

Analysis of Alternatives: objectives, approach and content

Seminar on applications for authorisation
- ECHA

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Content

- General considerations for substitution
- Analysis of alternatives: purpose, scope and content
- Key messages

General considerations for substitution



Substitution – an important objective of the REACH system

- REACH is setting an objective:
 - A progressive replacement of SVHCs by suitable alternatives substances or technologies which are less dangerous and suitable technically and economically
- Suitable alternatives may not be readily available but efforts to consider a substitution are mandatory for all applicants (both adequate control and SEA route) :
 - Applicants need to analyse alternatives, report on ongoing and planned R&D
 - Authorisations will be periodically reviewed and monitored
- Transparency! Most of your analysis will be made public

Instruments in planning for substitution

REACH requires each application to include:

- Analysis of alternatives considering their risks and the technical and economic feasibility of substitution, including information about any relevant R&D activities by the applicant
- If available alternatives identified (adequate control route) → Substitution plan including a timetable for proposed actions by the applicant

Analysis of alternatives: purpose, scope and content



Analysis of alternatives – purpose and scope (1/2)

- Purpose: to help to determine if there are any suitable alternative substances or technologies
- What would you do if you can no longer use the Annex XIV substance? What would be your alternative(s)?
- Applicant's perspective + additional/broader information (e.g. from third parties)
- Scope and level of details difficult to decide and case-specific
 - depends on complexity of the uses, number of potentially competing substances/technologies, available information on alternatives, if the alternative is obviously not suitable, etc.

Analysis of alternatives – purpose and scope (2/2)

- Strong link with SEA: at a broader scale, what would be the socio-economic consequences (costs and benefits) of the alternatives
- SEA and analysis of alternatives feed each other: to be performed in parallel and in an iterative way
 - also helps in scoping both analysis and can avoid going into unnecessary details (e.g. SEA concluding that an alternative is not feasible on a broader socio-economic point of view)

Analysis of alternatives template

- List of possible alternatives
- Description of efforts made to identify possible alternatives
- Research and development
- Data searches
- Consultations
- Alternative 1: Substance ID and properties/Description of technique
 - Technical feasibility
 - Economic feasibility
 - Availability
- Reduction in overall risk

Socio-economic analysis template

- Definition of "applied for use" scenario
- Definition of "non-use" scenario
- Human health and environmental impacts
- Economic impacts
- Social impacts
- Wider economic impacts
- Comparison of impacts
- Distributional impacts
- Uncertainty analysis

Analysis of alternatives – steps

- Identifying possible alternatives for each “use applied for”
- Assessing the suitability and availability of possible alternatives, on the basis of:
 - their technical and economic feasibility,
 - reduction in risk to the environment and to human health, and
 - their availability
- Identifying relevant R&D that is appropriate to the analysis
- Determining actions and timescales that may be required to make possible alternatives suitable and available for the applicant

Analysis of alternatives

– identification of possible alternatives

- What is an alternative?

Substance or technology which can either:

- possibly replace the Annex XIV substance in the **function** it performs
- or**
- by making this function unnecessary

- How to identify possible alternatives?

- understand the precise function performed by the substance
- understand the process where the substance is involved
- look for other ways of performing that function or making it unnecessary
- consultation on alternatives within and outside the supply chain

Assessing suitability of alternatives – technical feasibility

- Determine on which basis the alternative is fulfilling or replacing the function of the Annex XIV substance
- Assess the alternatives regarding the required technical criteria (performance, quality, safety, regulatory, etc.)
- Define the scope of process adaptations needed for the alternative to perform or replace the desired function

Assessing suitability of alternatives – economic feasibility

- Focus: changes in applicant's costs and revenues
- Scope of the analysis: to be considered throughout your supply chain since it might affect your own profitability
- The models and level of details to be used are up to you. In any case, explain the methodology, data and assumptions used in details
- SEA guidance provides practical information on how to estimate economic feasibility in the analysis of alternatives
- Key: to demonstrate that your assessment of costs of alternatives is sound, based on realistic assumptions and that these costs are not overestimated. Your analysis will be scrutinised!

