# 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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European Chemicals Agency

# 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

EUROPEAN CENTRAL BANK

Court of Justice of the European Union

CVRIA

CURIA RATIONIUM

EUROPEAN COURT OF AUDITORS

European Council

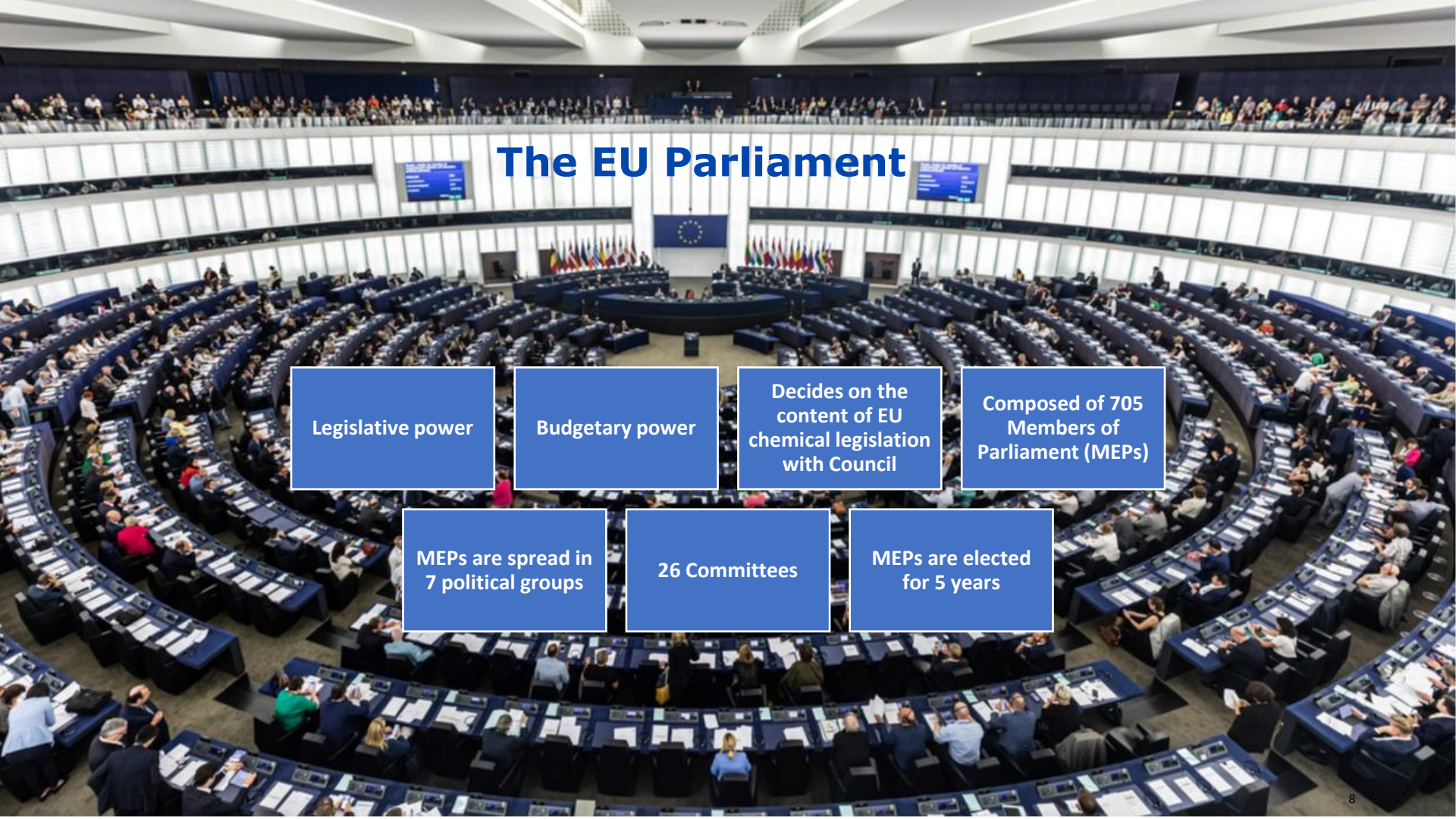
# The EU Commission

- 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

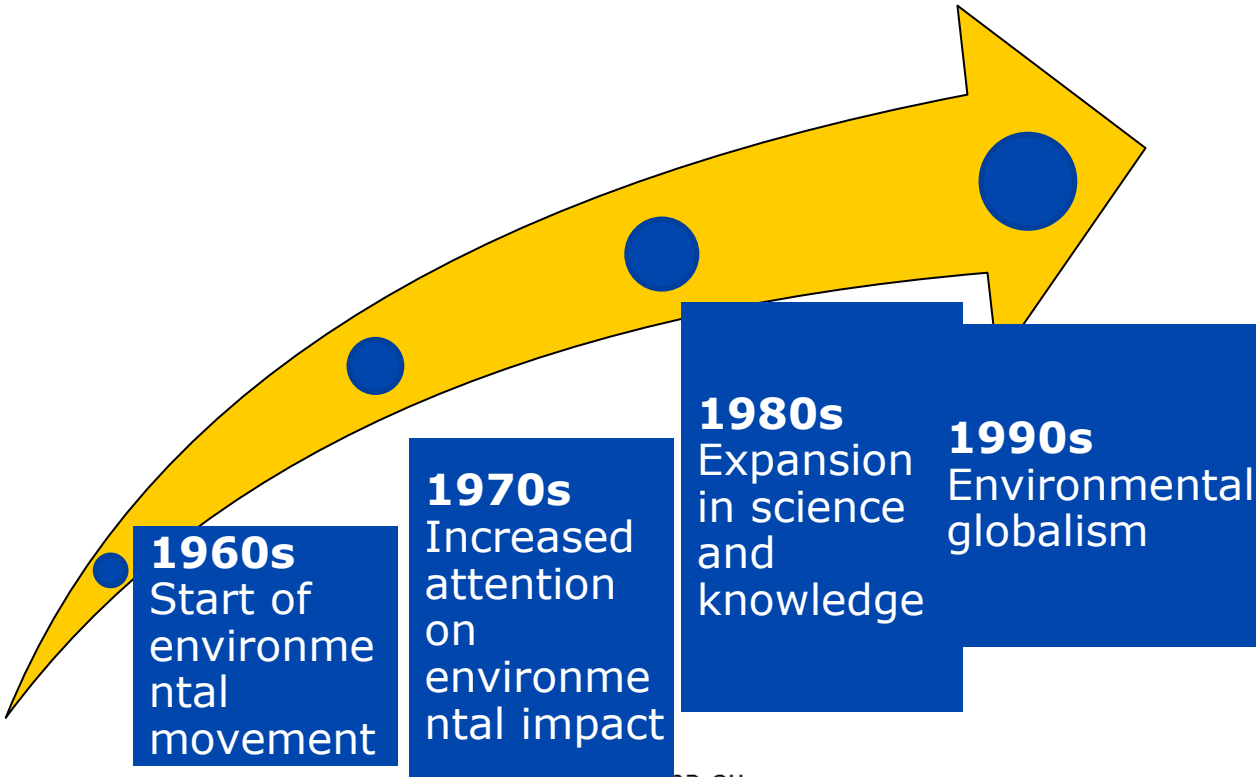
- The Council of the EU: negotiates and votes EU laws

# 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



ECHA
EUROPEAN CHEMICALS AGENCY

# EU chemicals legislation

**1967** Substance Directive → **1976** Limitation Directive → **1980** Chemical Risks Directive → **1988** Dangerous Preparation Directive

**1991** Plant Protection Products → **1993** Existing Substance Regulation → **1996** Seveso Directive → **1998** Chemical Agents Directive

