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Perspectives on and expectations to test method development by the EURION Cluster projects

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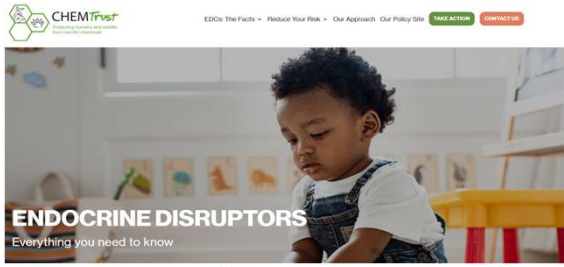
Who is CHEM Trust ?



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CHEM Trust is an NGO – a collaboration between UK charity CHEM Trust and CHEM Trust Europe in Germany

CHEM Trust is part of the NGO coalition

EDC FREE EUROPE
LET'S STOP HORMONE DISRUPTORS

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CHEM Trust is a member of:

EU expert groups: ECHA ED EG & CASG ED

OECD expert advisory group on testing/assessment of endocrine disruptors EDTA AG

CHEM Trust policy paper, July 2020

A new approach to protect people and wildlife from endocrine disruptors

July 15, 2020 By Anna Watson

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Policy paper
July 2020

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[1] and the 7th Environment Action Programme[2] (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[3] and submitted some first ideas for a way forward on ED regulation in our comments to the CARACAL ED subgroup work[4].

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

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:51999DC0706&from=EN

[2] https://ec.europa.eu/environment/action-programme/

[3] https://chemtrust.org/wp-content/uploads/CHEM-Trust-Submission-ED-Fitness-Check-Jan-2020.pdf

[4]

A new path for EU regulation of Endocrine Disruptors (chemtrust.org)

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The EU road to protect human health and the environment against EDCs

EDCs on the EU agenda for more than 20 years

1999 strategy envisaged ED identification, research, test methods, legislation

Huge research effort BUT
in reality, still insufficient protection of human health and the environment

- Lack of political will – economic interests
- Struggle about identification of EDs
- Lack of adequate ED test methods

New promising Chemicals Strategy for Sustainability
– commitments to minimize the exposure to EDCs

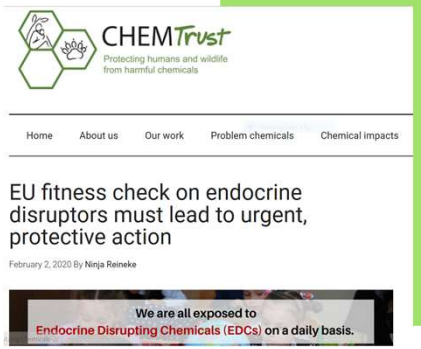
[Chemicals strategy (europa.eu)]

CHEM Trust's recommendations on the way forward….

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

Minimize exposure to EDCs by ensuring

- Inclusion of **protective rules** in **all** relevant EU legislation with **focus on phase out of EDCs**
- **Swift identification** of EDs
- Identification in two categories: **EDs and Suspected EDs**
- **Extended** information/**data requirements**
- More **transparency** - publication of lists of EDs and Suspected EDs
- **Ban** in **consumer products**



https://chemtrust.org/eu-urgent-action-edcs/

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Protection of human health and ecosystems against EDCs

- what is needed now

Identification of EDCs and suspected EDCs is a prerequisite for control of EDCs and thus, protection

Swift and proper ED identification

Swift

- **Quick screening of ED properties by non-test and *in vitro* test methods**
- **Quickly add new specific ED endpoints to existing OECD TGs**
- **New fast and decisive ED test methods available for EATS and other modalities**

EURION
European Cluster to Improve Identification of Endocrine Disruptors

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Protection of human health and ecosystems against EDCs

- what is needed now (continued)

Swift and proper ED identification

Proper

- **Test methods adequately reflect human diseases and environmental effects**
- **Current gaps filled: thyroid disruption, female effects, effects on invertebrates, effects on senescence**
- **Test methods cover a much broader spectrum of the dose range – low dose effects**

EURION
European Cluster to Improve Identification of Endocrine Disruptors

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CHEM Trust's comments to

update of REACH annexes

- **Systematic and predefined minimum information/data search strategy, including (Q)SARs, read across etc.**
- **Screening with wide range of *in vitro* tests covering all ED modalities**
- **Integration of human health & environment**
- **Intelligent testing strategy, and EOGRTS with DNT and DIT cohorts**

CHEM Trust's response to

EURION stakeholder consultation

Screening tests

Specificity for ED MoA
Suitable for screening
OECD accepted

Definitive tests

Specificity for ED MoA
High sensitivity
OECD accepted

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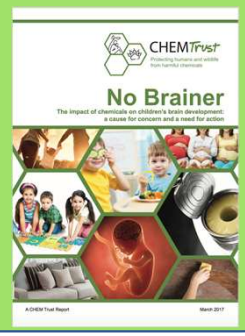
What does CHEM Trust expect from the EURION cluster work?

- **New knowledge to support the regulation of EDCs**

- **In the short term, we expect EURION to deliver:**
  - ***in vitro* assays for detection of ED MoA and for screening of substances**
  - **new definitive ED endpoints to be added to existing OECD TG**
  - **methods/endpoints specifically covering thyroid disruption**
- **In the long term: increased protection!**



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Conclusion

High time to control EDCs!

Swift and proper identification of EDCs imperative

EURION contribution important

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