs, will not be identified at all** and therefore go under the radar of the authorities. This is also the case for BPs and PPPs as the current data requirements do not include a systematic literature search and screening for ED properties. In addition, most of the test methods directed at endocrine disruption are not mandatory but only required if there are indications of ED properties from other test methods (so-called triggers for further testing). The current European Commission proposal for the update of the information requirements under the BPR\(^{36}\) seems not to sufficiently close these gaps\(^{37}\).

Effects caused by endocrine disruption may be identified under the CLP Regulation leading to hazard classification according to the specific endpoint, however, identification as ED is currently not a part of CLP. CLP only refers to existing data and does not include any new data requirements. In the context of compiling/generating information/data on ED properties for the safety evaluation of cosmetics, the ban for animal testing of chemical substances used in cosmetics, which is an important achievement for animal welfare, is further complicating a horizontal approach for identification.

Thus, there is clearly a need to improve the identification of EDs through extended information/data requirements and screening for ED properties. The requirements should include a systematic literature search, non-test identification methods as for example Quantitative Structure–Activity Relationship (QSAR) and read across, and relevant *in vitro* and *in vivo* test methods with relevant ED endpoints.

**By improving/changing the requirements for data/standard information** in REACH, BPR/PPPR, the requirements for standard information as regards ED properties will be consistent and concentrated on a few pieces of legislation. In the context of the safety evaluation of cosmetic products, *in vitro* testing of the ingredients should be required in case the substances have not been comprehensively assessed for their ED properties. By including a systematic procedure for information/data search and screening for ED properties, an increased number of EDs and Suspected EDs will ideally be identified independently of use and tonnages, and at the same time the results of animal experiments will be used in a more targeted way, reducing the use of laboratory animals over time. To make this reality, it will be important to develop regulatory approaches based to a larger extent on *in vitro* data.

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35 https://eurion-cluster.eu/
36 https://chemicalwatch.com/118697/eu-authorities-finalise-data-requirements-for-endocrine-disrupting-biocides

www.chemtrust.org
www.chemtrust.org/de

Twitter: @CHEMTrust
@CHEMtrust_de
CHEM Trust proposal:

3. Improved identification of EDs through extended data requirements and screening

- **Standard information/data requirements in REACH, BPR and PPPR should be extended/updated** to include systematic search for information/data on ED properties based on a predefined minimum data search strategy, including QSAR and read across, and to include relevant test methods and with adequate ED endpoints for reliable identification of substances with ED properties.

- **A wide range of in vitro tests** covering all ED modalities should be used for screening of substances for their potential ED activity.

- **Safety evaluation of cosmetics** should include a systematic search for ED information/data on ingredients based on a predefined minimum data search strategy, and in case ingredients have not been comprehensively assessed for their ED properties, they should be **tested for potential ED activity** by using *in vitro* test batteries.

- In the medium term, new regulatory approaches for identification should be developed that accept regulatory decisions based on *in vitro* data while not compromising environment and health protection.

- For all **inconclusive** ED assessments **strict deadlines** should be set for the companies to provide more data. **Non-compliance** should lead to an **immediate temporary ban**.

3.2.4 Changes to existing legislation and strict controls of sensitive uses of EDs

Currently, only confirmed EDs are controlled by not allowing their market approval or severely restricting their use (cut-off) under the BPR and PPPR. Under REACH, only substances identified as EDs with a level of concern equivalent to CMRs and PBTs/vPvBs will be identified as SVHCs and included in the REACH Candidate List (CL) to eventually be subject to authorisation and/or restriction. Under the CLP, EDs may be classified according to the specific adverse effect as a consequence of endocrine disruption which may lead to some downstream regulatory consequences. However, identification as ED according to a specific ED hazard class is not a part of CLP and hence, the subsequent triggering of information in the supply chain and downstream ED control measures.

These sectorial differences lead to several and different assessments of the same substance often leading to inconsistent and ambiguous hazard and risk assessment and risk management.

The aim of the European Commission’s proposed framework on EDs is the minimisation of exposure to EDs.

