Socio-Economic Analysis for Authorisation

A discussion of key aspects

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Socio-economic analysis – overview of the presentation

- Why do it? (How does it fit into REACH?)
- When to do it (in the application process)?
- Who should do it?
- How to do it?
- How much to do it

- Focus on some key aspects
- Building on previous presentations

Two routes to authorisation

Adequate control route

- Threshold CMRs (DNEL)
- Threshold substances of equivalent concern (DNEL or PNEC)
- Risks controlled below thresholds
- No suitable alternatives
- Suitable alternatives (substitution plan)

Socio-economic route

- Non-threshold CMRs
- Non-threshold substances of equivalent concern
- PBTs and vPvB
- Threshold substances without adequate control
- No suitable alternatives
- Benefits of continued use outweigh the risks

The make-up of an authorisation application

Article 62(4) An application SHALL include:

1. Substance ID, contact details, use to be authorised
2. Chemical Safety Report covering risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV
3. Analysis of alternatives, considering risks, and technical and economic feasibility of substitution
4. If '3' indicates suitable alternatives are available, a substitution plan with timetable of proposed actions

Article 62(5) An application may include:

1. Socio-economic analysis in accordance with Annex XVI

Where SEA fits into an application

Socio-economic route

- Article 60(4): [a]n authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk
- Annex XVI socio-economic analysis – benefits and risks of continued use

Both routes

- Chemical Safety Report (risks of continued use)
- Analysis of alternatives (risks and costs of alternatives)
- Time-limited review (development in availability of alternatives)
- Article 64(1): The draft opinion[…] shall include: […]an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives

Adequate control route

- Substitution plan (economic feasibility of alternatives over time)

What is covered in SEA for authorisation

Two scenarios

1. ‘Applied for use’ scenario – use of Annex XIV substance continues
2. ‘Non-use’ scenario – applicant adopts alternative (substance, activity etc)

Negative and positive impacts of ‘1’ *vs* ‘2’

1. ‘Applied for use’ scenario – use of Annex XIV substance continues
2. ‘Non-use’ scenario – applicant adopts alternative (substance, activity etc)

- 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 in restriction

When to do it (in the application process)?

AoA

- Defining scope of AoA
- Assessing overall reduction of risks to human health / environment from alternatives
- Assessing technical feasibility of alternatives
- Assessing economic feasibility of alternatives
- Assessing availability of alternatives
- Conclusion

SEA

- Defining aims of SEA
- Defining scope of SEA
- Assessing impacts of refused vs granted authorisation:
  - Human health and environment
  - Economic
  - Social
  - Wider economy
- Conclusion

Who should do it? (2)

- Certain aspects require specialist skills (e.g. EIA[1], CBA[2])
- Some data requirements require knowledge of specialist external sources (e.g. monetary economic values)
- Unlikely to be able to avoid using external resources
- Similar to undertaking (e.g.) an EIA for a planning application
- But needs EIA and internal business planning combined – integrated approach based on commercial decision-making incorporating SEA considerations

[1]EIA : Economic Impact Assessment
[2]CBA: Cost-Benefit Analysis

How to do it?

- Annex XVI (‘may include’)
- SEA, AfA guidance, other guidance
- Key technical features (e.g. discounting)
- Valuation of intangibles for complex cases
- ‘Good things to include’ (e.g. uncertainty, indirect costs, price-performance effects)

BUT

- Data often imperfect, methodologies vary
- Proportionality
- ‘No right and wrong answer’

How to do it? ‘More convincing analysis’

- Detailed quantitative business model using actual data to explain and estimate how costs and revenues would be affected over time
- Systematic consideration where appropriate of effects on downstream users, costs and demand
- Quantified impacts placed in context of wider business and financial performance, including business planning and future market trends
- Numerous actual data employed for known variables. Predictions for future values based on extensive databases and consultation with suppliers etc
- Integrated assessment of health and environmental impacts, with modelling of exposure and populations/receptors, and monetisation of estimated effects.
- Uncertainties and risks recognised and modelled formally through scenario analysis, sensitivity analysis, monte carlo analysis and so on

How (not) to do it? 'Less convincing analysis'

- Impacts presented in general terms in the form of qualitative statements and assertions
- No obvious or explicit logic to implied relationships underpinning impact statements. No quantitative modelling
- Partial range of impacts considered. No comprehensive assessment of which impacts relevant. Final choice largely arbitrary. Subjective and implied tradeoffs between non-comparable outcomes
- Little or no quantitative data used
- Short or unspecified time horizon. No consideration of baseline trends or future developments
- No contextual information or comparisons provided to judge scale, significance of impacts
- No or perfunctory consideration of uncertainty

Discussion example – Downstream users

- Recognising and describing possible effects is a start!
- Understanding customer business and processes might allow modelling of impacts – process changes, indirect costs, role of performance
- Sensitivity and scenario analysis to identify key drivers of results – how important could they be? (Proportionality)
- Indirect approaches – impact on own demand, prices, sales trends etc as a measure of impact downstream (n.b. double-counting)
- How would these market developments actually be modelled and market options actually selected by the firm? ('Real-world' analysis of need to consider substance ban – applicant's perspective)

Key points to take away

- SEA optional in theory but need to show benefits are greater than risks, so in practice SEA is key; but monetised CBA or just 'comparison'?
- The analysis of the existing substance and alternatives should be as 'real' as possible, e.g.Applicant's 'context' (e.g. locations, markets, technologies); Realistic plans for dealing with a substance ban – what would you do?
- Need for internal and external expertise; the SEA should be 'owned'
- There will always be difficulties and uncertainties due to data problems, uncertainty etc – there is no 'correct' answer
- 'Convincing' vs 'unconvincing' application – has the analysis addressed the issues in a 'serious' and critical way? Thinking through and understanding the issues is a large part of the answer – SEA as a process
- On what key aspects might ECHA be able to provide assistance?