

# Applications for Authorisations in REACH :

## Experience in the Committee for Socio-Economic Analysis

Tomas Oberg Chair of SEAC,  
Jean-Marc Brignon, member of SEAC  
Presented by Jean-Marc Brignon Jones Day REACH  
Seminar, Paris, 26/11/2015

# Outline

- What SEAC looks at when evaluating applications
- What we have received so far
- General recommendations to applicants
- Take home
- The case of "upstream" applications



# 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



## Upstream applications seen by SEAC

- More complex :  
Number and variety of supply chains, economic and technical situations
  
- Need to be assessed consistently with DU applications:  
Same assessment principles and methodology  
Quality of SEAC opinions equally needed
  
- ⇒ More time devoted to complex upstream application by rapporteurs but still **time constraints**
  
- ⇒ SEAC rapporteurs need a clear and helpful application

# Technical Feasibility of Alternatives (1)

Focus should be on the **function** of the substance by actors who **use** the substance

Technical assessment of alternative is to be carried out at **DU level**

Whether an alternative can or cannot be manufactured by the applicant is not the primary SEAC criteria

*Assessment of manufacturers' market situation difficult to be used by SEAC*

## Technical Feasibility of Alternatives (2)

In a broad scope application, it is unrealistic to expect that an alternative should cover **all** uses

=> Alternatives cannot be assessed one by one: need to consider **combination of alternatives** to cover the scope of the AfA.

## Technical Feasibility of Alternatives (3)

Address **transparently** the **number and variability of DUs** and technical situations

Tools that **describe /classify situations** of DUs in terms of **critical functions** of alternatives are welcome

Justify the **relevance and representativeness** of surveys, tools, case studies, actors selected in supply chain...

SEAC needs to assess whether the broad scope is justified and that sectors/situations where substitution is feasible are not included

## Economic Feasibility of Alternatives

Again, **representativeness** is a necessity.

Economic situations within DUs are likely to vary widely, Extensive and individual analysis likely to be impossible, *but*

The **evidence** given should demonstrate **that the broad scope is justified** regarding economic feasibility.

Some applications assessed by SEAC did not describe and justify enough economic (un)feasibility for all supply chains

# Socio-Economic Analysis (1)

## Complexity

For any AfA, the level of analytical detail should be proportionate to the relative size of costs and benefits.

For upstream AfAs, need to be proportionate also to broadness of scope and number of situations / DUs.

Consider **several partial/sectoral SEAs** to better depict the broad scope (e.g. grouping by similar reaction to non-use scenario)

Aim is to **limit uncertainty** in SEAC assessment of whether costs of non-use outweigh the risks (see "Review Period")

## Socio-Economic Analysis (2)

### **Non-use scenario**

Non-use means “non-use by DUs” and is not necessarily identical to the cessation of upstream production of the chemical.

Market and strategic considerations about whether it is possible to manufacture alternative chemicals are difficult to assess by SEAC

*Not being able to manufacture an alternative may also relate to a number of factors outside REACH (and SEAC remit)*

It is more important for SEAC to get descriptions of economic and technical links between the applicant and DUs, and justifications of the reactions of whole supply chains to the non-use scenario.

## **Socio-Economic Analysis (3)**

### **Non-use scenario / impacts**

Reactions of, and impacts on, supply chain actors and not only the applicant should be taken into account

Even if every single supply chain actor/sector cannot be fully assessed:

- explain assumptions and aggregations made
- describe differences in responses from and impacts on different sectors

Uncertainties should be described and analysed (e.g. through sensitivity analysis with different scenarios for main assumptions)



## Review period

If conclusions of the application can be agreed on by SEAC but with high uncertainty (for instance, level of detail or relevance of case studies not sufficiently convincing), it can have an impact on the review period  
=> Better transparency and **uncertainty analysis** is positive for both the applicant (possibly longer review period) and SEAC (better assessment of AfA)

Documenting variability of situations, of time needed to survey DUs, to implement RMMs in complex supply chains,... helps (RAC)/SEAC to set a relevant review period

## Main messages

SEAC methodology for upstream AfAs is the same as for DUs applications

But upstream AfAs are generally more complex (broad scope), therefore clarity and transparency, **representativeness of analysis** are **critical to reduce uncertainty**

**Specific tools / presentations** are to be considered for upstream applications (alternatives matrices, sectoral SEAs,...)

The **broad scope needs to be** reflected and **justified by the AoA and SEA** (situations where substitution is possible should not have remained within the scope)

Description of **reactions of the whole supply chains**, with particular focus on DUs **in the SEA**

# Thank you

[tomas.oberg@echa.europa.eu](mailto:tomas.oberg@echa.europa.eu)

Subscribe to our news at  
[echa.europa.eu/subscribe](http://echa.europa.eu/subscribe)

Follow us on Twitter  
[@EU\\_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook  
[Facebook.com/EUECHA](https://www.facebook.com/EUECHA)