

Overview of REACH and the revision

Seminar latest trends on chemicals
management in the EU

17 March 2023 Online with Japan

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About us

We protect you and the environment by taking action on harmful chemicals

OUR MISSION

We work for the safe use of chemicals

OUR VISION

To be the centre of knowledge on the sustainable management of chemicals for the benefit of citizens and the environment



Topics

- EU decision making
- Chemicals legislation in the EU before REACH
- REACH
- Recent developments in REACH
- Chemicals Strategy for Sustainability

EU decision making



EU institutions



European Parliament



European Commission



Council of the European Union



echa.europa.eu



EUROPEAN CENTRAL BANK



Court of Justice of the European Union



EUROPEAN COURT OF AUDITORS



European Council

- **Right of initiative: proposing new laws and policies;**
- **Policy implementation: managing European Union policies and the budget;**
- **Guardian of the Treaties: enforcing European Union law;**
- **International dimension: ensuring the Union's external representation.**



The EU Commission's DGs involved in chemicals management



DG GROW: Internal Market, Industry, Entrepreneurship and SMEs



DG ENV: Environment



DG SANTE: Health and Food Safety



DG EMPL: Worker's health and safety



DG RTD: Research and Innovation



JRC: Joint Research Centre



The EU Parliament



Legislative power

Budgetary power

Decides on the content of EU chemical legislation with Council

Composed of 705 Members of Parliament (MEPs)

MEPs are spread in 7 political groups

26 Committees

MEPs are elected for 5 years

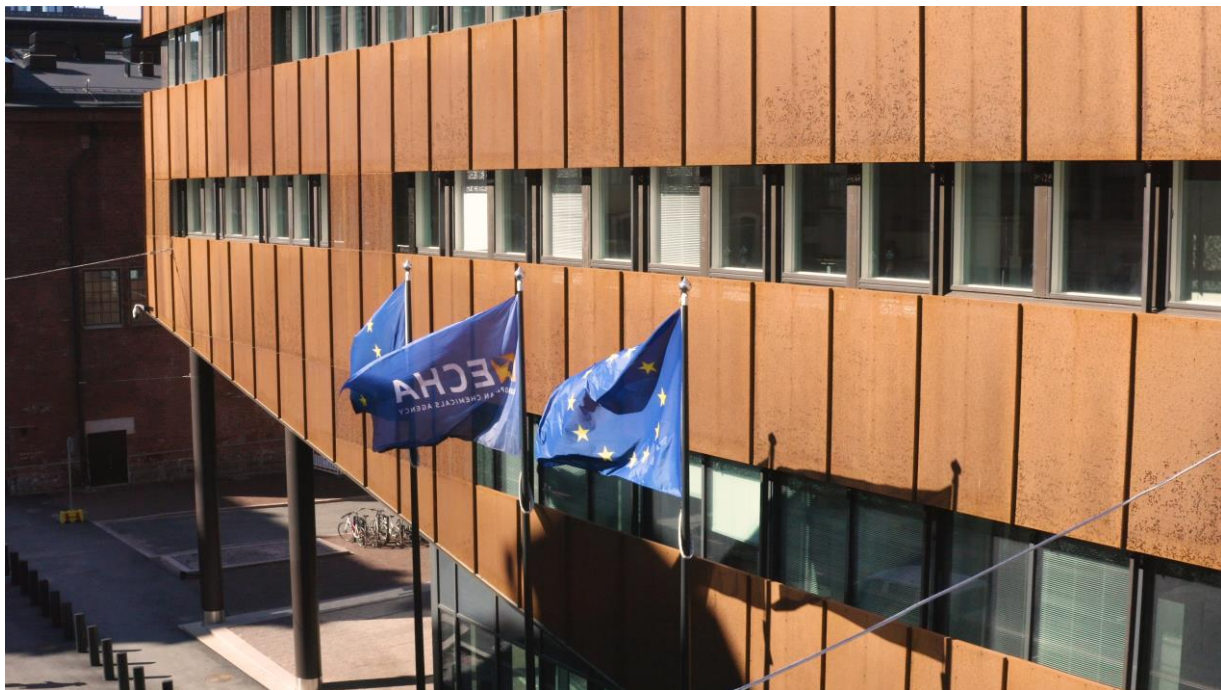
The Council

There are two distinct institutions, which share the same building:

- **The European Council:** sets the EU political agenda
- **The Council of the EU:** negotiates and votes EU laws



ECHA's mandate under current chemicals legislation

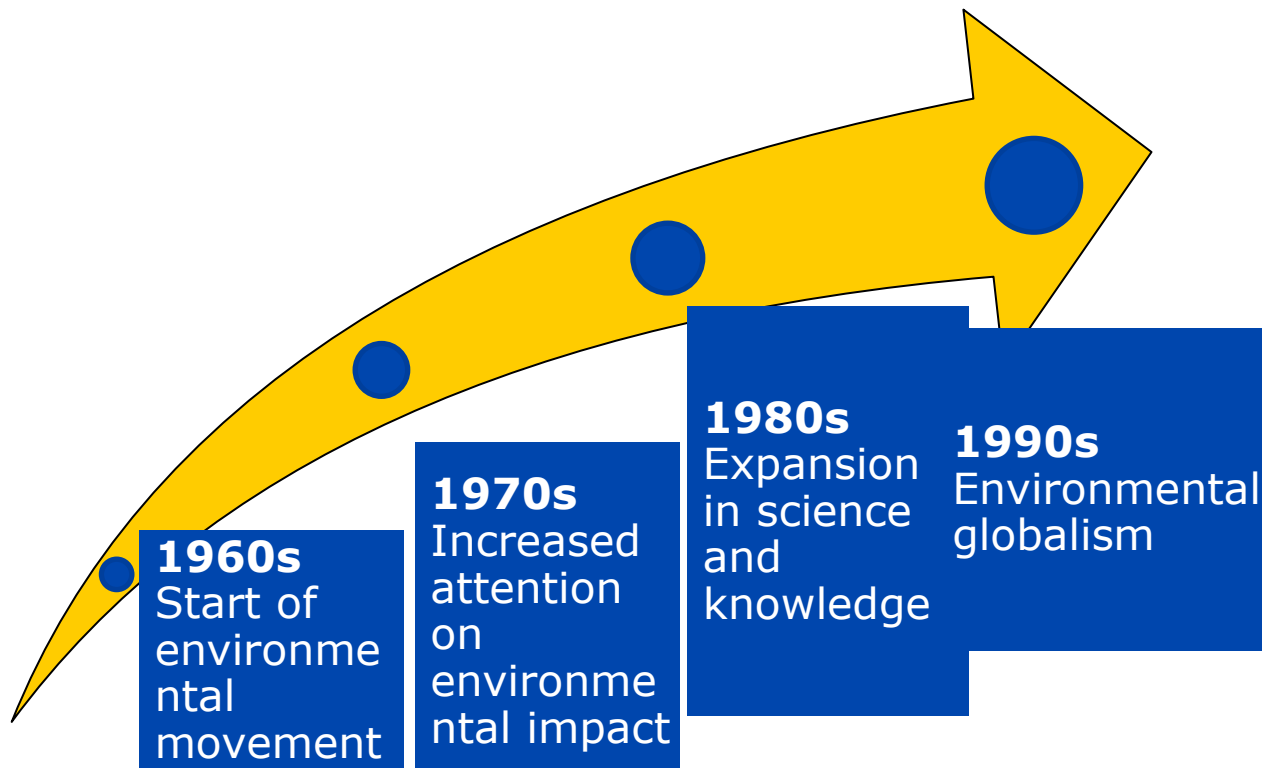


- REACH (Chemicals regulation)
- Classification, Labelling and Packaging (CLP)
- Persistent organic Pollutants (POPs)
- Prior Informed Consent (PIC)
- Biocidal product regulation (BPR)
- Waste Framework Directive (WFD)
- Drinking Water Directive (DWD)
- Occupational Exposure Limits (OEL)

