

Socio-economic analysis in authorisation

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Outline

1. What is SEA in authorisation?
2. Reasons for conducting SEA
3. SEA in the authorisation process
4. SEA methodology issues
5. Key messages

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 risks
- Makes use of:
 - Any methodology, examples in guidance document on SEA

2. Reasons for conducting SEA

With no adequate control, European Commission makes the decision on the basis of socio-economic information (Art 60(4))

"... an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk ..."

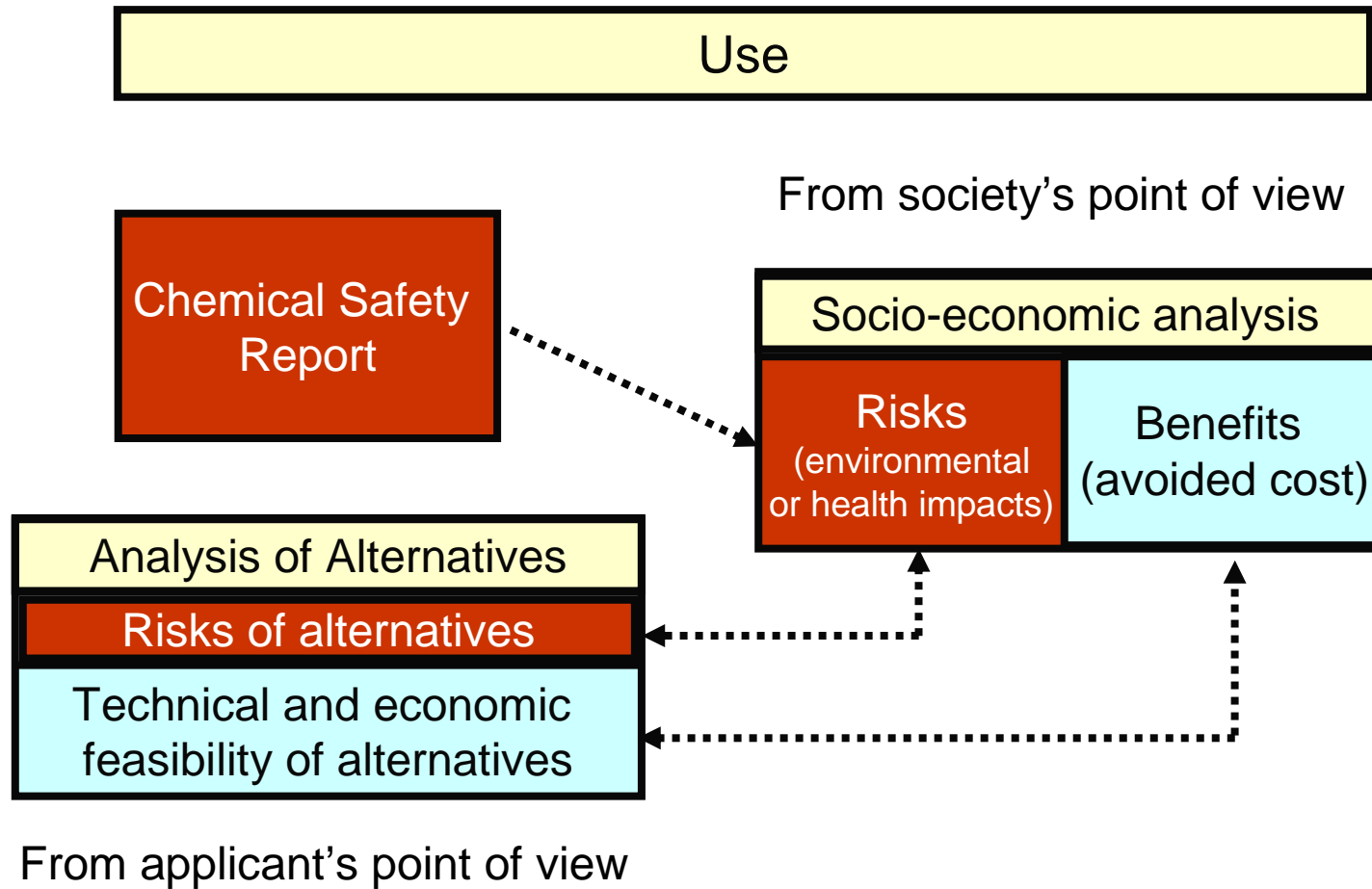
ECHA Committees base their opinions on socio-economic information (Art 64(4)(b))

" The draft opinions shall include... an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives..."

