REACH Authorisation Workshop, Brussels,
7th November 2014

Application for Authorisation (AfA) – Analysis of Alternatives (AoA) and Chemical Safety Report (CSR)

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Content

AoA and CSR

- General data requirements for an AfA
- CSR: scope, options, exposure assessment, implications on registration, lessons learned (RAC/SEAC)
- AoA: scope, technical and economic assessment, interplay with SEA, lessons learned (RAC/SEAC)
- Individual vs joint application
- Confidentiality claims
- Timing and organisational requirements

Requirements for the Application

Information	Adequate control (AC)	Socio-economic
CSR	Required: need to demonstrate AC	Required: need to show risks minimised
AoA	Required	Required: need to show no suitable alternatives
Research and development (R&D) plan	Required if no suitable alternatives	Required
Substitution plan	Required if suitable alternatives exist	N/A
Socio-economic analysis (SEA)	Advised: back-up if AC not demonstrated; can support review period	Required: need to show authorisation benefits exceed risks; can support review period

Decision	Adequate control	Socio-economic
Authorisation granted if	Risks adequately controlled	No suitable alternatives; benefits of authorisation exceed risks

General Scope of a CSR

- Hazard assessment
- Use(s)
  - Definition and description of uses
  - Process description and assignment of process descriptors (PROCs)
- Exposure assessment
  - Operational conditions (OC)
  - Risk management measures (RMMs)
  - Exposure estimation (data-based and/or model-based)

CSR – Authorisation Application Dossier

Three options

1. Refer to registrant CSR (subject to license)
   - Are the uses applied for sufficiently covered?
2. Add modified registrant CSR (subject to license)
   - Refinement to specifically address use for authorisation
3. Add own CSR
   - Hazard assessment
     - The CSR only need to cover properties of the substances that have caused it to be listed on Annex XIV {Article 62(4)(d)}, source: Annex XV dossier
     - It can be skipped if dose-response curves or derived no effect levels (DNELs) derived by RAC are used
   - Exposure scenarios
     - The exposure scenarios (ES) for the uses applied for are a key part of the CSR
     - The ES need to be sufficiently specific and precise

Exposure Scenarios – Information

- Identification of the different steps where exposure can occur (eg weighing, mixing, use in production)
- Description of operational conditions and risk management measures
  - Physical state (eg solid/liquid)
  - Concentration of substance in mixture
  - Duration of task/exposure
  - Technical and organisational risk management measures (eg enclosure, exhaust ventilation including efficiency, if available)
  - Personal protection (eg gloves, respirator as well as assigned protection factors(APF))
  - Indoors/outdoors
  - Process temperature

Exposure Assessment

Two options

1. Use of reliable measurement data, amended with modelled data
2. Use of measurement data as supportive information to modelled data

MEASUREMENT DATA

- Publicly available data (eg health and safety bodies, social accident insurance institutes)
- Company (confidential) data

ECHA expect that industry has measurement data available and is not satisfied with modelled data only