**Chemicals legislation in
the EU before REACH**

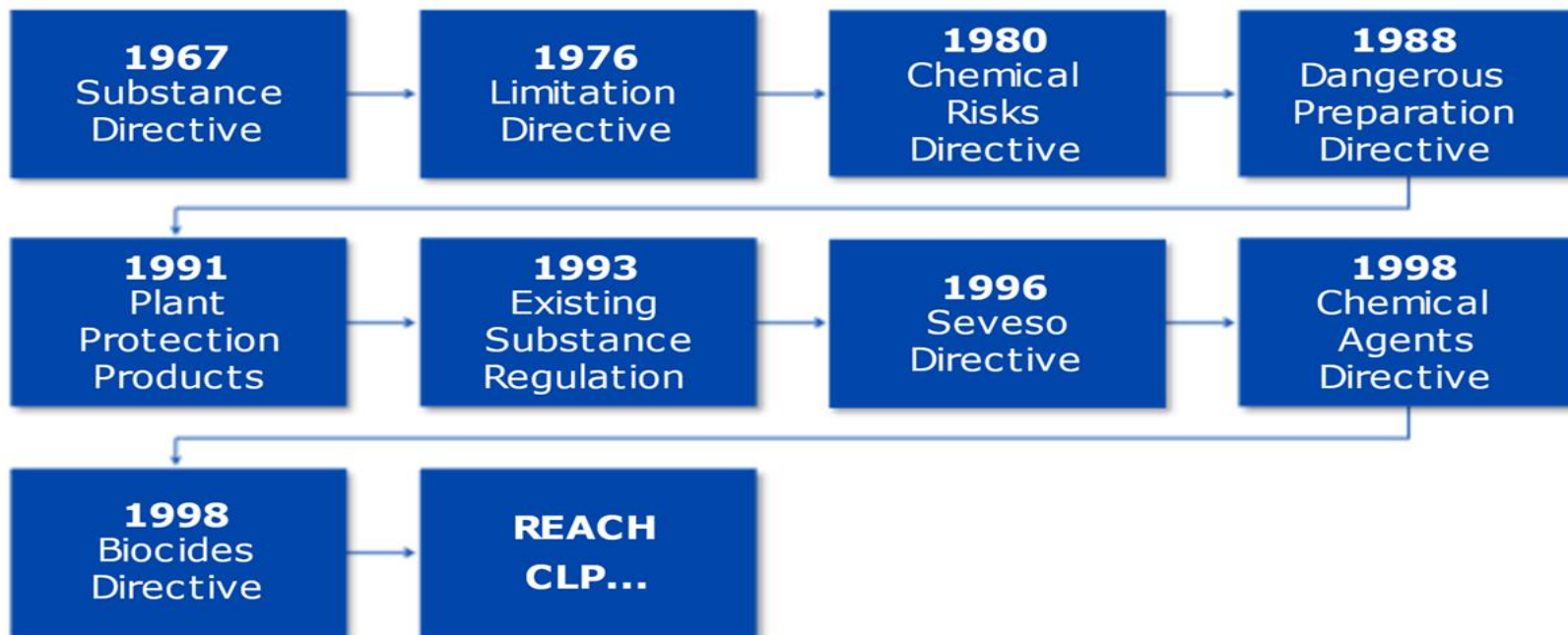


Environmental movement in Europe





EU chemicals legislation



By 2007 EU wide risk assessments



Successes

- Large data gathering and summarising process for high production volume chemicals
- Agreement on risk assessment principles
- Agreement on priority setting of chemicals
- EU harmonised risk assessments for many controversial substances, forming a solid basis for EU wide risk reduction measures





