Planning for substitution
Analysis of alternatives and the Substitution plan

Sebastian Gil
European Commission – DG Environment

Seminar on Application for Authorisation
12 April 2011, Helsinki

EUROPEAN COMMISSION

environment

Contents

- Substitution – an important objective of the REACH system
- Progressive replacement – a couple of considerations
- Instruments in planning for substitution
- Analysis of alternatives – step by step
- Planning the substitution
- Third parties
- The authorisation decision
- Recommendations

EUROPEAN COMMISSION

environment

Substitution
– an important objective of the REACH system

- REACH is setting an objective:
  A progressive replacement of substances of very high concern by suitable alternatives
  (Recitals 12 and 70; Article 55)

- NB: **without prejudices to the workers protection legislation,** which requires substitution of dangerous substances if safer alternatives exists (Recital 12)

EUROPEAN COMMISSION

environment

Progressive replacement – a couple of considerations

- A background temporal goal:
  The EU is aiming to achieve that, **by 2020,** chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment – 2002 World Summit on sustainable development (Recital 4)
- **Suitable alternatives may not be readily available:**
  While the objective is to phase out SVHCs, a replacement should be substances or technologies, which are less dangerous and suitable technically and economically (Recital 12; Article 55)
- **Efforts to consider a substitution is mandatory** for all applicants for authorisation (Recital 74). Applicants need to analyse alternatives, report on ongoing and planned R&D. Authorisations will be periodically **reviewed and monitored** (Recital 72; Article 61.2).

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 and including, if appropriate information about any relevant research and development activities by the applicant.
- **Substitution plan** including a timetable for proposed actions by the applicant, where the analysis shows that suitable alternatives are available.

(REACH Article 62.4)

EUROPEAN COMMISSION

environment

Analysis of alternatives – purpose and scope

- Purpose: to help determine if there are any suitable alternative substances or technologies
- Suitability and availability of alternatives:
  - risks from alternatives
  - technical feasibility of substitution
  - economic feasibility of substitution
- Robustness of the analysis: applicant's perspective vs. additional information
- Link with SEA - socio-economic consequences of substitution: what would be societal costs and benefits if suitable/unsuitable alternative would have been implemented (risks, technical and economic impacts)

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 accessibility
- 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?
  Possible replacement for an Annex XIV substance in the **function** that substance performs or making this function redundant
- How to identify possible alternatives?
  - understand the precise function performed by the substance
  - understand the process the substance is involved
  - look for other ways of performing that function
  - consultation on alternatives within and outside the supply chain
- NB. Some work might have already been done, e.g. the Carcinogens Directive

Assessing suitability of alternatives – comparative assessment of risks

- Alternative suitable if overall risks to human health and the environment reduced
- Consideration of the appropriateness and effectiveness of risk management measures that control risks
- Steps in comparing risks from alternative substances and the Annex XIV substance:
  - comparing hazard profiles
  - examining exposure levels and emissions (incl. modelling)
  - determining if alternatives would result in a lower level of risk
  - if appropriate, quantifying and valuing the change in risk (SEA)

EUROPEAN COMMISSION

environment

Assessing suitability of alternatives – technical feasibility

- Technical feasibility of an alternative is determined on the basis of the alternative fulfilling or replacing the function of the Annex XIV substance
- Highly dependent on the possibility of the process adaptations and changes that may need to be put in place in order for the alternative to perform or replace the desired function
- Documentation:
  - helpful to set technical feasibility criteria (c.f. Guidance)
  - document required changes in processes, equipment etc.

Assessing suitability of alternatives – economic feasibility

- Focus: changes in applicant's costs and revenues including possible pass-through of cost to customers
- One possible criterion: the net present value (NPV) of the revenues minus costs is positive (operations remain profitable)
- Other methods possible but should be explained in detail
- SEA guidance provides practical information on how to estimate economic feasibility in the analysis of alternatives
- Boundaries: analysis' perspective (e.g. supplier vs. downstream user)

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)
  - fulfil the relevant 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”: if the substitution is possible before the sunset date, the alternative considered available

Concluding on suitability and availability of alternatives

- The analysis of alternatives is the process of determining the suitability of the alternative and consideration of its availability
- If the conclusion is that there are suitable alternatives, the applicant has to present the Substitution plan
- If the applicant concludes that there are no suitable alternatives
  - robust documentation; recommended information on R&D
  - if alternative not yet ready for substitution, an explanation of actions that would be required, as well as the time-lines, to switch to an alternative substance/technology

Planning the substitution

- The substitution is the **ultimate objective** of the authorisation process, regardless whether the 'adequate control' or the 'socio-economic‘ route
- Legal text unclear: impossible to achieve the aim of co-legislators of having the substitution plan under both authorisation routes
- The Commission decided to propose to amend the basic REACH legal text in order to reflect this requirement for both routes
- In meantime: Guidance provides for the Substitution plan only under the adequate control route and under the socio-economic route requires information on the efforts undertaken by the applicant towards substitution (actions and time-lines), and by linking that information with the length of review period

