Experiences with Methods for AoA in REACH Authorisation
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Content

- The REACH authorisation procedure
- Experiences with the Method for Analysis of Alternatives (AoA) in REACH authorisation procedure
- Role of Economic feasibility in AoA
- Concluding remarks
REACH authorisation procedure /1

- 43 substances in “Authorisation list”, e.g.:
  - GHS/CLP-classification as carcinogenic, mutagenic, toxic for reproduction (CMR): Cat. 1A or 1B
  - Persistent, bioaccumulative, toxic (PBT)/vBvT

- As a Principle: **Not allowed to use listed substances**

- Specific use can be allowed for a limited time (4/7/12 years) **under conditions:**
  - Adequate control of risk (threshold substances) or
  - Socioeconomic benefits > Risk to human health & the environment and
  - **No suitable alternative substances or technologies**
REACH authorisation procedure /2

- Burden of proof on company:
  - Analysis of Alternatives (AoA),
  - Socio-Economic Analysis,
  - Chemical Safety Report
- Evaluation by
  - Committee for Risk Assessment – RAC
  - Committee for Socio Economic Analysis – SEAC
- Decision by European Commission („Implementing act“)
Experiences with AoA in REACH
Evaluation of AoA

Company´s AoA
1. Description of efforts (R&D, Literature search, Consultations)
2. Suitability of alternatives (Criteria)
3. Conclusions

Supply chain communication (Supplier, Customer, End user)

Information

Evaluation

ECHA committees (RAC & SEAC)
• Expertise
• Publicly available information
• Conformity check
• Requested additional information

Public consultation
Interested third parties: suppliers of alternatives, NGOs, ...

1. November 2018 2nd International Symposium on Alternatives Assessment
Experiences with “broad” AoA

- Definition of key requirements for alternatives often not sufficiently use specific
  - Background:
    - Suppliers (manufacturers, importers) or substance users can jointly apply.
    - AoA can cover substance use in manufacturing a full range of products
  - Analysis aims to identify a general alternative suitable for all uses

→ Uncertainty about technical feasibility of alternatives
Experiences with “broad” AoA /2

Key requirements for critical uses extended to all uses?
(e.g. Use of Chromium trioxide for surface treatment)

Key Requirements A:
No suitable alternative

Key Requirements B:
Suitable alternative

Really assessed?

Aviation
Industry sectors
Automotive

Components/ Product types
Experiences with information gaps in AoA

- Search on possible alternatives often not sufficiently substantiated or not documented, e.g. ....
  - Missing validation of past and ongoing R&D activities (e.g. test trials), desktop research, expert consultations
  - Missing commitment about future R&D, about communication and cooperation with customers
  - Level of detail not sufficient to demonstrate non-suitability

Consequences:
→ Uncertainty on non-suitability of alternatives
→ Additional information requested from companies
→ Remaining uncertainties result in short review periods
Role of economic feasibility in AoA
As a Principle: Equal weighting of criteria

In Contrast: German Guidance on substitution (TRGS 600):
*Always substitute CMR (Cat. 1 and 2) substances if alternatives are technically suitable and reduce risk.*
Practical role of economic feasibility criteria

- Main focus of AoA is on technical feasibility (e.g. use of chromium compounds for surface treatment)

- In case alternatives are not technical feasible: No need for SEAC to conclude on economic feasibility on substitutes

- For reason of completeness
  - Only qualitative and very brief discussion on economic feasibility for most promising alternatives
  - No detailed analysis of risk reduction of alternatives \(\rightarrow\) Comparison of CLP/GHS classifications only
Assessment of Economic feasibility

- In case alternatives are technical feasible...
- Economic Arguments brought forward (accepted by SEAC) for continued use of substance...
  - **Investment costs** of shift to alternative technology
    (e.g. shift from Sodium Dichromate in Ammonia Absorption Deep Cooling System to Vapour Compression Cooling)
  - **Lower effectiveness** of alternative substance
    (e.g. shift from Diglyme to alternative process solvent)
  - **Lower recycling ratio** of alternative substance
    (e.g. shift from Diglyme/EDC to alternative process solvent)
  - **Sales losses** during time needed for approval of product change by customers
    (e.g. use of arsenic acid in manufacturing Printed Circuit Boards)
REACH regulation foresees tools to address uncertainties in AoA (e.g. Public consultation, conformity check).

- But, more participation of suppliers and users of alternatives in Public consultations needed.

- A broad range of uses covered in AoA causes uncertainty about possibilities for substitution for specific uses.

- Economic factors can play a decisive role in authorizing ongoing uses also of CMR substances.
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