Challenges

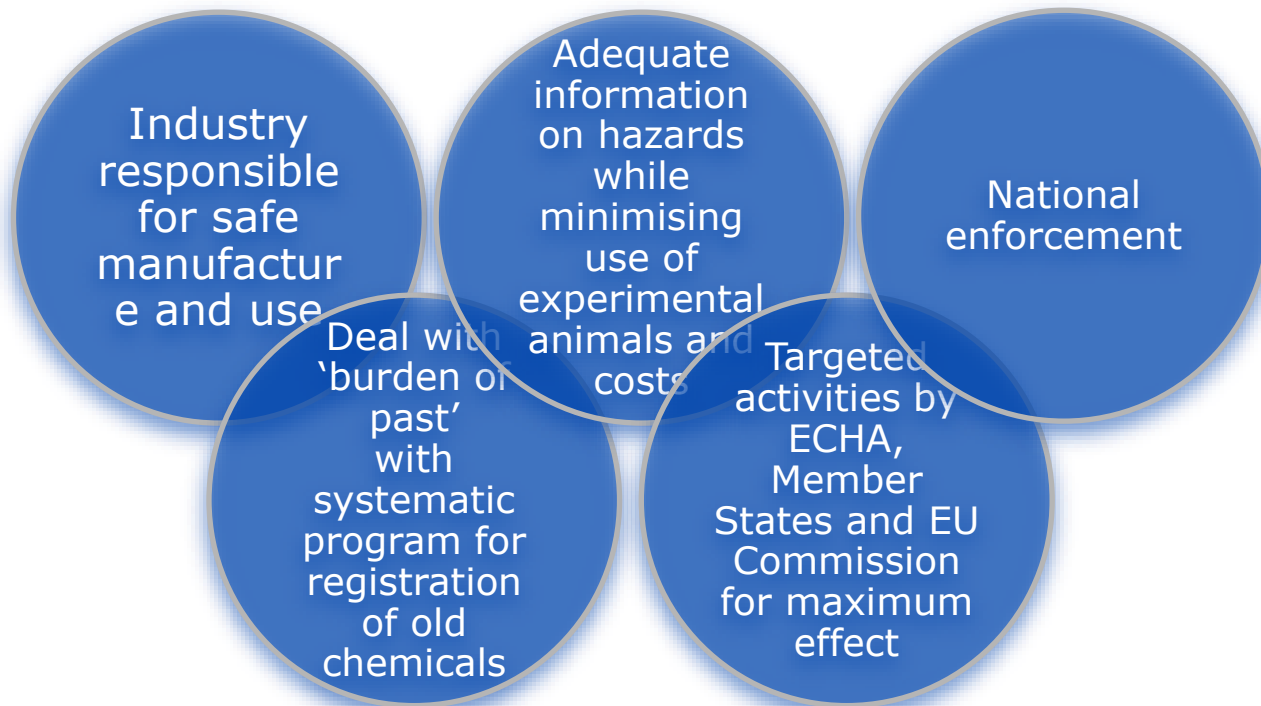
- Data gaps. 86% of high production volume chemicals – less than base dataset
- Risk assessment process took too much time
- Burden of proof on public authorities
- Generally downstream users out of the picture and actual uses of chemicals remained unknown
- Inefficient system: Industry faced with myriad of directives and regulations
- Administrative burden for new, mostly low volume, chemicals – prevented innovation

REACH

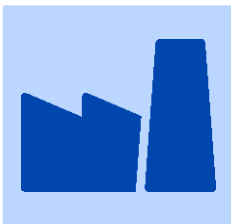




Principles of REACH



REACH - Key processes



Registration

Industry gathers information on their chemicals, ensures management of risks and documents in a registration dossier submitted to ECHA



Evaluation

ECHA and Member States control and request further information when needed
Member States enforce legislation