The fact that there is a considerable difference in the availability of data under the different pieces of legislation, the limited data available on EDs, the seriousness of effects, and that EU research has demonstrated the presence of many EDs and groups of EDs in human and environmental monitoring studies, shows the need for a more protective approach.

Thus, the challenge is to set up more protective, coherent, and consistent controls of EDs across different pieces of legislation, yet acknowledging that the requirements for risk management may be different in different regulatory sectors.

The new proposed overarching ED legislation will provide a horizontal and consistent approach for the identification, assessment, and control of EDs. The current risk management approach of the PPPR and BPR to prevent the use of known EDs (except for some derogations) should be extended

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38 [https://www.hbm4eu.eu/](https://www.hbm4eu.eu/)
39 [https://www.solutions-project.eu/](https://www.solutions-project.eu/)
to other sectors to include stricter controls for sensitive uses of EDs. And an identification as a Suspected ED should also lead to regulatory consequences, in particular, stricter ones for consumer use.

By inclusion of ED as a new hazard class in the CLP Regulation, all chemical substances - including those produced/imported in low tonnages - will be covered, and furthermore, the CLP triggers control measures in other legislation. This will further ease the possibility of labelling of products as being EDs/Suspected EDs. However, the overall proposal would still be functional without inclusion of ED as a hazard class in the CLP Regulation.

This collectively will improve consistency across legislation, yet still allow sector specific risk management.

A more precautionary approach should also explicitly specify that a threshold for effects cannot be established with reasonable certainty for many EDs\(^{40}\) and that EDs are considered of particular concern. In CHEM Trust’s view EDs should, as default, be treated as non-threshold substances and equivalent to chemicals with PBT/vPvB properties. This is because EDs can lead to serious and irreversible effects even in future generations, and because of the many uncertainties relate to the assessment of EDs.

**CHEM Trust proposal:**

4. Changes to existing legislation to ensure strict controls of sensitive uses of EDs

- As a general principle **EDs (cat. 1) should not be allowed for sensitive uses**, i.e. consumer use and widespread environmental use. This includes e.g. BPs, PPPs, food contact materials (FCMs), toys, cosmetics, medical devices, and devices for drinking water.
- Furthermore, **Suspected EDs (cat. 2) should not be allowed for consumer use** e.g. FCMs, toys, cosmetics. medical devices for consumer use and devices for drinking water. Under BPR/PPPR/REACH these substances should not be authorised until further information becomes available that dispels concerns about the ED properties and until then, they shall be considered candidates for substitution.
- EDs should by default be **regarded as non-threshold substances and considered of particular concern** due to irreversible, severe and unpredictable effects. This should be reflected by including the horizontal ED approach in REACH, thereby ensuring that **EDs are by default identified as ELOC** and regarded as non-threshold substances. Furthermore, ED assessment should be included as a part of the chemical safety report under REACH Annex 1.
- A **new hazard category for ED** based on the new overarching ED legislation and the horizontal ED criteria should be included in the CLP Regulation. This should ensure hazard identification of EDs independently of tonnage levels, should lead to downstream regulatory consequences and facilitate supplementary labelling indicating ED properties.
- Regulation should be based on **grouping of substances**; substances with similar structure or similar properties identified as EDs or Suspected EDs should be regulated similarly.

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\(^{40}\) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0814&from=en
**Figure 4: ED identification**

ED identification

New EU overarching ED legislation

Horizontal ED criteria integrating BPR/PPPR criteria

+ mandatory info search and extended data requirements for ED endpoints

<table>
<thead>
<tr>
<th>PPPR</th>
<th>BPR</th>
<th>REACH</th>
<th>CLP</th>
</tr>
</thead>
</table>

[+ new Art. 57 (g)]? + ED cat. 1 A/B

+ Annex 1 ED assessment + ED cat. 2

**Figure 5: ED management**

ED Management

New EU overarching ED legislation

Ban of EDs cat. 1 for all sensitive uses (consumer + widespread use)
Ban of EDs cat. 2 for all consumer uses

<table>
<thead>
<tr>
<th>FCM</th>
<th>Toys</th>
<th>Cosmetics</th>
<th>Medical devices</th>
<th>Others e.g. drinking water devices</th>
</tr>
</thead>
</table>

+ treating EDs as default non-threshold chemicals

+ addressing groups of similar EDs
3.2.5  A transition period with specific measures for immediate protection from EDs

The identification of EDs is fundamentally hampered by a lack of ED regulation, a lack of knowledge and a lack of adequate test methods to identify the ED properties. These substantial obstacles to reliable identification endanger protection from exposure to EDs. This is exacerbated by the fact that many of these substances are ubiquitous in the environment, and that the foetus is especially sensitive to exposure. All this calls for immediate action to prevent exposure in order to protect current and future generations.

