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)

Lack of data & adequate IR

False sense of safety

Slow identification

Independent scientific alerts ignored

Continued exposure

Lack of adequate control
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**
- Scientific evidence since 1930’s
- EU EDC identification 2017

**Bisphenol S**
- CORAP listing 2012
- Assessment still ongoing

**Propylparaben**
- CORAP listing 2015
- 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* (e.g., 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!

Find out more:
www.env-health.org
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Read HEAL & CHEM Trust proposals for update of IR for EDCs under REACH