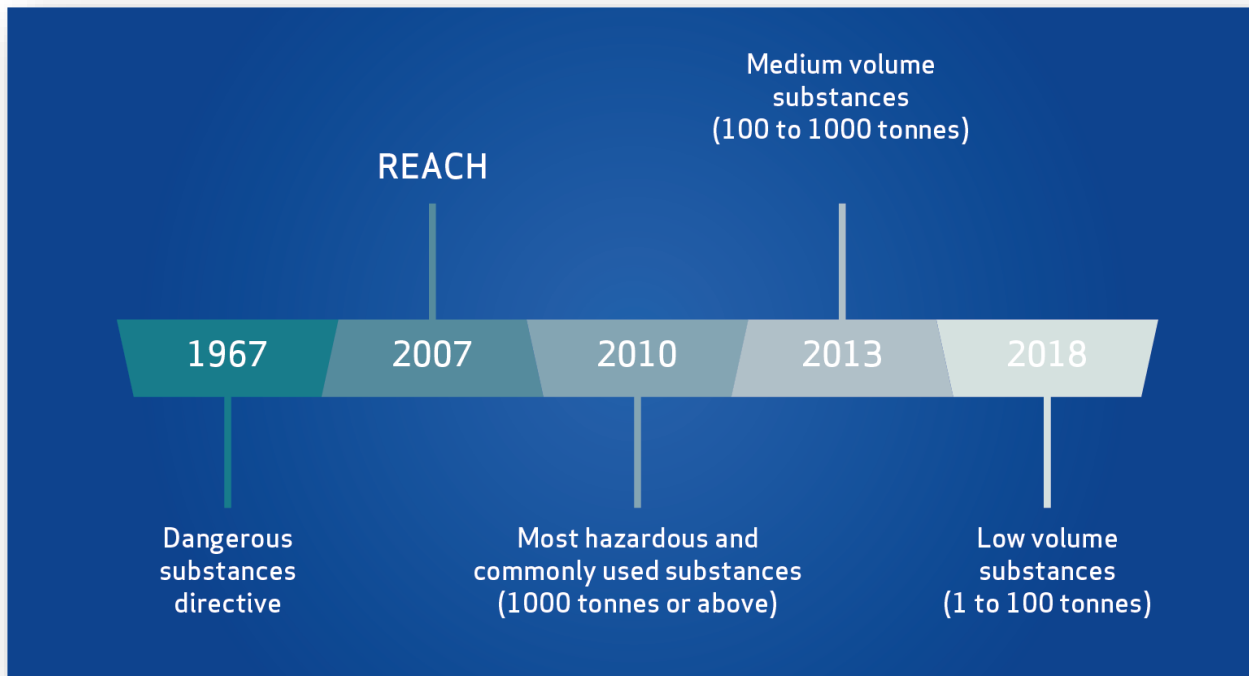


EU-wide risk management

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

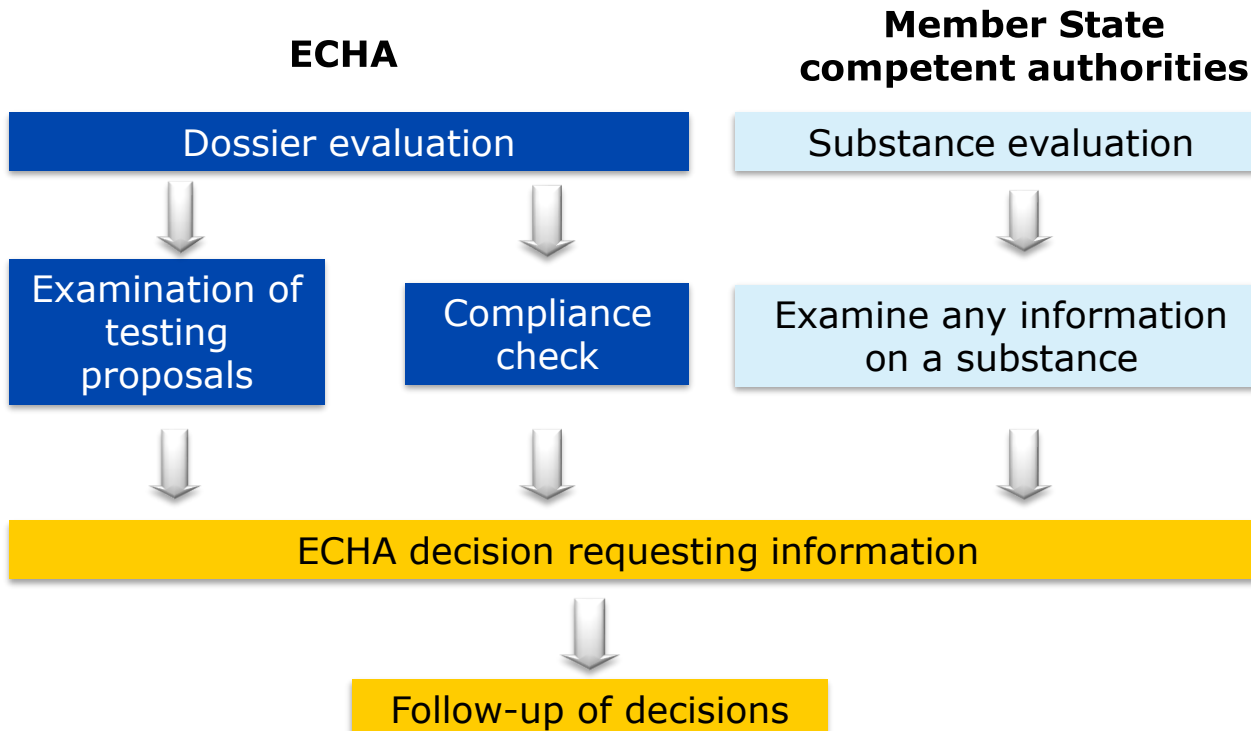


Registration journey





Evaluation: overview



Risk management: restrictions

- When unacceptable risks to our health or the environment 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