As it will probably take another decade to implement this new ED approach and put it into practice, there should be a transition period that ensures swift identification and control of EDs based on interim criteria for ED identification specifically for certain sensitive consumer uses to protect vulnerable groups. Such a moratorium has previously been used in the EU for the protection of children from certain phthalates in toys. The proposed interim criteria should be based on existing substance classifications such as Carcinogenic and Toxic to Reproduction, combined with knowledge on endocrine activity from well-established EU databases, and various EU or Member State work or lists confirming a strong suspicion of ED properties of a substance.

**CHEM Trust proposal:**

5. A transition period with specific measures for immediate protection from EDs

- As a precautionary action, a transition period with *swift ED identification and control* based on *interim criteria* and existing regulation and current knowledge should be established. This will ensure *immediate protection* of human health and environment until the new legislation on EDs and the process of identification of EDs are fully in place and well-functioning.
- This should include a moratorium: a temporary ban of EDs identified through the interim criteria to protect the particularly vulnerable, the unborn child, and children from daily exposure to FCMs (including devices for drinking water), toys, cosmetics and medical devices for consumer use.
- The *interim ED criteria for substances for certain sensitive consumer uses* identify by default all those substances as EDs that are
  1. classified according to CLP as Carc 1, Carc 2, Rep 1, Rep 2 or as STOT and that are included in the EU EASIS database on endocrine-active substances and show endocrine activity, or
  2. considered to be an ED/Suspected ED based on a Member State expert assessment, or
  3. included in the Community Rolling Action Plan, the CORAP list, as a potential ED, or
  4. identified as ED or Suspected ED under option 3 in the screening study as part of the impact assessment on criteria to identify EDs in the context of the PPPR and BPR.
- For substances identified as EDs by the interim ED criteria, a mechanism should be established to *initiate a process for further clarification* as to whether the substance meets the new horizontal ED criteria. When a substance has been assessed according to the horizontal ED criteria it will no longer be covered by the interim ED criteria.

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[^41]: Specific Target Organ Toxicity
3.2.6 Easily accessible public information on EDs – full transparency of ED assessments

CLP as well as REACH, BPR and PPPR do provide some information on the harmful effects of EDs to consumers, workers and companies, although in most cases this is based on the classification for endpoints such as reproductive toxicity.

Currently, information on substances identified under REACH as SVHCs due to ED properties can be found on the ECHA website but there is no official EU list of substances that are identified as EDs, nor a list of the status of the ED assessments under BPR/PPPR. Recently, five EU Member States joined forces and launched a website which gives a very useful overview of EDs already identified in the EU, or those which are undergoing an assessment, or are identified as potential EDs by one of the co-operating countries. However, it still remains very difficult to obtain official information on the status of all ED assessments.

Transparency in the assessment processes is essential as this will allow companies and consumers to obtain the knowledge on which substances are already identified as EDs or Suspected EDs. Only then, will consumers be able to make informed choices and avoid using the substances in their daily life. Only then, are companies likely to substitute EDs with safer alternatives.

Therefore, there is a need for transparency of the status for EU ED assessments and easy public access to this information. Further, information to the public and the supply chain via the labelling of chemical substances and products that contain EDs or Suspected EDs should be introduced, as this may provide relevant information to assess the risk of combination effects from other EDs.

CHEM Trust proposal:

6. Full transparency of assessments to facilitate substitution and informed choices

- The new proposed overarching ED legislation should ensure full transparency and easy access to information. Status for ED assessments and official EU lists of identified EDs and Suspected EDs should be published, enabling the public to make informed choices, to guide authorities and companies in the prioritization of work, and in the substitution of EDs with safer alternatives.

