Upstream applications from a socio-economic perspective

Specific issues from SEAC

Streamlining Applications for Authorisation
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Jean-Marc Brignon, Member of SEAC,
Prepared with the members of the AfA Task Force

Outline

What SEAC looks at when evaluating applications

Specific issues for Upstream applications

- Analysis of Alternatives
- Socio-Economic Analysis
- Review Period

Recap Main messages

What does SEAC look at when evaluating applications?

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

A. Technical feasibility (**function**), economic feasibility, availability of alternatives

B. Whether the socio-economic benefits of authorisation (avoided costs) outweigh the risks of continued use (human health impacts)

C. Review period (consideration of several criteria and overall **uncertainty**)

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**

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