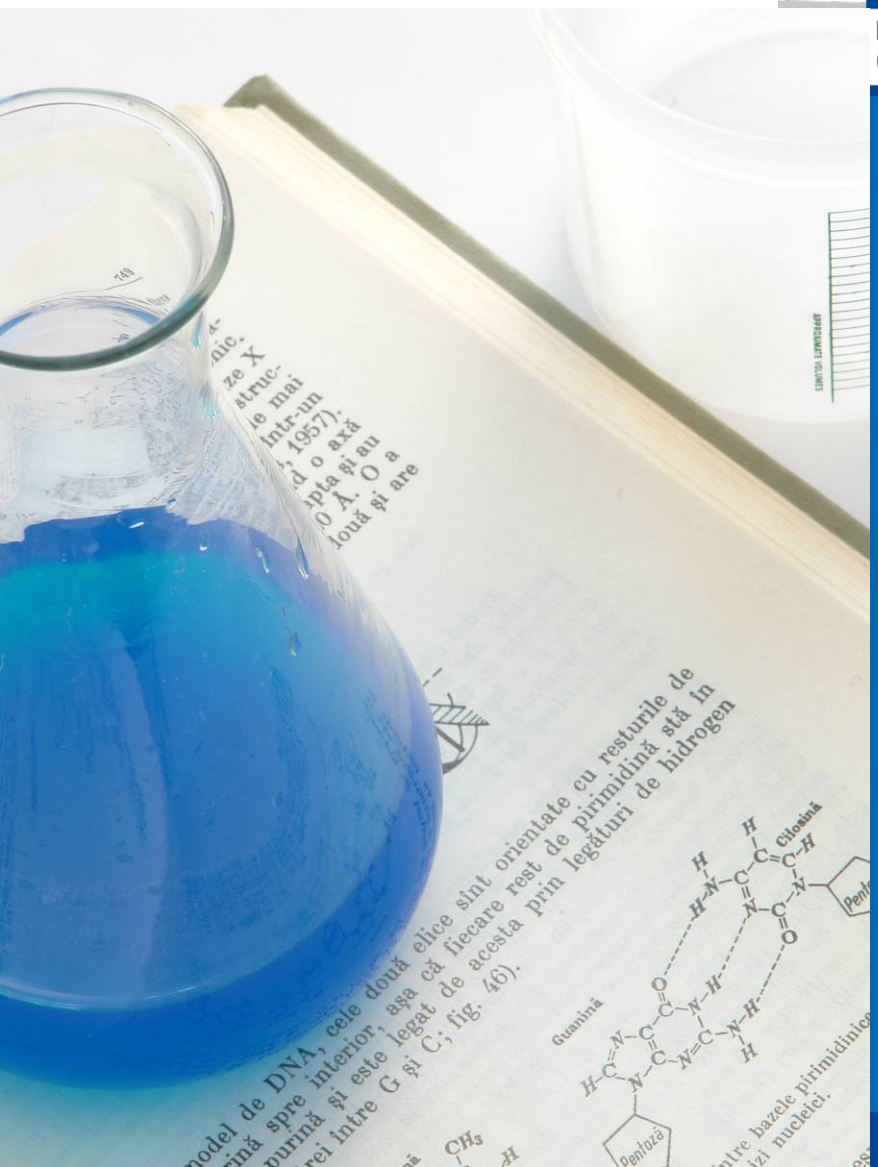

European Commission

How to be successful in REACH authorisation

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Why is a discussion of authorisation topical?

- Authorisation is a new concept in chemical legislation
- We are at the beginning of the learning curve
- Only a few applications have been processed

Issues at stake

- Industry views:
  - Complex and costly procedure
  - Lack of legal certainty with negative consequences on long-term investments
  - Authorisation does not apply to substances present in imported articles
  - Sometimes disproportionate (needed even for 1 kg/year).
  - Socio-economic aspects only taken at the very end of the process (authorisation application)

- Public authorities views:
  - Authorisation has advantages over other regulatory routes: fewer resource needs for authorisation

Background on authorisation

- Aims – Article 55 of REACH:
  - Internal market
  - Control of risks from substances of very high concern (SVHC)
  - Replacement by suitable alternatives where technically and economically viable
- Basic principles:
  - Authorisation is based on control of risk: the risks posed by the use of a SVHC are assessed by RAC
  - The applicant should demonstrate that the risk is adequately controlled or that the socio-economic benefits outweigh the risks arising from the use of the substance – to be reviewed by SEAC
  - Commission takes a final decision

How to approach authorisation

- Industry to develop a strategic approach to deal with SVHCs
- Where viable, substitution of SVHC through innovation
- Where authorisation is required, industry to prepare convincing application dossiers and ensure respect of risk management and operational conditions – good communication in the supply chain is essential to prepare successful authorisation dossiers at the right level of detail

Applications for authorisation

- Who can apply for authorisation
  - Manufacturers, importers or only representatives (OR)
  - Formulators
  - Downstream users
  - Any combination of the above
- What can be applied for
  - (Group of) substances
  - Their own use(s)
  - Their customers' use(s)
  - Any combination of the above