CSR: Typical Mistakes – Lessons Learned

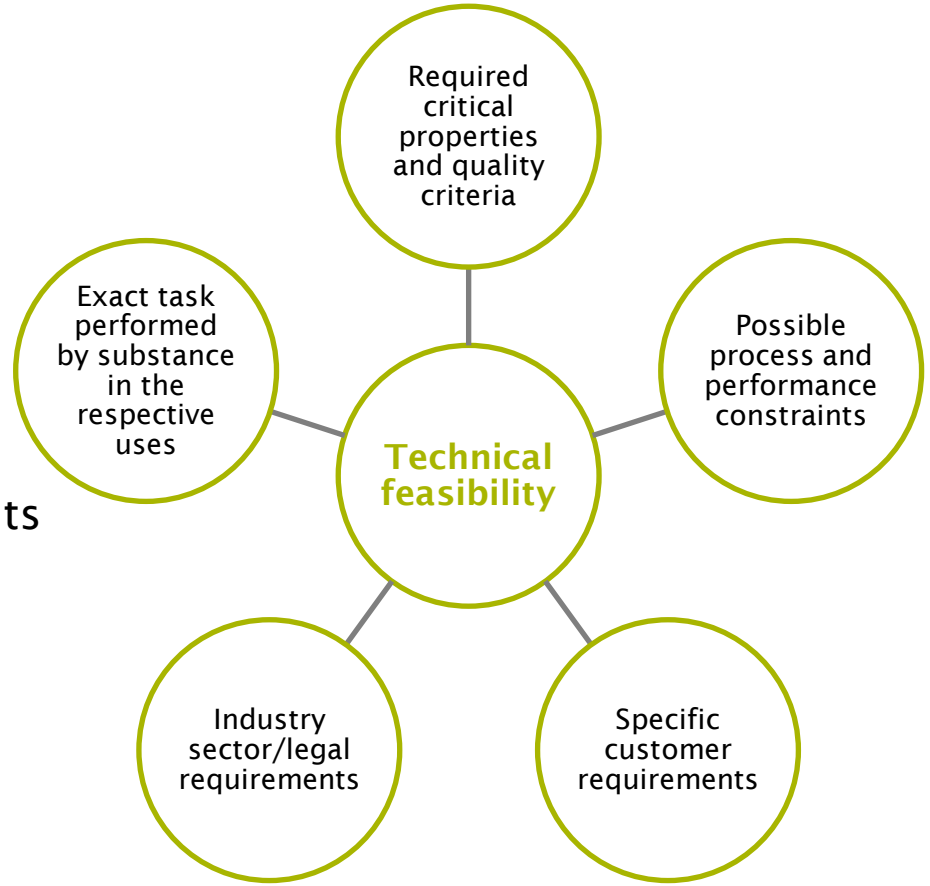
- Workers (workplace)
  - Processes regarding the exposure described insufficiently (add pictures or videos)
  - Allocation of tasks of employees not clearly defined (workspace exposure scenarios summarised without justification)
  - Unclear if personal protective equipment (PPE) has been included in the modelling
  - In case of manufacturers/formulators applications, representative data on exposure of downstream users often missing
- Population exposed via the environment (man via environment)
  - No clear statements about existing emission control (local requirements)
  - Use of inappropriate models (eg man via environment exposure not sufficiently described)