**1998** Biocides Directive → **REACH CLP...**

# By 2007
## EU wide risk assessments

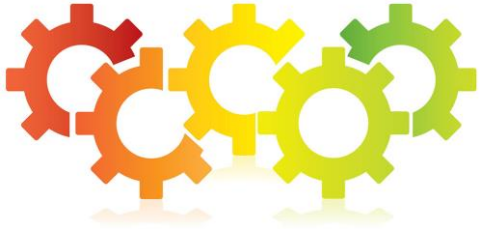
**141**
**chemicals prioritised at EU level**

**137**
**Agreed assessment for human health and environment**

**11:** no concern
**59:** risk management
**2:** further information

# 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

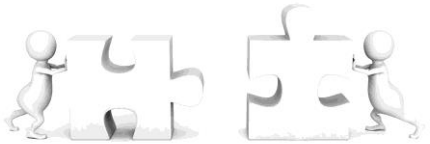


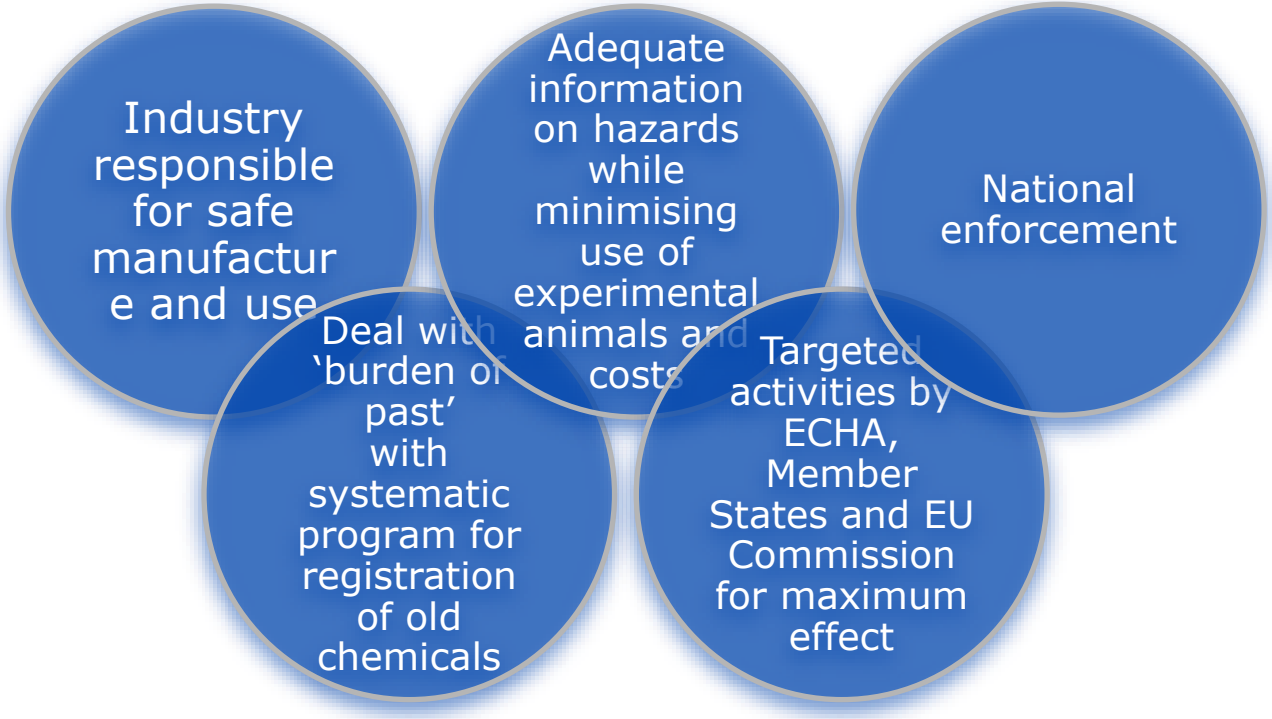
# Challenges

- 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

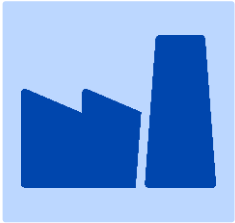
# REACH

# Principles of REACH





# REACH - Key processes

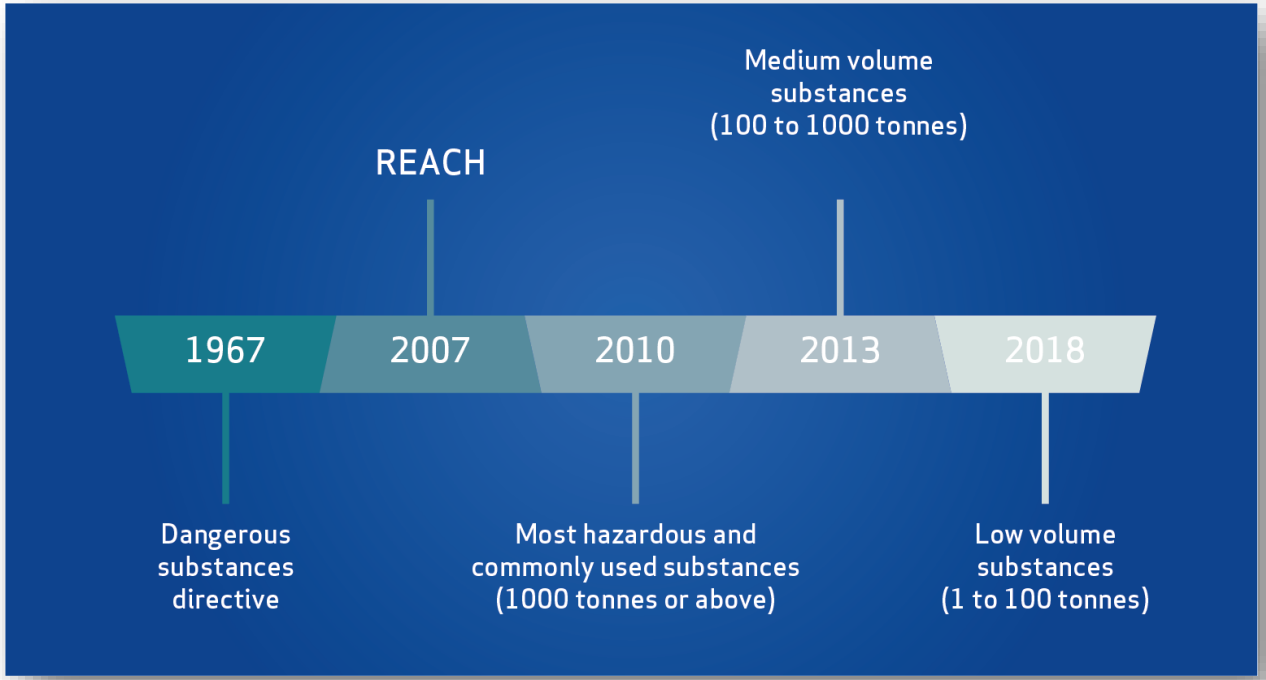


**Registration**
Industry gathers information on their chemicals, ensures management of risks and documents in a registration dossier submitted to ECHA

