



Reduction of risks as a result of the authorisation requirement and the opinion development

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A Member State view

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Role of Member States

- Decision making process: Member States vote on Commission Proposals in REACH-Committee
- Enforcement of the Commission Decissions



Basis for Decision-Making

- RAC/SEAC-Opinion is the basis for decision-making
- What Information is needed for decision-making?
 - Hazardous Properties of the Substance, Use, Tonnage
 - Risk
 - Benefit (Economic Impact)
 - Measures to reduce Risk (Conditions)
 - Alternatives
 - Uncertainties



Evaluation of Risks

- RAC evaluates environmental and health risks
- For a number of applications RAC has not enough information to conclude:
 - “Due to the uncertainties related to the representativeness...RAC considers ...”
 - “RAC also notes that there are significant uncertainties related to the representativeness of the available monitoring/ biomonitoring data...”
- Currently dialogues between RAC or SEAC and applicants often fail to remove deficiencies

Consequence: Decisions on applications are taken without adequate knowledge of risks



Observation regarding Risk Control

- In some applications for authorisation risk is higher than MS can accept
- RAC concluded several times: RMM and OC are not appropriate and effective in limiting this risk
- There is a need to impose specific risk reduction measures
- Most conditions imposed to applicants are vague:
 - ...the authorisation holder and/or the authorisation holder's downstream users ... shall conduct regular occupational exposure measurements...
 - ... the authorisation holder and his downstream users shall use the information gathered... to regularly review the effectiveness of the RMM and OC and to introduce measures...

Consequence: The level of risk remains unclear.
Enforcement is impeded.



Evaluation of Socioeconomic Benefits

- SEA: risks and benefits are standardised (converted into sums of money) and compared
- Methods for monetarisation have not been agreed on the political level
- Ethical questions involved: What is the value of health? (median value of statistical life employed is €4.1 mio)
- economic benefits have become the dominant factor in the decision-making
- risk to individuals has become almost irrelevant

Conclusion: A discussion on the approach taken by SEAC is required



Alternatives

- In some cases it is not clear for SEAC whether alternatives exist
 - “...questions nevertheless remain about the scope of alternatives considered, as well as the extent to which alternatives have had their technical infeasibility assessed...”
- Alternatives are only discussed from the perspective of the applicant (technical and economical feasibility)

Conclusion:

- A more rigorous examination of alternatives is required
- Alternatives not feasible for the applicant but available on the market should be taken into account



Is authorisation reducing the Risk from SVHC?

- Very difficult to know
- An answer is only possible if we exactly know the risks (before and after)
- Examples for possible indicators of risk reduction:
 - Uses without AfAs (possibly by tonnages, uses not longer supported, questionnaires to industry, interviews with top-executives, etc.)
 - RMM / OC that are more stringent than those before authorisation
 - Risk Assessment of Applicants (Comparison of application and review report)
 - Monitoring of exposure trends (HBM, environmental monitoring, product analysis, etc.)