Scope of the AoA

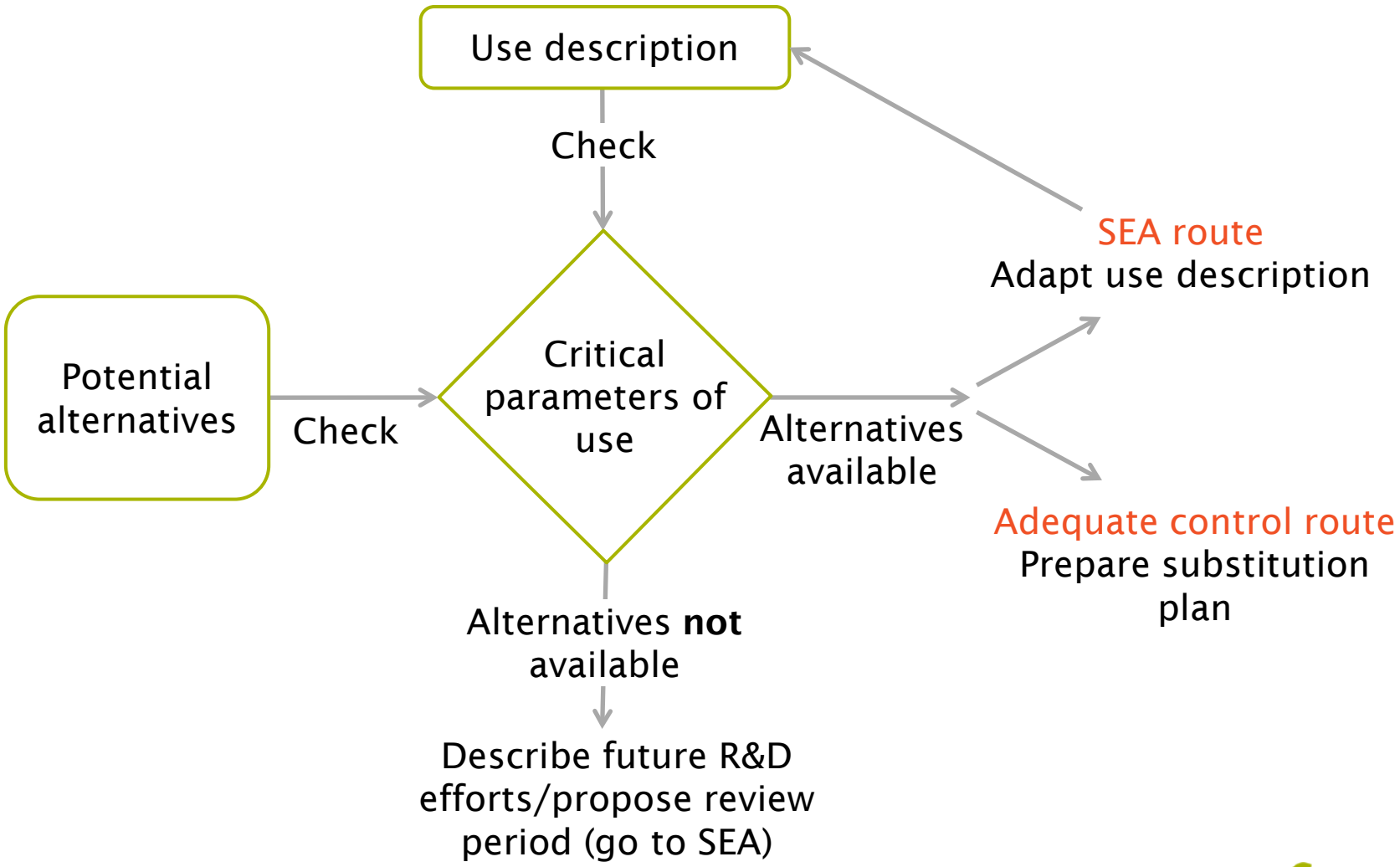
- Analyse substance function for the use
- Provide annual tonnage used of the Annex XIV substance
- Identify possible alternatives for the applied use from an applicant's perspective
- Evaluate suitability and availability of possible alternatives
  - Technical feasibility
  - Economic feasibility
  - Reduction in risk to the environment and human health
  - Availability
- Describe relevant R&D activities (past, current, future)
- Determine required actions and timescales to make possible alternatives suitable and available for the applicant
  - Proposal for review period

AoA Approach and Technical Feasibility

- Scoping
  - Identify processes, critical parameters and potential alternatives
- Data gathering and draft AoA
  - Early workshop with experts (company/sector)
  - Targeted information gathering (questionnaire)
  - Bilateral expert discussions (site visit)
  - Early draft presenting first results and addressing gaps
- Final evaluation
  - Availability and qualification (review period)
  - Economic feasibility
  - Reduction of overall risk



