

Concept and overview of REACH

Seminar on Chemicals Management in EU

10 March 2025

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European Chemicals Agency





OUR PURPOSE

We protect health and the environment through our work for chemical safety

OUR VISION

Chemical safety through science, collaboration and knowledge

Agenda

- EU decision making
- Chemicals legislation in the EU before REACH
- REACH
- ECHA's data availability activities
 - Transition to ECHA CHEM & ECHA CHEM modules
 - Current status REACH registrations
 - Legal obligations and regulatory activities
- ECHA's current and upcoming responsibilities

EU decision making

EU institutions



echa.europa.eu



Court of
Justice of the
European
Union



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

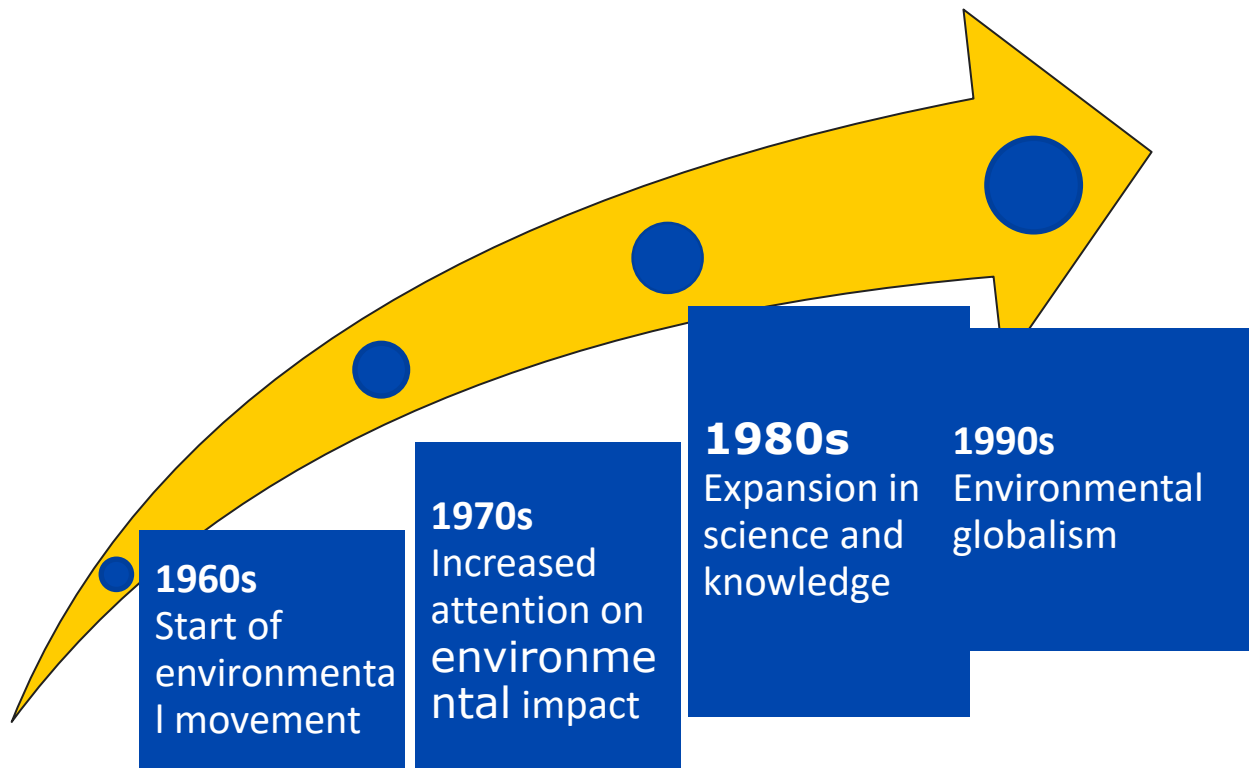
There are two distinct institutions, which share the same building:

