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

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ECHA – a regulatory EU Agency

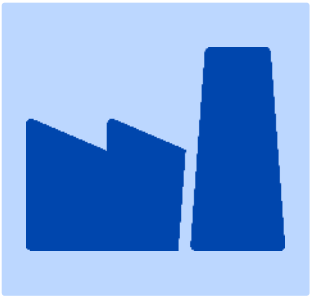
- Established 1 June 2007
- Located in Helsinki, Finland
- Responsible for industrial chemicals and biocides
- Staff (ca. 600) from EU and EEA countries

REACH	CLP	BPR	PIC
Registration Evaluation Authorisation	Classification Labelling Packaging	Biocides	Prior Informed Consent
All chemicals ≥ 1 tonne per year	All chemicals and mixtures	Active substances and biocidal products	Import/export of certain hazardous chemicals
	United Nations standards		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

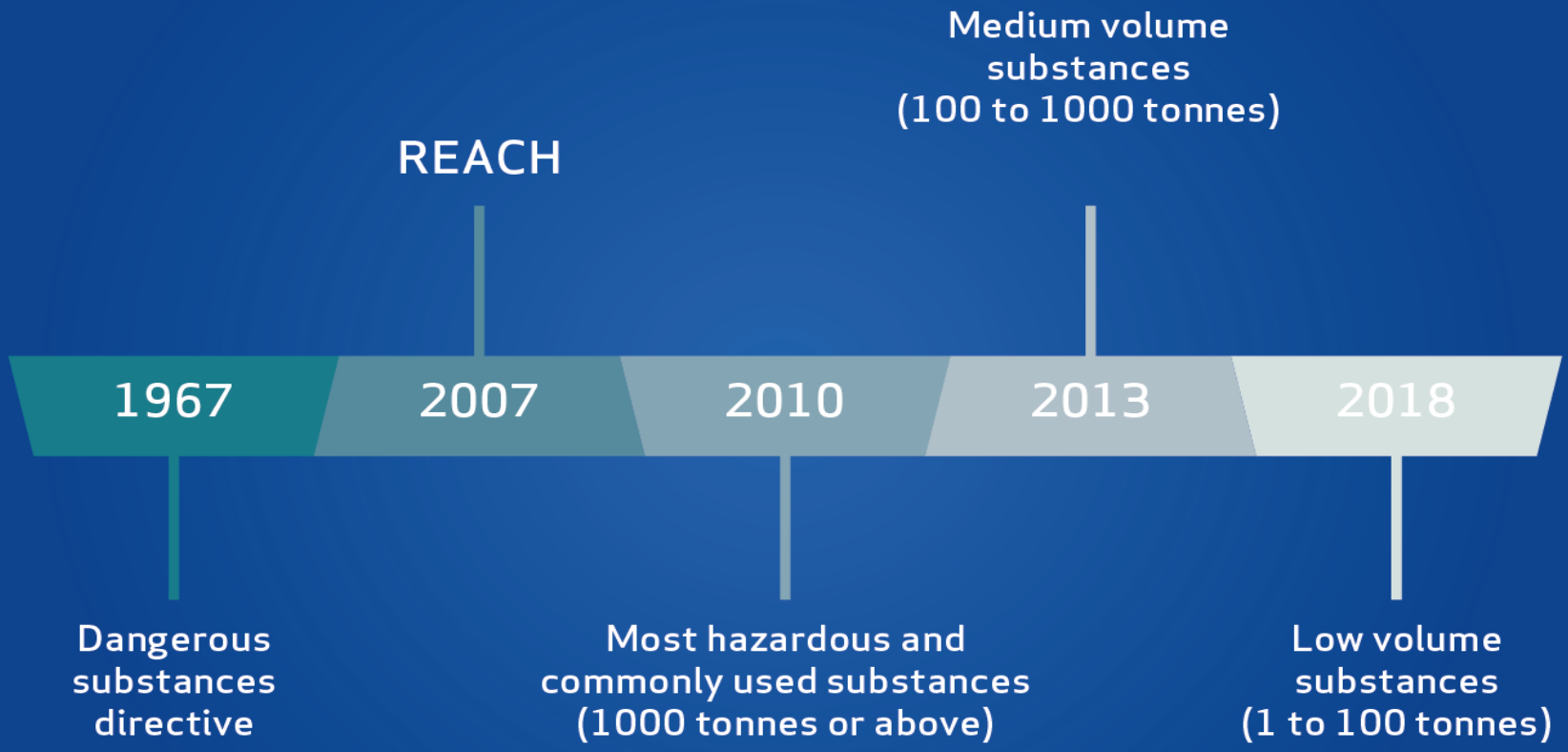
EU-wide risk management
Commission, with support of ECHA and Member States, applies EU-wide risk management measures: authorization, restrictions, harmonised classification and labelling

Currently on our website...

181	Substances of Very High Concern
580	Risk management proposals
1 600	Dossiers for HPV chemicals checked for compliance
21 000	Substances registered under REACH
142 000	Substances classified with GHS
>2 million	Study summaries on properties and effects of chemicals

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 succesful 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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