AoA: Technical Feasibility Iterative Process



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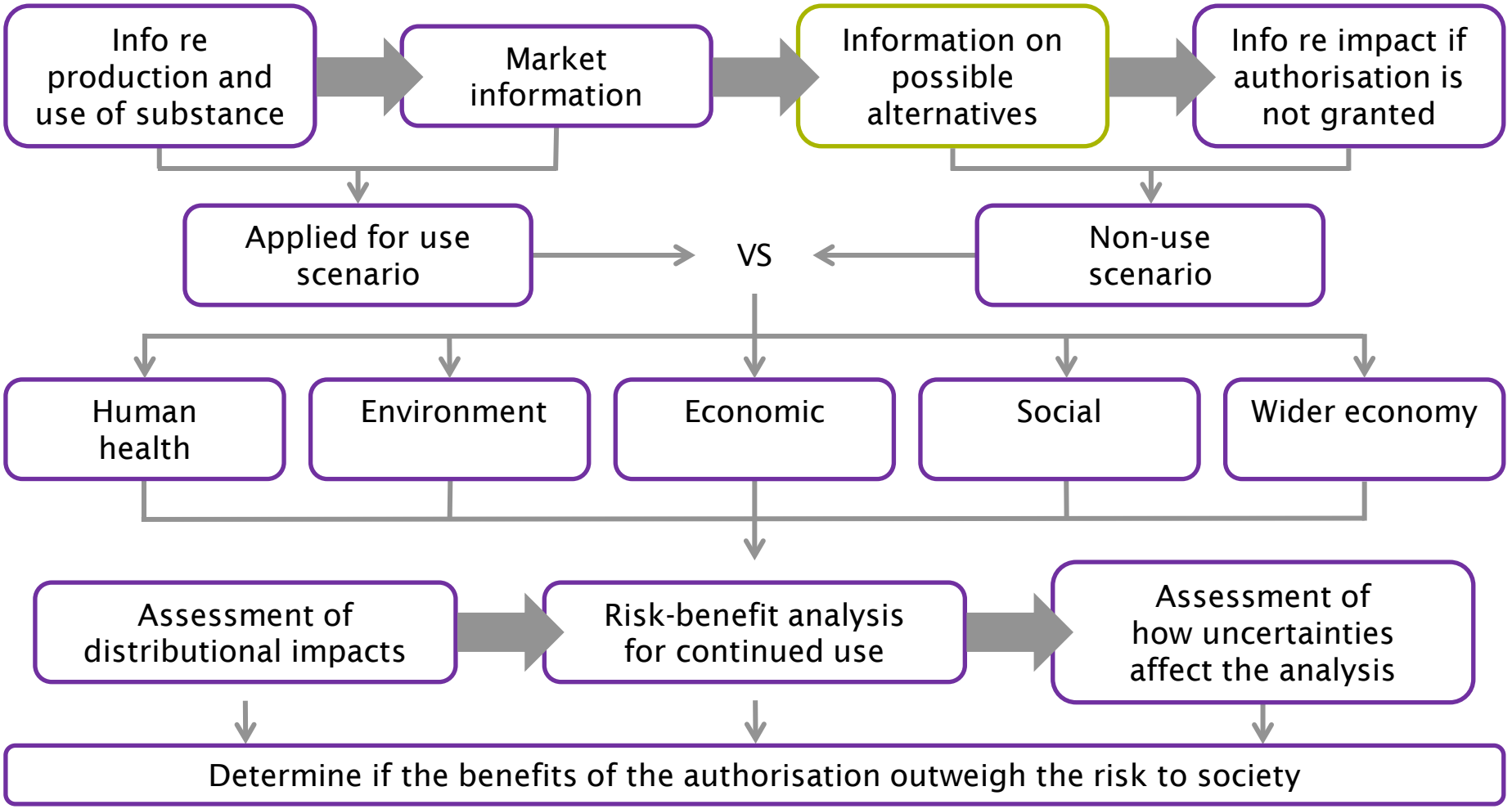
AoA Economic Feasibility and Availability

- Economic feasibility
  - Change in applicant's net costs (production line / value chain)
  - No threshold defined by SEAC (case-by-case decision)
  - SEAC will scrutinise cost estimates/assumptions to ensure costs have not been overestimated
- Availability (available = alternative is reasonable accessible before sunset date)
  - Available in the required quantities (substance)
  - Technology at implementation state (supply chain)
  - Fulfilling the relevant quality and legal requirements

Public consultation might indicate alternatives

Superficial analysis might have impact on conditions and/or the review period

Interplay of AoA and SEA



AoA Typical Mistakes – Lessons Learned

- Unclear choice of the alternatives taken into account
- Unclear delimitation of sub-uses that were already substituted
- Contradictions between AoA and SEA
- Know the needs of the supply (producers vs downstream users)
- Qualitative description if quantitative data is missing
- Anticipate point of view of SEAC (plan peer review)
- Learn from previous applications (all available on ECHA's website)