2. Reasons for conducting SEA

- Analysis of socio-economic impacts practically a must for
 - Non-threshold CMRs as well as PBTs and vPvBs
 - Threshold substances for which adequate control of risks cannot be demonstrated
 - No prescriptive reporting format but Annex XVI SEA report seems an appropriate recommendation
- SEA report can act as a 'back up' to adequate control and might require only marginal extra work
 - Impacts (from Chemical Safety Report and Analysis of Alternatives),
 - Economic feasibility of alternatives (from Analysis of Alternatives)
- Review periods shall be based on socio-economic information (Art 60(8))
 - Socio-economic benefits of use; socio-economic implications of non-use; analysis of alternatives (Art 60(4))

3. SEA in the authorisation process



4. SEA methodology: "Applied for use" vs. "non-use" scenarios

"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

4. SEA methodology: Benefits of authorisation

- What is the cost if an authorisation is not granted?
 - Both applicant's and society's perspective are relevant
- If not authorisation, applicant must use an alternative or stop altogether
 - Alternative is more expensive (if it was cheaper he would use it) or poorer quality (e.g. cost more to the downstream user)
 - If stopping altogether we would lose 'the service' provided by the substance
- If authorisation is granted, applicant avoids these additional costs
 - Avoiding additional costs of non-use = benefit of authorisation

4. SEA methodology: Direct and indirect costs (of non-use)

- **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 (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

4. SEA methodology: Changes in risks - Human health and environmental impacts

- Toxic, ecotoxic or physicochemical properties of Annex XIV substance
- May have been partly generated already (in CSA)
- For SEA, more analysis might be useful
 - Severity of impacts
 - Exposure
 - e.g. assessing how many people or what environmental populations are exposed to describe the impacts on human health or the environment
- Alternative substances or technologies might have other impacts
 - e.g. increased energy use generates air pollution and CO₂
- Example
 - Differences in emissions in “applied for use” and “non-use” scenarios

4. SEA methodology: Benefits vs risks

Benefits of authorisation

- Avoided cost increases and/or reductions in profit
- Avoided reductions in economic performance, employment, investment
- Avoided environmental and health impacts (e.g. energy use, transport)

Risks of authorisation

- Environmental and health impacts from using the substance (Annex XIV risks)
- (Can be zero if risks are adequately controlled)

- ⇒ Authorisation more likely when costs of the alternatives are higher and/or costs of current risks are lower (e.g. current risks are more controlled)
- ⇒ Lack of suitable alternatives does not guarantee an application will be granted! The benefits still need to outweigh the risks

