

An introduction to socio-economic analysis in the REACH authorisation process

Richard Dubourg, Risk Management
Implementation Unit, ECHA

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Context and introduction

- REACH aims 'to encourage and in certain cases to ensure that substances of high concern are eventually replaced' (Recital 12)
- The world according to REACH: trends in the use of hazardous chemicals are downwards, and firms switch to alternatives
- Authorisation permits the use of hazardous substances to continue temporarily until substitution or re-authorisation – it's a continuous process, not a one-off hurdle
- Socio-economic analysis (SEA) plays a multiple role in authorisation:
 - The decision to apply for authorisation or not
 - The composition of the application
 - The decision to grant the authorisation
- This presentation is about the SEA 'way of thinking', not a technical, step-by-step guide
- The intention is to demystify SEA, not to over-complicate it

So what is socio-economic analysis in REACH?

- “A tool to evaluate what costs and benefits an action will create for society”
- “An approach used to describe and analyse all relevant impacts (i.e. both positive and negative effects) of granting an authorisation compared to refusing to grant the authorisation”
- Costs and benefits
- Positive impacts, negative impacts
- “Pros and cons”

associated with some sort of change or decision or choice

- Always measured against what would happen if the change did not occur (‘the baseline’, ‘do nothing’, ‘business as usual’)
- The exact methodology can vary

How does socio-economic analysis fit into the authorisation process? (1)

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

How does socio-economic analysis fit into the authorisation process? (2)

Socio-economic route

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

Both routes

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

Adequate control route

- Substitution plan (economic feasibility of alternatives over time)

How does socio-economic analysis fit into the authorisation process? (3)

- More fundamentally, socio-economic analysis is also relevant to the decision about whether to submit an authorisation application or not
- The question to ask: What will my business do if an Annex XIV substance can no longer be used in the EU?
- What are the options?
- What would be the positive and negative impacts of each option?
- Compared against if the substance could continue to be used

What are the options?

- Switch substances
- Adapt technologies or processes, develop new ones
- Use additional inputs
- Switch products
- Import products
- Change product specification
- Stop producing, using

What would the impacts be?

- Process performance
- Product performance
- Efficiency, resource requirements
- Quality, aesthetics
- Costs, revenues, profits
- Commercial performance, investment, employment
- Competitive position
- Environmental and health risks

Case for authorisation if benefits > 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
- (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)
- ⇒ Authorisation more likely when the difference is bigger – a stronger case is likely to be a clearer and simpler case

Analysing options and impacts says whether an application for authorisation is justified

- Alternatives might cost less than the environmental and health risks of continuing to use the substance
 - ⇒ Adopting one of the alternatives is better than continuing use
 - ⇒ Authorisation is unlikely to be granted so submitting an application is probably not worthwhile (and you've saved the costs of applying)
- Viable alternatives might be found
 - ⇒ The analysis has revealed an option which is cheaper and/or better than authorisation (and you've saved the costs of applying)
- Alternatives might be found to be more costly than the current risks
 - ⇒ There is a case for authorisation
 - ⇒ **The analysis needed for the application has been done**

Analysis of alternatives template

- List of possible alternatives
- Description of efforts made to identify possible alternatives
- Research and development
- Data searches
- Consultations
- Alternative 1: Substance ID and properties/Description of technique
 - **Technical feasibility**
 - **Economic feasibility**
 - **Availability**
 - **Reduction in overall risk**

Socio-economic analysis template

- Definition of “applied for use” scenario
- Definition of “non-use” scenario
- **Human health and environmental impacts**
- **Economic impacts**
- Social impacts
- Wider economic impacts
- Comparison of impacts
- Distributional impacts
- Uncertainty analysis

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 - ⇒ There is a case for authorisation
 - ⇒ The analysis needed for the application has been done
 - ⇒ **And if the analysis has been done appropriately, RAC and SEAC should agree with the assessment**

The scope and perspective of SEA is wide – ‘society’, not just the applicant

- A substance might be critical to a business, but its suppliers, customers or competitors might easily do without it
 - The applicant might not think there are any viable alternatives, but third parties might identify some (through public consultation)
 - The applicant might control risks to its immediate environment and health, but the substance might also generate risks to its downstream users and customers
- ⇒ **You need to look wider than your immediate (commercial, technical, environmental) context**
- ⇒ But it might help the case as well (e.g. higher costs for downstream users)

What should a SEA contain, and what is likely to be most important? (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

And what might constitute 'appropriate analysis'?

- Balanced and objective – the case is driven by the analysis; the analysis is not constructed to 'prove' the case
- Recognises the audience for the application is the Committees, not senior management
- Focuses on the factors which are likely to make a difference
 - A small impact on a large number of actors can be a large social impact
 - A small risk for a large population can be a large societal risk
- Not overly complicated – a clear case is one where benefits are big (costs of alternatives are high) and/or risks are small
 - "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."
- One which you would be prepared to stand up and defend

Thank you

Richard Dubourg, Risk Management
Implementation Unit, ECHA

richard.dubourg@echa.europa.eu