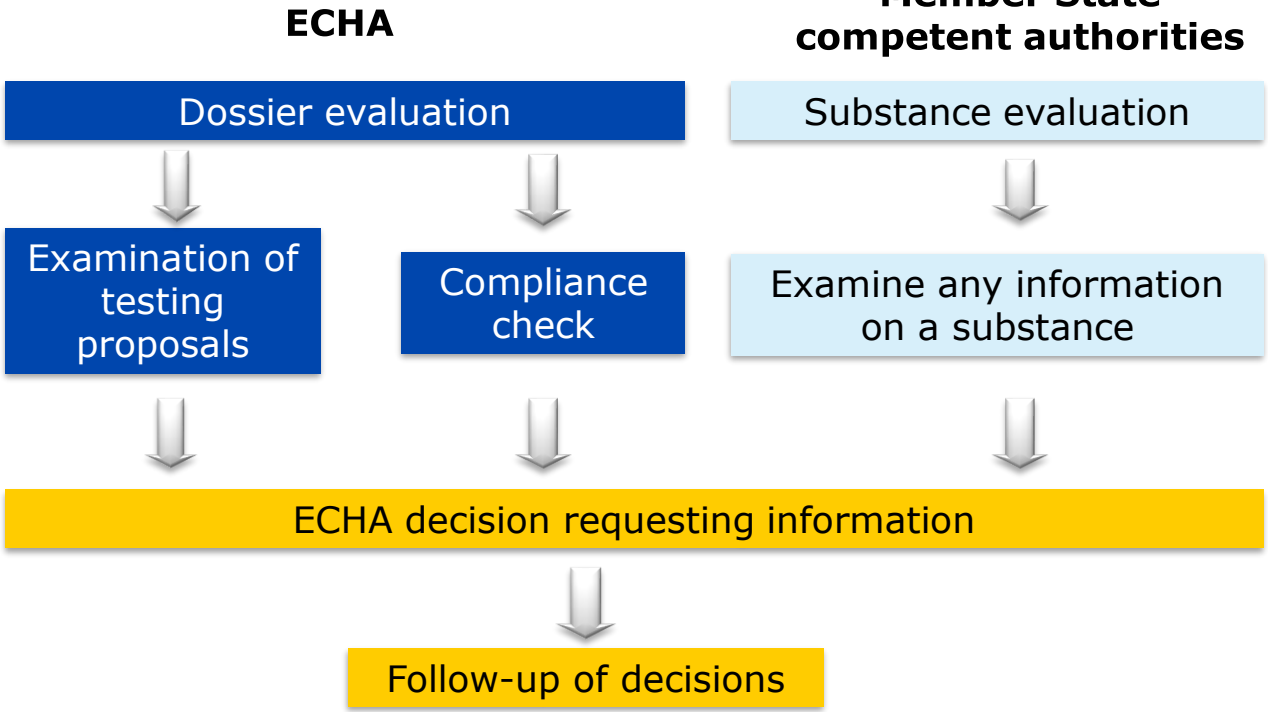

**Evaluation**
ECHA and Member States control and request further information when needed
Member States enforce legislation

