Authorisation - update

REACH IMPLEMENTATION WORKSHOP XI

19 June 2012
Sheraton Brussels Airport Hotel

cefic

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Scope of presentation

Industry experiences to date: an update:

1. Single applicants and substitution in mixtures
2. Preparing an Application for Authorization for a substance with no registration

Some numbers: companies and authorisation

Have you considered your short-term and long-term exposure risk

As an example, there is a company with:

- Substances on Candidate List 13/73
- Substances listed in Annex XIV 4/14

- CMR substances registered 30/406

Single applicant and substitution in mixtures

- Limited issues with Competition Law Compliance
- Substitution in mixtures, articles
  - Example: mixture contains 5 substances
    - 2 substances already in Annex XIV; different sunset days
    - 2 on Candidate List with potential to be prioritized
  - Can substitute one with problems
  - Another one with colossal problems
  - But the rest?
  - How to describe this in Analysis of Alternatives?

Preparing an Application for Authorization for a substance with NO registration

- Substance found pre-registered but not (yet) registered on ECHA website
- Company did not pre-register (manufacture less than 1 ton per year) = no access to the pre-SIEF on ECHA website
  - How to contact potential applicants?
    - No entry in ESIS, not HPVC substance

- No CSR, ES ⇨ make a dossier first?
  - Prepare Analysis of Alternatives simultaneously?
    - Risk of changes in uses applied for in later stage

Conclusion

- For a single applicant, challenges need to be faced/decided on alone.
- Essential to have the best possible consultant/s
- For non-(pre-)registered substances, considerable challenges

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Linda-Jean Cockcroft

Chairperson: DEHP Authorisation Task Force

Scope of presentation

Industry experiences to date: an update:

1. Communicating: the expectations of authorisation
2. Socio-economic analysis – the requirements
3. Socio-economic analysis – early industry experience
4. What's new in authorisation
5. Conclusion

Communication and expectations

- Authorisation – the Regulation
- Who expects what?
  There are many stakeholders and decision makers
- What does this mean for industry?

Remember: Each AfA* is unique!

*Application for Authorisation

Authorisation: the Regulation

REACH Art. 55:The aim of authorisation is to

"*ensure the good functioning of the internal market while assuring that the risks from substances of very high concern (SVHC) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable*."

Communication – far REACHing implications

Candidate list and Annex XIV

- " The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for **eventual** inclusion in Annex XIV. (59.1)"

Authorisation application routes

Route: ADEQUATE CONTROL		SOCIO-ECONOMIC
Adequate control & No suitable alternative	**Adequate control** & Suitable alternative	**Socio-economic benefits > risks** (No adequate control & No suitable alternative)
Applicable for:		
Threshold substances	**Threshold substances**	**Threshold and Non-threshold substances**
Application content		
CSR **Analysis of Alternatives** **SEA** **Substance/ Applicant info**	**CSR** **Analysis of Alternatives** ***Substitution Plan*** **SEA** **Substance/Applicant info**	**CSR** **Analysis of Alternatives** **SEA** **Substance/ Applicant info**

Socio-economics: the requirements

Regulatory requirements for SEA

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

Authorisation & Socio-Economic Analysis

1. The Commission shall grant an authorisation if:
   risks are adequately controlled –
   “adequate control route”
2. **Authorisation ‘question’:** Do the lower costs of continuing use of the substance justify the higher risks?
   (Note: for adequate control route, risks of continuing use are ‘minimal’)
3. What will be the impact on my business if the substance can no longer be used in the EU?

Authorisation & SEA* (2)

4. Authorisation is more likely when costs of the alternatives are higher and/or current risks are more controlled - Authorisation more likely when the case is clearer – a stronger case is likely to be a simpler one

5. A strong case for authorisation probably means an easier application; the more marginal the case becomes, the more resources, time, analysis etc the application will need

*Socio-Economic Analysis

Authorisation & SEA (3)

6. It is in the applicants' interest to make a thorough application - well documented, clear and transparent
7. You might find that the costs of alternatives exceed the current risk:
   You have a case for authorisation
   And you have the analysis you need for your application
   And if you have done your analysis right, RAC and SEAC should agree with your assessment

BUT, it's not quite as simple as that...

