NO DATA, NO MARKET?

REACH Compliance – A workshop on data quality in registration Dossiers
23 – 24 August 2018, Berlin

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European Environmental Bureau

EUROPEAN ENVIRONMENTAL BUREAU (EEB)

- Europe’s largest network of environmental citizens’ organisations
  - around **140 civil society organisations**… including a growing number of **European networks**
  - …from more than **30 European countries**
- Over 40 years of EU environmental policy expertise

EEB: WHAT ISSUES DO WE FOCUS ON

- EEB tackles **Europe's most pressing environmental problems** by agenda setting, monitoring, advising on and influencing the way the EU deals with these issues.
- Our areas of work include:
  - **Climate and Energy**
  - **Nature and Sustainable Agriculture**
  - **Industry and Health**
  - **Resource Efficiency**
  - **Sustainability and Governance**
  - **Global and Regional Policies**

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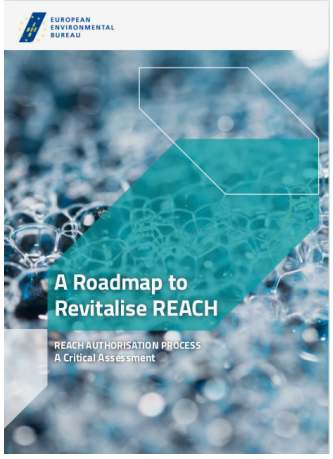
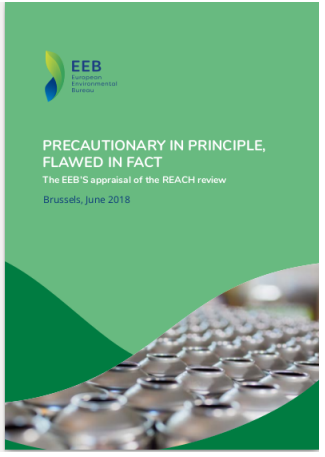
EEB & REACH

- The EEB participates actively at all ECHA Committees (MB, MSC, RAC and SEAC) and nano and PBT expert groups as well as CARACAL.
- Follows closely REACH, ECHA, Commission and MS activities in order to ensure proper implementation.
- **Make proposals for improvement**





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REACH REGULATION

Article 1. Aim and scope

1. The purpose of this Regulation is to **ensure a high level of protection of human health and the environment**, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

3. This Regulation is **based on the principle that it is for manufacturers, importers and downstream users to ensure** that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its **provisions are underpinned by the precautionary principle.**

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REACH AIMS

Article 5 **No data, no market**

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles **shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions** of this Title where this is required.

REACH AIMS

Article 22 **Further duties of registrants**

1. Following registration, **a registrant shall be responsible on his own initiative for updating his registration** without undue delay with relevant new information and submitting it to the Agency in the following cases:

....

e) **new knowledge of the risks of the substance** to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;

REACH AIMS

Registration is the pillar of the REACH Regulation:

Should provide the information on hazards, uses and exposure needed to identify and control the risks and ensure safe use.

It is the basis for further regulatory action

It is the basis for ensuring proper information along the supply chain and to consumers.

REACH REVIEW

"However, the **shortcomings** in relation to the **high level of non-compliance** of the registration dossiers,
the insufficient flow of information along the supply chain and the challenges associated with the **evaluation, authorisation and the restriction** processes are slowing down the delivery of those benefits.
(SWD, pages 126-127)

REACH implementation needs to improve!

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REACH REVIEW

"Work is still needed to rectify important data gaps or inappropriate adaptations in registration dossiers for specific endpoints and for information on uses and exposure. The data gaps or data quality issues in dossiers hamper the identification of priority substances for SVHC identification or other regulatory action". (SWD, page 26)

The poor quality of information in registration is hampering REACH Implementation

Non compliance remained well over 50% for the last nine years

REACH REVIEW

"systemic shortcoming in terms of a lack of incentives for registrants to update their files, despite an obligation to do so"

"... only 25% of dossier owners conduct a regular routine review of their REACH data and 50% of updates were requested by ECHA. ECHA concluded in 2016 that stronger incentives may be needed for companies to stimulate updates of registration dossiers, especially on the use, exposure and tonnage information. **The only incentive working in practice might be enforcement actions** by the Member State Competent Authorities on dossiers which updates are overdue." (SWD, page 26)

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REACH REVIEW

"REACH is addressing emerging issues by increasing knowledge and addressing current gaps. Nonetheless, some challenges have been identified, **generating relevant and specific** information for nanoforms of substances, ensuring the identification of endocrine disrupting properties and addressing the **combination effects of chemicals.** Efforts are still needed to reflect on ways to **integrate scientific developments into REACH** so that it further addresses those emerging issues."
(SWD, page 117)

Need to address emerging issues and scientific developments not captured by Standard Test Methods and in Guidance requirements

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REACH REVIEW

"REACH has also promoted alternative methods for testing though the legislative requirements to only test on animals as a last resort has been implemented **at the expense of hazard** information relevant for the protection of **human health and the environment.**" (SWD, page 126)

Misuse of alternatives to animal testing is hindering the identification of new SVHC

REACH 10 YEARS REVIEW COMMISSION PROPOSALS

Action 1: *Encourage updating of registration dossiers*

The Commission in collaboration with ECHA, Member States and industry will identify why registrants are not updating their dossiers and make proposals for improvements by first quarter 2019, as appropriate.

Action 2: *Improve evaluation procedures*

ECHA is requested to significantly increase the efficiency of the evaluation procedures by 2019 by:

(1) identifying the main reasons for non-compliance of registration dossier and developing remedies;

(2) where appropriate, applying the various evaluation procedures in parallel;

(3) systematically implementing a grouping approach[25], where this is possible;

(4) improving work-sharing across evaluation activities with Member States; and

(5) improving decision-making procedures.

Lack of ambition, not solving the problem

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EEB PROPOSALS: ENFORCE REACH

Don’t grant registration to non compliant dossiers

Withdraw registration of non compliant dossiers (Art. 5)

Ensure updating of registration dossiers (Art 22.1)

Regulatory actions for substances with bad quality dossiers: evaluations, restrictions

Avoid mis-use of non animal testing methods (Art 5)

EEB PROPOSALS: IMPROVE REACH

- Increase number of compliance checks, extend to chemical safety report

  Ensure all scientific evidence not captured by standard testing methods is used. Need to change information requirements.

- Bring low-volume production substances and polymers into the REACH regulation

EEB PROPOSALS: IMPROVE REACH

The **evaluation process needs to be more efficient** and overall being simplified and streamlined:

Increase MS ambition: only 16 new substances were added to CoRAP in 2018 and almost 50% were postponed)

Shorten the Evaluation procedure:

- DEv targeted on endpoints of concern
- DEv and SEv simultaneously if possible: Combine evaluation efforts and requests for new data, improve interplay between EGs and MSC
- Identification of SVHCs: identify NEW SVHCs and art 57f of SVHCs with ELOC. Need change in data requirements.

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EEB PROPOSALS: TRANSPARENCY!

- Name/Fame and Shame:
  - Name of compliant & non-compliant companies
  - Traffic light system for dossiers regarding quality
  - For which dossiers is safety not proven?

- Publish date of dossier updates and which data have been updated
- Publish Chemical Safety Reports

Allow third party submissions of information missing in registration dossiers

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