Getting started with Authorisation

REACH IMPLEMENTATION WORKSHOP X

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cefic

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Scope of presentation

From an industry perspective

- **The Regulation**
- **Getting started**
- **Key issues**
- **Use descriptors**
- **Communication and authorisation**

Authorisation under REACH

The Regulation on authorisation:

- **The objective**
- **Routes for applying for authorisation**
- **Application options**

The aim of authorisation

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*."

General principle: unless an authorisation has been granted, a substance subject to authorisation may not be used or placed on the EU market after the « sunset date » specified for that substance.

Authorisation: the Regulation

Authorisation is a *new regime* created by REACH.

1. **TITLE VII – AUTHORISATION (Articles 55 to 66)**
2. **Guidances:**
   - Guidance on the preparation of an application for authorisation
   - Guidance on the preparation of socio-economic analysis as part of an application for authorisation
   - DSM 22: How to Prepare and Submit an Application for Authorisation using IUCLID 5
   - **How to develop the description of uses in the context of Authorisation**
3. **Formats for assessment reports and supporting documents:**
   - Templates, tables, forms, recommendations

Application routes

Route			
	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**

From an SEA perspective

Required /highly recommended where

- No demonstrable adequate control and no suitable alternatives (substances and/or technologies)
  - Need to demonstrate *socio-economic benefits >risks*

- *Adequate control route:* to support the analysis of alternatives where there are *no alternatives**

- *Adequate control route*, where there are *suitable alternatives*
  - To support the substitution plan*

- To support review period argumentation
  - Impact on review period, conditions and monitoring arrangements

Getting started with authorisation

Getting started from the corporate perspective:

1. Strategy and objectives
   - use/s; route;
   - alone or in group
2. Budget
3. Timing
4. Teaming
5. Business risk management
6. Resources
7. Dealing with uncertainty

Learning by doing

Getting started - from a substance perspective

- Cold start
  - Nothing known about other potential applicants
- Top gear
  - Proactive

Consortium approach

- Select the Contractor(s) to handle the full process with care
- Authorisation is a very different process to registration, a wider skill set is required.
- Be realistic on costs and time required, it is an expensive process
- Finalising contractual agreements is a time-consuming process, start early.
- Strong leadership by the lead applicant is essential.
- Authorisation requires reasoned arguments and justifications rather than box ticking and data provision.
- It is a political as well as a technical process, and it is still developing

Some current key issues

- Making information in the authorisation application public
  - **Making public** information in authorisation applications
    - Public consultation on alternatives
    - ECHA RAC and SEAC opinions
    - Commission decisions
  - **ATDs** [Access To Documents]
- Uses
  - Broad information on Uses [BiU] – defined by/with ECHA
  - Developing a description of uses in the context of Authorisation

Developing your use description for your authorisation application

- Article 62(4)(c): “a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;”

- “Given that authorisation will be granted for a specific use, its **sufficiently detailed description** can be considered as one of the **key elements** of the authorisation process.”

Communication and authorisation

- Registration and uses
- Authorisation and uses
- Communicating on authorisation

Using the same language

- “If you put an ecotoxicologist and economist in the same room it is unlikely that they will speak the same language.”

- “... socio-economic analysis needs to bring together risk assessment and economic considerations. This requires that ecologists and economists, scientists and regulators understand each other's needs and languages.”

Decision-making

- The politics
- The processes
- The people

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

- The possibility must remain of obtaining an authorisation for substances where *adequate control* can be ensured. Cefic will monitor developments closely to ensure that the possibilities offered by the legal text are respected.

- The only way to obtain an authorisation if no concentration without a concern can be defined is to demonstrate that there are more benefits to society than disadvantages to human health or environment *on the basis of socio-economic factors*. ***If this is not handled correctly, 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.

Thank you