- To inform the public and workers, as well as the entire supply chain about the hazards from EDs and the risk of combination effects, supplementary labelling of chemicals that are identified as EDs or Suspected EDs should be introduced e.g. via the CLP.

3.3 In conclusion

1. Control of EDs should be part of all relevant EU legislation on chemical substances and products. A horizontal approach for identification and control of EDs is both preferable and needed. Although criteria for endocrine disrupting BPs and PPPs have recently been adopted, these cannot be transferred directly to other legislation on chemical substances and products due to the significant difference in the requirements of information/data under the different pieces of legislation.

2. Identification of EDs should be based on horizontal ED criteria that reflect the level of evidence for ED properties. Therefore, substances should be identified in 2 categories: as ED (cat. 1) or as Suspected ED (cat. 2). Identification of EDs should be improved by extending the information and data requirements for a reliable identification of EDs.

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45 https://echa.europa.eu/da/information-on-chemicals
46 https://chemtrust.org/new_edc_website/
It is crucial for the future protection of human health and the environment that the huge data gap for ED properties of chemicals are taken into account. Therefore, an approach is needed that reflects the huge lack of data on ED properties, that less data is available for industrial chemicals and that many chemical products are intended for consumer use. These circumstances require a much higher degree of precaution and transparency: so that industry/the supply chain is able to decide on which substances are candidates for substitution, as they are suspected to be EDs; so that authorities can prioritise focus upon key substances; and so the public will be able to make informed choices, where they wish to avoid EDs and Suspected EDs in their daily life.

3. As EDs may cause very serious and irreversible effects even in subsequent generations they should be strictly controlled, not allowed for sensitive uses leading to considerable consumer and widespread environmental exposure, and they should be substituted with safer alternatives as far as possible. Therefore, EDs and Suspected EDs should not be allowed in consumer products as e.g. FCMs, toys, cosmetics, and medical devices for consumer use.

4. To protect vulnerable groups, and in particular the unborn child, there is a need for immediate protective measures for swiftly identification and control of EDs in consumer products for daily use because setting up a new horizontal ED approach will take many years. Furthermore, until now only very few substances have been identified as EDs although regulation on EDs under REACH, PPPR and BPR has been in force for many years - and at the same time many of these substances are ubiquitous in our daily life.

5. To minimise exposure to EDs it is very important to immediately

• include control of EDs in all relevant EU legislation on chemicals substances and products, e.g. for cosmetics, toys, and FCMs
• improve the basis for identification to swiftly identify all substances with ED properties, and
• ensure transparency of assessments and easy public access to official information on substances’ ED properties.

**Figure 6: Horizontal ED approach**

<table>
<thead>
<tr>
<th>Horizontal ED approach</th>
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<tbody>
<tr>
<td>New EU overarched ED legislation</td>
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</table>

**Identification:**
- Categories for ED hazard identification cat. 1 A/B and cat. 2 to be introduced in REACH & CLP
- One substance - one assessment principle (carried out by one EU institution)
- Official EU ED lists and status of all ED assessments for transparency

**Management:**
- Bans of ED cat. 1 for all sensitive uses (all consumer uses and wide dispersive use)
- Bans of ED cat. 2 for all consumer uses
- Requirements for more info for ED cat. 2 prior to approval and authorisation

**Transition measures:**
- Temporary ban for certain sensitive consumer uses based on interim criteria for swift identification of EDs
**Figure 7: Horizontal ED criteria and proposed regulatory consequences**

<table>
<thead>
<tr>
<th>WHO-def.</th>
<th>Horizontal ED criteria</th>
<th>BPR</th>
<th>PPPR</th>
<th>REACH</th>
<th>CLP</th>
<th>Cosmetics</th>
<th>Toys</th>
<th>FCM*</th>
<th>Medical Devices*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED</td>
<td>ED (cat. 1) Known + 12 Presumed</td>
<td>Prohibited</td>
<td>Prohibited</td>
<td>SVHC¹</td>
<td>EU list²</td>
<td>Prohibited</td>
<td>Prohibited</td>
<td>Prohibited</td>
<td>Prohibited</td>
</tr>
<tr>
<td>Potential ED</td>
<td>Suspected ED (cat. 2)</td>
<td>More info before approval</td>
<td>More info before approval²</td>
<td>More info, SEV²</td>
<td>EU list²</td>
<td>Prohibited</td>
<td>Prohibited²</td>
<td>Prohibited²</td>
<td>Prohibited²</td>
</tr>
</tbody>
</table>

