Socio-economic analysis in authorisation

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Purpose

- Overview of SEA
  - Understand the role of the SEA in the Authorisation process
- Introduction of some methodological issues
  - Cost calculation
- Take home messages

Outline

1. What is SEA in authorisation?
2. Reasons for conducting SEA
3. SEA as part of an application
4. SEA methodology in authorisation processes
5. Complementarity of SEA and adequate control reasoning?
6. Conclusions
7. Take home

1. What is SEA in authorisation?

- Analysis of negative and positive impacts of one scenario ("applied for use") vs. another ("non-use").
- Impacts considered:
  - human health, environmental
  - economic, social and wider economic
- Benefits of authorisation:
  - reduced costs to the applicant, other actors in the supply chain (incl. consumers) and society as whole
- Costs of authorisation:
  - negative human health or environmental impacts
- Makes use of:
  - Any methodology, examples in guidance document on SEA

2. Reasons for conducting SEA

- SEA is essential in setting review periods
- Analysis of socio-economic impacts is practically a must for
  - Non-threshold CMRs as well as PBTs and vPvBs
  - Threshold substances for which adequate control of risks cannot be demonstrated
  - A different issue is how these are reported
    - a SEA report probably the best option
- Either synthesises or gives further details on
  - impacts (from Chemical Safety Report and Analysis of Alternatives),
  - economic feasibility of alternatives (made in the Analysis of Alternatives)

Legal reasons (Art 60(4))

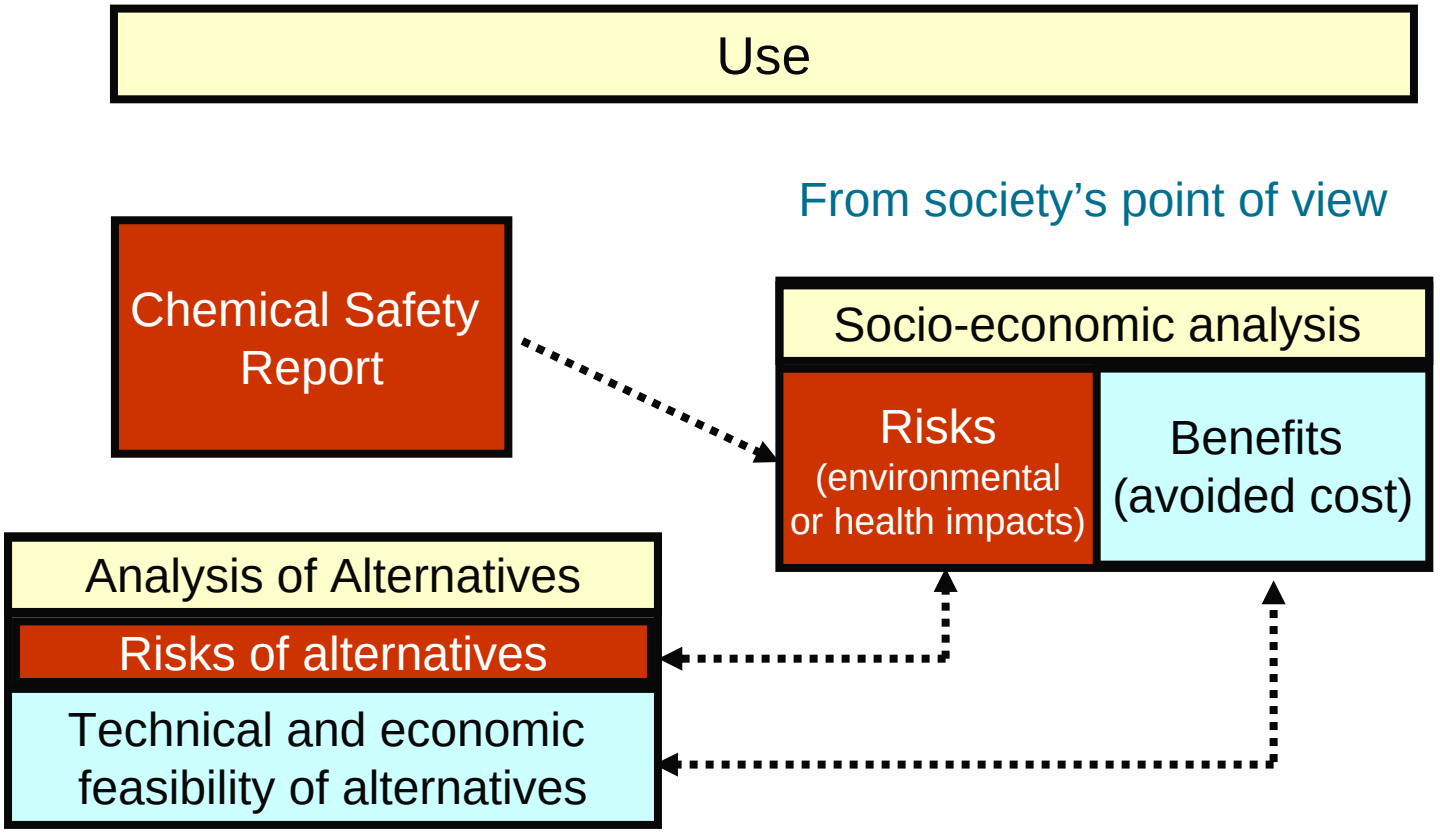
European Commission needs this information

