

The Analysis of Alternatives and Socio- Economic Analysis

Seminar on Applications for Authorisation
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Substitution – an important objective of the authorisation system

REACH sets a substitution objective:

The progressive replacement of SVHCs by suitable alternatives substances or technologies which are less dangerous, and which are technically and economically feasible

Efforts to substitute are mandatory for all applicants:

Analyse alternatives to continued use

Report on on-going and planned R&D

Monitoring and periodic review

They must apply for authorisation if they wish to continue use

Applying for authorisation involves potentially significant costs

Requirements for authorisation applications

| | Adequate control | Socio-economic |
|--------------------------------|--------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Chemical Safety Report | Required: need to demonstrate AC | Required: need to show risks minimised |
| Analysis of alternatives (AoA) | Required | Required: need to show no suitable alternatives |
| 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 in practice: need to show authorisation benefits exceed risks; can support review period |

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

Role of the Analysis of Alternatives and SEA

| Analysis of Alternatives | Socio-economic analysis |
|------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| What <i>can</i> you do if you can no longer use the substance | What will be the impact on society as a whole of the things you could do if you can no long use the substance |
| What <i>will</i> you do if you can no longer use the substance – the ‘non-use scenario’ | Is society as a whole better off if authorisation is granted or not (benefits > risks) |
| What are you doing to switch to suitable alternatives (substitution plan) | |
| What are you doing to prepare for the possibility that you will not be able to use the substance in future (R+D) | |

Applicant’s (user’s) perspective

Society’s perspective

AoA and SEA in the application

| AoA Template | SEA Template |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| List of possible alternatives | Definition of “applied for use” scenario |
| Description of efforts made to identify possible alternatives | Definition of “non-use” scenario |
| Research and development | Human health and environmental impacts |
| Data searches | Economic impacts |
| Consultations | Social impacts |
| Alternative 1: Substance ID and properties/Description of technique Technical feasibility Economic feasibility Availability Reduction in overall risk | Wider economic impacts Comparison of impacts Distributional impacts Uncertainty analysis |
| Applicant’s (user’s) perspective | Society’s perspective |

Avoid double counting

Impacts to the downstream users may have been already counted when looking at changes in costs, revenues and profits to the applicant.

Always report net impacts to the society

Sponsor money, lost revenues in the supply chain

Steps in the analysis of alternatives

Identify possible alternatives for each "use applied for"

Assess the suitability and availability of possible alternatives:

- Technical and economic feasibility
- Reduction in risk to the environment and to human health
- Availability

Describe relevant R&D efforts

Determine required actions and timescales to make possible alternatives suitable and available for the applicant

Note: There is always an alternative!

Analysis of alternatives - methodology

See guidance and ECHA website for more detail

But ultimately the appropriate methodology is the applicant's

Key principle is that the analysis should be 'real'

Substitution is the long-term goal of REACH

Authorisation is not guaranteed

Applicants must think about what they will do if authorisation is not granted

However,

Public consultation might indicate other alternatives (threat and opportunity)

Analysis must meet the needs of the application (esp SEA route)

Superficial analysis might have impacts on conditions/review

Economic feasibility

Focus is on change in applicant's (net) costs – see costing annex in guidance

No 'required' methodology for appraisal, and no specific threshold imposed to distinguish 'feasible' from 'infeasible'

SEAC will scrutinise cost estimates and assumptions to ensure costs not over-estimated e.g. feasibility might be sensitive to investment time horizons

Public consultation will be used to help ensure full range of possible alternatives is identified

Availability

When can alternatives be regarded as available?

Reasonably accessible without undue delay
Available in the required quantity (substances)
Developed enough to allow implementation (technologies)
Fulfill the relevant quality or legal requirements

Key issue: Timing

May need to consider trends over time – alternative might not be available in all respects now but could be in foreseeable future

Availability defined in relation to the Sunset Date – is an authorisation required to give enough time for substitution?

The likely key components in a SEA?

The SEA is largely driven by the question: Do benefits exceed risks?

Benefits of authorisation are principally the avoided costs of switching to the alternative (non-use scenario)

Costs of alternative substance or technology: Direct and indirect costs

e.g. Higher price, higher quantities used, shorter life-times, higher maintenance costs, higher energy use, worse performance for applicant and customers

Costs of switching location of activities: Economic impacts (employment etc), local economic performance

Costs of stopping use: Profits and value-added in the supply chain

Advice from outside experts may help

How much to quantify and monetise?

Quantification of environmental and health impacts will often be difficult, and quantification 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’, but avoid ‘quantification bias’

Present information in context; provide comparators etc

Advice from outside experts may help

Key messages

The Analysis of Alternatives identifies what happens if authorisation is not granted. The Socio-Economic Analysis assesses whether that is better for society or not

The methodology for appraising the alternatives and defining non-use scenario should be whichever you use, because the analysis should be real

But you need to present the results in a way which allows you to demonstrate your case and for it to be scrutinised

So read the cost guidance (Appendix I of SEA guidance), present break-down of costs and supportive documentation

Quantification and valuation will often be impossible (especially for risks)

Socio-Economic Analysis is not inherently complicated – the key is to identify and focus on the main drivers/factors

Thank you

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