

REACH AND ENDOCRINE DISRUPTORS: PRECAUTIONARY IN PRINCIPLE, FLAWED IN FACT

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Europe's largest network of environmental citizens' organisations:

- around **150** civil society organisations, including a growing number of European networks
- ...from more than **30** European countries

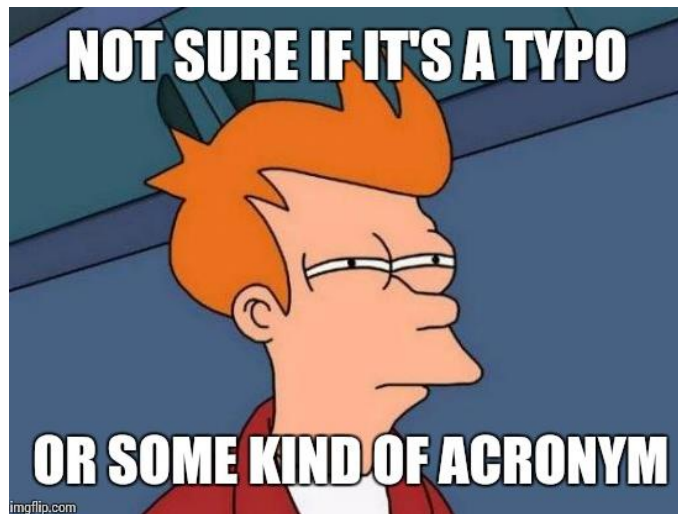
Over **40 years** of EU environmental policy expertise

WHAT ISSUES DO WE FOCUS ON

- EEB tackles Europe's most pressing environmental problems by agenda setting, monitoring, advising on and influencing the way the EU deals with these issues.
- To summarize, our areas of work include:
 - Climate and Energy
 - Nature and Sustainable Agriculture
 - Resource Efficiency
 - Sustainability and Governance
 - Global and Regional Policies
 - Industry and Health

REACH AND ENDOCRINE DISRUPTORS: PRECAUTION IN PRINCIPLE, FLAWED IN FACT

How REACH applies the PP to EDCs ?



HOW REACH APPLIES THE PRECAUTIONARY PRINCIPLE TO ENDOCRINE DISRUPTORS

- I. The landscape: definitions, principles, regulation applicable
- II. REACH as a pioneer precautionary legislation to regulate endocrine disruptors
- III. REACH failing to apply the precautionary principle to endocrine disruptors in practice

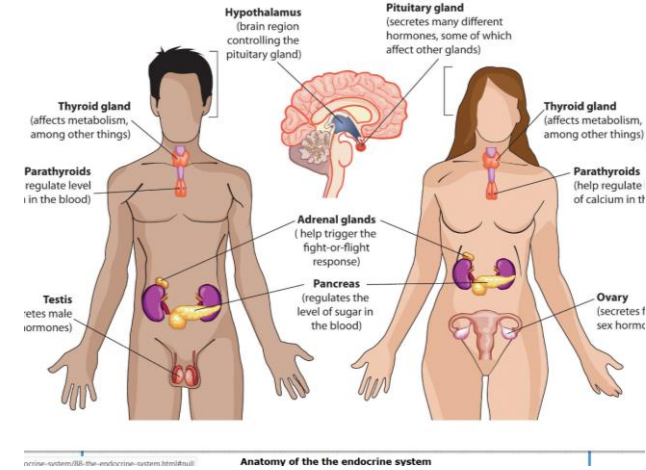
ENDOCRINE DISRUPTORS

Definitions

Endocrine system: is the hormonal system orchestrating physiological development and functions of (all) organs

Endocrine disruptor: Exogenous substance, altering function(s) of the endocrine system, causing adverse effects (WHO 2003)

Mode of action: Paracelsus (16th century) "*The dose makes the poison*"; now: **powerful at infinitely small doses**, the timing makes the poison



WHAT IMPACTS ENDOCRINE DISRUPTORS HAVE?

- Health impacts (chronic health disorders, obesity, endocrine-related cancers, loss of IQ)
- Environmental impacts (abnormalities and impaired reproductive performance in species, changes in immunity and behavior, skeletal deformities)

Aggravating factors?

- Ubiquity (pesticides, plastics, dust, bodies) and cumulative effects
- Insufficient regulation (cumulative effects, food contact materials)
- Costs on society (estimates: between 22 and 196 billion €; other estimates: between 46 and 288 billion€)

WHAT PRECAUTIONARY PRINCIPLE?

The Commission's approach:

- Applying to risk-management (only?)
- Subject to the “5 tests”



Science for Environment Policy

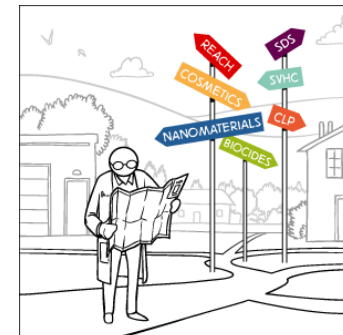
FUTURE BRIEF:

The precautionary principle: decision-making under uncertainty

September 2017
Issue 18



EDCs are ubiquitous: horizontal, harmonised framework needed to ensure protection of human health and the environment