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



Chemicals legislation in the EU before REACH

Environmental movement in Europe





EU chemicals legislation



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



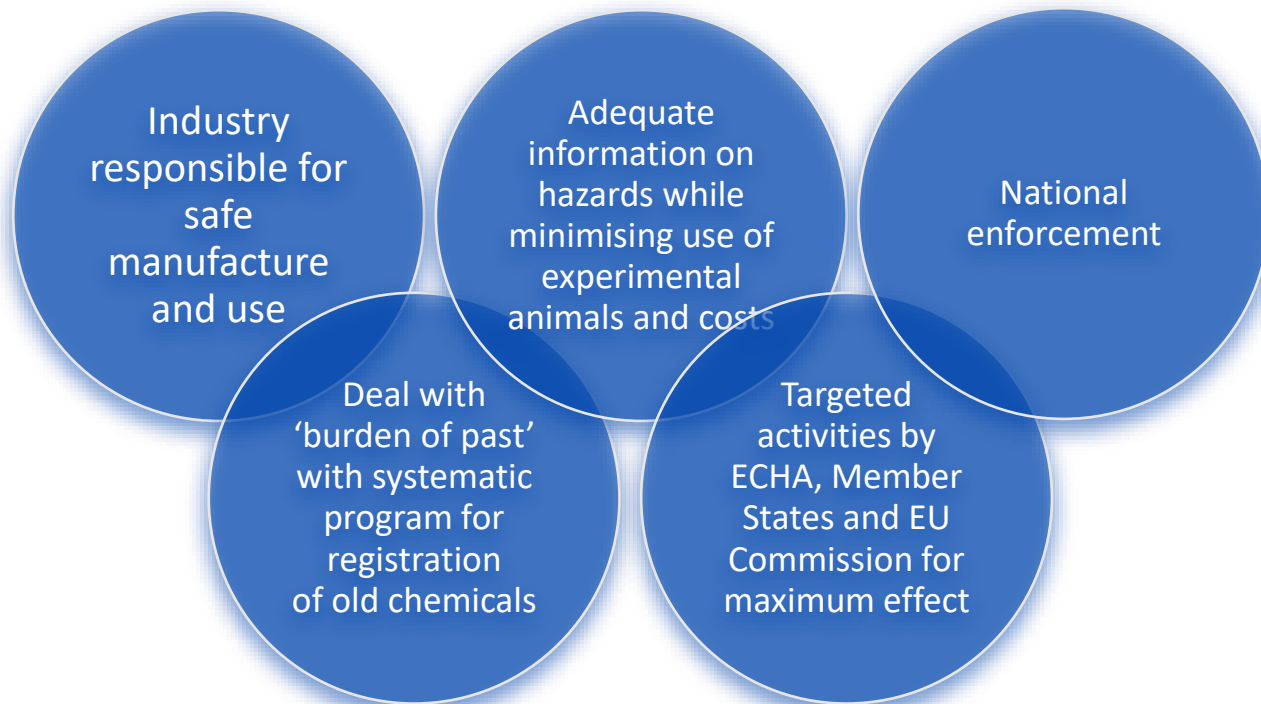


Challenges

- 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

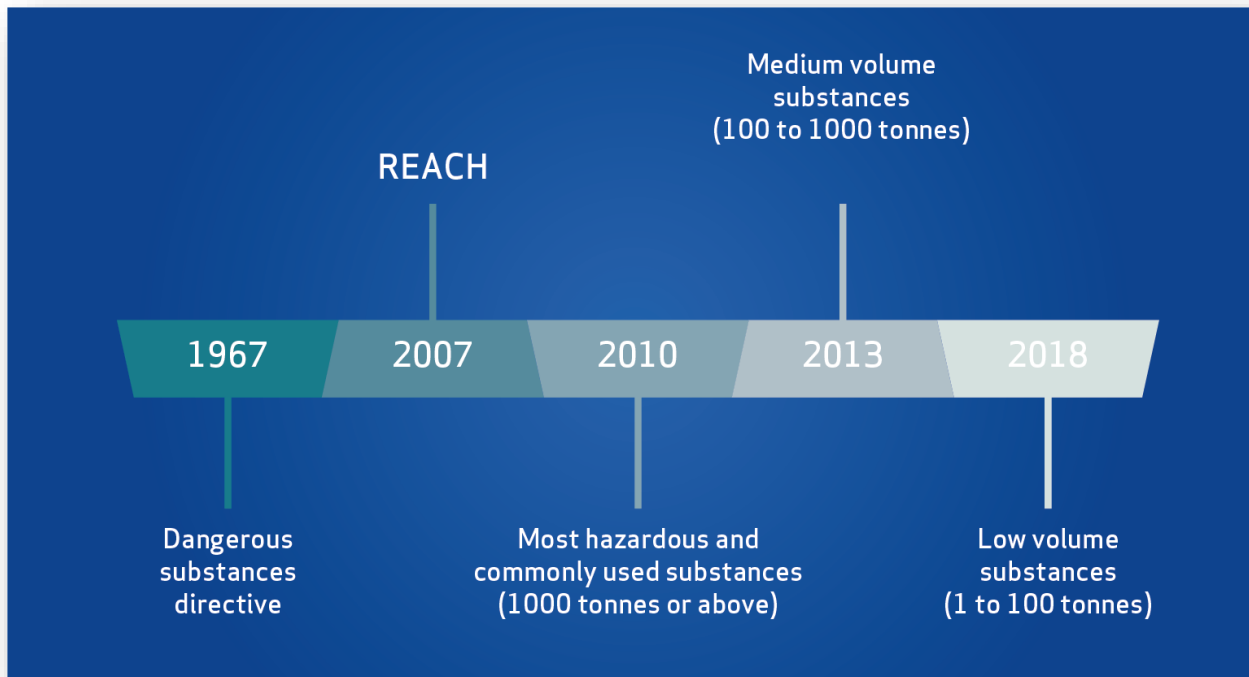


EU-wide risk management

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

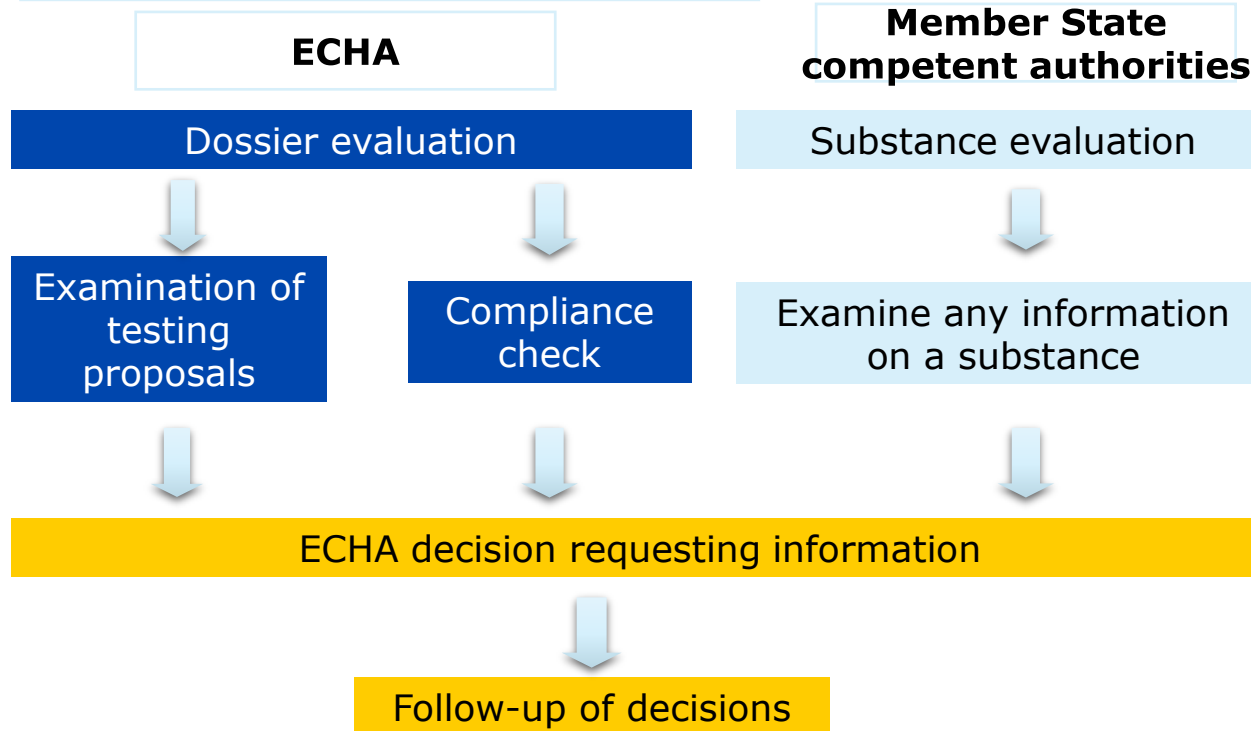


Registration journey





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



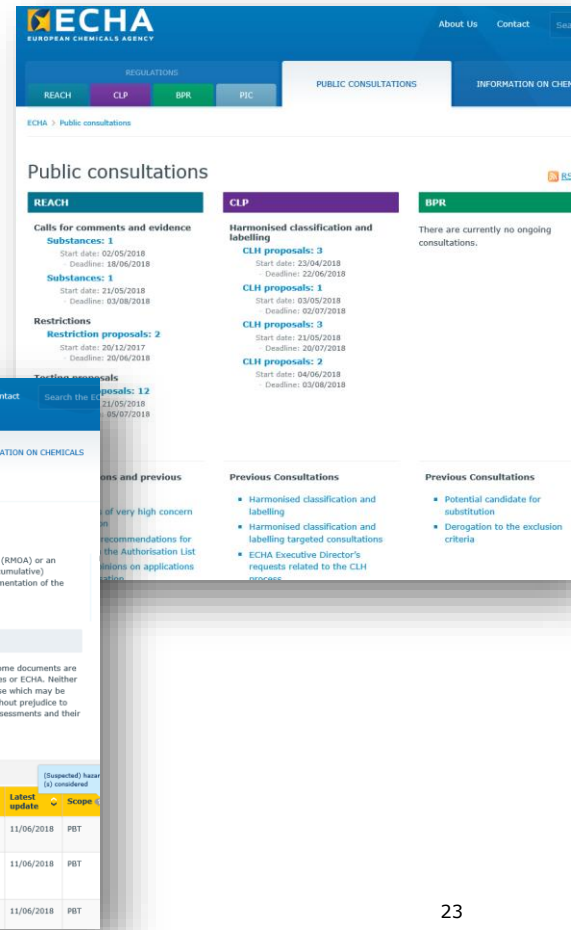
Risk management: authorisation

- 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)



The screenshot shows the ECHA Public Consultations page. The top navigation bar includes 'About Us', 'Contact', and 'Search'. Below this, there are tabs for 'REGULATIONS' (REACH, CLP, BPR, PIC) and 'PUBLIC CONSULTATIONS'. The main content area is titled 'Public consultations' and lists various consultation activities with their start and end dates.

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: 29/12/2017
Deadline: 20/06/2018

CLP

Harmonised classification and labelling

CLH proposals: 3

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

CLH proposals: 1

Start date: 03/05/2018