**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

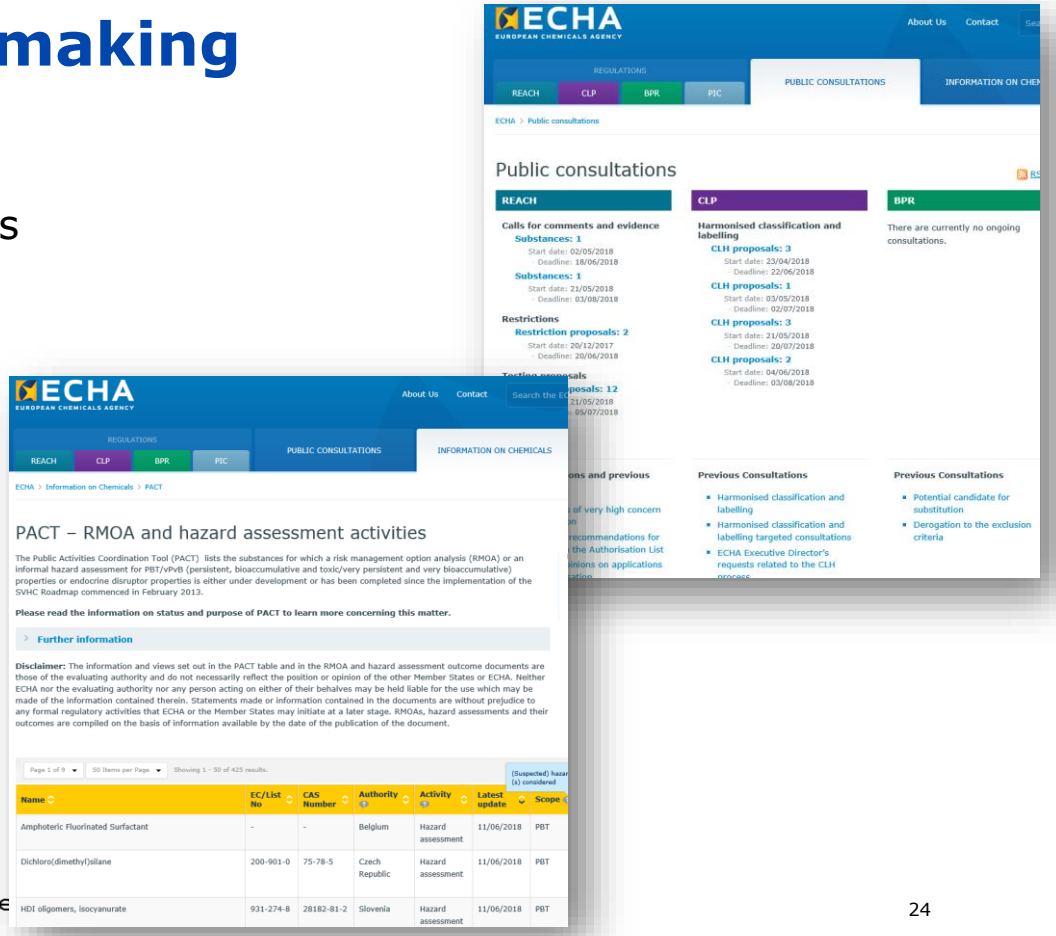
- When unacceptable risks to our health or the environment identified
- Member State competent authorities can submit dossiers proposing restrictions (or European Commission asks ECHA to submit)
- European Commission Decision based on an ECHA opinion
- Annex XVII of REACH lists all restrictions

