

Difficulties and urgency to regulate EDCs on European level

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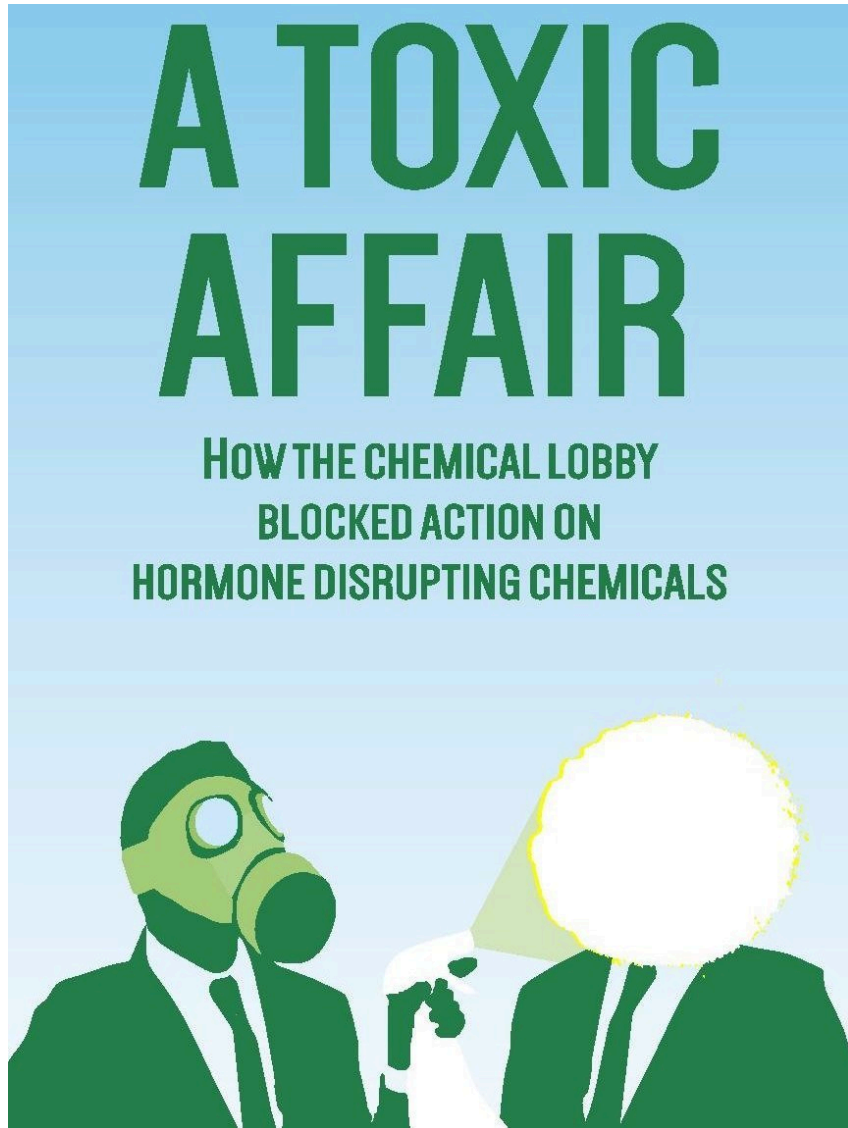
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Introduction

- Precautionary principle
- Hazard-based approach instead of a risk-based approach.
- EU Regulation: too little and too late
- European Parliament very active on EDCs





Discussion on the criteria (1)

- Regulation (EC) 1107/2009 on plant protection products called for criteria
- While the deadline was 2013, criteria were adopted only in 2018
- Industry tried to block and delay the criteria

Discussion on the criteria (2)



2009: European Commission tasked to develop criteria

2013: Deadline passed

2015: Sweden goes to the ECJ and wins

2016: Parliament resolution, calling on the Commission 'to comply immediately with its obligations'

2016: European Commission proposed criteria

2017: European Parliament, raising opposition to the text submitted by the Commission.

2018: Criteria were –finally- adopted

Shortcomings of the criteria

- X Criteria are only for pesticides. So not for toys, cosmetics, etc.
- X Definition is less strict than the WHO definition.
- X No category of 'suspected EDCs' and therefore not fit for horizontal application.



Medical Devices Regulation

- **MDR Annex I.II section 10.4** relevant for EDCs:
 - **0.1% concentration limit** for category 1A and 1B CMR substances and EDCs in devices that are invasive and come into direct contact with the body.
 - Medical devices will only be permitted to contain such substances at a level above this limit if a justification is provided to the **Notified Body** (NB).
 - Once in force, the presence of such hazardous substances must be indicated on the **device's labelling** and added to the **EUDAMED Database** by the manufacturer.
- MDR will apply from May 2020, **success will depend on its implementation**
 - Only 7 notified bodies designated under the MDR today
 - EUDAMED database will not be ready on time
- Link with the **discussion on the criteria**

Bisphenol A

- « A substance of very high concern »
- 2011 ban on BPA in baby bottles
- 2018 Stricter regulation for BPA in food contact materials, but no ban
- 2019 Court Case by Plastics Europe



Communication 2018



X Lack of a concrete action plan and timeline

X Fitness check should have been conducted years ago.

Endocrine disruptors drop the curtain on this European Parliament

By Gerardo Fortuna | EURACTIV.com reporting from Strasbourg

📅 Apr 19, 2019 (updated: 📅 Apr 30, 2019)



The vote on the endocrine disruptors was the last on Thursday's plenary agenda and the last of the current legislative term.

[DOSSMANN/EP]

Parliament resolution April 2019

- ✓ **Legislative proposal no later than June 2020.**
- ✓ EDCs or potential EDCs should be **treated on an equal footing with substances classified as carcinogenic, mutagenic or toxic for reproduction**, the so-called CMR substances.
- ✓ The EU should have
 - **a horizontal definition** (so not only for pesticides, but also for cosmetics, toys, food contact material)
 - **based on the WHO definition**
 - **for suspected EDCs as well as for known and presumed EDCs**
 - **in line with the classification of CMRs in the CLP Regulation.**

New Commission

« For the health of our citizens, children and grandchildren, Europe needs to move towards a **zero-pollution ambition**. I will put forward a cross-cutting strategy to protect citizens' health from environmental degradation and pollution, addressing air and water quality, hazardous chemicals, industrial emissions, pesticides and **endocrine disruptors**. »



On EDCs, our overall goal should be to protect EU citizens and the environment from the risks presented by these substances and minimize exposure. I am well aware of the views expressed by the EP in the past years on the topic, in particular the last resolution of April 2019.

As part of the zero-pollution ambition, a wide-ranging approach looking at hazardous chemicals, pesticides and endocrine disruptors will be crucial.

