

EU Laws / Policies on Phthalates + other EDCs

State of Play & NGO View



*Promoting environmental policy
that contributes to good health*

Lisette van Vliet, Health & Environment Alliance
Milan Conference on EDCs
November 2016

Which EU Laws & Policies Cover EDCs?



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Relevant EU Laws

Directly

- REACH (industrial chemicals)
- PESTICIDES & BIOCIDES
- MEDICAL DEVICES
- TOYS / CHILDCARE Articles

Indirectly

- COSMETICS
- FOOD CONTACT MATERIALS
- PHARMACEUTICALS
- WATER & more (Emissions, Mercury, POPs, etc)

Relevant EU Policies -1-

- 7th Environmental Action Programme
 - **Minimising exposures** to hazardous chems
 - Harmonised, **hazard-based ID criteria** for EDCs
 - Strategy for a **Non Toxic Environment**
 - promote non-toxic **material cycles**
 - reduce **indoor** exposure

Relevant EU Policies -2-

- CIRCULAR ECONOMY

- Non toxic material cycles for reuse / recycling / repair (waste laws)

BETTER REGULATION

- Reviews of all laws 'Refits' including REACH, Pesticides & Biocides, etc.

(Danger of rollback here!)

EDCs in REACH



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EDCs as SVHCs

Repro toxicants

- DEHP
- BBP
- DBP
- DIBP
- DCHP

VOTE soon by EU govts
in REACH Committee!
NOTE: Italy opposed

Equivalent Concern

ED for Environment

- Octylphenol
- Octylphenol etoxylated
- Nonylphenol
- Nonylphenol etoxylated
- DEHP

ED for Human Health

- DEHP – maybe December?
- DCHP – maybe December?

Authorisations - DEHP

Given

- for airplane engine blades;
- for propellants & charges in rockets + missiles

Pending /on hold

- for PVC (Czech company DEZA)
 - 3 NGOs in court for access to documents
- for recycled PVC (3 companies) til 2019
 - Client Earth contesting!

Restrictions – phthalates

- One now going through ECHA Committees
 - For consumer products
 - On any single product with any combination of dehp, bbp, dbp, dibp
 - Because of reproductive toxicity, NOT directly for their ‘EDC’ properties!
- *public consultation til 15 December*

EDCs in Pesticides & Biocides



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Big Step Forward on EDCs

2009 Pesticides law:

- No authorization for EDCs

exception: unless exposure is negligible
(no human contact, closed system)

2012 Biocides law similar

but different exception conditions
(socio-economic analysis)

To ban, first identify

Official Criteria to identify EDCs

Under construction since 2011



The EU criteria battle



a film by
Stéphane Horel

Criteria: What's at Stake

- Global precedent: world's 1st regulatory ID criteria!
- Correctly identifying what people are exposed to
- Implementing existing laws
 - Pesticide & Biocides, Medical Devices
 - Influence REACH, Cosmetics, Water, & others
- Correctly reflecting / eliciting science
 - Avoiding over simplifying / under interpreting
 - Incentive for further research

PROTECTING HEALTH & ENVIRONMENT

Identification proposal

3 key elements:

- shows an adverse effect
but show how?
- has an endocrine 'Mode of Action',
altered function
difficult to demonstrate mode of action
- adverse effect is consequence of mode of action
too high a burden of proof



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Identification proposal

Other features

- Methodology for identification
'weight of evidence'

privileges internat'l test protocols
belongs in guidance documents

- Separate for human health &
for non target organisms

problematic for use in other legislation
(e.g. medical devices directive)



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Derogation proposal

Original derogation from ban:

if the exposure is negligible

(excludes human contact, closed system)

Commission now proposes:

- if RISK from exposure is negligible
- only AIMING to exclude human contact



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- *EU Parliament estimates illegal*
- *NGO analysis concludes illegal*
- *If adopted, maybe challenged in court*



Our verdict

- unprecedentedly high level of proof
- inconsistent with approach to CMRs
- few, maybe no EDCs will be identified
- humans will probably be harmed before action is taken
- illegally changes what was agreed in 2009

A circular logo with a dark background and white text.

EDC
Free
Europe

A white banner with a large arrow pointing to the right, containing the text "what's disrupting you?".

what's **disrupting** you?

A red circular logo with white text.

stop
hormone
disrupting
chemicals

Our recommendations

- Use a practical burden of proof
- Keep consistent with approach to CMRs
- Respect the science: use categories
- Don't bring risk assessment in by back door
- Treat academic & oecd-protocol studies equally

A circular logo with a dark grey background and a white border. The text "EDC Free Europe" is written in white, with "EDC" on the top line, "Free" on the second line, and "Europe" on the third line.

EDC
Free
Europe

A white banner with a black outline, featuring the text "what's disrupting you?" in a bold, sans-serif font. The word "disrupting" is in red, while "what's" and "you?" are in black.

what's **disrupting** you?

A red circular logo with the word "stop" in white, bold, sans-serif font. Below it, the words "hormone disrupting chemicals" are written in a smaller, white, sans-serif font.

stop
hormone
disrupting
chemicals

What's next

- EU 28 discussion in Pesticides Committee
- Vote in Committee Dec 7? **Italian position?**
- Parliament & Council scrutiny
- Rejection or Commission final approval



CONCLUSIONS



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CRITERIA

- Major victory created major pressure: Pesticides EDC ban put the political storm on criteria
- Huge industry lobbying to re-install risk assessment & put potency in criteria
- Nearly all other policies frozen til criteria sorted
- Pressure also to widen exceptions (change from hazard to risk basis): future court case?
- World's first regulatory ID very soon: will they be good enough?

