



How the EU chemicals legislation has created a
standard for chemicals legislation across the world

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Overview

- Main elements of any chemicals management system
- ECHA as driving force among other EU authorities implementing legislation
- Overview of REACH and CLP processes and how effective they are
- Key findings of the second REACH/CLP review by the Commission and follow up
- ECHA's international activities and how the EU chemicals management system set a standard for the rest of the world

Main elements of any industrial chemicals management system

- Know what is on the market:
 - Inventory of new and existing substances, notification or registration, import/export control
- Gather & generate information on substances
 - Volume and uses
 - Hazards and exposure
- Classification and labelling (GHS)
- Priority setting for risk assessment and reduction
- Assessment, evaluation, bridging data gaps per substance
- Regulatory risk management of chemicals of concern
 - Restrictions and/or authorisation
 - May include: Alternatives assessment, socio-economic analysis

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

ECHA committees and bodies

- Management Board (MB) nominated by the European Council, the European Parliament and the European Commission
- The ECHA 'secretariat' led by the Executive Director nominated by the MB
- Member States Committee and Biocidal Products Committee, one per country nominated by the EU/EEA Member States (MS)
- Risk assessment (RAC) and Socio-economic assessment committee (SEAC) experts proposed by MS and nominated by the MB
- Forum on Enforcement one per country nominated by the Member States
- Board of Appeal nominated by the Management Board
- HelpNet of national helpdesks' representatives nominated by the Member States

Role of Member States in implementing EU chemicals legislation

- Each Member State (MS) must have a(t least one) competent authority for implementing REACH, CLP, BPR and PIC but most MS have more than one
- Each Member State should have a national REACH-CLP-BPR helpdesk
- Each Member State must be properly resourced for taking up its own duties under these legislations and taking part in ECHA's bodies
- Each Member State can undertake substance evaluation on substances of concern to identify data gaps and remaining risks, and propose Annex XV REACH dossiers to manage that risk at EU level
- Each Member State must enforce these regulations on the basis of national enforcement legislation and contribute to ECHA's enforcement forum
- National courts should be prepared to judge on non-compliant companies

Key processes of REACH & CLP



Registration and CLP notification

Industry gathers information on their chemicals, ensures management of risks and document this in a registration dossier or CLP notification submitted to ECHA



Evaluation

ECHA and Member States control completeness and compliance and request further information whenever needed



EU-wide risk management

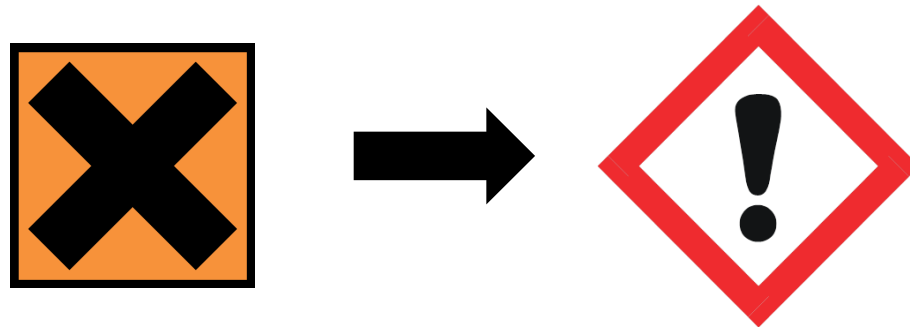
The Commission, with support of ECHA and Member States, applies community wide risk management measures, e.g. authorisation or restriction of certain uses

Classification, labelling and packaging regulation

- First step to define the hazards of chemical substances and mixtures to facilitate safe use
- CLP Regulation (adopted 2008)

Implementation of UN-wide system (GHS) in the EU

Applies to any hazardous chemical whatever its volume



Classification and labelling – ECHA's role

- Establish and maintain C&L inventory

Self classification by industry of hazardous substances

Over 6 million notifications covering more than 140 000 substances

- Harmonised C&L

Proposals by Member States or industry

Always necessary for biocidal and plant protection substances

Opinion by ECHA Risk Assessment Committee

Commission decision (Annex VI of CLP)

Over 300 ECHA opinions

REACH, EU system for industrial chemicals



Registration of chemicals

Evaluation of selected registered substances

Authorisation of (certain) Chemicals

Restriction of (certain) Chemicals

Aims of REACH:

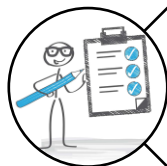
Ensure a high level of protection of human health and the environment

Promote alternatives to animal testing

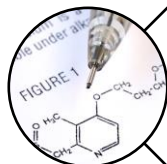
Ensure the free circulation of substances on the internal market

Enhance competitiveness and innovation

Principles of REACH



Industry responsible for safe
manufacture and use



Deal with the 'burden of the past'
with a systemic program for registration
of 'old' chemicals



Get adequate information on hazards while minimising
the use of experimental animals and the costs



Targeted activities by ECHA, Member States and the
European Commission to get maximum effect



Enforcement at national level

Registrations' outcome after the 2018 deadline

	All	DL 2018
Registrations	91 536	33 363
Substances	21 787	11 114

A small number of registrations still being processed by ECHA

17% of registrations from SMEs

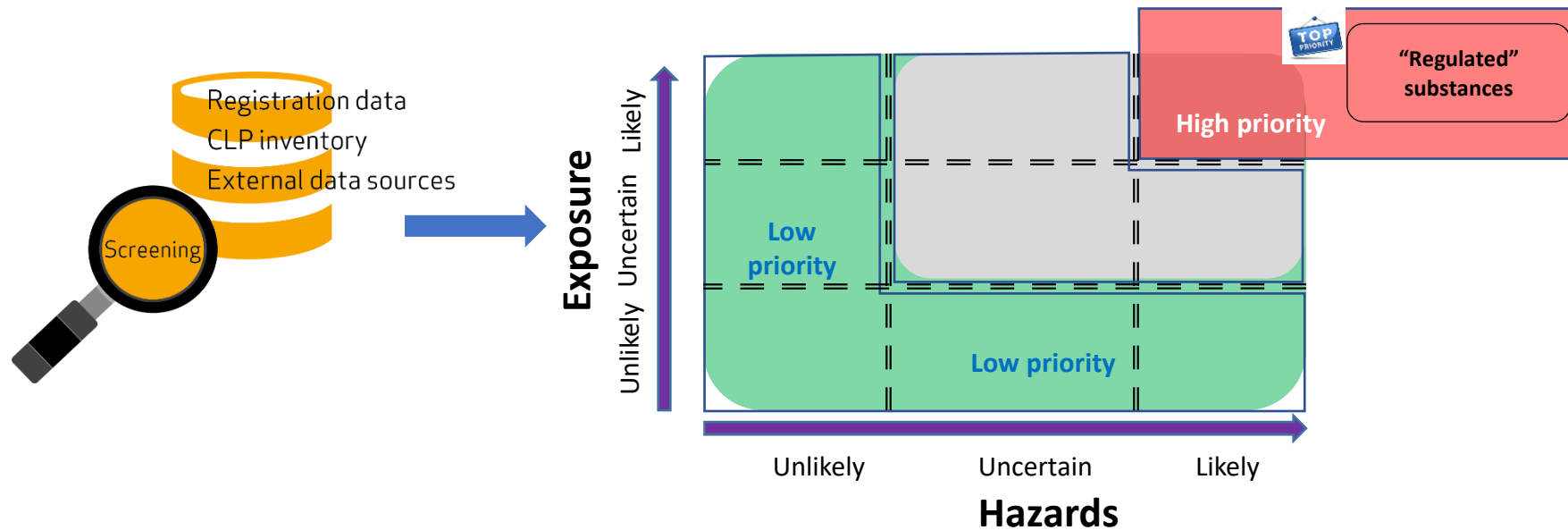
Registrations from outside of EU: 48% from importers and 29% from OR

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 made publicly available
 - Beware of proprietary rights of data owners
- ECHA prepares decisions requesting further testing and information
 - Dossier and substance evaluation
- Data is disseminated via ECHA website and OECD eChemPortal
 - Also a downloadable IUCLID file with key results available

Screening and prioritisation

- All registration dossiers screened and prioritised for further assessment by ECHA and MS authorities: evaluation or risk management



Find out which substances are on ECHA's radar

- Substances of - potential - concern
 - Screening of substances is an annual process to identify substances for evaluation and risk management
 - ECHA focuses on substances that may need regulatory action -> risk management option analysis (RMOA) for chemicals of concern
 - Substances of very high concern (SVHC)
 - Proposals for harmonised classification or restriction
 - Other risk management measures such as OEL's
 - Increased focus on grouping of substances
- See on ECHA website:
 - E.g. PACT – public activities coordination tool

