



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

# NGO view on ED regulation

5<sup>th</sup> International Fresenius Conference “Endocrine Disruptors”,

29 and 30 October 2014

Ninja Reineke, PhD, Senior Policy Adviser, CHEM Trust



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

# CHEM Trust





# CHEMTrust

Protecting humans and wildlife  
from harmful chemicals



## EFFECTS OF POLLUTANTS ON THE REPRODUCTION OF MALE VERTEBRATES

**A CHEM Trust and HEAL Briefing:**  
Challenges and solutions in the regulation of chemicals with endocrine disrupting properties

The EU is developing an agreed way of identifying chemicals with endocrine disrupting (ED) properties for regulatory action. This briefing particularly addresses two vitally important issues with respect to getting sufficiently protective controls over chemicals with ED properties: (1) that a potency threshold should not be included in the hazard-based criteria that must be developed to identify chemicals with ED properties and (2) that non-OECD test methods must be given due weight in hazard assessment. These two issues are further elaborated in sections 2 and 3, following an introductory section on the development of the criteria for use in law. Section 4 considers burden of proof issues related to the definition of endocrine disruption and section 5 summarises the conclusions and recommendations.

**Contents:**

**Summary**

**Box 1: What are endocrine disrupting chemicals (EDCs)?**

EDCs are substances that derail the hormones of living organisms, and are therefore also called hormone disruptors. Hormones are secreted by the endocrine glands and are the body's internal chemical messengers, orchestrating many functions including reproduction, metabolism and brain development.

Hormones particularly guide development in the womb, and exposure of the foetus to an EDC at this time can cause irreversible damage. Defects of the genitalia are evident at birth, but many other health problems, such as low sperm counts and behavioural effects only manifest later in life. EDCs are now strongly suspected of playing a role in the increased incidence of various chronic diseases and disorders. These include male reproductive health problems, hormone related cancers including testicular, prostate, and breast cancer, as well as obesity and diabetes. Wildlife has also been affected, and many adverse effects have been seen in fish, birds, reptiles and mammals, particularly including the 'feminisation' of males and reduced reproduction.



## Male Reproductive Health Disorders and the Potential Role of Exposure to Environmental Chemicals



Written by Professor Richard Sharpe  
Commissioned by CHEM Trust

Blog: <http://www.chemtrust.org.uk/tag/endocrine-disruptors/>



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

## EC Commission roadmap on ED criteria

- Identification
- Approaches to regulation

## Thresholds for EDs under REACH authorisation



**CHEMTrust**  
Protecting humans and wildlife  
from harmful chemicals

## 4 options proposed in ED Roadmap

- Option 1: *No specific ED criteria*

Interim



Permanent

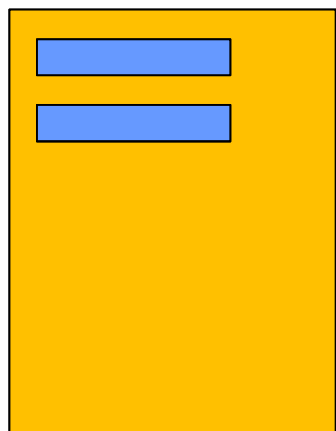


**CHEMTrust**  
Protecting humans and wildlife  
from harmful chemicals

## 4 options proposed in ED Roadmap

- Option 1: *No* specific ED criteria
- Option 2: *Yes/No* decision based on WHO/IPCS

### *Confirmed EDs*



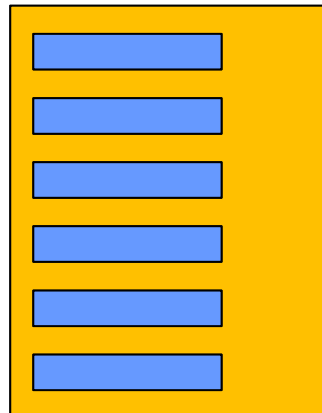


**CHEMTrust**  
Protecting humans and wildlife  
from harmful chemicals

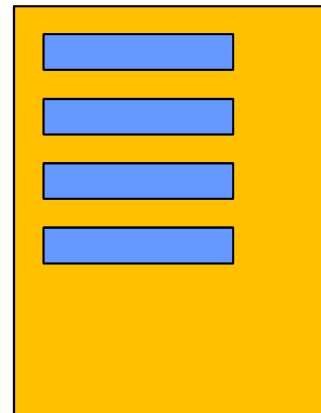
## 4 options proposed in ED Roadmap

- Option 1: *No* specific ED criteria
- Option 2: *Yes/No* decision based on WHO/IPCS
- Option 3: 3 Categories with different strength of the evidence