Planning the substitution – R &D

- R&D, if appropriate, should be part of the analysis of alternatives
- R&D documents applicant's efforts towards the substitution:
  - search for alternatives
  - generating data on risks/ feasibility of identified alternatives
  - test trials by the applicant, his suppliers or downstream users
- May justify the applicant's conclusion on non-suitability or unavailability
- Applicant's plans to initiate new R&D may play a critical role in fixing the review period. Absence of R&D activities should lead to fixing shorter review periods

Planning the substitution – Actions to make alternatives suitable and available

- Actions that would be required, as well as the time-lines, to switch to an alternative substance/technology – crucial for the length of the review period (where no Substitution plan)
- Examples of situations where actions to make alternatives suitable and available should be presented:

  • investments that take considerable time
  • approval or a review of a permit
  • customer approval
  • need to increase the production volume of an alternative
  • investment in new equipment/techniques dependant on other planned investments, age of the current equipment, etc.

EUROPEAN COMMISSION

environment

Planning the substitution – the Substitution plan

- Compulsory if the applicant concluded in the analysis of alternatives that substitution by suitable alternatives is feasible
- Commitment to take actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable
- Will be used by ECHA Cttees and the Commission in the opinion/decision process: duration of the review period
- Scope and contents:
  - description of proposed actions with justification
  - who will conduct the proposed actions
  - timetable for proposed actions with justification
  - uncertainties and possible mitigation
- NB. different alternatives may suit different uses: multiple SPs

Third parties

- Third parties: e.g. suppliers of alternatives, academics, innovators, NGOs, Trade Unions, (inter)governmental agencies, downstream users
- Information about alternative substances and technologies and other contributions (e.g. considerations beyond the suitability of an alternative for the applicant – societal perspective)
- Will be taken into account in the assessment of suitability and availability of alternatives and establishing the review period
- Specific time windows for submissions (but may still submit relevant information to ECHA following the granting of an authorisation):

ECHA / Commission	Third party
Notice that Annex XV dossier has been prepared placed on ECHA website (Article 59(4))	Comments invited from interested parties within specified time period (Article 59(4))
Substance placed on candidate list, recommendations for priority substances published on ECHA's website (Article 59(10))	Comments invited from interested parties, in particular on uses that should be exempted within 3 month time period (Article 58(4))
Substance placed on Annex XIV, applicant applies for authorisation, ECHA publishes information on broad uses on website (Article 64(2))	Information on alternatives invited from third parties within a specified time period (Article 64(2))
ECHA may request further information from third parties (Article 64(3))	Interested parties may still provide information on alternatives to ECHA (Article 61(2))
Granting of authorisation (Article 60)	
Review of authorisation (Article 61)	Comments invited from interested parties (Article 61, 64(2))

EUROPEAN COMMISSION

environment

Authorisation decision – criteria

- Authorisations are granted by the Commission on two bases:
  - adequate control of risks, or
  - risks outweighed by the socioeconomic benefits and absence of suitable alternatives
- Adequate control:
  exposures from uses don't exceed appropriate DNELs taking into account the appropriateness and effectiveness of risk management measures
- Socio-economic balance:
  - costs/benefits to the society
  - costs linked with health and environmental risks lower than costs of not-authorising (e.g. products' quality; availability of function/service; market distortion etc.)

Authorisation decision – criteria (cont.)

- Suitability and availability of alternatives:
  "all relevant aspects, including reduction in overall risk and technical and economic feasibility of alternatives for the applicant" (consider: information on alternatives from interested third parties; availability within "sunset date")
- To support eventual substitution - authorisations will be subject to time-limited reviews (determined case-by-case) and conditions, including monitoring

Recommendations (1)

- Be specific in the assessment of the suitability and availability of alternatives. Make the documentation clear and transparent: for each part of the analysis present the information used, including data/information gaps and assumptions made, as well as provide explanations and justifications for the conclusions made
- Consider all possible alternatives, both substances and technologies, including alternatives not being products from the applicant's own portfolio (e.g. where the applicant is a M/I). An incomplete analysis of alternatives may lead ECHA to question the accuracy of such an analysis, e.g. when received well-documented information that suitable alternatives exist

Recommendations (2)

- Include information about relevant R&D activities. While not mandatory, it will be a critical factor for fixing the review period, in particular in cases where the analysis of alternatives concludes that there are no suitable alternatives
- Provide information on what would be required to make possible alternatives suitable and available within an estimated timescale. If no information is provided, the review period would be short, as it would be necessary to assess whether there have been any changes
- Keep in mind the objective: **progressive** replacement by **suitable** (safer + technically and economically viable) alternatives

Thank you!

http://ec.europa.eu/environment/chemicals/index.htm

http://ec.europa.eu/enterprise/sectors/chemicals/index_en.htm

EUROPEAN COMMISSION

environment