Currently on ECHA website

201	Substances of Very High Concern
>600	Risk management proposals
>2000	Registration dossiers checked for compliance
>22000	Substances registered under REACH
>140000	Substances classified with GHS
>2 million	Study summaries on properties and effects of chemicals

Transparent decision making process

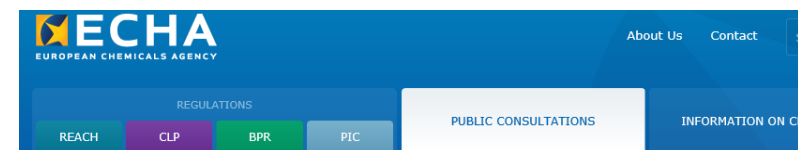
Activities and regulatory processes explained clearly

Open decision making

Indication of when and how stakeholders can interact

Information available in a timely manner

Public Activities Coordination Tool (PACT)



ECHA > Public consultations

Public consultations

REACH

Calls for comments and evidence

Substances: 1

Start date: 02/05/2018
Deadline: 18/06/2018

Substances: 1

Start date: 21/05/2018
Deadline: 03/08/2018

Restrictions

Restriction proposals: 2

Start date: 20/12/2017
Deadline: 20/06/2018

Testing proposals

Testing proposals: 12

Start date: 21/05/2018
Deadline: 05/07/2018

Adopted opinions and previous consultations

- Substances of very high concern identification
- Submitted recommendations for inclusion in the Authorisation List
- Adopted opinions on applications for authorisation

CLP

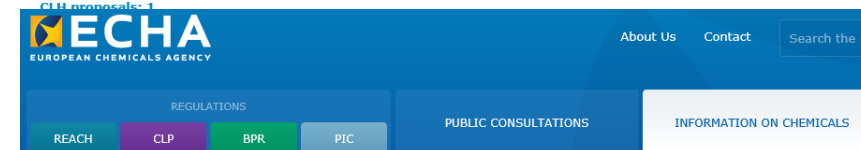
Harmonised classification and labelling

CLH proposals: 3

Start date: 23/04/2018
Deadline: 22/06/2018

CLH proposals: 1

There are currently no ongoing consultations.



ECHA > Information on Chemicals > PACT

PACT – RMOA and hazard assessment activities

The Public Activities Coordination Tool (PACT) lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative and toxic/very persistent and very bioaccumulative) properties or endocrine disruptor properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013.

Please read the information on status and purpose of PACT to learn more concerning this matter.

> [Further information](#)

Disclaimer: The information and views set out in the PACT table and in the RMOA and hazard assessment outcome documents are those of the evaluating authority and do not necessarily reflect the position or opinion of the other Member States or ECHA. Neither ECHA nor the evaluating authority nor any person acting on either of their behalfs may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the documents are without prejudice to any formal regulatory activities that ECHA or the Member States may initiate at a later stage. RMOAs, hazard assessments and their outcomes are compiled on the basis of information available by the date of the publication of the document.

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50 Items per Page

Showing 1 - 50 of 425 results.

(Suspected) ha

(s) considered

Name	EC/List No	CAS Number	Authority	Activity	Latest update	Scope
Amphoteric Fluorinated Surfactant	-	-	Belgium	Hazard assessment	11/06/2018	PBT
Dichloro(dimethyl)silane	200-901-0	75-78-5	Czech Republic	Hazard assessment	11/06/2018	PBT
HDI oligomers, isocyanurate	931-274-8	28182-81-2	Slovenia	Hazard assessment	11/06/2018	PBT

ECHA's dissemination website

Tailored access to all information on chemical substances contained in ECHA databases in **one single point of access** to