*Temp. ban

# Including devices for drinking water

*² Except when their function is to induce a hormonal effect. Prohibited for consumer use, and only allowed for professional use in case of essential use and when suitable alternatives are not available

¹ Official ED list as ED. ² Official ED list as Suspected ED

³ In vitro testing in the context of safety evaluation of cosmetic products

## Improved data requirements

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<th>X</th>
<th>X</th>
<th>X</th>
<th>X²</th>
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4 The implications of a new horizontal ED approach for existing regulations

4.1 Implications for REACH

REACH standard information requirements should be updated for the lowest tonnage level to include a systematic search for ED information/data, including in the open literature, and in combination with the use of in silico methods, based on a predefined minimum search strategy.

If there are any signs of endocrine activity/effects, this should trigger in vitro/in vivo testing depending of the sort of evidence, e.g. by advancing the level of evidence according to OECD GD 150. As GD150 primarily focuses on Estrogenic Androgenic, Thyroid and Steroid (EATS) modalities there is also a need to address substances acting by non-EATS modalities.

At higher tonnage levels requirements for adequate and more definitive test methods should be included to properly identify ED properties, e.g. the Extended One Generation Reproductive Toxicity Study (EOGRTS), including the cohorts for immunotoxicity (DIT) and developmental neurotoxicity (DNT) and the Fish Sexual Development Test (FSDT). CHEM Trust has further described these proposals in the context of the relevant CARACAL subgroup.47

The new horizontal ED criteria for identification of EDs should be included in REACH by the overarching ED legislation. This would for example mean that identification as ED according to the horizontal criteria should count by default as being of equivalent level of concern (ELOC) cf. Art 57(f) and thereby, identification as a SVHC.

Further, EDs should as default be considered non-threshold substances of particular concern, which means that an application for authorisation would always have to follow the socio-economic route and a continued use should only be authorized when the applicant can justify the benefits are outweighing the risks and no safer alternatives are available.48 In case REACH is opened, this could be reflected by a new Art. 57(g) that should also be covered by Art. 60(3).

Substances identified as ED cat. 1 should be identified as SVHC, included in the CL and listed at the official EU ED list as an ED.

Substances identified as ED cat. 2 should be subject to requests for additional information by initiation of a Substance Evaluation (SEv) and listed at the official EU ED list as a Suspected ED.

Requirements for an ED assessment as part of the chemical safety report should be included as part of REACH Annex 1.

Due to serious and irreversible effects EDs are of particular concern. Therefore, EDs and Suspected EDs should be restricted for all consumer use, which can be done by amending 68.2 if REACH is opened, or by revising REACH Annex XVII.

4.2 Implications for CLP

CHEM Trust has contributed to the discussions on including ED in the CLP Regulation and summarised first views in our submission to the CARACAL ED subgroup work.

A new hazard category on EDs, referring to the overarching ED legislation, should be included in the CLP Regulation if the EU can move ahead without having to change GHS first. The CLP should be updated accordingly, in particular regarding the criteria for hazardous effects to the environment as currently only aquatic toxicity is covered.

As endocrine disruption may lead to many different adverse effects, a substance with ED properties will usually be classified (and labelled) according to the specific adverse effects caused by endocrine disruption, e.g. as Toxic to Reproduction, Carcinogenic or STOT. Introduction of a new hazard class of EDs should also lead to supplementary labelling to inform the supply chain, workers and citizens specifically about the hazard due to ED properties and the risk of combination effects.

Substances identified as ED cat. 1 should, in addition to the requested hazard labelling due to specific effects, be provided with a supplementary labelling informing about the content of EDs, e.g. “Contains EDs”, and they will be listed on the official EU ED list as an ED.

