How a developing country can benefit from a Regulatory Cooperation Initiative?

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ECHA – a regulatory EU Agency

- Established 1 June 2007
- Located in Helsinki, Finland
- Responsible for industrial chemicals and biocides
- Staff (ca. 600) from EU and EEA countries

**REACH**
Registration
Evaluation
Authorisation

All chemicals ≥ 1 tonne per year

**CLP**
Classification
Labelling
Packaging

All chemicals and mixtures
United Nations standards

**BPR**
Biocides

Active substances and biocidal products

**PIC**
Prior Informed Consent

Import/export of certain hazardous chemicals
Rotterdam Convention
Main elements of any industrial chemicals management system

- Know what is on the market:
  - Inventory, notification, registration...
- Gather & generate information on substances
  - Uses and exposure
  - Hazards
- Priority setting
- Assessment, evaluation
- Classification and labelling (GHS)
- Regulatory risk management
  - Restrictions, authorisation
  - May include: Alternatives assessment, socio-economic analysis
**Key processes of REACH & CLP**

**Registration**
Industry gathers information on their chemicals, ensures management of risks and document in a registration dossier submitted to ECHA.

**Evaluation**
ECHA and Member States control and request further information whenever needed.
Member States enforce the legislation.

**EU-wide risk management**
Commission, with support of ECHA and Member States, applies EU-wide risk management measures: authorization, restrictions, harmonised classification and labelling.
Currently on our website...

<table>
<thead>
<tr>
<th>Count</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>181</td>
<td>Substances of Very High Concern</td>
</tr>
<tr>
<td>580</td>
<td>Risk management proposals</td>
</tr>
<tr>
<td>1,600</td>
<td>Dossiers for HPV chemicals checked for compliance</td>
</tr>
<tr>
<td>21,000</td>
<td>Substances registered under REACH</td>
</tr>
<tr>
<td>142,000</td>
<td>Substances classified with GHS</td>
</tr>
<tr>
<td>&gt;2 million</td>
<td>Study summaries on properties and effects of chemicals</td>
</tr>
</tbody>
</table>
All substances > 1 tpa now registered

- 21 500 substances - 89 000 registration dossiers
- Can be searched via ECHA website
Understanding registration information

• Registrations are prepared by companies, the data is owned by them
  • Data quality is not systematically reviewed by authorities
• Most of the data is publically available
  • N.B. intellectual property rights of data owners
• ECHA prepares decisions requesting further testing and information
  • Dossier and substance evaluation
• Data can be consulted via ECHA website and OECD eChemPortal
  • Also a downloadable IUCLID file with key results available
Risk management: restrictions

• When unacceptable risks to humans or the environment have been identified
• Member State competent authorities can submit dossiers proposing restrictions (or European Commission asks ECHA to submit)
• European Commission Decision based on an ECHA opinion
• Annex XVII of REACH lists all restrictions

21 ECHA opinions
Risk management: authorisation

- Substances of very high concern (SVHCs): CMRs, PBT/vPvB or ‘equivalent concern’
- Identification by Member States (or European Commission instructing ECHA) onto the ‘Candidate List’
- Some transferred onto the ‘Authorisation List’, Annex XIV
- Once on the Authorisation List, the substance can only be marketed or used after ‘sunset date’ if authorised by the European Commission who decides based on ECHA opinion

191 substances on Candidate List – 43 on Authorisation List – 208 ECHA opinions - 53 Authorisation Decisions
Classification and labelling – ECHA’s role

- Establish and maintain C&L inventory
  - Self classification by industry
  - Over 6 million notifications covering more than 140,000 substances
- Harmonised C&L
  - Proposals by Member States or industry
  - Opinion by ECHA Risk Assessment Committee
  - Commission decision (Annex VI of CLP)

298 ECHA opinions
Find out what is on our radar

• Substances of potential concern
  • Screening of substances is an ongoing process
  • We focus on substances that may need regulatory action -> risk management option analysis (RMOA)
    • Substances of very high concern (SVHC)
    • Persistent, bioaccumulative, toxic (PBT, vPvB)
    • Endocrine disruptors
  • Increased focus on grouping of substances

• See on ECHA website:
  • E.g. PACT – public activities coordination tool
Conditions and benefits of successful regulatory cooperation

• Use of OECD tools and methodologies
  • Test guidelines & GLP,
  • Alternative methods, hazard assessment methodologies, data formats …
  • New/starting: Priority setting, alternatives assessment, socio-economic analysis

• Electronic submission of data
  ➢ Easier to benefit from the data and assessment of other jurisdictions
  ➢ Easier to exchange data
  ➢ Sharing experiences, shorter learning curves
  ➢ Sharing workload, spread good practice
Thank you!

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