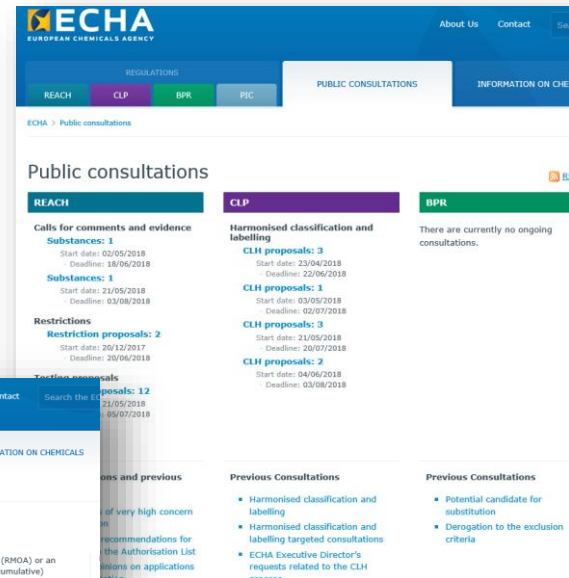
Risk management: authorisation

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



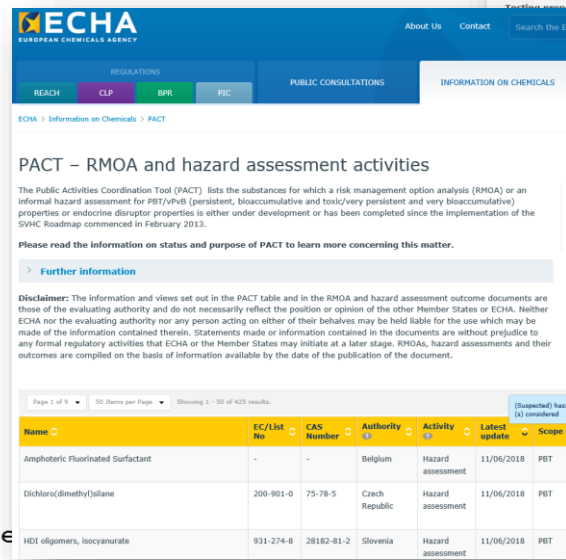
Transparent decision making process

- Activities and regulatory processes explained clearly
- Open decision-making
- When and how stakeholders can interact
- Information available in a timely manner
- Public Activities Coordination Tool (PACT)



The screenshot shows the ECHA Public Consultations page. It features a navigation bar with tabs for REACH, CLP, BPR, PIC, PUBLIC CONSULTATIONS, and INFORMATION ON CHEMICALS. The main content area is titled 'Public consultations' and lists various regulatory activities with their start and end dates. A sidebar on the right provides additional context for ongoing consultations.

Regulation	Substances	Start date	Deadline
Calls for comments and evidence	Substances: 1	02/05/2018	18/06/2018
	Substances: 1	21/05/2018	03/08/2018
Restrictions	Restriction proposals: 2	20/12/2017	20/06/2018
	Technical proposals: 12	21/05/2018	05/07/2018
Harmonised classification and labelling	CLH proposals: 3	23/04/2018	22/06/2018
	CLH proposals: 1	03/05/2018	02/07/2018
CLH proposals: 3	Start date: 21/05/2018	Deadline: 20/07/2018	
	CLH proposals: 2	Start date: 04/06/2018	Deadline: 03/08/2018



The screenshot shows the ECHA PACT - RMOA and hazard assessment activities page. It includes a disclaimer and a table of substances under assessment.

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/vPb (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.