Substances identified as ED cat. 2 should in addition to the required hazard labelling due to specific effects, be provided with a supplementary labelling informing about the content of suspected EDs, e.g. “Contains suspected EDs”, and they will be listed as a Suspected ED on the official EU ED list.

4.3 Implications for BPR

Data requirements should be updated to include as the very first step a systematic information/data search on ED properties based on a predefined minimum data search strategy that also includes searches in the open literature and databases as well as QSAR screening, grouping and read across.

The next step should then be the application of a wide range of sensitive in vitro test batteries to screen for endocrine activity and for guiding further testing to avoid unnecessary animal testing. There should be a request to include comprehensive test methods that cover relevant and adequate ED endpoints to properly predict ED properties in accordance with OECD GD 150, and as GD150 primarily is focusing on EATS modalities, also to address substances acting by non-EATS modalities.

If existing data originates from studies with outdated test methods or test methods that do not include the relevant ED endpoints e.g. the two-generation reproduction toxicity study, new supplementary studies covering relevant ED endpoints should be required.

The new horizontal criteria embrace the criteria for endocrine disrupting BPs, as substances identified as ED cat. 1 are not allowed for sensitive uses, including BPs, which is reflected by the cut-off criteria for endocrine disrupting BPs (including active ingredients, metabolites and co-formulants and biocidal products for consumer use) in terms of human health effects and effects on non-target organisms. The possibilities for derogations from the cut-off should be restricted to strictly exceptional situations.

Identified ED cat. 1-substances should be listed on the official EU ED list as an ED.

Substances identified as ED cat. 2 should be subject for requirements of additional information/testing for advancing the level of evidence in accordance with OECD GD 150 before they can be authorised, and they will be listed on the official EU ED list as a suspected ED. These substances should not be permitted for consumer use, be candidates for substitution, and should only be authorised for a short period of time e.g. 5 years.

4.4 Implications for PPPR

Data requirements should be updated to include, as the very first step, a systematic information/data search on ED properties based on a predefined minimum data search strategy that also includes searches in the open literature and databases as well as QSAR screening, grouping and read across.

The next step should then be the application of a wide range of sensitive in vitro test batteries to screen for endocrine activity and for guiding the further testing to avoid unnecessary animal testing. There should be a request to include comprehensive test methods that include relevant
adequate ED endpoints to properly identify ED properties in accordance with OECD GD 150, and as GD150 primarily is focusing on EATS modalities also to address substances acting by non-EATS modalities.

If existing data originates from studies with outdated test methods or test methods that do not include the relevant ED endpoints e.g. the two-generation reproduction toxicity study, new supplementary studies covering relevant ED endpoints should be required.

The new horizontal criteria embrace the criteria for endocrine disrupting PPPs, as substances identified as ED cat. 1 are not allowed for sensitive uses, including PPPs, which is reflected by the cut-off criteria for endocrine disrupting PPPs in terms of human health effects and effects on non-target organisms. The cut-off covers active ingredients, safeners and synergists, however, it should be enlarged to also cover metabolites and all co-formulants. The possibility for derogations from the cut-off due to negligible exposure should be limited and subject to close scrutiny by authorities.

Identified ED cat. 1-substances should be listed on the official EU ED list as an ED.

Substances identified as ED cat. 2 should be subject to requirements of additional information/testing for advancing the level of evidence in accordance with OECD GD 150 before they can be authorised, and they will be listed on the official EU ED list as a suspected ED. These substances should not be allowed for consumer use, be candidates for substitution and should only be authorised for a short period of time e.g. 5 years.

4.5 Some consequences for other legislation

Most of the other legislation on chemical substances and products would refer to REACH and the CLP and therefore, standard information requirements, identification and potential labelling will be covered by these laws and may trigger downstream control measures for EDs.

In the following, the impact on and consequences of the horizontal ED approach for some other pieces of legislation are briefly outlined, however, not fully exhaustive.

In general ED cat. 1-substances should not be allowed for sensitive uses, i.e. widespread environmental and consumer use. ED cat. 2-substances should not be allowed for consumer use.