# Risk management: authorisation

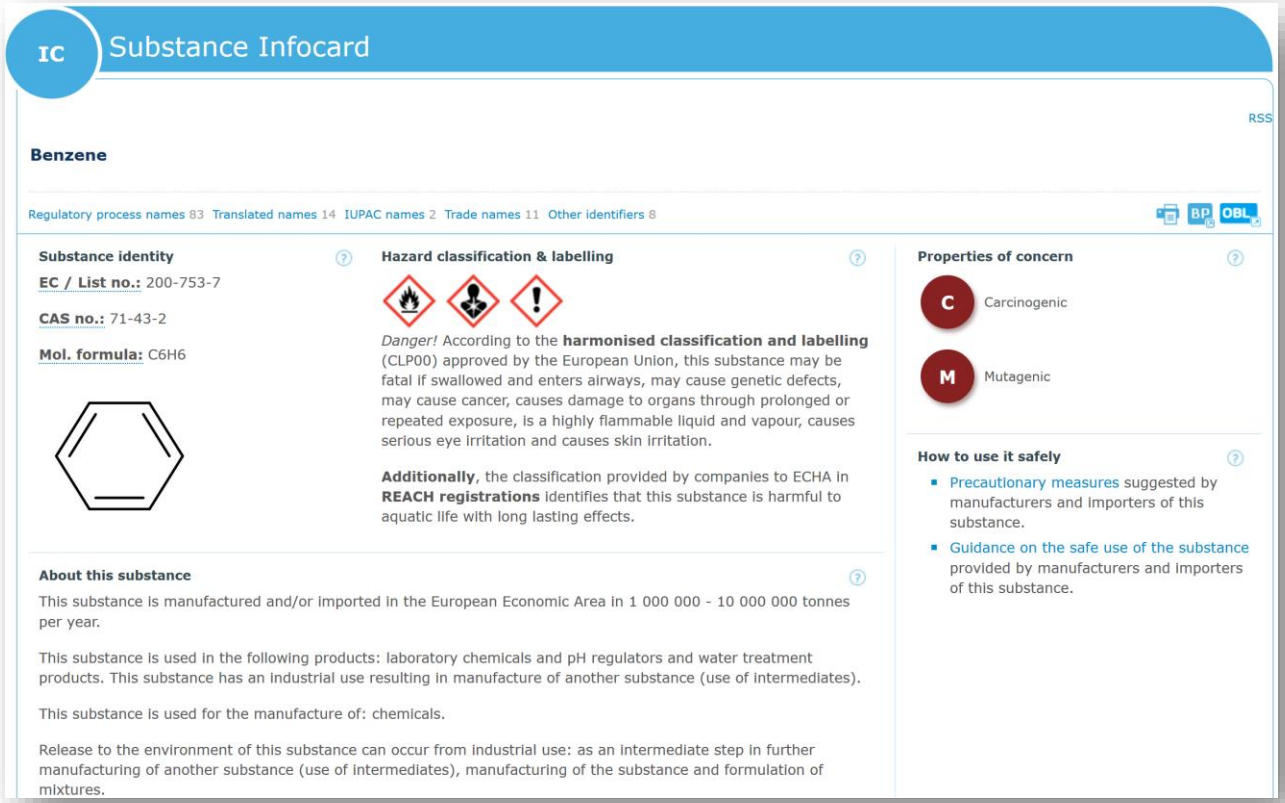
- Substances of very high concern (SVHCs): CMRs, PBT/vPvB or 'equivalent concern'
- Identification by Member States (or European Commission instructing ECHA) to 'Candidate List'
- Some transferred to 'Authorisation List', Annex XIV
- Once on Authorisation List, substance can only be marketed or used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



# Dissemination of information



# 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

# Database objectives

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

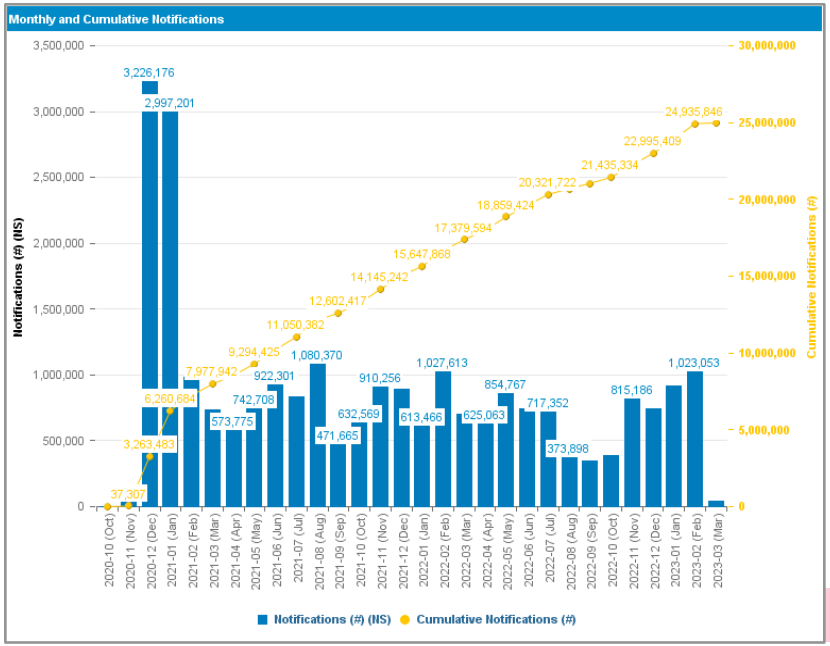
Safer products & cleaner materials cycles