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

Dissemination of information

IC
Substance Infocard
RSS

Benzene

Regulatory process names 83 Translated names 14 IUPAC names 2 Trade names 11 Other identifiers 8 BP OBL

<p>Substance identity ?</p> <p>EC / List no.: 200-753-7</p> <p>CAS no.: 71-43-2</p> <p>Mol. formula: C₆H₆</p> <div style="text-align: center; margin-top: 10px;">  </div>	<p>Hazard classification & labelling ?</p> <div style="text-align: center; margin-bottom: 10px;">  </div> <p><i>Danger!</i> According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance may be fatal if swallowed and enters airways, may cause genetic defects, may cause cancer, causes damage to organs through prolonged or repeated exposure, is a highly flammable liquid and vapour, causes serious eye irritation and causes skin irritation.</p> <p>Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is harmful to aquatic life with long lasting effects.</p>	<p>Properties of concern ?</p> <div style="margin-top: 10px;"> <div style="background-color: #800000; color: white; border-radius: 50%; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center; margin-bottom: 5px;"> C Carcinogenic </div> <div style="background-color: #800000; color: white; border-radius: 50%; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> M Mutagenic </div> </div> <p>How to use it safely ?</p> <ul style="list-style-type: none"> Precautionary measures suggested by manufacturers and Importers of this substance. Guidance on the safe use of the substance provided by manufacturers and Importers of this substance.
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About this substance ?

This substance is manufactured and/or imported in the European Economic Area in 1 000 000 - 10 000 000 tonnes per year.

This substance is used in the following products: laboratory chemicals and pH regulators and water treatment products. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used for the manufacture of: chemicals.

Release to the environment of this substance can occur from industrial use: as an intermediate step in further manufacturing of another substance (use of intermediates), manufacturing of the substance and formulation of mixtures.

**Recent developments in
REACH**



Draft CoRAP (2023 – 2025)

- The draft CoRAP contains 24 substances, including 6 new substances compared to the current CoRAP 2022-2024; 5 substances are being planned for evaluation in 2023, and 19 are divided for evaluation in 2024 and 2025.
- From the 27 substances included in the CoRAP update published on 22 March 2022, 5 are proposed to be withdrawn as substance evaluation has been considered currently of low priority or unnecessary. For 3 out of these, the data obtained from compliance check or public literature are already considered sufficient to clarify the initial concerns, while for the remaining 2, relevant information is requested under dossier evaluation processes.
- [Substance evaluation - CoRAP - ECHA \(europa.eu\)](#)

SCIP Database

- Database of information on **S**ubstances of **C**oncern **I**n articles, as such or in complex objects (**P**roducts)
- Established under the Waste Framework Directive (WFD)

echa.europa.eu/scip-database



Driver for **substitution** of substances of concern and **prevention** of (hazardous) waste generation