To specifically protect vulnerable groups from daily exposure to EDs, certain sensitive daily consumer uses are prioritised for immediate action.

Therefore, the use of toys, cosmetics, FCMs, and medical devices for consumer use should be covered by immediate protective measures, moratorium measures: ED identification and control according to interim criteria based on current regulation and knowledge on endocrine activity/effects as specified under 2.2.5.

The recent EU Farm to Fork Strategy49 includes a clear commitment for a revision on the law for FCMs. CHEM Trust has contributed to the development of five key principles50 - jointly advocated for by NGOs - for future EU regulation of chemicals in FCMs.

4.5.1 Cosmetics

The legislation on Cosmetic Products includes a safety evaluation (risk assessment) and at the same time there is a ban of use of animal testing. This ban was an important achievement for animal welfare but at the same time makes it challenging to identify and assess substances with ED properties as the current criteria for endocrine disrupting BPs and PPPs require the evidence of ED effects in vivo.

Therefore, a safety evaluation51 of cosmetic products should be based on a systematic search for ED information/data based on a predefined minimum search strategy, including QSAR, }
chemical categories, grouping, and read across as described in the notes of guidance for the testing of cosmetic ingredients and their safety evaluation. In addition, in case ingredients have not been comprehensively assessed for their ED properties, they should be tested using an in vitro ED test battery covering all ED modalities (including in accordance with OECD GD 150) to identify potential endocrine activity.

In general, ED cat. 1 and ED cat. 2-substances should not be allowed for use in cosmetics.

Due to the serious and irreversible effects EDs are of particular concern. Therefore, exemptions from the ban (cf. Art. 15) should only be possible in exceptional cases. This could for example be addressed by introducing a new Art. 15(b) covering EDs.

If substances test positive for ED activity by in vitro testing or there are other signs of ED properties, the substances should not be allowed for use in cosmetics, except where it can be justified that these properties are not relevant in relation to human health and the environment.

Substances showing endocrine activity in in vitro test batteries or for which there are other signs of ED properties should be listed on an “ED flag-list” for further investigation.

4.5.2 Other sensitive uses

Other sensitive uses are e.g. devices for drinking water, medical devices in general, and pharmaceuticals. Content of EDs in devices for drinking water should not be allowed just as it is the case for FCMs. For pharmaceuticals and medical devices there are other considerations to take into account, including risk-benefit analyses. But as a general principle, EDs cat. 1 and 2 should not be allowed for use as auxiliary substances in pharmaceuticals, and only be allowed as ingredient in medical devices for professional use in case of an essential use and when suitable alternatives are not available, or in case their function is to induce a hormonal effect. They should not be allowed for medical devices for consumer use except when their function is to induce a hormonal effect.

3.5.3 Eco-labelling

EU rules for eco-labelling52 should be amended in a way to ensure that EDs and Suspected EDs cannot be allowed for use in Eco-labelled products.

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5 Conclusions

A protective and horizontal ED approach needs to be a priority for the Green Deal and the upcoming European Chemical Strategy for Sustainability. A long-term vision and concrete plan with ambitious timelines to effectively protect people and environment from EDs is required.

With this document CHEM Trust has suggested how a new path for EU ED control can become a reality. This will ensure a horizontal ED approach that, at the same time, acknowledges the criteria for endocrine disrupting BPs and PPPs in force, integrates with the current EU legislative framework, and paves the way for a more precautionary ED approach and prevention of exposure to EDs.

The only way forward to protect human health, including future generations, and the environment from the serious impact of EDs is to avoid/minimize exposure which can achieved by

- **Rapid and improved identification** of substances with ED properties
- **Strict control** of substances with ED properties
- **Full transparency** to inform the supply chain and the public about EDs

5.1 For further information

- CHEM Trust publications and other information on EDs are available on our website; our blogs covering EDs are available here: [https://chemtrust.org/tag/endocrine-disruptors/](https://chemtrust.org/tag/endocrine-disruptors/)
- For information and publications of the EDC-Free Europe coalition, please see: [https://www.edc-free-europe.org/](https://www.edc-free-europe.org/)

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