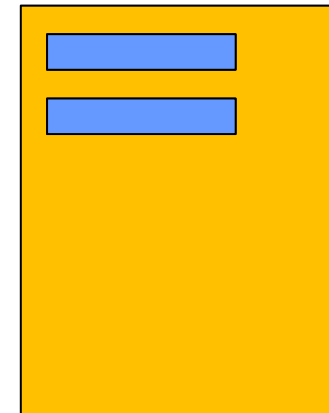
***Endocrine active***



***Suspected***



***Confirmed***

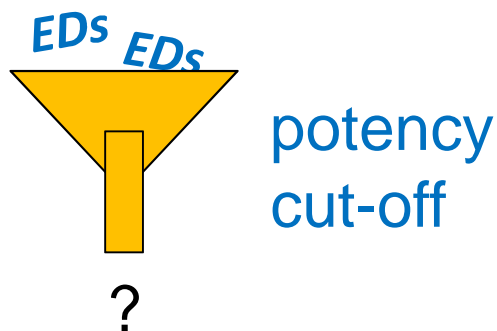




**CHEMTrust**  
Protecting humans and wildlife  
from harmful chemicals

## 4 options proposed in ED Roadmap

- Option 1: *No* specific ED criteria
- Option 2: *Yes/No* decision based on WHO/IPCS
- Option 3: 3 Categories with different strength of the evidence
- Option 4: Potency included in hazard characterisation







## CHEM Trust prefers option 3

- Transparent overview of the level of evidence
- All data considered (beyond EATs), trigger for more data

*BUT:*

- Keep in mind legal text (“may cause adverse effects”)
- Aim for “plausibility” rather than “final proof”

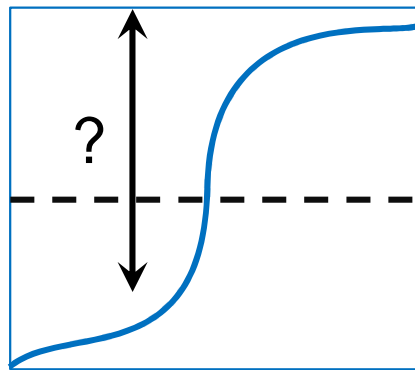


**CHEMTrust**  
Protecting humans and wildlife  
from harmful chemicals

## Option 4 is *not* an option

No potency cut-off because

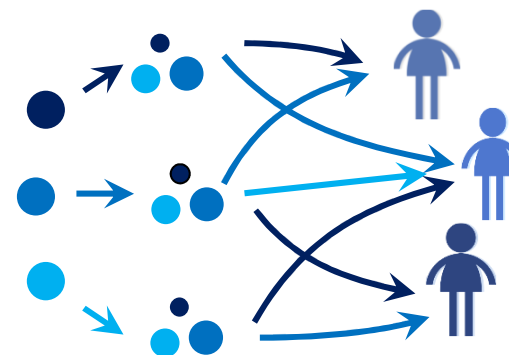
- Arbitrary: no science-based justification
- Great variation between different species, therefore a cut-off may overlook harmful EDs



## Option 4 is *not* an option

### No potency cut-off because

- Weakly potent EDs with high exposures not addressed
- Many weak EDs can act together



- Identification of CMRs not based on potency



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

## EC Commission roadmap on ED criteria

- Identification
- Approaches to regulation

## Thresholds for EDs under REACH authorisation



## COM suggests 3 approaches

- A** No change in regulatory provisions
- B** Introduction of further elements of risk assessment
- C** Introduction of socio-economic considerations



**CHEMTrust**  
Protecting humans and wildlife  
from harmful chemicals

## CHEM Trust prefers approach A

No regulatory changes to the existing EU laws

- Essential elements adopted by the legislator cannot be changed via delegated acts
- Derogations available, for well-justified cases
- ED cut-off only implemented at re-authorisation



