EDC information requirements (IR) in REACH

Civil society expectations for current update process

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About HEAL

>90 organisations in 28 countries

- Doctors associations
- Patient groups
- Nurses associations
- Public health institutes
- Research institutes
- Not-for-profit health insurers
- Women's groups
- Youth groups
- Environmental groups

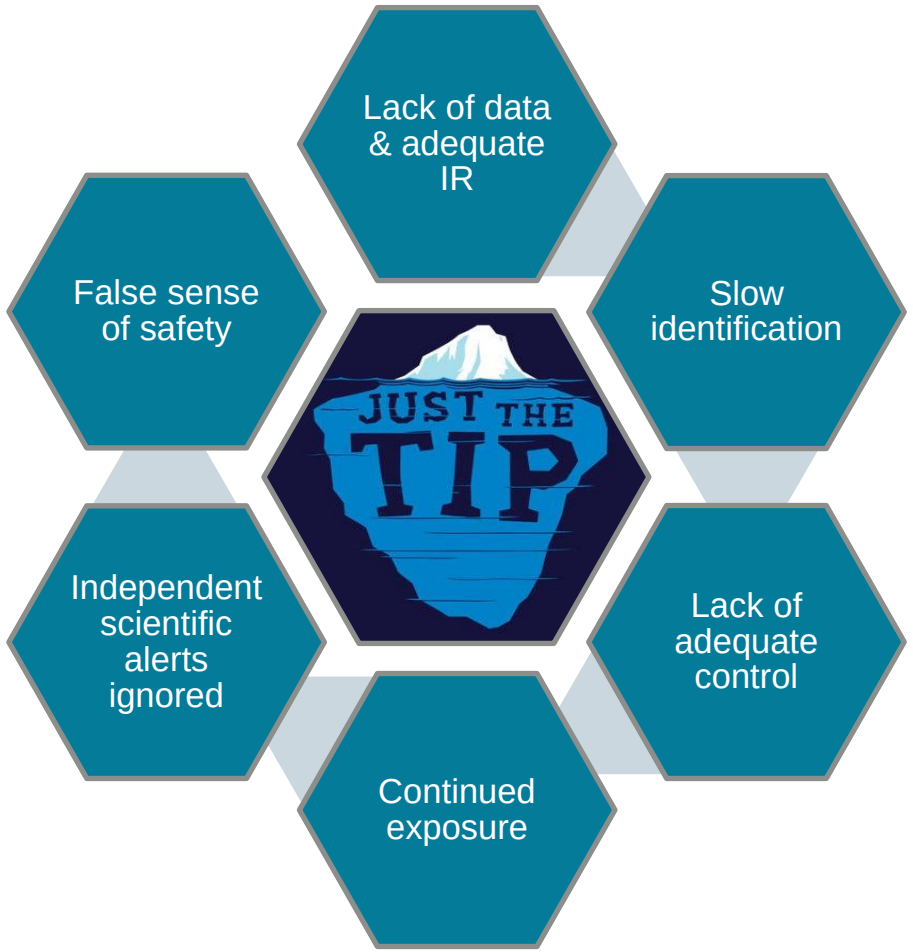
Working for better health through a healthier environment

Why care about requirements for ED information?

REACH: 'no data, no market'

But

No clear requirements for information regarding ED properties (Annex VII to X)



EUROPEAN COMMISSION

Brussels, 7.11.2018
COM(2018) 734 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Towards a comprehensive European Union framework on endocrine disruptors

Real-life examples of lack of adequate IR

- < 20 substances identified EDCs under REACH
- Traffic jam in EU assessment list vs high burden of proof for identification (on authorities?)
- Inadequate protection despite scientific alerts

Bisphenol A	Bisphenol S	Propylparaben
Scientific evidence since 1930's	CORAP listing 2012	CORAP listing 2015
EU EDC identification 2017	Assessment still ongoing	Assessment still ongoing

Way forward for improved ED identification

- Consider **EDC specificities & challenges in testing**
  - **Low-dose effects** – low-volume chemicals can be of concern
  - **Lack of relevant ED endpoints** – risk of false negatives
  - Importance of **expert judgement - authorities need flexibility** in studies/parameters requested

- **Make better use of ALL available data**
  - Necessary to reduce animal testing
  - Use all independent scientific evidence
  - Integrate Human Health and Environment data
  - Use data for one substance to inform assessment of analog compounds (grouping)

Expectations for current REACH IR update process

- **Point of departure = well-known overall lack of data**
  - Integrate **latest science on predicting serious health impacts** (eg on brain development, fertility)
  - Request **early in vitro test batteries** – incl for low-tonnage substances
  - Highlight **TRIGGERS** rather than **WAIVERS** for tests: **always follow-up on positive testing results** (early in vitro & later in vivo) or use **precautionary principle**

- **CSS protection promise in the context of EDCs**
  - Failed EDC identification results in health conditions & environmental effects
  - ECJ: **economic considerations irrelevant** to ED identification (T-521/14)

Take away messages

- **Urgent need to generate data on ED properties under REACH:**
  - 'No data, no market' is industry's responsibility; long overdue
  - REACH principles & protection potential currently undermined
- **Sufficient & adequate ED data crucial to:**
  - Accelerate ED identification (next to CLP hazard class)
  - Implement appropriate regulatory measures & control
- **Priority focus of new REACH ED information requirements:**
  - Integrate ALL latest scientific evidence on EDC effects
  - Serve the goal of prevention of diseases & environmental impacts

Thank you!

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EDC FREE EUROPE
LET'S STOP HORMONE DISRUPTORS

Read HEAL & CHEM Trust proposals for update of IR for EDCs under REACH
https://www.env-health.org/wp-content/uploads/2021/04/2021.04.26-HEAL_CHEMTrust_Comments_IR_April2021_draft-final.pdf

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