Deadline: 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

BPR

There are currently no ongoing consultations.

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.

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

Substance identity

EC / List no.:

200-753-7

CAS no.:

71-43-2

Mol. formula:

C₆H₆



Hazard classification & labelling





Danger! 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.

Additionally, the classification provided by companies to ECHA in **REACH registrations** identifies that this substance is harmful to aquatic life with long lasting effects.

Properties of concern

C

Carcinogenic

M

Mutagenic

How to use it safely

- [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.

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.

REACH revision

- Commission Work Programme 2015
- Moving forward together: A Bolder, Simpler, Faster Union
 - The **targeted revision of the EU's rules on chemicals (REACH)** will contribute to simplifying rules for the chemicals industry without compromising on safety and environmental protection.
 - Q4 2025

ECHA's data availability activities

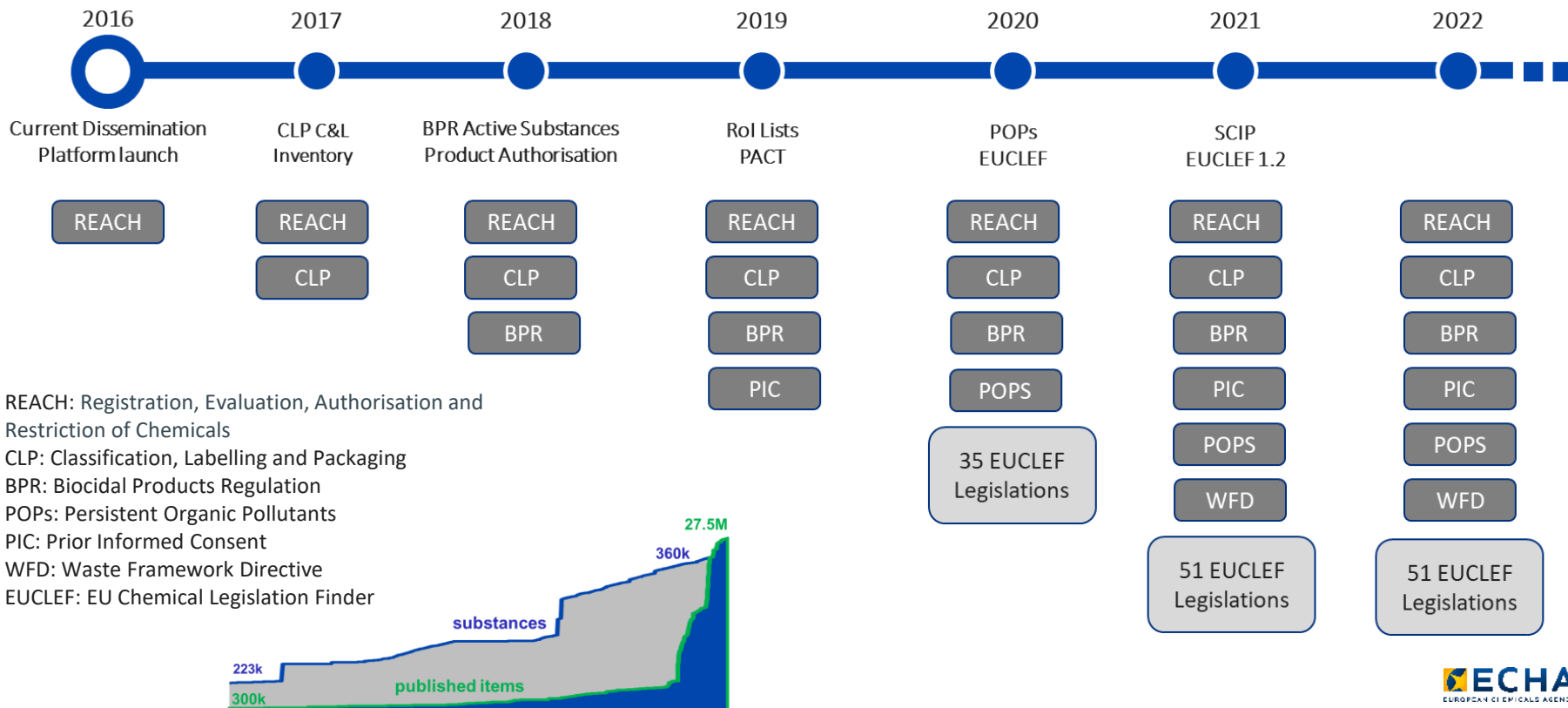
ECHA's data availability activities

- For ECHA, obligations to make data publicly available come via various chemicals regulations and directives, and delegated tasks:



