

# The Analysis of Alternatives and Socio- Economic Analysis

Seminar on Applications for Authorisation  
February 2013

Richard Dubourg  
Risk Management Implementation Unit  
ECHA

# 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
<b>Authorisation granted if</b>	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)	

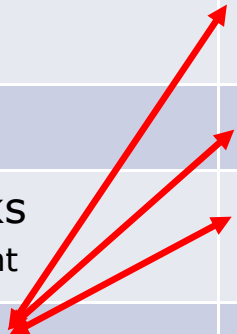
<b><i>Applicant’s perspective</i></b>	<b><i>Society’s perspective</i></b>
---------------------------------------	-------------------------------------

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 <div data-bbox="315 1034 752 1235" style="border: 1px solid green; padding: 5px; margin: 5px;">             Technical feasibility              Economic feasibility              Availability           </div> <div data-bbox="293 1235 875 1299" style="border: 1px solid red; border-radius: 50%; padding: 5px; margin: 5px;">             Reduction in overall risk           </div>	Wider economic impacts
	Comparison of impacts
	Distributional impacts
	Uncertainty analysis

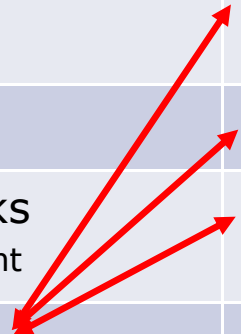
***Applicant’s perspective***

***Society’s perspective***

Analysis of Alternatives	Socio-economic analysis
Technical; product performance	Applicant's costs, revenues, profits
Efficiency, resource requirements	Technical; product performance <i>for supply chain</i> (including consumers)
Quality, aesthetics	Efficiency, resource requirements <i>FSC</i>
Environmental & health risks Occupational, public and environment	Quality, aesthetics <i>FSC</i>
<b>Costs, revenues, profits</b>	Environmental and health risks Air and water pollution, global warming, public health, ecosystems etc
Commercial performance, investment, employment	<b>Costs, revenues, profits <i>FSC</i></b>
Competitive position	Commercial performance <i>FSC</i>
	Economic performance ( <b>local, regional</b> )



Analysis of Alternatives	Socio-economic analysis
Technical; product performance	Applicant's costs, revenues, profits
Efficiency, resource requirements	Technical; product performance <i>for supply chain</i> (including consumers)
Quality, aesthetics	Efficiency, resource requirements <i>FSC</i>
Environmental & health risks Occupational, public and environment	Quality, aesthetics <i>FSC</i>
<b>Costs, revenues, profits</b>	Environmental and health risks Air and water pollution, global warming, public health, ecosystems etc
Commercial performance, investment, employment	<b>Costs, revenues, profits <i>FSC</i></b>
Competitive position	Commercial performance <i>FSC</i>
	Economic performance ( <b>local, regional</b> )



Applicant's perspective **AVOID DOUBLE-COUNTING** Society's perspective

## 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 previous workshop presentations 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

Analysis is akin to a business plan/case for substitution

**BUT**

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

SEAC will challenge applicants to explain why identified alternatives are not feasible for them

## 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

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

***Judgement of outside experts can help here***

## 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 can help, but beware ‘supplier-induced demand’***

## 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 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)

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**

**[richard.dubourg@echa.europa.eu](mailto:richard.dubourg@echa.europa.eu)**