



Introduction to Authorisation and Restriction
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Content



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- **Cefic Authorisation and Restrictions Platform**
 - **Chemicals Risk Management tools**
 - **Restrictions – some observations**
 - **Authorisation – some observations**
 - **Conclusions**

Cefic Authorisation and Restriction Platform



- **Cefic working group set up in 2008**
- **About 35 members**
 - **Companies, National Industry Associations, Sector Groups**
- **Scope**
 - **Regulatory processes including guidances, format, templates etc...**
 - **Input towards RAC/SEAC/MSC and MSCAs on Annex XV developments**
 - **Horizontal aspects i.e alerting, raising awareness, and developing information tools**
- **Interface with Cefic Research and Innovation, ECETOC, Cefic LARIT(lawyers), Cefic Industrial Policy Group and Sector Groups...**

Chemicals Risk Management Tools



- **REACH**
 - **Registration**
 - **Information in the supply chain**
 - **Evaluation**
 - **Authorisation and Restrictions**
- **Community Legislation**
 - **Target specific**
 - **Workers**
 - **Consumers**
 - **Environment**
 - **Product specific**

Aims of Authorisation and Restrictions in REACH



- The two regulatory risk management tools
- Authorisation
 - to assure that the **risks from substances of very high concern** are properly controlled and
 - (...) are **progressively replaced by suitable alternative** substances and technologies where these are **economically and technically viable**
- Restrictions = **the safety net**

Principles



Authorisation

- **“Banned” unless “authorised”**
- reversal of the burden of the proof
- Applicant for authorisation

Restrictions

- **“Permitted” unless “banned”**
- no reversal of the burden of the proof
- Member State, ECHA

Which Substances ?



Authorisation

➤ **Substances of Very High Concern**

- Meeting the criteria of Article 57, identified according to Article 59
- (Candidate List) and included in the Annex XIV
- (List of Substances Subject to Authorisation)
- Article 57 : CMRs 1A & 1B, PBT, vPvB and substances of “equivalent concern”

Restrictions

- **Any substance when there is an unacceptable risk which needs to be addressed on a Community-wide basis**

Restrictions – Some observations



- **Old wine ...**
 - **Restrictions existed from 1976 ... 30 years before REACH**
- **... in a new bottle**
 - **Stringent timelines**
 - **New process to propose, consult interested parties and handle restrictions**
 - **ECHA Committees opinions prior to Commission's decision**
- **Annex XVII of REACH**
 - **One decision covers all actors in the EU**

Authorisation – Some observations



- **REACH novelty ... (political) high expectations**
- **REACH defines in great details the process**
 - Candidate List of Substances of Very High Concern for authorisation
 - Comparative assessment of alternatives
 - Socio-economic analysis of chemicals
 - Time-limited authorisations for certain uses leading to ban/phasing-out
- **Many actors involved**
- **Public consultation/commenting at each critical steps**
- **ECHA Committees opinions prior to Commission's decisions**
- **Applicant/supply chain specific authorisation decisions (OJ)**



Conclusions

- **The Authorisation and Restrictions processes are both working**
- **However, the applications for authorisation are entering a “ learning by doing phase “**
- **Authorisations and Restrictions are both Community risk management measures but they have different scopes, timelines, steps, impacts ...**
- **Both routes including other Community legislation and their interfaces have to be considered prior to deciding on the process**
- **Early engagement of Industry is essential**



**Thank you for your
attention !**