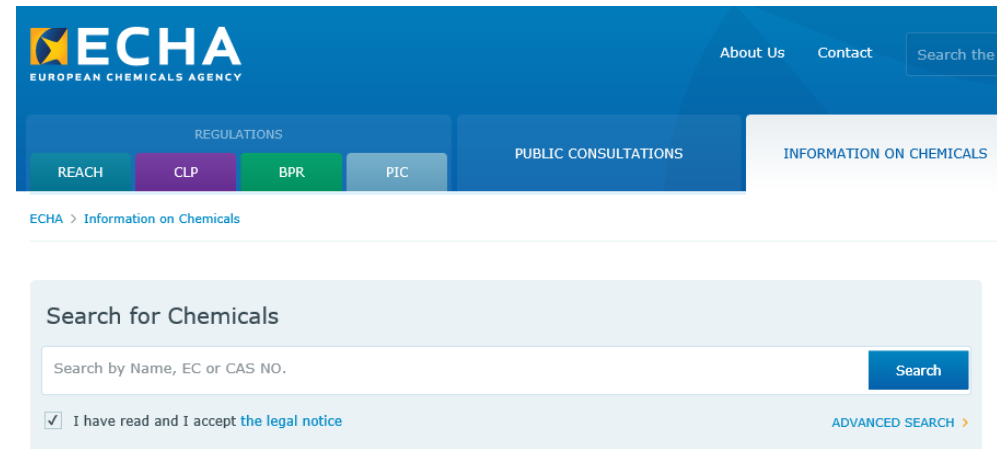
Provide meaningful and relevant information on chemicals

Increase the transparency

Promote quality of data

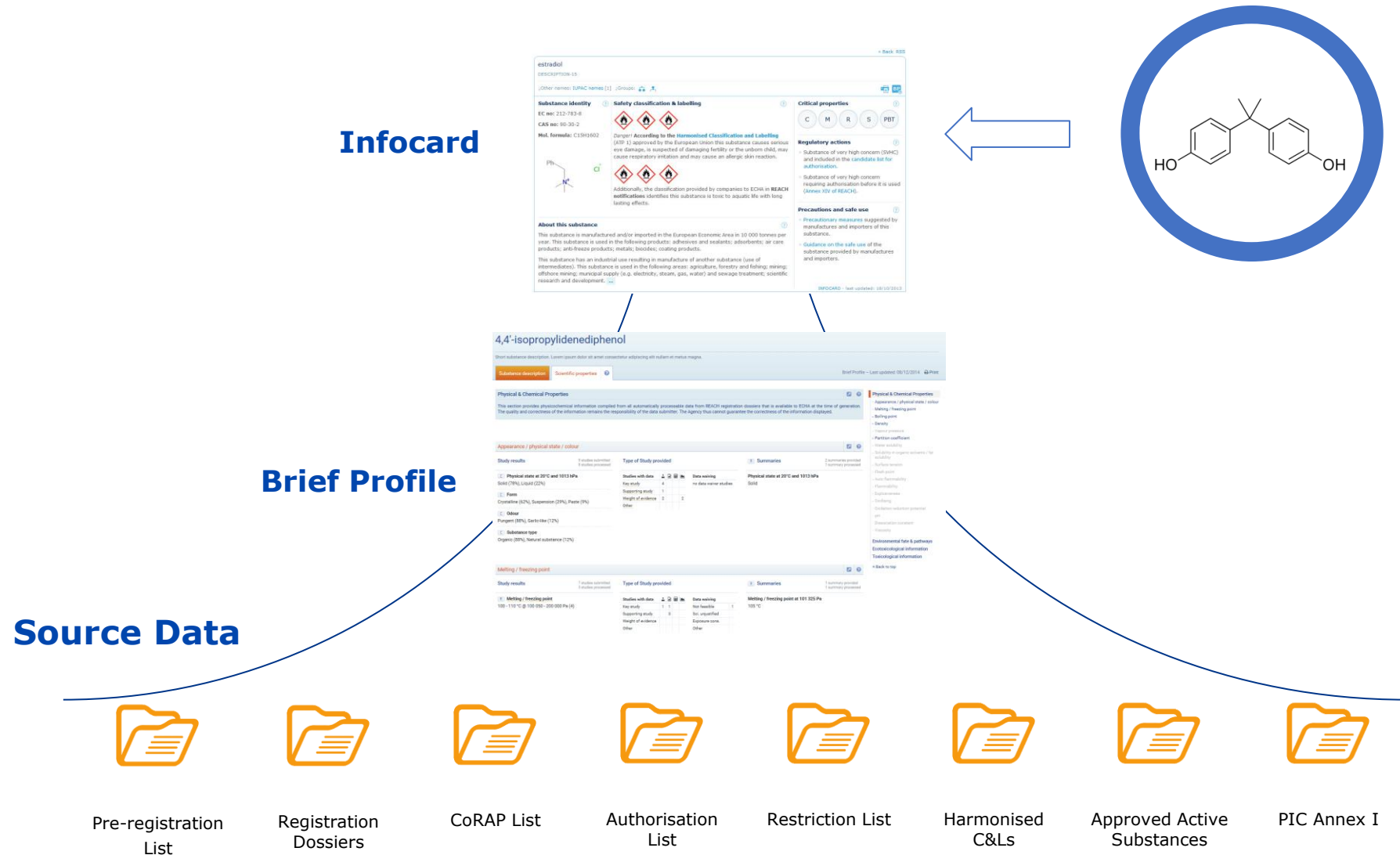
Promote the safe use of chemicals for consumers