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

## EC Commission roadmap on ED criteria

- Identification
- Approaches to regulation

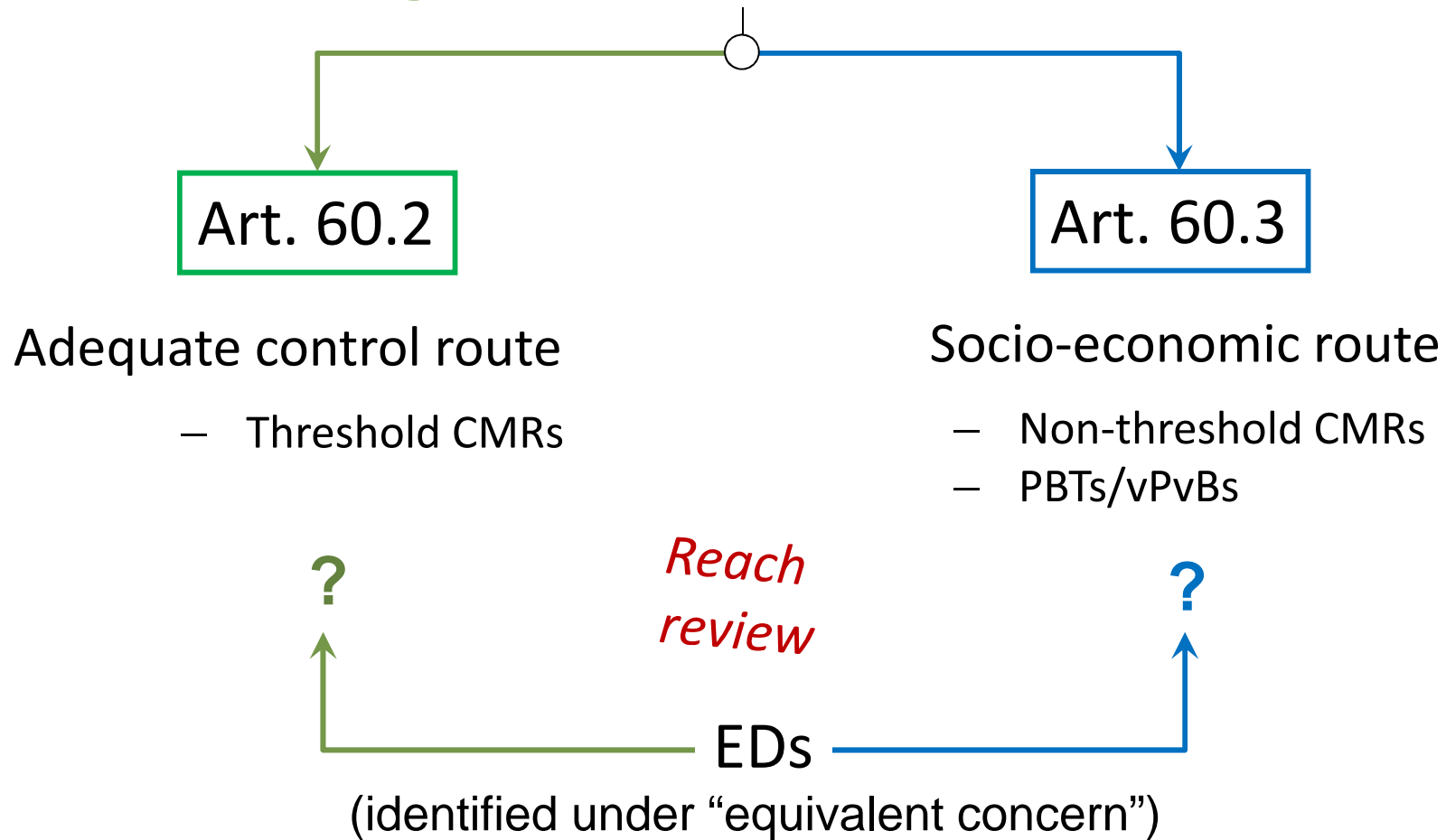
## Thresholds for EDs under REACH authorisation