REACH REGULATION

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, *applies to EEA*

REACH-Regulation (EC) No. 1907 / 2006



R EGISTRATION,



E VALUATION,



A UTHORISATION
(AND RESTRICTION) OF



CH EMICALS

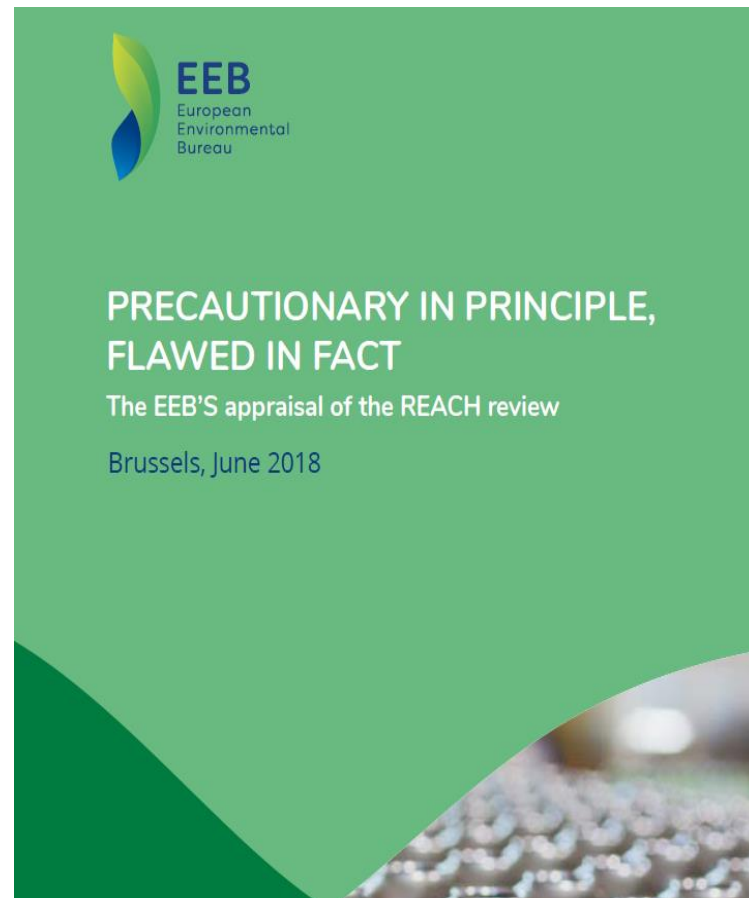
X Does not apply to substances used in biocidal products, plant protection products (pesticides) as already registered; does not apply to cosmetics, waste

REACH, PIONEERING PRECAUTIONARY LEGISLATION TO REGULATE EDCS

- Burden of proof on the applicant to demonstrate the substance's safety
- “Underpinned” by the precautionary principle, since 2006
- Safeguard clause, Article 129
- No criteria to identify EDCs:
 - case-by-case identification: demonstration of a concern equivalent to: carcinogenic, mutagenic, toxic for reproduction substances (“CMRs”);
 - can be considered as “non-threshold substances “

REACH Review 2018:

- The Commission has not proposed measures based on the principle
- ECHA and its committees did not assess scientific uncertainties to enable its application



PRECAUTION ON SUBSTANCES OF VERY HIGH CONCERN?

The principle applies to the management of substances of very high concern – “SVHCs” - (criteria in Article 57):

- (69) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorised if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.

- Impacts to a Candidate List inclusion (Annex XIV):
 - Obligation to inform consumers upon request, eventual inclusion in the authorisation process (Annex XVII);
- 13 endocrine disruptors identified as SVHC under REACH
 - 127 substances identified as EDCs by Chemsec



HELPING YOU STAY AHEAD OF THE EU'S REACH REGULATION

Search through the SIN List database of 919 hazardous chemicals likely to be banned or restricted in the future.

[SINlist](#) (Substitute It Now!) by CHEMSec

RAPID PRECAUTIONARY ACTION VS THE AUTHORISATION LIST

Authorisation, Annex XIV: not allowed for use unless specific authorisation is granted

- 43 substances (out of 1400 foreseen), 16 EDCs -including 12 EDCs for environment, 6 for human health;

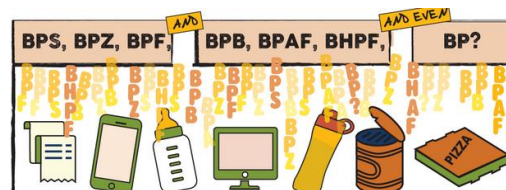
Lengthy procedure, chemicals can still be used in the meantime
Companies applying for authorisation can still use the substance (subject to conditions)

RESTRICTION: REACTION RATHER THAN PRECAUTION

Restriction for substances presenting “unacceptable risks” to human health/environment, including for substances toxic to reproduction

Restrictions: phthalates, thresholds and bisphenols:

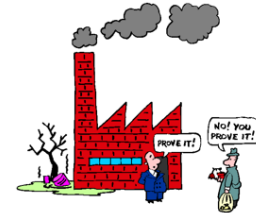
- Entries 51 and 52 of REACH Annex XVII restrict 6 phthalates, in toys and childcare articles (DEHP; DBP; BBP; di-isononyl phthalate (DINP); diisodecyl phthalate (DIDP); and di-n-octyl phthalate (DNOP)).
- Entry 66: restricts bisphenol A in thermal paper



Chemtrust, Toxic soup



- Precautionary principle should be applied
- An impact assessment on the withdrawal of EDCs from the market is not relevant for defining what an EDC is
- Criteria based on hazard



EEB, 2014

CONCLUSION

- The focus on risk management is problematic
- Possible to apply it the PP under REACH: ex. grouping, restrictions based on uncertainties MP case
 - Grouping
 - Consider EDCs as non-threshold substances, like persistent, bioaccumulative and toxic substances
- The principle is constantly threatened
- Broader picture: pesticides and biocides regulation criteria



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THANK YOU!

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