- First integrated dissemination platform in launched 2016, making available information about chemicals and regulatory activities
- As of 2024, information is gradually moved to the new data availability system ECHA CHEM

From REACH to a CHEMICALS database



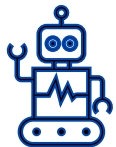
New data availability system ECHA CHEM 2024

ECHA CHEMICALS DATABASE

- rolling out ECHA's new strategic priorities & IT principles



*Modular,
expandable,
scalable
architecture*



*Modern technology
& high automation*



Cloud-based



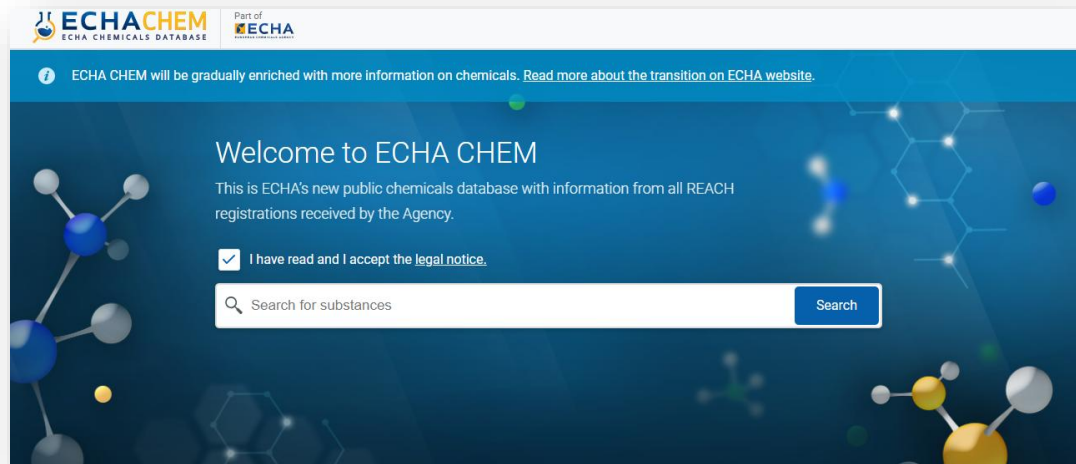
*Agile,
incremental
development*



*User experience,
stakeholder input*

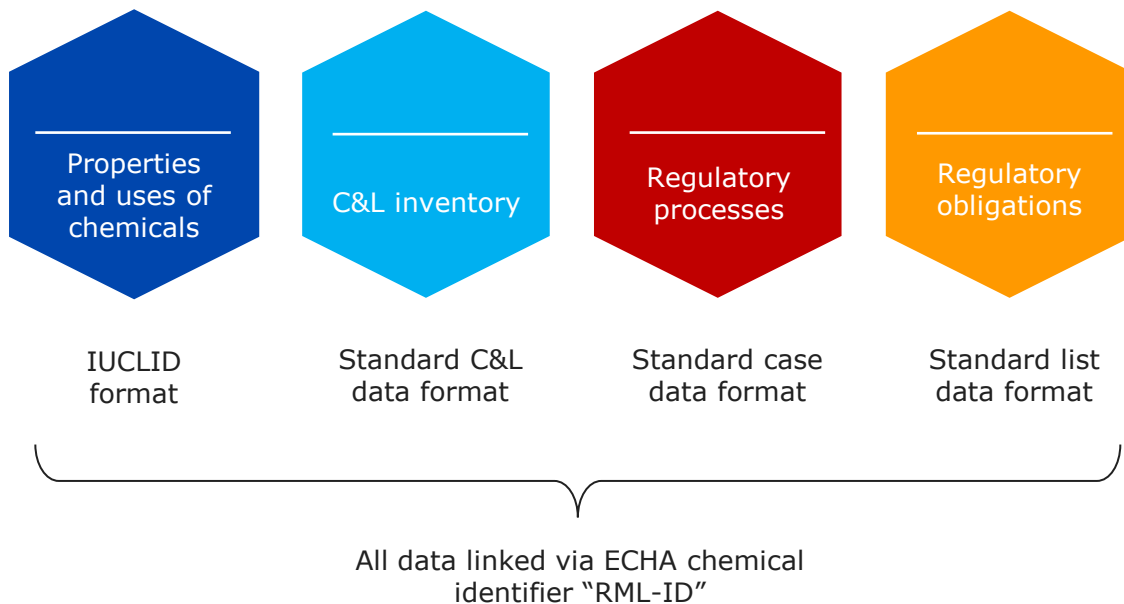


*Findable, inter-
operable and
accessible data*



ECHA CHEM design principles

→ Modular, expandable, scalable architecture



ECHA CHEM design principles

- Incremental development
 - Enabled by modular architecture
- Findable, inter-operable and accessible data
 - From aggregating all data to presenting it more “raw” with context data
 - Readiness to develop public API (Application Programming Interface)