Safer products & cleaner materials cycles



Contribute to a more **circular** economy: improve waste treatment operations

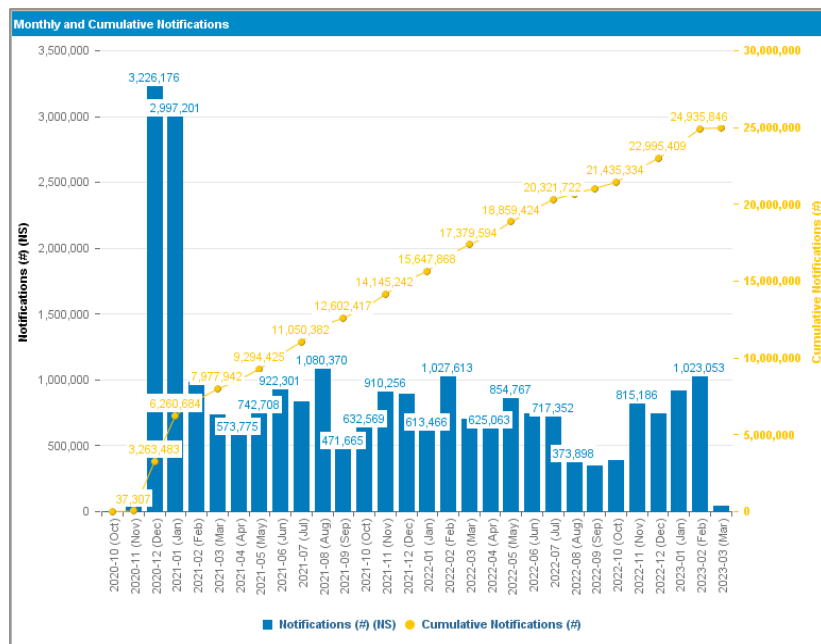


Increase authorities' **information** basis on substances in articles



Companies are delivering

Number of successful SCIP notifications received: approx. 25 million

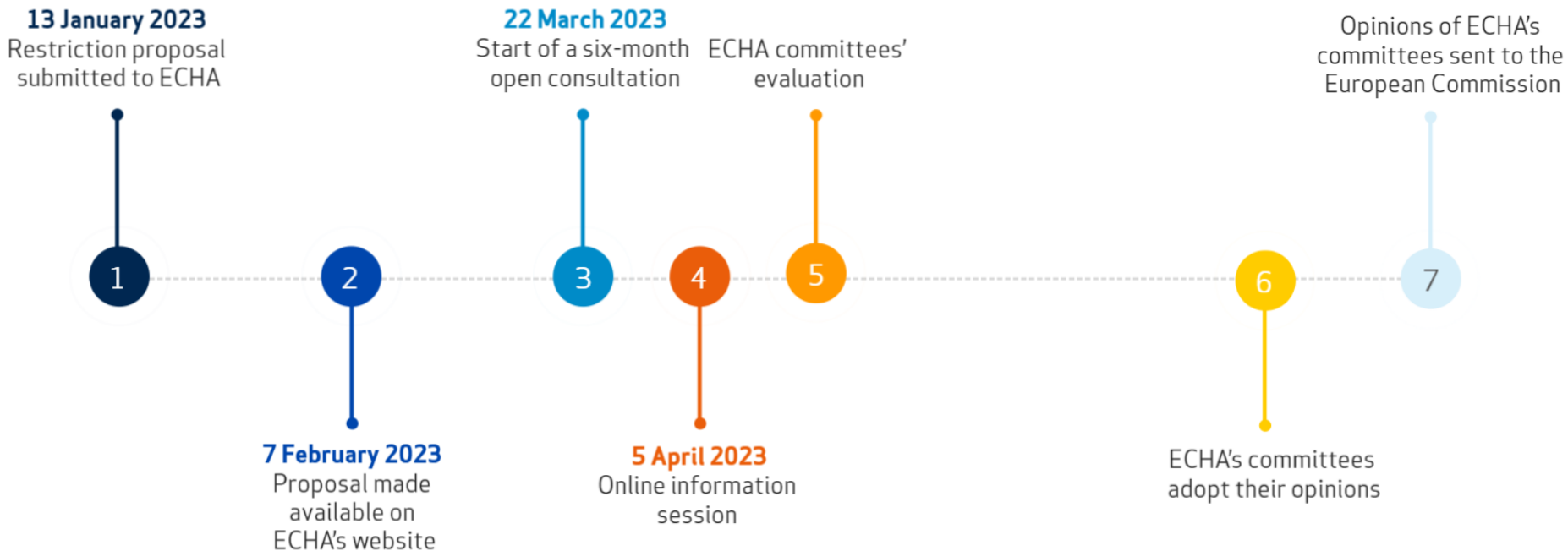


by > 9200 companies

Number of entries/factsheets in the SCIP database: >9 million

Time period: 28.10.2020 – 01.03.2023

Universal PFAS restriction



Universal PFAS restriction

Info session and live Q&A

Restriction of per- and polyfluoroalkyl substances (PFASs) under REACH

5 April 2023
11:00 - 13:00
Helsinki time

Chemicals Strategy for Sustainability



Chemicals Strategy for Sustainability main work streams

- REACH revision
- CLP revision
- One substance, one assessment
 - Data regulation
 - Regulation on reattribution of scientific and technical tasks
- ECHA basic regulation



More high-level/long-term topics

- Safe and Sustainable by Design
- Indicators
- Strategic Research and Innovation Agenda
- Global
- Etc.

Main policy options REACH revision

- Polymer registration
- Extending REACH information requirements (*information on volumes, uses, exposure/emissions, taking into account also NAMs*)
- Introduction of a Mixture Assessment Factor (MAF)
- Improve evaluation procedures
- Improve enforcement (*strengthen role Forum, new European Audit Capacity?*)

Main policy options REACH revision

- A reform of restrictions and authorisations
- Develop generic approaches to risk management (GRA)
- Define criteria for essential uses
- And until REACH is reviewed to include GRA, a restrictions roadmap has been established

Thank you

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