> "… **authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk**

ECHA Committees shall formulate their draft opinions within 10 months (Art 64(1))

> " The draft opinions shall include… "**an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives**…" (Art 64(4)(b))

3. SEA as part of an application



4. SEA methodology

”Applied for use” vs. ”Non use”

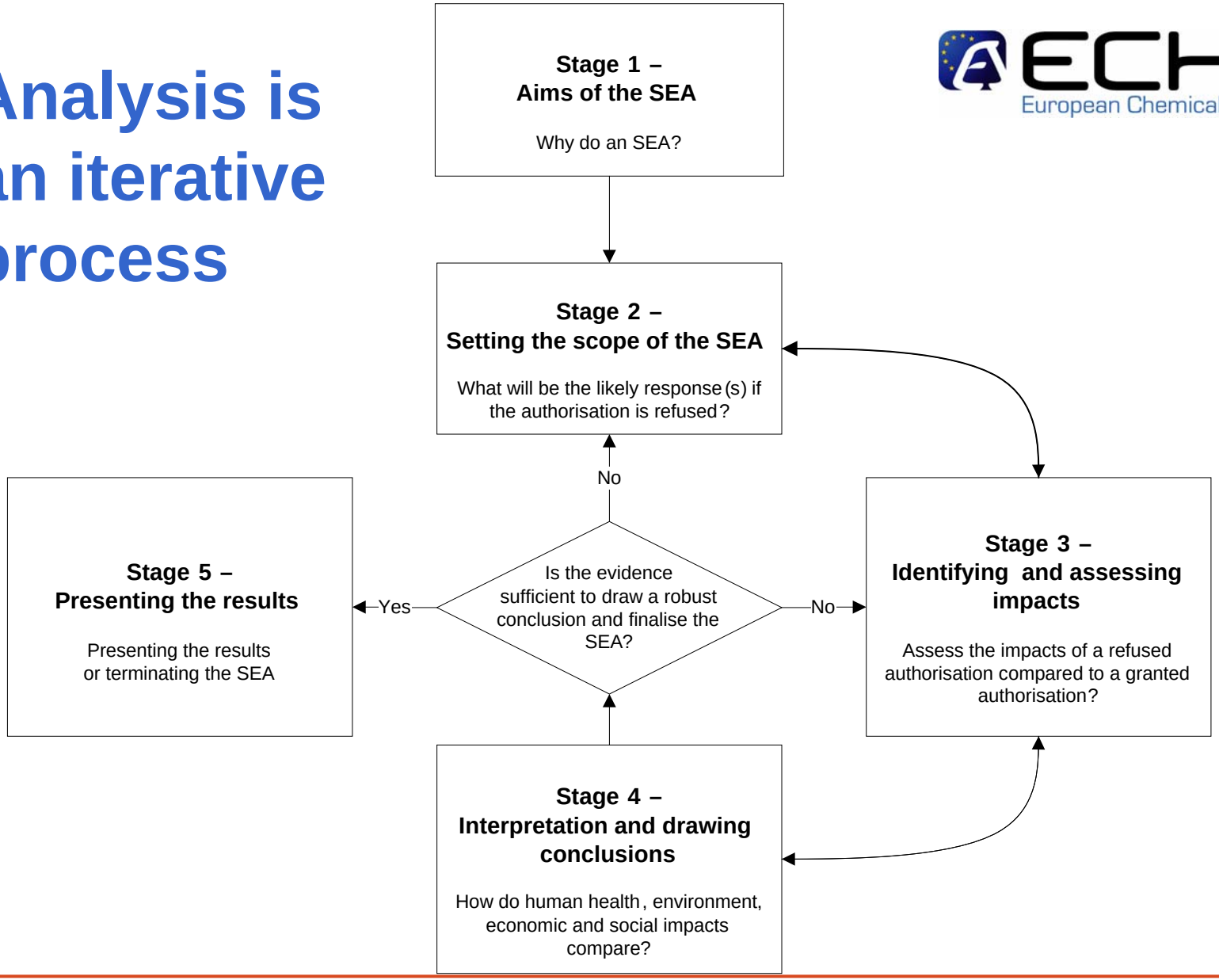
“Applied for use” scenario

- Authorisation is granted
- Applicant/his DUs can continue using the substance for specific uses