Transition to ECHA CHEM & ECHA CHEM modules

Transition period

→ Incremental approach



→ Continuous access to information



→ We'll continue engaging with stakeholders

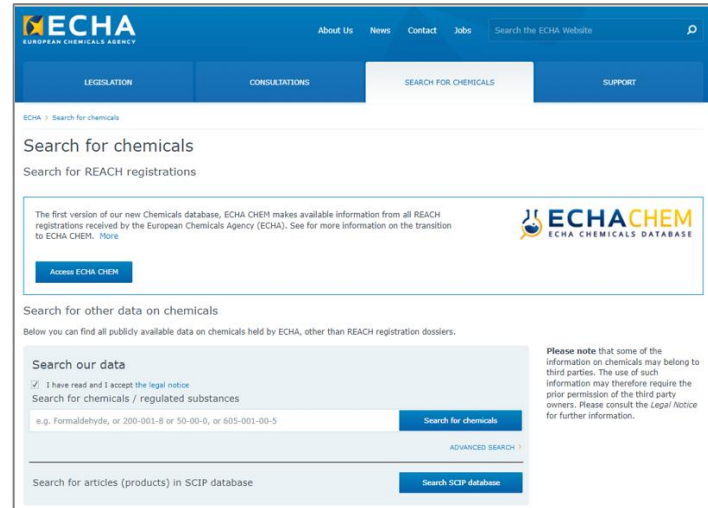
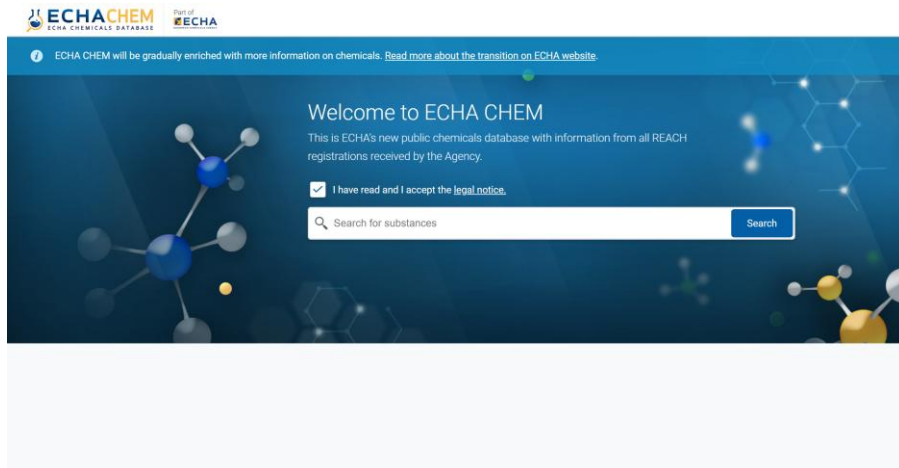


→ Support material prepared to guide users in this journey



Gradual transition

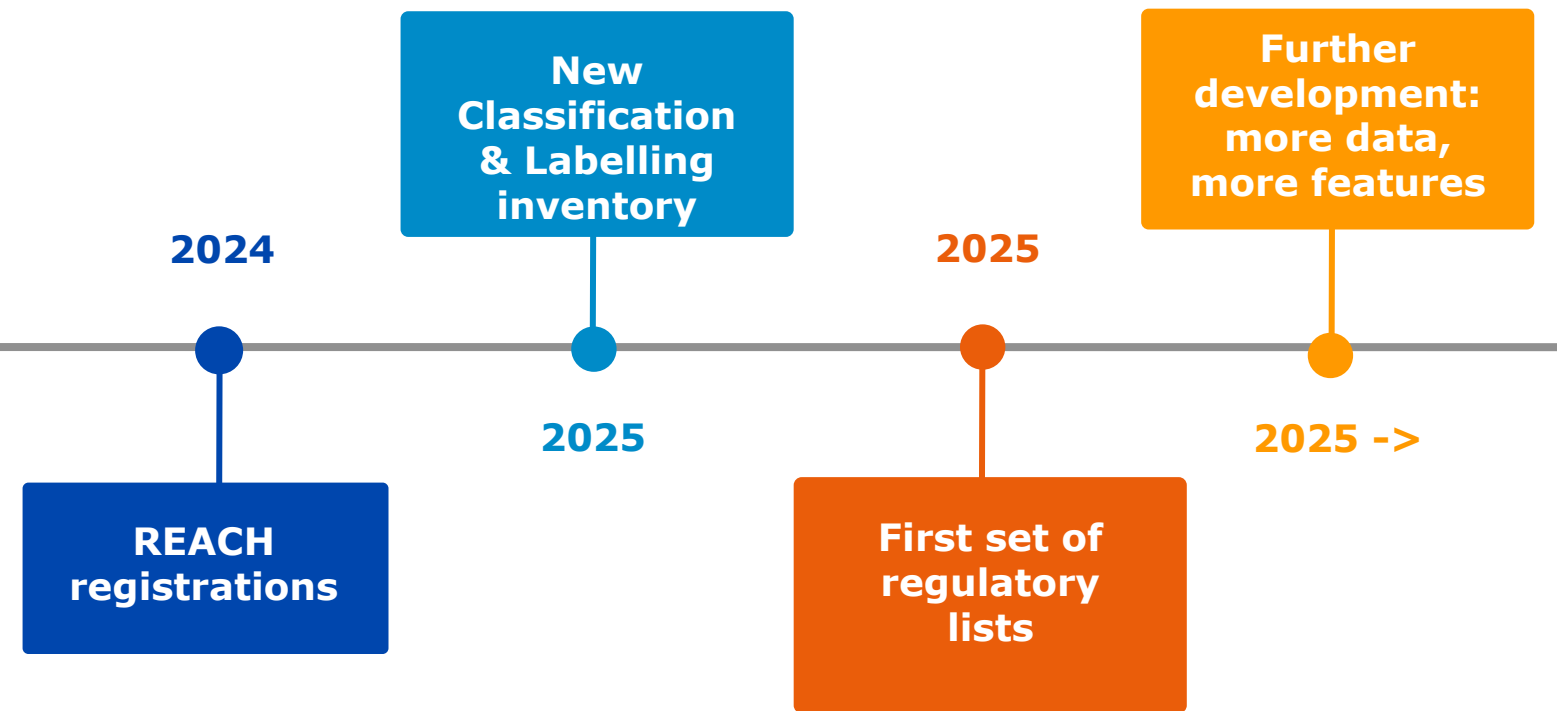
- First ECHA CHEM module was released in Q1/2024
- Two systems in parallel



- chem.echa.europa.eu
- Now available: REACH registrations
- Coming up in Q2:
 - C&L inventory
 - Regulatory activities and obligations

- echa.europa.eu
- At the moment still available
 - C&L inventory, Regulatory lists
- Transferred datasets will be decommissioned after a transition period.

ECHA CHEM Release Timeline



Current status: REACH
registrations

ECHA CHEM: released in January 2024!