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

## Granting of authorisations based on







**CHEMTrust**  
Protecting humans and wildlife  
from harmful chemicals

## COM review paper (July 2014)

- Non-threshold, unless applicant demonstrates a threshold
- thresholds of adversity may be very low or even absent during development
- Limitations of test methods to identify a possible threshold
  - Not all relevant sensitive endpoints covered
  - Effects manifesting in old age are not included
  - Extrapolation from high doses to low doses may be problematic



**CHEM**Trust

Protecting humans and wildlife  
from harmful chemicals

## CHEM Trust view on COM review

- Missed opportunity to treat EDs similar to PBTs/vPvBs
- No mention of rising trends of endocrine related diseases and disorders
- Increased uncertainties in the determination of safe thresholds is acknowledged
- Advice to companies: take it as a strong steer to substitute



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

## SIN list 3.0

- Early warning system for SVHCs
- SIN list includes substances with ED properties
- used by companies, investors, authorities





**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

# Green Chemistry

Dynamic Article Links 

Cite this: DOI: 10.1039/c2gc35055f

[www.rsc.org/greenchem](http://www.rsc.org/greenchem)

**PAPER**

## Designing endocrine disruption out of the next generation of chemicals†

T. T. Schug,<sup>\*a</sup> R. Abagyan,<sup>b</sup> B. Blumberg,<sup>c</sup> T. J. Collins,<sup>d</sup> D. Crews,<sup>e</sup> P. L. DeFur,<sup>f</sup> S. M. Dickerson,<sup>g</sup>  
T. M. Edwards,<sup>h</sup> A. C. Gore,<sup>i</sup> L. J. Guillette,<sup>j</sup> T. Hayes,<sup>k</sup> J. J. Heindel,<sup>a</sup> A. Moores,<sup>l</sup> H. B. Patisaul,<sup>m</sup> T. L. Tal,<sup>n</sup>  
K. A. Thayer,<sup>o</sup> L. N. Vandenberg,<sup>p</sup> J. C. Warner,<sup>q</sup> C. S. Watson,<sup>r</sup> F. S. vom Saal,<sup>s</sup> R. T. Zoeller,<sup>t</sup>  
K. P. O'Brien<sup>\*g</sup> and J. P. Myers<sup>\*a</sup>

*Received 12th January 2012, Accepted 4th September 2012*

DOI: 10.1039/c2gc35055f

A central goal of green chemistry is to avoid hazard in the design of new chemicals. This objective is best achieved when information about a chemical's potential hazardous effects is obtained as early in the design process as feasible. Endocrine disruption is a type of hazard that to date has been inadequately addressed by both industrial and regulatory science. To aid chemists in avoiding this hazard, we propose an endocrine disruption



# CHEMTrust

Protecting humans and wildlife  
from harmful chemicals



## MOVING TOWARDS SAFER ALTERNATIVES



[Home](#)

[News](#)

[Newsletter](#)

[About the Portal](#)

[Substitution Steps](#)

[Substitution in  
Legislation](#)

[Identifying  
Substances of  
Concern](#)

[Restricted and](#)



### Support for Substitution

Substitution of hazardous

### Latest News

#### Serbian version of GHS Column Model now available

**Publications & Tools** |  
10.09.2014

Realised by the NGO ALHem –  
Safer Chemicals Alternative –  
the Serbian translation of the  
GHS Column Model can now be



### Substitution Steps

Substitution may be fast and  
easy or a more complex  
process. Generally it includes  
the following steps:

### Search SUBSPORT

- Website
- Restricted and  
priority substances  
database » [link](#)
- Case story  
database » [link](#)

» [Overview](#)

<http://www.subsport.eu/>

www.chemtrust.org.uk



**CHEMTrust**  
Protecting humans and wildlife  
from harmful chemicals

# Conclusions

- 😊 Prerequisite for ED regulation: separate science-based identification from economic considerations
- 😊 No place for potency cut-off in ED identification
- 😊 Put resources into substitution instead of searching for uncertain 'safe' levels
- 😊 Impact assessment needs to address benefits of EDC reductions for health and environment



Contact:  
[ninja.reineke@chemtrust.org.uk](mailto:ninja.reineke@chemtrust.org.uk)

[www.chemtrust.org.uk](http://www.chemtrust.org.uk)