Federal Institute for Occupational Safety and Health

Experiences with Methods for AoA in REACH Authorisation

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- 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) <u>or</u>
  - Socioeconomic benefits > Risk to human health & the environment <u>and</u>
  - **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

Information

Evaluation

ECHA committees (RAC & SEAC)

- Expertise
- Publicly available information
- Conformity check
- Requested additional information

Supply chain communication
(Supplier, Customer, End user)

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

Experiences with “broad” AoA /1

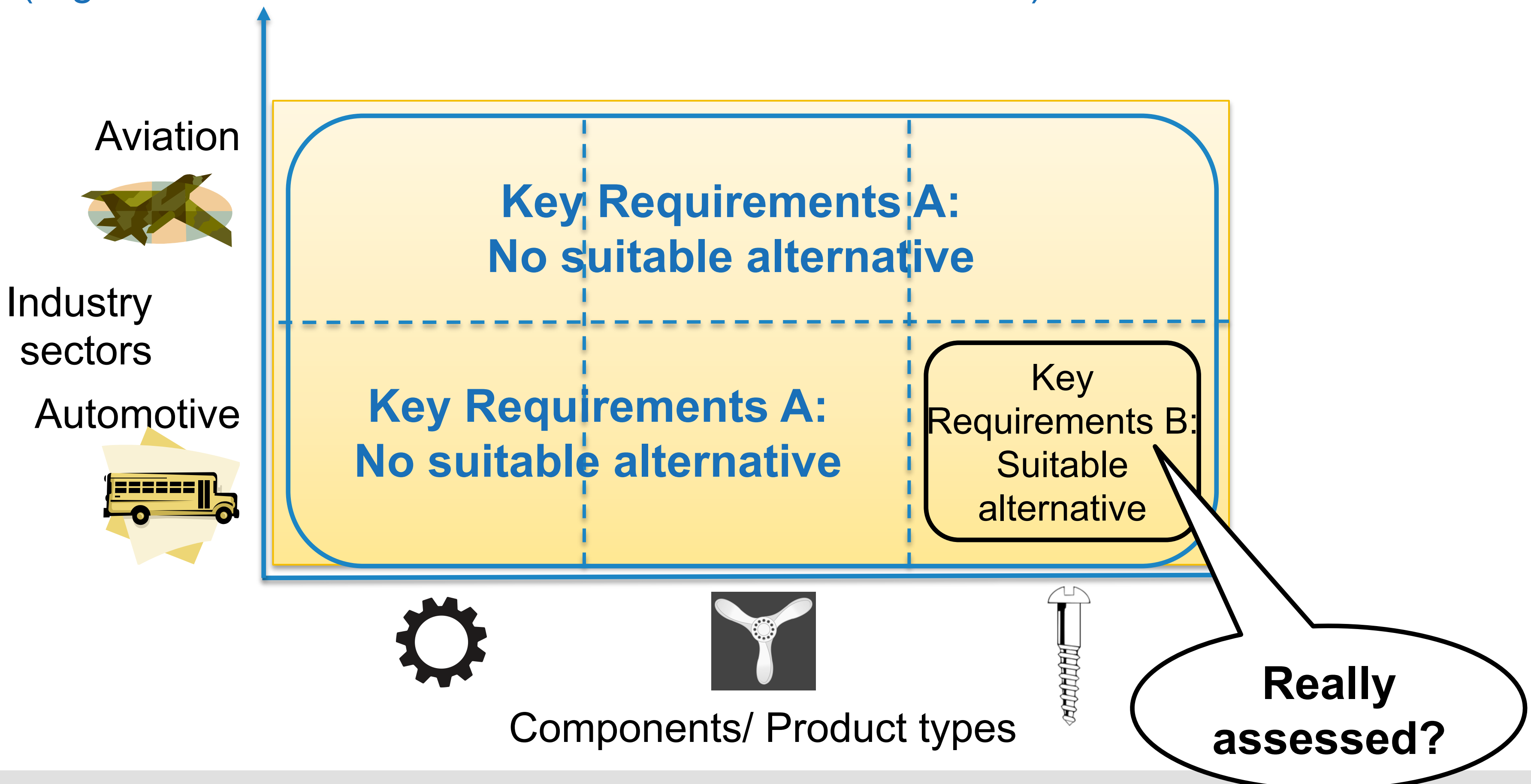
- **Definition of key requirements for alternatives often not sufficiently use specific**
  - Background:
    - Suppliers (manufacturers, importers) or substance users can jointly apply.
    - AoA can cover substance use in manufacturing a full range of products
  - Analysis aims to identify a general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



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

Technical feasibility
Key requirements
Technical performance

Overall risk reduction
Human health, environment

Economic feasibility
Life cycle costs
Implementation costs
Market losses

<u>In Contrast</u>: 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
    → 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)

Concluding remarks

- 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.

Thanks a lot for your attention

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