Assessing suitability of alternatives – comparative assessment of risks

- Alternative suitable if overall risks to human health and the environment is reduced compared to the remaining risks of the Annex XIV substance
- Consider the appropriateness and effectiveness of risk management measures
- Adopt a stepwise and flexible approach in the assessment, starting with information on hazard and possibly ending in the assessment of the risks
- Focus comparison on the risk related to the Annex XIV endpoint. All other risks are additional risks to be compared in one way or another to the ones of the Annex XIV substance

Assessing availability of alternatives

- 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. Alternatives may not be available immediately or they may not be available in the required quantities but could become available in the market at some point in the future
- The “sunset date” is the reference: if the substitution is possible before the sunset date, the alternative considered available

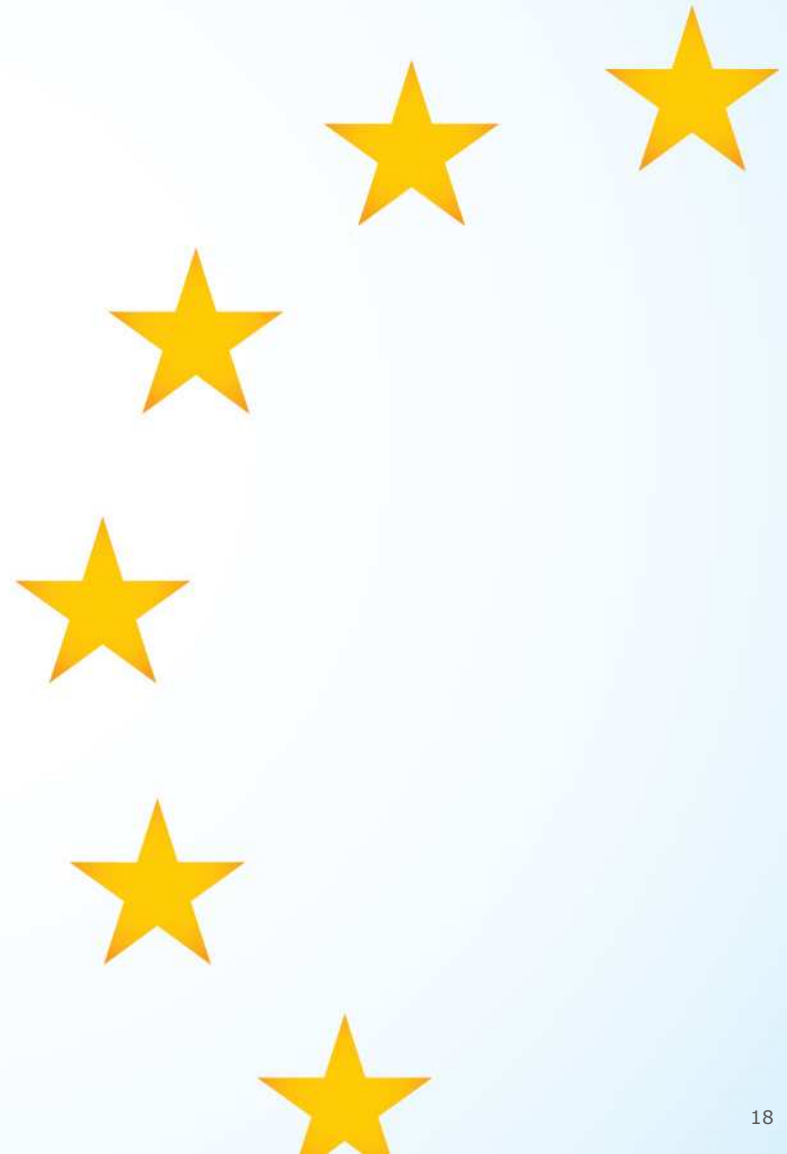
Concluding on the suitability and availability of alternatives (1/2)

- If the conclusion is that there are suitable alternatives, the applicant has to present the Substitution plan (proposed actions and timelines, influencing factors and monitoring; cfr. Guidance)
- If the applicant concludes that there are no suitable alternatives
 - robust documentation!
 - if alternative not yet ready for substitution:
 - an explanation of actions (R&D activities) that would be required, including the time-lines, to switch to an alternative substance/technology

Concluding on the suitability and availability of alternatives (2/2)

- “No suitable alternatives” is only a pre-condition for being granted an authorisation (under the SEA route). You still have to demonstrate that the benefits outweigh the risks!
- Your analysis will be peer-reviewed...

Key messages



Key messages

- What would you do if you can no longer use the Annex XIV substance? What would be your alternative(s)?
- Make a good analysis!
- Assess the technical and economic feasibility first
- Ensure that your evaluation of costs is adequately performed
- Your analysis will be subject to scrutiny

Thank you