→ Substance centric approach

The screenshot shows the ECHA CHEM search results page. At the top, there's a header with the ECHA CHEM logo and 'Part of ECHA'. Below this, a 'Search results' section contains a checkbox for 'I have read and I accept the legal notice.' and a search bar with 'benzene' entered. The search results are displayed under a 'Substances' heading, showing a table of 2,364 substances. The table has columns for Name, EC number, and CAS number. The first four results are listed:

Name	EC number	CAS number
Benzene IUPAC name: benzene	200-753-7	71-43-2
Benzenethiol IUPAC name: benzenethiol	203-635-3	108-98-5
Benzenesulphonamide IUPAC name: benzenesulfonamide	202-637-1	98-10-2
Benzene-1,3-dicarbonitrile IUPAC name: benzene-1,3-dicarbonitrile	210-933-7	626-17-5

- ECHA CHEM search functionality is similar to substance search on ECHA dissemination website.
- Currently limited to substances with a REACH registration.

ECHA CHEM: substance overview

 Part of 

←  Benzene
EC number 200-753-7 • CAS number 71-43-2

Overview

Overview
Identity
Dossiers
REACH registrations

Identity | [View more details](#)

Name	Benzene
EC number	200-753-7
CAS number	71-43-2
Description	-
Molecular formula	C ₆ H ₆
IUPAC name	benzene
Other identifiers	67



Dossiers


REACH registrations
133

Legal notice Cookies Feedback

- Substance information from different sources are displayed modularly in widgets
- Now available:
 - Identity
 - REACH reg dossiers
- Coming up:
 - C&L
 - Regulatory activities
 - Legal obligations
 - Substance relationships
- New sources can be integrated and updated independently without affecting the others
- Substance overview will gradually replace the current InfoCards

REACH Registrations

- Dossier list (New!)
- Display of latest submitted dossier per registration instead of the previous aggregated view
- Enables users to understand context of submitted data

← Benzene
EC number 200-753-7 • CAS number 71-43-2

REACH registrations

Under the REACH regulation, companies must register substances they import or manufacture in the EEA at 1 tonnes per year and above. As part of the registration, companies submit a so-called registration dossier to ECHA, with information on the identity, properties, classification and uses of... [Show more](#)

Estimated tonnage band 100 000 - 1 000 000 tonnes

Dossiers Registration numbers Registrants

Active Not active

103 Dossiers View rows 100 1-100 of 103 < > Export

Status	Dossier subtype	Registration role	NONS	Registration date	Last updated on	View Dossier
Active	Article 10 - full	Lead (joint submission)		20-May-2010	10-Mar-2021	
Active	Article 18 - intermediate	Individual		29-Jun-2010	9-Dec-2011	
Active	Article 18 - intermediate	Member (joint submission)		4-Nov-2010	18-Apr-2024	
Active	Article 18 - intermediate	Member (joint submission)		4-Oct-2010	19-Dec-2023	
Active	Article 18 - intermediate	Member (joint submission)		21-Jul-2010	12-Oct-2023	
Active	Article 18 - intermediate	Member (joint submission)		21-Jul-2010	11-Jul-2023	
Active	Article 18 - intermediate	Member (joint submission)		22-Oct-2010	2-Mar-2023	

REACH Registrations

→ Information on substances follows the IUCLID structure

The screenshot displays the ECHA Dossier publication for Benzene (EC number 200-753-7, CAS number 71-43-2). The interface is divided into a left sidebar for navigation and a main content area for details.

Entity details (Expand all):

- 1 General information 5
- 2 Classification & Labelling and PBT4 assessment
- 3 Manufacture, use and exposure 5
- 4 Physical and chemical properties 40
 - S-01 | Physical and chemical...
 - 4.1 Appearance / physical state / 3 colour
 - S-01 | Summary
 - 001 | Key | Other result ...
 - 002 | Supporting | Other ...
 - 4.2 Melting point / freezing point 3
 - 4.3 Boiling point 3
 - S-01 | Summary
 - 001 | Key | Experimenta...
 - 002 | Supporting | Experi...
 - 4.4 Density 3
 - 4.5 Particle size distribution (Granulometry) 1
 - 4.6 Vapour pressure 4
 - 4.7 Partition coefficient 3
 - 4.8 Water solubility 3
 - 4.9 Solubility in organic solvents / fat solubility

Boiling point

Administrative data

Confidentiality	[Empty]
Justification	[Empty]
Use restricted to selected regulatory programmes	[Empty]

Link to relevant study record(s)

Link to relevant study record(s) [Empty]

Description of key information

The boiling point of benzene is 80.09 °C at standard pressure

Key value for chemical safety assessment

Boiling point	80.09 °C
at the pressure of	101,325 Pa
Temperature of decomposition	[Empty]

Additional information

The CRC Handbook is a peer reviewed handbook and so can be considered reliable and suitable for use as the key study for this endpoint. The supporting study (Merck 2006) is also a peer reviewed handbook and supports the value reported in the key study, giving a boiling point of 80.1 °C.

Jump to

- Administrative data
- Link to relevant study record(s)
- Description of key information
- Key value for chemical safety assessment
- Additional information

Next steps

- This is an MVP, system will evolve gradually
- In the MVP the focus was making the data available through website for browsing in the display
- In further development we will look into other ways of interacting with the data
 - Download (existing/upcoming)
 - API (Application Programming Interface) (for context data)

Legal obligations and regulatory activities

First set of regulatory lists to ECHA CHEM in 2025

Content transferred from current Dissemination website to ECHA CHEM

Regulatory activities	Legal rights & obligations
REACH: Restriction process	REACH restriction list (Annex XVII)
REACH: Identification of SVHC	REACH Candidate list
REACH: Recommendations for inclusion in the Authorisation list	REACH authorisation list (Annex XIV)
REACH: Dossier evaluation	
REACH: Substance evaluation	
CLP: CLH process (RoI CLH)	CLP: Harmonised classifications (Annex VI)
POPs: Substances proposed as POPs	POPs: Substances subject to POPs regulation

The first set transfers most of the PACT* list content to ECHA CHEM.