EU progress on EDCs -2-

ASIDE FROM CRITERIA

- REACH: very slow in ID & Restrictions;
Authorisations recently bad
- Other laws: need explicit phase out provisions,
especially major exposures,
e.g. food packaging

➤ **Need medical groups
to engage more:
talk to your political
representatives!**



What you can do

Ob-gyns from 125 countries say...



"exposure to toxic chemicals is damaging your health."



Tell policymakers to listen.

#HealthNotToxics

Contact your
government –
ask for major
changes to
Criteria
(in Pesticides
Standing
Committee)

➤ **Vote Dec 6-7?**

Join EDC-Free Europe Coalition



Join Health & Env't Alliance!

Over 70 members in >28 countries

Doctors
Nurses
Patient groups
Scientists
Public Health Research Institutes
Environmental groups
Women's groups
Youth groups
Public Health Insurers



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THANK YOU!

Questions? Comments?

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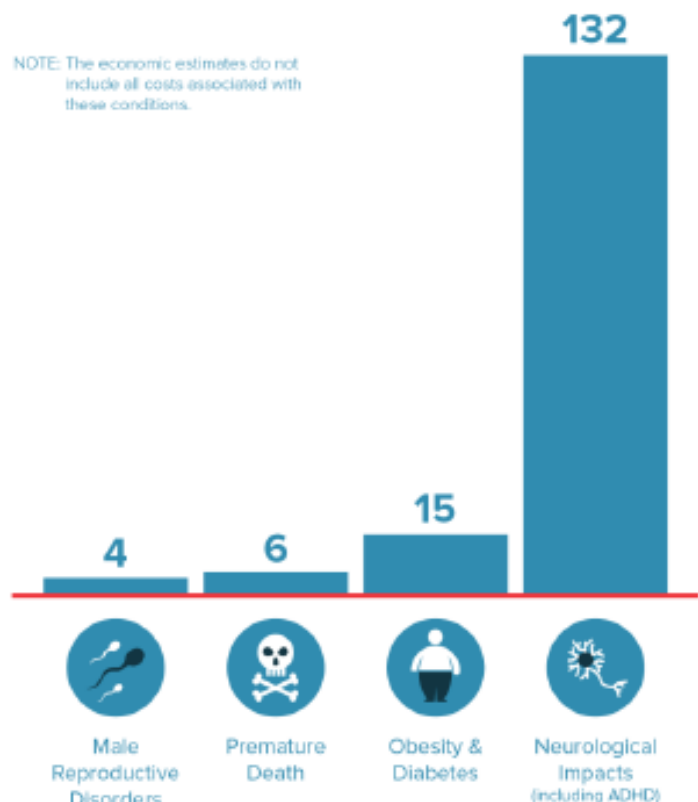


HEALTH EFFECTS FROM ENDOCRINE DISRUPTING CHEMICALS COST THE EU 157 BILLION EUROS EACH YEAR.

This is the tip of the iceberg: Costs may be as high as €270B.

€157B Cost by Health Effect

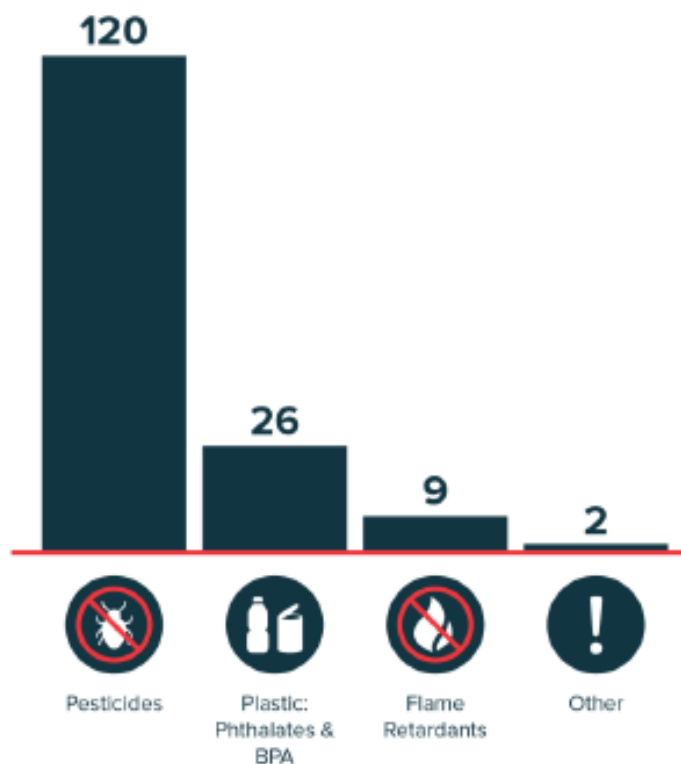
NOTE: The economic estimates do not include all costs associated with these conditions.



SOME EDC-RELATED HEALTH OUTCOMES NOT INCLUDED:

- Breast Cancer
- Prostate Cancer
- Immune Disorders
- Female Reproductive Disorders
- Liver Cancer
- Parkinson's Disease
- Osteoporosis
- Endometriosis
- Thyroid Disorders

€157B Cost by EDC Type



SOME EDCs NOT INCLUDED:

- Atrazine
- 2, 4-D
- Styrene
- Triclosan
- Nonylphenol
- Polycyclic Aromatic Hydrocarbons
- Bisphenol S
- Cadmium
- Arsenic
- Ethylene glycol

Endocrine Disrupting Chemicals (EDCs) interfere with hormone action to cause adverse health effects in people.

“THE TIP OF THE ICEBERG”

The data shown to the left are based on fewer than 5% of likely EDCs. Many EDC health conditions were not included in this study because key data are lacking. Other health outcomes will be the focus of future research.

See Trasande et al. The Journal of Clinical Endocrinology & Metabolism
<http://press.endocrine.org/edc>

Slide courtesy of Leo Trasande, NYU