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



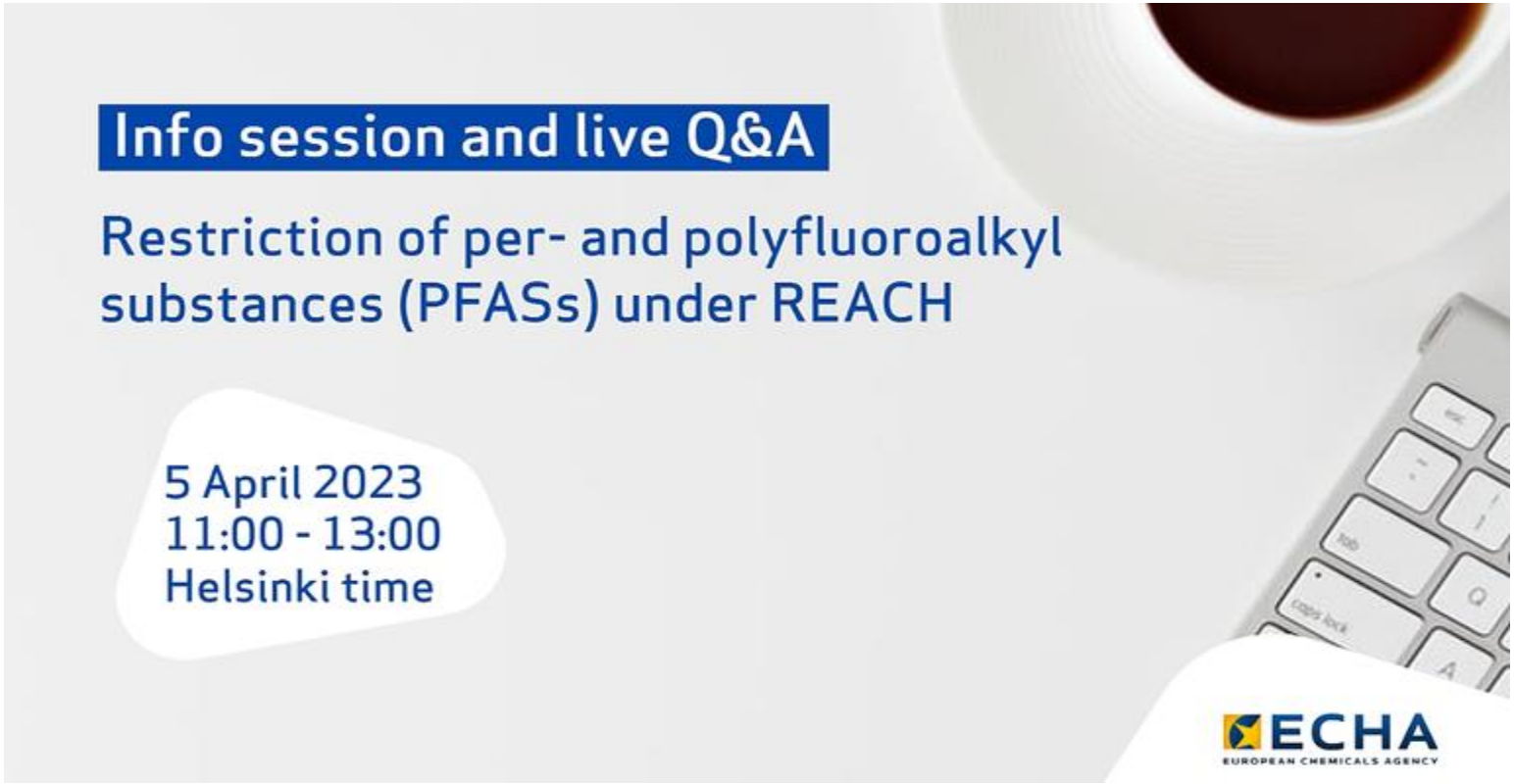

⚠ by > 9200 companies

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

Time period: 28.10.2020 – 01.03.2023

# Universal PFAS restriction

# Universal PFAS restriction



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# 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 *(strenghthen 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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