+ New content (new task for ECHA)

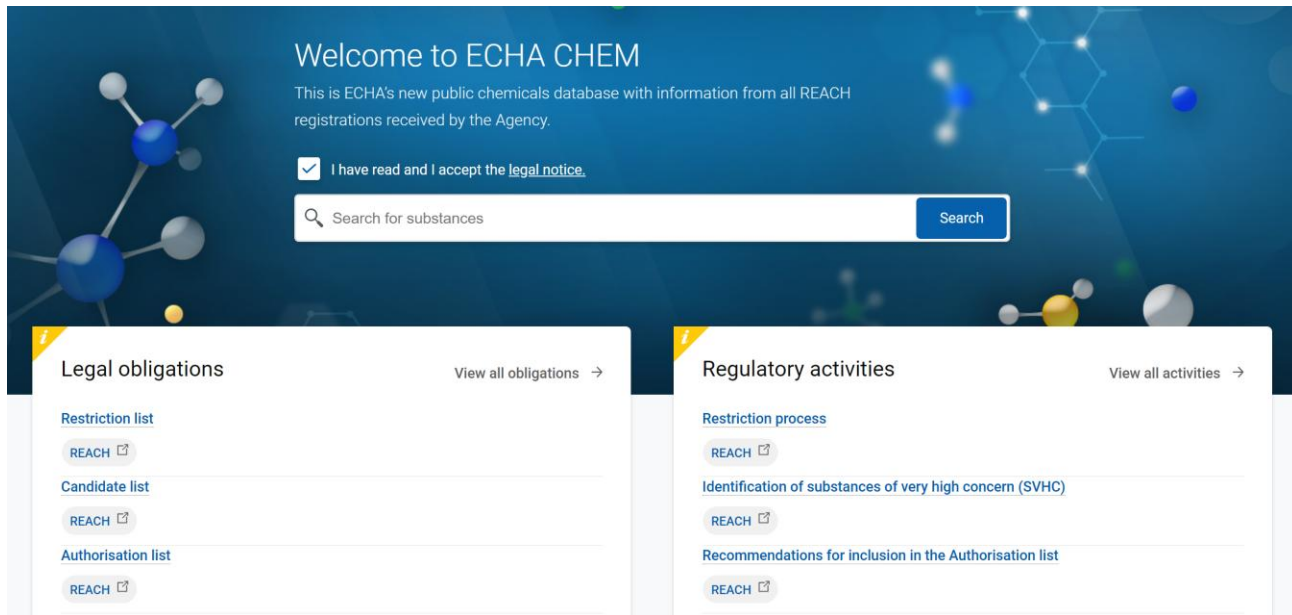
DWD: EU positive list

+ Further content to be added 2025-2027

Regulatory lists in ECHA CHEM

Please note that the screenshot examples shown in the next slides are not necessarily based on real or full set of data. They are here only for illustrative purposes.

→ ECHA CHEM Landing page extended with links regulatory lists



Separate sections for

- Legally binding lists (Legal obligations)
- Regulatory activities = ongoing or closed regulatory processes

Access by substance: Search → Substance overview

 **ECHACHEM**
ECHA CHEMICALS DATABASE

Part of
 **ECHA**
EUROPEAN CHEMICALS AGENCY

←  Tetraethyllead
EC number 201-075-4 • CAS number 78-00-2

Overview

Overview

Identity

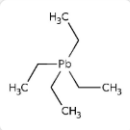
Dossiers

Regulatory context

Classification & labelling

Identity | [View more details](#)

Name	Tetraethyllead
EC number	201-075-4
CAS number	78-00-2
Description	-
Molecular formula	C ₈ H ₂₀ Pb
IUPAC name	tetraethylplumbane



Other identifiers 39

Dossiers


REACH registrations
3

Legal obligations
[All legal obligations](#) →
2
[View some obligations](#)
[Authorisation List](#)
[Candidate List](#)

Regulatory activities
[All regulatory activities](#) →
8
Most recent activities
 [Annex XIV Recommendations list](#)
 [Restriction process](#)

DRAFT



Whateverium 8

EC number 999-608-8

CAS number 933-08-0

Whateverium's exceptional strength-to-weight ratio renders it invaluable in the

Restriction process

Intentions and Annex XV restriction proposals received by ECHA • The Restriction process list includes the intentions and

Timeline

Restriction Intention

22-Mar-2023

[Show more](#)

Restriction start call for evidence

13-Aug-2023

[Show more](#)

Restriction proposal first submission

13-Jan-2024

Remarks

Some public remarks

Related documents

SomeDocument: [Preliminary report on case](#)

[Show less](#)

Start consultation on restriction proposal

Restriction final RAC opinion

Start consultation on SEAC draft opinion

Restriction final SEAC opinion

Decision on restriction list inclusion

DRAFT

New feature: Regulatory activity timeline

- Main steps of the regulatory activity shown on timeline
 - Past events
 - Current stage
 - Future events
 - Documents together with the event

New feature: Enhanced overview of substance status in regulatory activities



Part of
 ECHA
EUROPEAN CHEMICALS AGENCY

 Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine deriv...
EC number 272-712-1 • CAS number 68909-77-3

←

Regulatory activities

Overview

Identity

Dossiers

Regulatory context

Obligations

Activities

Classification & Labelling

4 activities

View rows 100 ▾ 1-4 of 4 < > [Export](#)