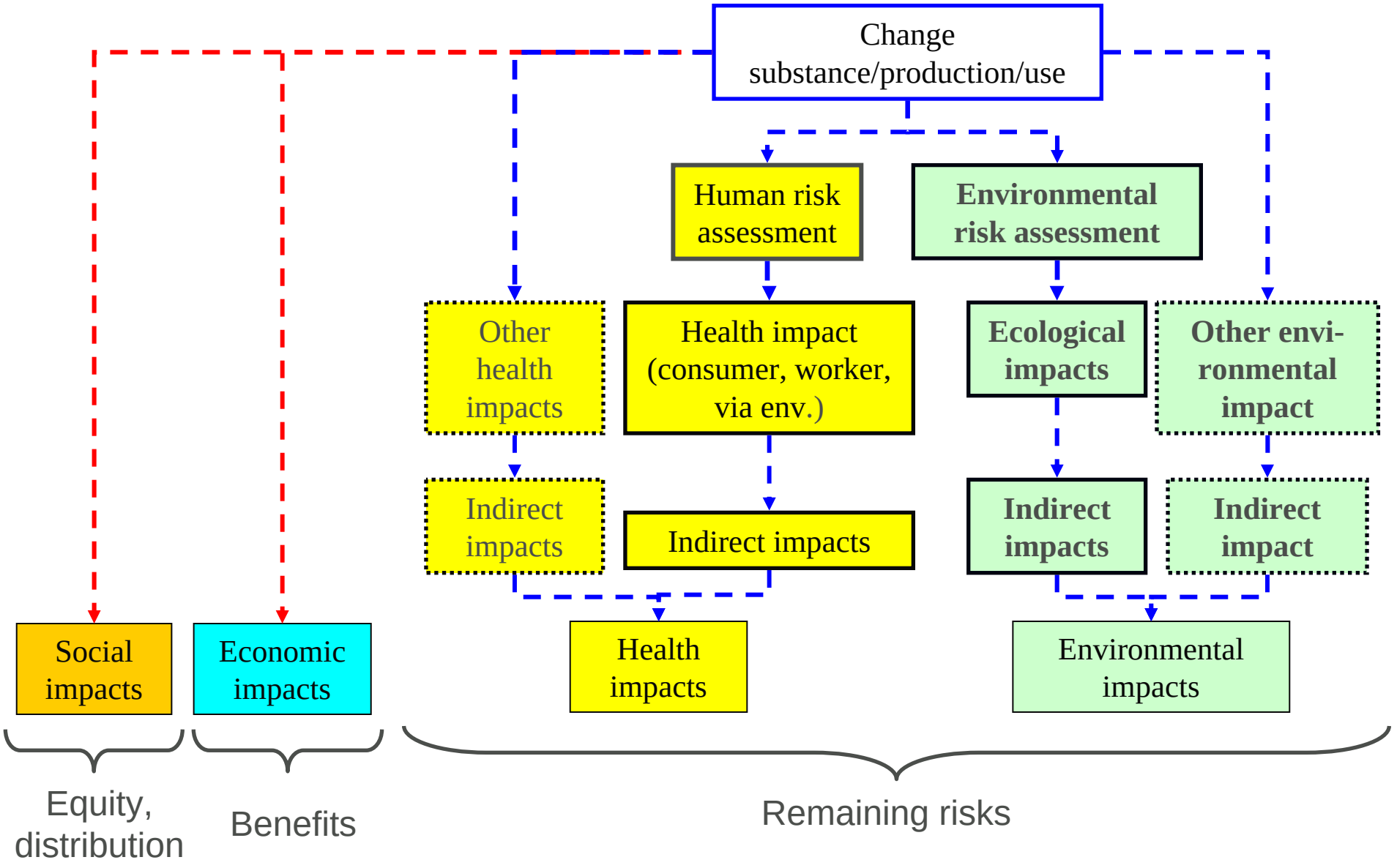
“Non use” scenarios

- Authorisation is refused: substance cannot be used

Analysis is an iterative process



Change in risks and benefits due to an authorisation



Benefit of an authorisation

- What is the cost if an authorisation is not granted ?
  - To the applicant or to the society?
- What would happen to the applicant if he could not use the substance?
  - He would use an alternative or stop all together
  - Alternative is more expensive (if it was cheaper he would use it) or poorer quality (i.e. cost more to the downstream user)
  - If stopping all together we would lose ‘the service’ provided by the substance
- If authorisation is granted, applicant avoids additional costs
  - Avoiding additional costs = saving money = benefit

