REACH registration and endocrine disrupting chemicals

Forum -16

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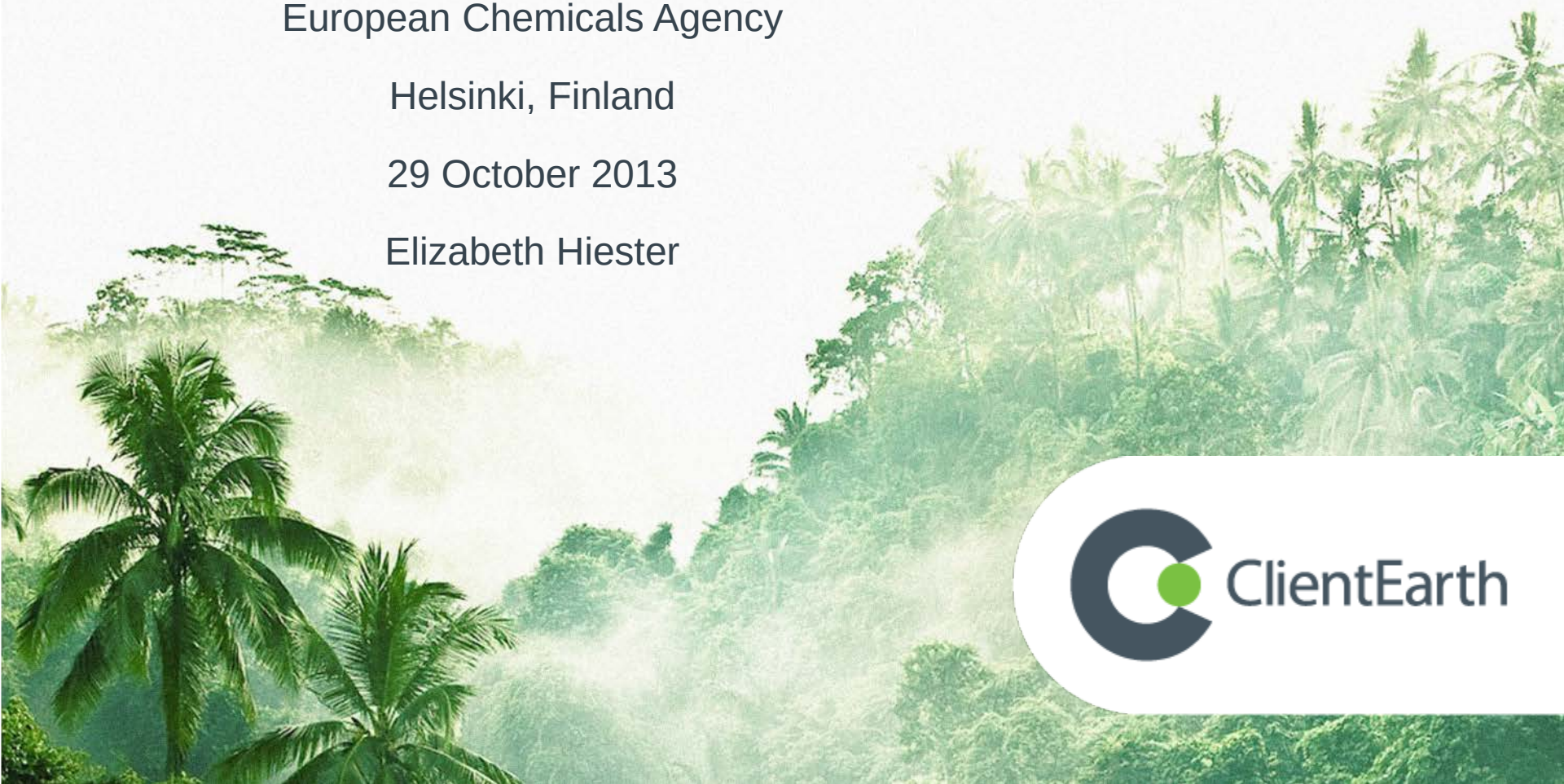

Scope of presentation

1. Introduction
2. EDC dossier study – background and rationale
3. Objective, scope and approach of study
4. Key findings and conclusions
5. Potential solutions
6. Recommendations for action

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Introduction

ClientEarth's Health and Environment Programme

- ClientEarth
  - a not-for-profit environmental law organisation
  - using the power of law to develop legal strategies and tools to address major environmental issues
- Health and Environment Programme
  - work to remove adverse impacts on human health and the environment caused by toxic chemicals

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EDC dossier study – background and rationale

- Increasing concern about adverse effects of EDCs
- Growing call for precautionary regulatory action
- The ambition of REACH
  - “no data, no market”
  - burden of proof shifts to industry
- The potential of REACH
  - enforcement mechanisms

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Objective of the study

- Does online dossier information satisfy information requirements of REACH registration process?
- If not, what are the extent and nature of the deficiencies?
- Are there mechanisms to address the problem?

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Scope of the study

- 5 endocrine disrupting chemicals
  - diethyl phthalate (DEP)
  - bisphenol A (BPA)
  - tetrabromobisphenol A (TBBPA)
  - triclosan
  - octyl-methoxycinnamate (OMC)
- In the SIN List
- Widely used in consumer products
- 4 included in CoRAP

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Approach of the study

- REACH **requires**
  - all **available** and **relevant** information
  - information which is **reliable** and **adequate**
- **Availability** – scientific literature search
- **Relevance** – identify ED mediated changes
- **Reliability** – careful evaluation – beyond Klimisch
- **Adequacy** – more than standard threshold approach

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Key findings

- All dossiers deficient in one or more respects
  - Out of date studies
  - Unattributed material in robust summary studies
  - Flawed use of Klimisch categories
  - Lack of consistency in methodologies to assess adverse effects

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Key conclusions

- Non-compliance by registrants with REACH information requirements
- “No data, no market” replaced by “no registration number, no market”
- Urging compliance by registrants may fall on deaf ears
- Lack of mechanisms for demonstrating shifting of burden of proof
- Effective implementation and enforcement is required

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Potential solutions

- How can registrants be held to account?
  - MSCA action for infringement of REACH
  - Acceptance of responsibility by registrant
  - ECHA compliance checks

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Recommendations for action

- MSCA responsible for enforcing and setting penalities for REACH non-compliance, e.g.
  - Article 12 – relevant and available information in dossiers
  - Article 14(7) – keeping CSR up-to-date
  - Article 22(1) – updating registration with new knowledge of risks

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Recommendations for action

- Overriding requirement to hold registrant to account.
    - Article 1 requires industry to ensure that substances are safe – deficient dossiers do not demonstrate this
    - Article 5 requires observance of no data, no market
- Compliance undertaking by registrant's senior management
    - To verify and validate discharge of burden of proof

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Thank you

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