Don't forget: the goal of Annex XIV is substitution

Individual vs Joint Application

INDIVIDUAL APPLICATION

CSR

- Individual data (modelled or measured)
- Very specific exposure scenarios

AoA

- Focussed on limited number of alternatives (precise requirements)
- Clear review period based on company specific R&D
- Detailed analysis of costs/revenues in case of transition to an alternative is possible
- Economically unfeasible alternative can concretely be presented in the non-use scenario in the SEA

JOINT APPLICATION

CSR

- 90th percentile of all data (modelled or measured)
- Broader exposure scenarios

AoA

- Complex with high number of alternatives (range of different requirements)
- Compromise for review period based on sector specific R&D
- Presentation of individual situations regarding economic feasibility of alternatives is not possible (> focus on technical aspects)

Consequence: Individual application on basis of a general data record

Economic Feasibility Example Electroplating

CURRENT SITUATION

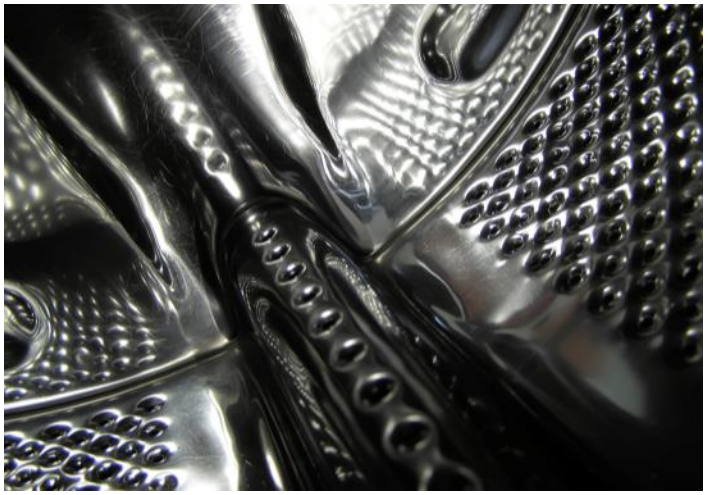
Cr^{VI} (CrO_3) for the production of chrome surfaces for fulfilment of technical parameters (eg corrosion resistance)

Cr^{VI} plating bath (100% parts)

ALTERNATIVE

No drop-in alternative, however alternatives for individual parts

Cr^{VI} plating bath (70%parts) | PVD | Cr^{III}



› Complex problem for the assessment of the economic feasibility of the alternative(s) for joint applications!

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CBI: Confidentiality Claims

CONFIDENTIALITY LEVELS

- Non-confidential information (public consultation)
- Confidential information (blanked out for public consultation, only accessible for ECHA, RAC and SEAC – not to the observers)
- Strictly confidential information (consortia: only accessible for consultants and not other consortia members)

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS

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Strategic Approach

- Evaluation whether authorisation is needed or not can only be done on case-by-case basis
- Start assessment on options as early as possible (don't wait until substance is listed on Annex XIV)
- Authorisation is very demanding in terms of time and company resources > elaborate submission plan (time schedule with interconnected milestones)
- Communication is key (suppliers, customers, opinion makers)
- Thoughtful compilation of the authorisation team
  - REACH expert (headquarter/site)
  - HSE – specialists for exposure and toxicology
  - R&D experts and process engineers
  - Business/commercial director
  - Site manager

ENVIRON's Strength

- Global footprint of 1000 consultants in 90 offices
- Inter-disciplinary team of (eco)-toxicologists, pharmacologists, chemists, engineers, economists, focussing on safety and supply chain security for industry
- Substantial experience of preparing and submitting authorisations for substances through both the SEA and adequate control routes
  - CrO_3/chromates: CCST, CTAC and COD
  - Phthalates: Roxel (Safran)
  - TCE: Solvent sector (Dow, Ruhrkohle, Alcantara)
  - Diglyme: Pharmaceutical sector
- Deep knowledge of industry (products, processes, concerns) gained from working extensively with OEMs and supply chain, on the shop floor and in the boardroom

Thank you for your attention!

Questions?

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