Applications for authorisation

- What does an application contain
  - Description of the use(s) applied for
  - Chemical Safety Report
  - Analysis of alternatives and socio economic analysis

- REMEMBER: Every actor in the supply chain has to be "covered" – communication in the supply chain is key

- IMPORTANT
  - Use description is essential
    - Too broad: difficulties for RAC and SEAC to assess whether risk is controlled, the alternative analysis and the socio-economic costs ⇒ final decision could include restrictive conditions or a short review period
    - Too specific: many applications for authorisation, higher costs, slightly different uses not covered
  - Make use of available support from ECHA

Feedback on the experiences

Applying for authorisation has improved the way companies manage chemicals

In many cases manufacturers and downstream users applied separately

- Sometimes even for the same use
- Competition law (antitrust risk), CBI and ease of communication (no coordination needed) may explain this
- Going separate did not necessarily resolve all of the above
- Application fee seemed not to be a driver

Some hiccups as the system is new

Opinion making pretty efficient already (average about 6 instead of maximum of 10 months)

Feedback on the experiences

Public consultations on alternatives have overall worked well in terms of both quantity and quality

Sometimes Committees spent much time on a specific issue

- Documentation in applications not always clear
- New, unexpected issues

Committee members and ECHA staff are learning fast

ECHA reacted: Version 3.0 of application formats issued

- Has improved the clarity and transparency of documentation
- ECHA has also combined the formats of the Analysis of Alternatives and Socio-economic analysis to help applicants to document their case

While deficiencies, overall applicants have done a good job

- given also that they are shooting partly in the dark

Feedback on the experiences

Trialogues and communication with applicants and even competitors have been very good

Applications for authorisation

- Extensive support to applicants available from ECHA
  - Guidance Documents and user manuals
  - Formats for application
  - Instructions for submitting the documents
  - Pre-submission information sessions (PSIS)
  - Seminars, webinars & workshops
  - Updated "Questions & Answers" section
  - ECHA Helpdesk

    http://echa.europa.eu/contact/helpdesk-contact-form
  - Partner Service: find who to collaborate with (to prepare an application or to share experiences)

    http://echa.europa.eu/web/guest/applying-for-authorisation/partners-service-for-applicants

Recent policy developments

- First authorisation decision for a substance in Annex XIV – August 2014
- Positive vote on a second authorisation decision - October 2014
- Several more on the pipeline
- Selection of substances: roadmap to identify all relevant SVHCs by 2020
  - Increased predictability for the identification of substances and decision on relevant EU level risk management measures
  - Process based on Risk Management Option Analysis (RMOA)
  - Transparency on substances selected for RMOA

  http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern
    - stakeholders can now submit contributions to the authorities conducting RMOAs
    - Some authorities organise public consultations on RMOAs (FR, DE)

Recent policy developments

- Socio-economic elements considered at the RMOA stage
  - in some cases, quite extensively (Ni RMOA)
  - not all MSCAs consider them relevant

- ECHA Public consultation on 6th recommendation to include substances in Annex XIV
  - Commission is asking for information on costs and benefits of adding substances to Annex XIV
  - This information will not be considered by ECHA for the recommendation, but by the Commission and REACH committee before inclusion in Annex XIV

Commission proposals to improve the authorisation process

- Objectives
  - Reduce uncertainty on the outcome
  - Reduce workload for applicants and for the Committees
  - Find solutions for cases where authorisation procedure appears to be disproportionate compared to the expected benefits
- Further improvements for the authorisation process
  - For all cases: clarify what is the appropriate level of information required for an authorisation dossier
  - For specific cases: simplified requirements to be defined in an implementing regulation
    - Simplified CSR, SEA & Analysis of alternatives
    - Simplified procedure for ECHA committees
    - Significant reduction of application costs

Possible cases for simplified authorisation

- Low volumes (below 10 and 100 kg)
- Essential elements for biological processes
- Spare parts
- Final products subject to type approval/authorisation
- Use with clear, very high socio-economic value (i.e. medicines, in-vitro diagnostic systems, ..)

Discussion is currently on-going in CARACAL and in ad-hoc authorisation Task Force

Key messages for companies

- Networking(industry association, chambers of commerce, etc.)
- Consolidate links in supply chains
- Keep an eye on substances on which RMOA has been initiated on ECHA website …
- … and on ECHA public consultations.
- Make sure that registration dossier is complete (include all relevant downstream uses)
- Make use of the available support

Other key messages

1. Start early
   - ✓Read and understand the guidance!
2. Communicate with your key customers and suppliers
   - ✓use “Partner’s service”
3. Learn from concrete examples of applications
   - ✓Check ECHA’s website now
4. Own your application: it is a business decision
5. Don’t overdo it:
   - ✓For instance, no hazard data if reference DNEL or dose-response used
6. Participate in ECHA’s (free) workshops, request PSIS
7. Contribute to the public consultations on alternatives
8. Ask, suggest

For further information please visit:

http://ec.europa.eu/enterprise/reach/index_en.htm

http://ec.europa.eu/comm/environment/chemicals/reach.htm

http://echa.europa.eu

Thank you

Any questions?

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