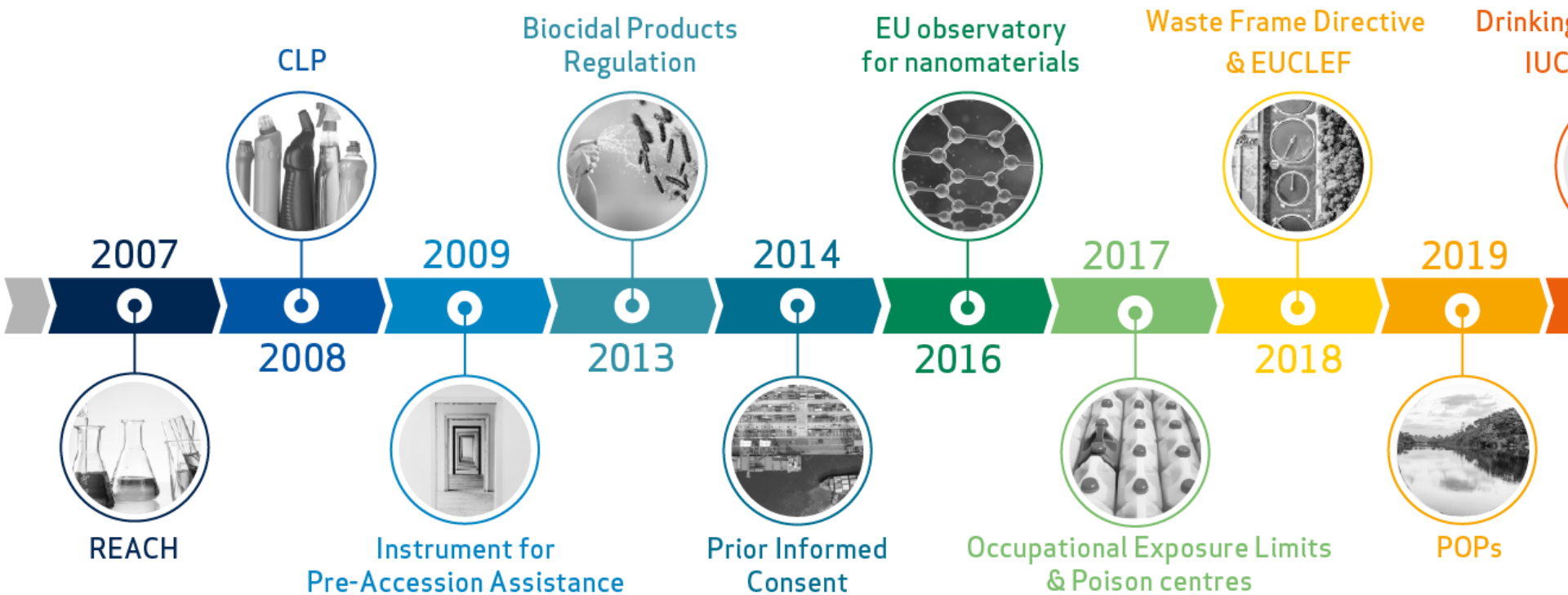
Regulatory activity ▴ ▾	Status ▴ ▾	Current stage ▴ ▾	Current stage date ▾	Relevant legislation ▴ ▾	View activity details
Restriction process	Ongoing	Start consultation on restriction proposal	22 May 2023	REACH 	
Recommendations for inclusion in the Authorisation list	Ongoing	Annex XIV end of consultation	21-May-2023	REACH 	
Identification of substances of very high concern (SVHC)	Ongoing	SVHC start of MSCA consultation	10-May-2023	REACH 	
Restriction process	Closed	Withdrawal of restriction proposal	5-May-2022	REACH 	

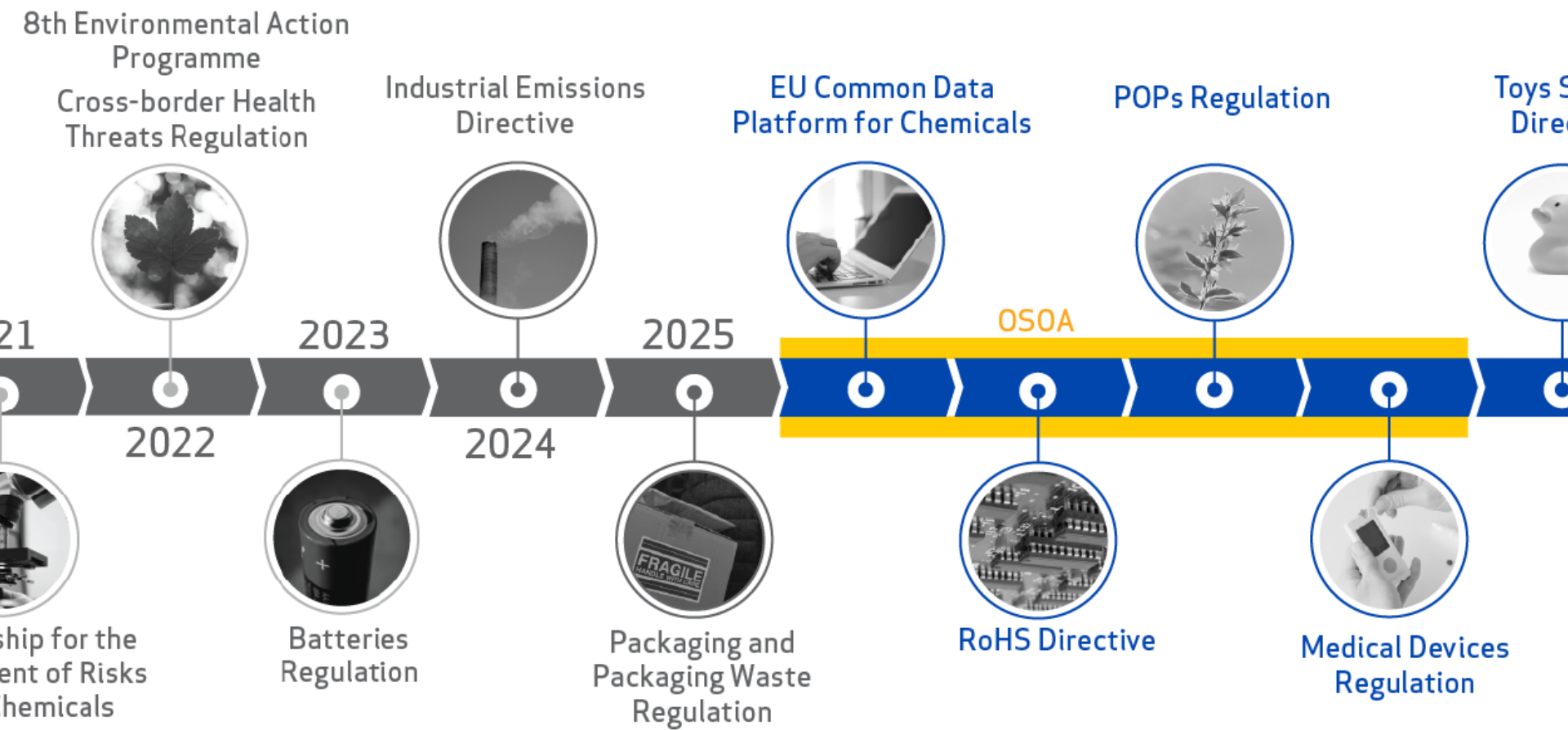
DRAFT

Data consumption methods

- Download features available in 2025
 - Basic list export first
 - More comprehensive export a bit later
- Looking into API (Application Programming Interface) next year

ECHA's current and upcoming responsibilities





Thank you

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European Chemicals Agency



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