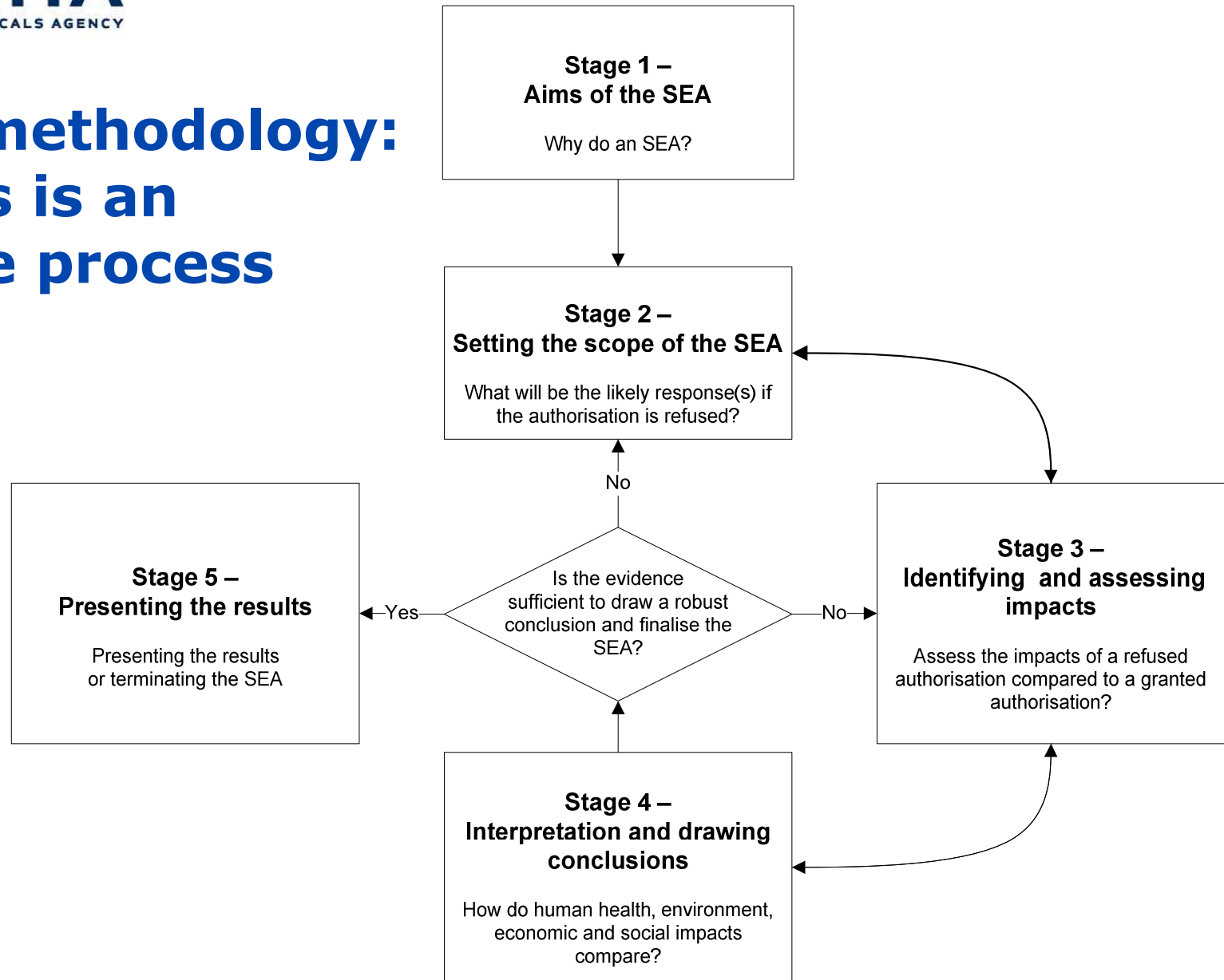
4. SEA methodology: What should a SEA contain? (Annex XVI)

- Commercial impact on the applicant and others of no authorisation
 - **Investment, R&D, one-off and operating costs (e.g. compliance, changes to processes, installing new technology)**
- Impact on consumers of no authorisation
 - **Product prices, change in composition/quality**, availability, choice, human health and environment
- Social implications, for example, job security and employment, and wide implications on trade, competition and economic development
- *Availability, suitability and technical feasibility of alternatives and economic consequences thereof*
- Wider implications on trade, competition and economic development
- **Benefits for human health and the environment** if authorisation refused – Annex XIV (etc) risks

4. SEA methodology: How much to quantify and monetise?

- Quantification of environmental and health impacts will often be difficult and monetisation frequently impossible!
 - e.g. lack of dose-response relationships, lack of monetary values
- “It will be a matter of judgement for the applicant in determining how far the assessment should involve quantification and monetisation of impacts. The overall aim should be to have gained, and be able to communicate, an understanding of (or a ‘feel for’) the significance of the impacts.”
- Quantify ‘as far as you can’
- Present information in context; provide comparators etc
- Cost estimates should be as detailed and rigorous as you can make them, based on realistic business assumptions

4. SEA methodology: Analysis is an iterative process



5. Key messages

- SEA is the key decision rule if there is no adequate control
- Demonstrating an absence of suitable alternatives is not sufficient – benefits must outweigh the risks
- Stopping completely is an option!
- Good estimates of (additional) costs of alternatives are crucial – they will be scrutinised
- Role of monetisation of impacts probably overplayed
- Need to be able to show 'costs would be high' and 'risks are low' – contextual information, comparisons etc

Thank you!