

Experience in the Committee for Socio-Economic Analysis

Lessons learnt on Applications for Authorisation
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Outline

- What SEAC looks at when evaluating applications
- What we have received so far
- Recommendations to applicants
- Take home



What does SEAC look at when evaluating applications?

SEAC evaluates the application (and public consultation comments) to formulate an opinion on:

- Whether the socio-economic benefits of authorisation outweigh the risks of continued use when risks are not adequately controlled
- Technical feasibility, economic feasibility and availability of alternatives
- Review period

A. Suitability & Availability of Alternatives

- Conclusion on the technical feasibility of alternatives
 - whether the alternative is able to perform an equivalent function (or eliminate the need for the function)
- Conclusion on the economic feasibility of alternatives
 - whether the transition to the alternative will result in net costs for the applicant
- Conclusion on RAC's assessment of the risks of alternatives
 - whether the alternative is less risky (has less hazardous properties)
- Conclusion on the availability of alternatives
 - whether the alternatives are available in the necessary quantities before the sunset date and then within the review period

B. Whether socio-economic benefits outweigh risks

- Risks
 - SEAC's assessment is based on
 - RAC's conclusion on the remaining (excess) risk to human health and the environment (focus on intrinsic properties for which the substance is listed on Annex XIV)
 - The applicants assessment of human health and environmental impacts in the submitted socio-economic analysis (a necessary part of the SEA when there is a remaining risk)
- Benefits
 - SEAC's evaluation of the societal benefits of continued use in terms of
 - Economic impacts (usually quantitative analysis)
 - Social impacts (usually qualitative analysis)
 - Wider economic impacts (usually qualitative analysis)

C. Review period

Review period: Runs from the sunset date. The applicant needs to re-apply 18 months prior to the end of this period if they wish to continue to use/place on the market for a use

SEAC's criteria during opinion-making:

- RAC's recommendation regarding magnitude and uncertainty in remaining risks and the risks of alternatives
- Time to transition to an alternative or to find a suitable alternative, including certification and other regulatory requirements
- Other socio-economic factors and relevant considerations, such as investment cycles, bridging applications, spare parts, uncertainties etc.

Length of the review period: standard (7 years), short (e.g. 4 years) or long (12 years)

Some general impressions of AfA thus far

- Most (90%) information is now non-confidential, after the change in format in April 2014
 - effective public consultation
- Many applications of good quality
 - When good quality, efficient opinion making (many opinions adopted well ahead of 10 months)
- Generally detailed responses to SEAC's questions on alternatives and to public consultation comments
- Dialogues and communication with applicants and even competitors have been useful, e.g. to show additional material about the case (videos, pictures, graphs etc.)
- Applicants' feedback to ECHA positive, e.g.
 - 70% strongly (30% somewhat) agree that Pre-Submission Information sessions (PSIS) helpful
 - 100% strongly agree that ECHA staff has been helpful

What we have received



The big picture

- Many applicants had done a thorough job in AoA and SEA
 - Sometimes overly lengthy documentation: avoid futile information
 - ECHA's advice to focus on the business reasons for applying seems to have born fruit in later applications (more focussed)
- All had used the RAC's reference values
 - Simplified also the applicants' work and helped SEAC when evaluating the health impact assessment and valuation
- Many had carried out a full cost-benefit analysis
 - Helped SEAC to evaluate and draw conclusions for their opinion
- Paradox
 - Downstream applications are easier to prepare, understand and evaluate
 - Upstream applications provide system efficiency and are desirable as long as they are representative of all downstream users
- The following slides describe where deficiencies were found and where we see room for improvement

Analysis of alternatives

- Identification of alternatives
 - Data sources sometimes unclear
 - Some did not explain
 - how the short-list of alternatives was derived
 - if the function of Annex XIV substance could be replaced
 - why some "sub-uses" could be substituted while others not
- Assessment of alternatives
 - Time and resources required to transition to an alternative could have been clearer in some applications
 - Analysis of commercially available alternatives sometimes missing
 - When Manufacturer or Importer applied, they sometimes forgot to analyse the technical and economic feasibility for DUs. Still, SEA should include costs to Manufacturers/Importers even if there are alternatives from the DU's perspective.
- Sometimes the AoAs were not written with the view in mind that the AoA is used to define the non-use scenario in the SEA

Socio-economic Analysis

- The non-use scenario seemed not always credible
 - “Shut down” or “complete relocation” not analytically justified and seemed not to be the companies’ real business alternatives
 - Sometimes no discussion of alternatives identified in AoA – what would be the impacts of changing to a worse alternative?
- Impacts were not always analysed from society’s perspective
 - Lost revenue of someone in the supply chain may be compensated by increased revenue of those supplying or using the alternatives
- Treatment of costs in “Applied for” vs. “non-use” scenarios
 - Sometimes investment in “non-use” scenario was incorrectly considered an additional cost while it was not treated so in “applied for use” scenario.
 - Applicant had not realised that he would need to make the investment in both scenarios (and only the difference between the investment costs, if any, would have been relevant).

Comparison of impacts

- Difficulty comparing risks and benefits if temporal scope was not the same for the various impacts
 - Annualising risk and benefit estimates may sometimes help
- Some applications did not focus on net costs
 - If an operation is closed down, there will be “savings” as well
 - An alternative could be more expensive but result in some gains (e.g. in energy consumption or quality)
- Some applications have estimated the loss of revenues
 - This would inflate the losses (as the expenditure would go down too). Loss of eg. net margin or net operational profit would be a more accurate comparator

Uncertainties

- To understand the impacts of uncertainty
 - A clear description needed in the applications and opinions
 - Use of different scenarios would have been helpful
- Highlighting uncertainties in the application helps
 - SEAC and RAC to provide a clear opinion
 - Especially with regard to risks and benefits and how a change in input factors will affect the outcome

Level of detail

- Important to maintain focus
 - Presentation of the business case was not always clear
- In AoA, the requirements in terms of R&D, costs, time, product changes, certification were sometimes unclear
- SEAC could not always reproduce the estimates
 - Give clear and brief overviews and comparisons of risks and benefits
 - Estimates should be justified by calculation details (eg with spreadsheets) to enable SEAC to scrutinise the analysis
- Some applicants did not demonstrate if benefits outweighed risks
 - Quantify impacts when possible and use qualitative descriptions otherwise

Recommendations to applicants

- Writing an AfA is also about communication:
 - Don't dilute the main messages with unnecessarily lengthy text
 - Maintain focus by presenting a business case: non-use vs. applied for use scenarios
- Non-use scenario should reflect what your company would actually do if it could not obtain authorisation
- Be transparent about numbers, assumptions and methodology
 - Data should be traceable
 - Consider to include Excel sheets for the calculations
- Avoid unjustified confidentiality claims
 - Transparent application shows confidence of your business case
- Justify your review period request with clear arguments

Take home

- AoAs and SEAs have had varied quality
 - Some excellent, some good, some overly lengthy, some unclear...
- AoAs and SEAs have had varied consistency
 - Some very consistent, but sometimes clearly written by different groups of people in an uncoordinated manner
- The business case why you apply varied
 - Sometimes clear and focused, but not always the case
- SEAC has learned quickly to evaluate applications
 - It is still learning but is building fast its capacity
- Application and opinion formats constantly improved
 - In 2014, application formats improved to bring clarity and transparency
 - In 2015, opinion formats improved to better document the justifications

Thank you

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