Changes in risks: Human health and environmental impacts

- Toxic, ecotoxic or physiochemical properties of
  - Annex XIV and alternative substance
  - Other impacts in all supply chains for alternatives
- Example
  - Differences in emissions in “applied for use” and “non-use” scenarios
- May have been partly generated already (in CSA)
- For SEA, more analysis might be useful
  - severity of the effects and
  - exposure
    - e.g. assessing how many people or what environmental populations are exposed to describe the impacts on human health or the environment

Changes in benefits: Economic impacts (or costs) if use is not authorised

- Cost to society not the same as private costs
  - Private costs are incurred by specific sectors or groups
  - Some “lose” and some “gain” – for a society net effect matters
- Private costs are a good starting point
  - Theoretically will (in practice may) require adjustment
  - Example: correction for taxation (value added or energy taxes)
- Methodological notes!
  - In SEA we ALWAYS talk about changes in costs
    - Eg. additional costs if an authorisation is not granted
  - If you cannot calculate a cost, it does not mean it does not exist
    - Example of where qualitative analysis becomes important!

Direct and indirect costs (if authorisation is not granted)

- **Investment (i.e. capital) costs**: **changes in**
  - Equipment or modification costs
  - Other costs (eg. general site, decommissioning, R&D)
- **Operating (i.e. recurrent) costs**: **changes in**
  - Labour costs
  - Raw materials costs
  - Energy costs
  - Materials and services cost
  - Design, monitoring, training
- **Savings** (i.e revenues) may occur

- **Effectiveness of system may change**
  - Longer production process
  - More quality control
- **Product quality may change**
  - Change in application times (e.g. paint 3 instead of 2 times)
  - Material costs may increase
  - Durability of product may change (replacement costs increase)
- **Indirect costs may be important**
  - Probably particularly challenging to quantify

5. Complementarity of SEA and adequate control reasoning?

- Adequate control reasoning *(threshold substances)*
- Socio-economic reasoning *(non-threshold substances)*
- Complementarity?
  - applicant may decide to use both reasonings
    - e.g. if RAC considers that risks are not adequately controlled the applicant could have analysed that the benefits > risks
    - SEA is useful when setting the duration of review period

Authorisation List (Annex XIV)

Justification based on

SEA Art 60(4)

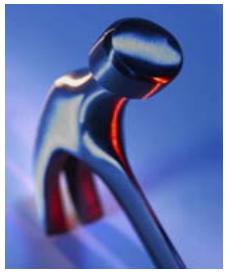
- Musk xylene
- MDA
- HBCDD

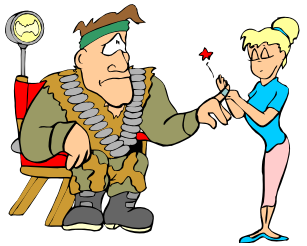
(Non-threshold, PBT or vPvB substances)

Adequate control Art 60(2) (or SEA)

- DEHP
- BBP
- DBP

6. Conclusions





- SEA is a tool to help decision making
  - Tools need to be used wisely
- Iterative, open process
  - Well carried out analysis informs first of all the applicant of the options
- SEA draws upon and complements Analysis of Alternatives and Chemical Safety Assessment
  - Enlarged scope: from society's point of view
- Cannot be done in isolation
  - Need a team of experts with a common goal: good analysis to understand what the implications are if authorisation is not granted
- In the interest of the applicant, in particular for
  - All non-threshold substances and if adequate control not demonstrated
  - For establishing review periods
- Aims at assessing if benefits compared with (residual) risks

7. Take home

- Companies know best benefits if an authorisation is granted (i.e. costs if authorisation is not granted)
  - Clear, transparent cost estimation vital
  - Quality or functionality of the product!
  - Do not double count!
  - Use 4% (real) discount rate (you can carry out sensitivity analysis)
- Avoid ”quantification bias”
  - Good qualitative analysis (indicating the order of magnitude) may be more important than quantitative analysis (of only part of the impacts, e.g. costs)
  - Equally important in costs as well as environmental and health impacts
- ECHA is willing to co-operate
  - Guidance and methodologies (costs, impacts) used in SEA
  - Needs to treat all applicants equally

Thank you!