Assist citizens to make informed decisions on the safe use of chemicals



The screenshot displays the ECHA (European Chemicals Agency) website interface. At the top, the ECHA logo is visible alongside navigation links for 'About Us' and 'Contact', and a search bar. Below this, a horizontal menu categorizes content into 'REGULATIONS' (with sub-links for REACH, CLP, BPR, and PIC), 'PUBLIC CONSULTATIONS', and 'INFORMATION ON CHEMICALS'. The 'INFORMATION ON CHEMICALS' section is currently selected, as indicated by a breadcrumb trail 'ECHA > Information on Chemicals'. The main content area features a 'Search for Chemicals' section with a text input field labeled 'Search by Name, EC or CAS NO.', a 'Search' button, and a checkbox for 'I have read and I accept the legal notice'. An 'ADVANCED SEARCH >' link is also present.

Dissemination - Tiered approach





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)
- These dossiers must include a socio-economic analysis
- European Commission Decision based on an ECHA opinion
 - Annex XVII of REACH lists all restrictions (including those preceding REACH)

26 ECHA opinions

Risk management: authorisation

- Substances of very high concern (SVHCs): CMRs, PBT/vPvB or 'equivalent concern'
- Proposals of SVHCs by Member States (or European Commission instructing ECHA) for the 'Candidate List'
- Some transferred by the Commission with majority support of REACH committee onto the 'Authorisation List'
- 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 and after majority support from REACH committee

201 substances on Candidate List – 43 on Authorisation List – 219 ECHA opinions - 91 Authorisation Decisions



Second REACH review: key findings

After 10 years the Commission concluded last year that REACH is fully operational and delivers the expected results:

- A comprehensive data set on substances
- Creation of new substances was stimulated by lower R&D and new substance requirements
- Information needs for nanomaterials are addressed by amendments of REACH annexes
- Progress in the phasing out of substances of very high concern
- Improvement of the risk management measures at the workplace
- Improvement of the communication and transparency in the supply chain
- Increased confidence of consumers in chemicals
- ECHA is playing an instrumental role on REACH implementation

Second REACH review: key findings

- Studies prove that REACH met its objectives: it has significantly improved the protection of human health and the environment, promoted alternatives to animal testing and ensured the free movement of chemicals on the EU market
- REACH contributed to the EU meeting the World Summit Sustainability Development 2020 goal on chemicals
- REACH review concluded that
 - Legal requirements and obligations are well tuned to needs and objectives
 - But currently no need to change the legal act
 - A number of actions were identified that can further improve REACH

ECHA's international activity

- Technical and scientific support to OECD
 - Development/revising of TG/GD
 - eChemPortal
 - QSAR Tool
 - IUCLID
- Awareness raising of legal obligations in the EU to third countries
 - Visits from and to other regulatory authorities
 - Workshops/conferences
 - Industry partnerships (ICCA)
- WHO/CEN/ISO/UN
- Support organisation of the Helsinki Chemicals Forum

Countries following REACH/CLP chemicals management system

- REACH and CLP apply to EU-28 and 3 EEA countries
- UK after brexit committed to apply identical REACH/CLP
- Future EU accession countries are preparing for EU acquis application
- Turkey introduced its own REACH/CLP laws and implementation
- Switzerland applies CLP and most of REACH through own legislation
- A high number of countries apply their GHS version (UN commitment!)
- South Korea has adopted REACH-K, which is the closest to REACH
- Taiwan applies a REACH like legislation
- China is preparing chemicals legislation which is dubbed as China REACH
- Canada, Australia, Japan and US cooperate with ECHA but keep own systems



Any questions?