SEA - some early industry experience

What route to take and scope?

- Adequate control route: Is there agreement on a threshold? Is SEA *de facto* mandatory?
- SEA route: How broad should the assessment be? How 'strong' does the justification need to be?

Analysis of alternatives

- Technical feasibility – what is an acceptable loss in functionality?
- Economic feasibility – what is an *acceptable* cost to a company?
- How do you provide convincing arguments on the availability of alternatives?

Lack of Clarity

How to prepare arguments in a manner that is convincing?

- Non-technical vs. technical
- Reasoned arguments vs. opinions
- Theoretically correct vs pragmatic

Best or most convincing approaches?

- SEAC still discussing approach to assessing economic feasibility
- How much detail? Simple explanation? Full explanation?

What is the minimum needed for a sound SEA:

- Scenarios considered, data sets, qualitative vs quantitative information, generic data vs company specific?

How will issues concerning global competitiveness, off-shoring and shift of risks, etc. really be taken into account?

SEA – Initial industry perspectives

- Hazard, risk, impact – speaking the same language

  Logic Framework

- Cost benefit analysis and SEA

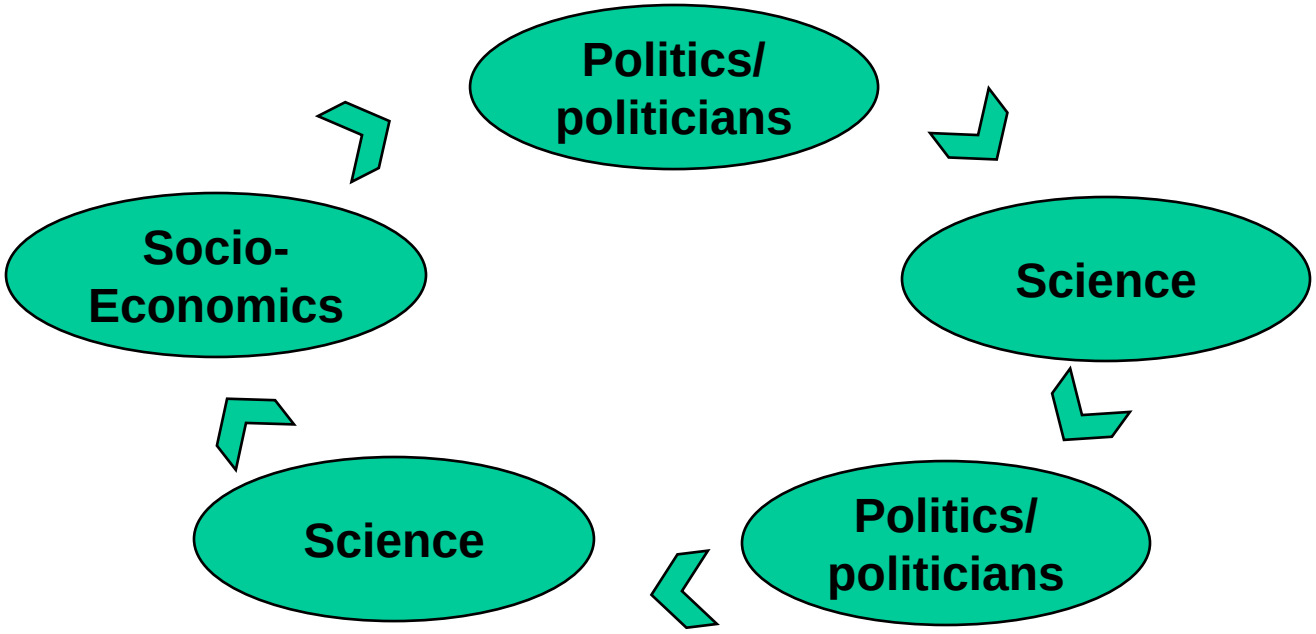
- Analysis of alternatives:
  Strategic assessment of choice

SEA – Initial industry perspectives

Economic and technical feasibility:

- REACH and SEA guideline requires SEAC to consider the economic and technical feasibility of alternatives
- Technical feasibility - properties, functionality
- Economic feasibility – still being defined
- Technical and Economic feasibility will differ depending on the company and on the application

What's new in authorisation?



Conclusion:

the intricacies of an extensive process:

- Authorisation was the most debated part of the REACH Regulation during the second reading in the European Parliament in 2006. Several years later**, *it is becoming clear what an extensive process this really is*.**

Cefic's position

- Applicants must be assured of the possibility to obtain an authorisation for substances where ***adequate control*** is demonstrated. Cefic will monitor developments closely to ensure that the possibilities as stated in the legal text are respected.

- For substances where there is no agreed-upon no concern level (i.e., threshold), the only way to obtain an authorisation is to demonstrate benefits to society outweighs the risks to human health or the environment ***on the basis of socio-economic factors*****.** If this is not assessed correctly and objectively, industry may find itself in a situation where hardly any authorisations will be granted.

Cefic's conclusion

The process is

entirely new

for industry and for regulators,

and

difficulties in the analysis of alternatives and substitution plans are to be expected for the first substances that will go through the process.

Authorisation – Future Vistas?

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Steve Williams , BP -

Cefic Authorisation/Restriction Platform

Authorisation – Future Vistas?

- Background
- History – not to be forgotten
- A Regulatory Perspective & Issues
- What does success look like?

Authorisation – Future Vistas?

- Authorisation is designed to be an integral part of REACH Regulation.
- REACH is predicated on the objective assessment of data
- Historical Chemicals Myths – e.g.,
  - Chemicals were unregulated before REACH
  - All chemicals were perfectly regulated before REACH

Existing Substances Regulation - Conclusions Statements

- *"**.....**no need for risk reduction measures beyond those which are being applied already*."
- "….. risk reduction measures which are already being applied shall be taken into account."
- TODAY Risk Reduction measures already being applied include :
  - Compliance with OCs/RMMs in REACH Exposure Scenario
  - Other regulatory controls in addition to REACH e.g., Chemical Agents Directive, Carcinogens Directive, Food Contact Materials Regulations etc,
- The selection of substances for inclusion to Annex XIV can be well-informed by post REACH-registration data

A New Experience – we are all learning by doing

- This is a novel regulatory process
- Ideally with a new process, progress should be steady with time for reflection and refinement
- Initial Risk Management Option (RMO) assessment, based on current data and current understanding of the place of a substance in the EU economy, could deliver major benefits in terms of effectiveness and efficiency
- Substitution may seem theoretically possible but may not be an option in particular circumstances

Authorisation Efficiency

- All resources are limited, so effective and efficient use will facilitate the best possible progress
- “If it ain’t broke don’t fix it”
- Based on a Risk Management Options assessment, decide if restriction or another measure is a more appropriate option
- Annex XIV listing should follow an appropriately detailed review, based on up-to-date data
- It is possible to conclude that a candidate list substance does NOT warrant Authorisation

Some industry issues

- Some emerging issues
  - Non-intermediate process chemicals with strict levels of containment and lack of exposure might be adequately controlled or better suited to a different RMO
  - Registered threshold substances are already demonstrably controlled by REACH registration. The success of this new measure should be considered before proposing Authorisation or another appropriate RMO

Further comments

Existing legislation covers:

- Cat 1CMRs which should not be in consumer mixture due to Restrictions
- Articles – REACH provides some controls on articles

Special considerations:

- Special cases

Industry progress and data:

- Initiatives to eliminate/ reduce use of substances of concern has already happened in many cases
- Past work done and evidence that no realistic alternative exists should be taken into account

Authorisation : What does Success Look Like ?

- Authorisation should be a tool of last resort to manage aspects that cannot be managed by any other or more appropriate RMOs
- Effective authorisation needs effective enforcement
- Industry must be prepared with detailed knowledge down and *BEYOND* its own supply chain

Authorisation : What does Success Look Like ?

- REACH is a powerful regulatory tool.

- Use of authorisation should be carefully considered against other RMOs to avoid unintended consequences. Otherwise, “inappropriate” use of Authorisation could be seen as undermining the strengths and spirit of REACH