



Concept and overview of REACH

Seminar on Chemicals Management in EU

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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



- **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

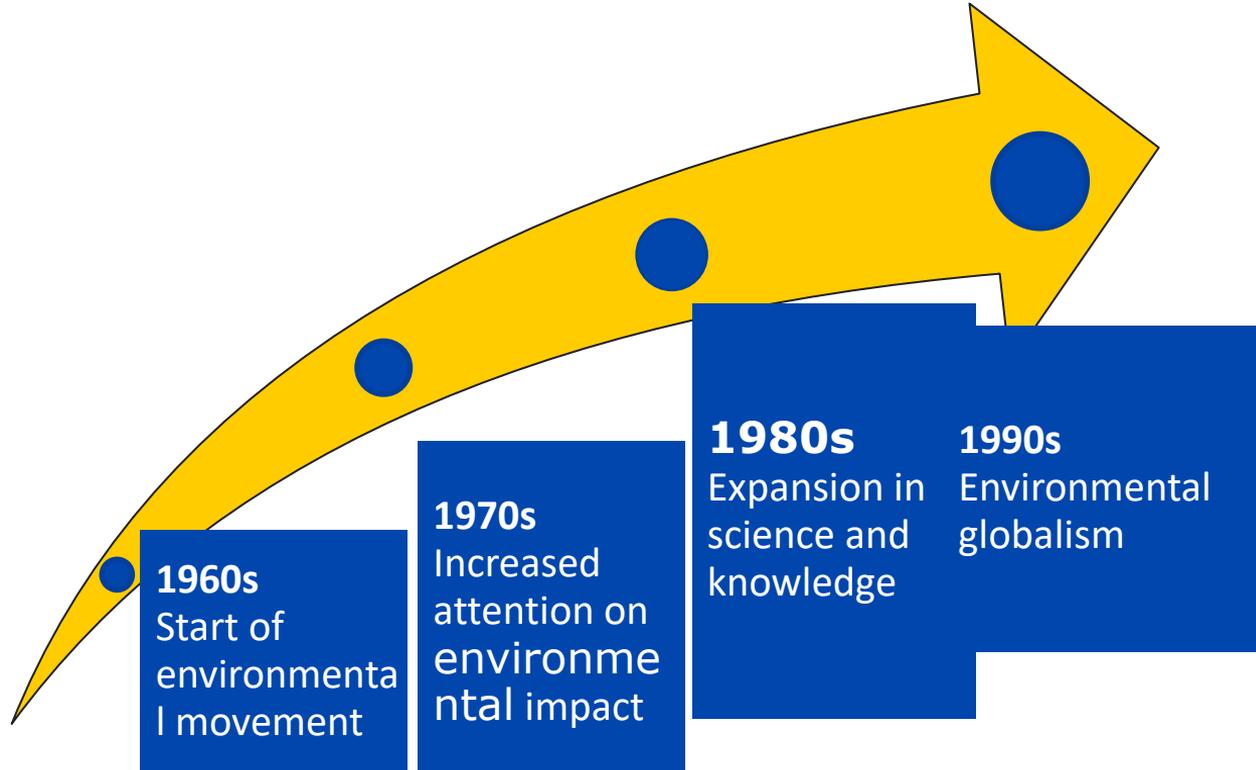
There are two distinct institutions, which share the same building:

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



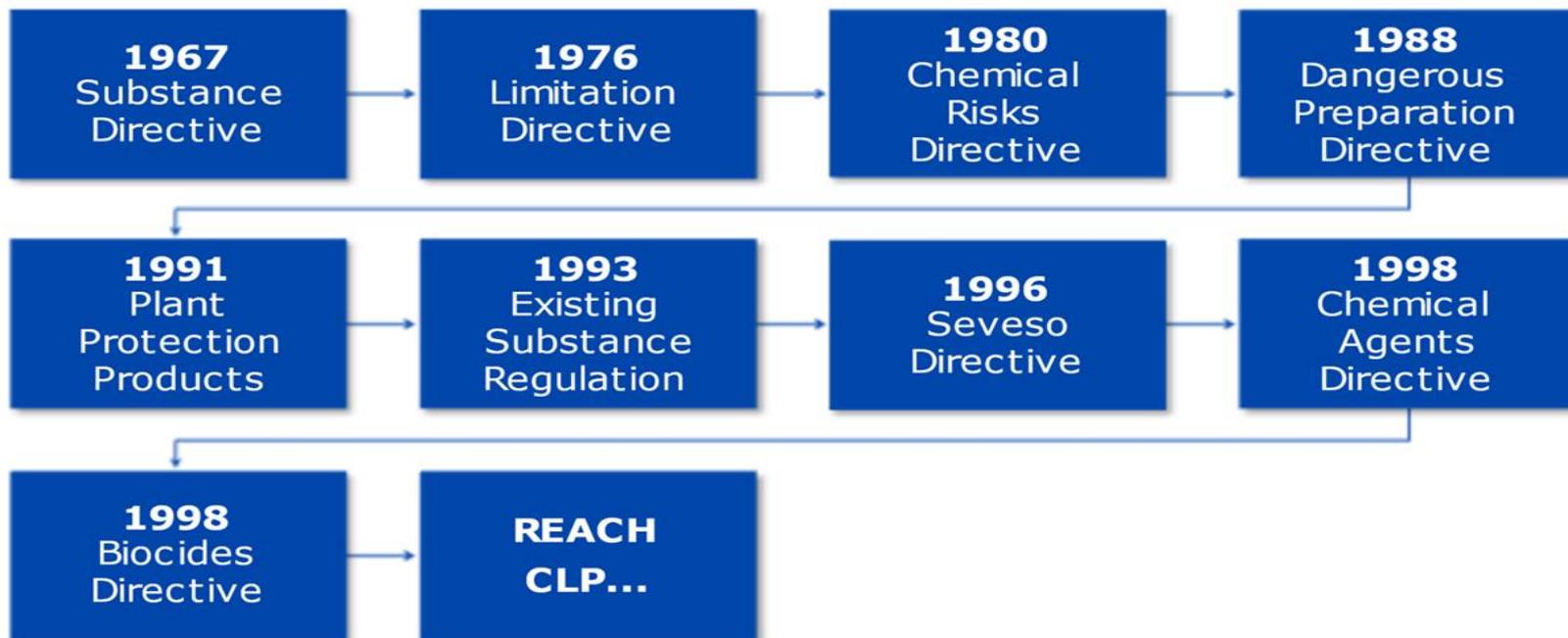
Chemicals legislation in the EU before REACH

Environmental movement in Europe





EU chemicals legislation



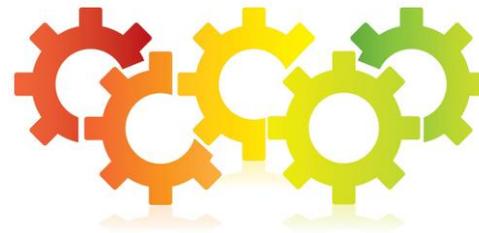
By 2007 EU wide risk assessments



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





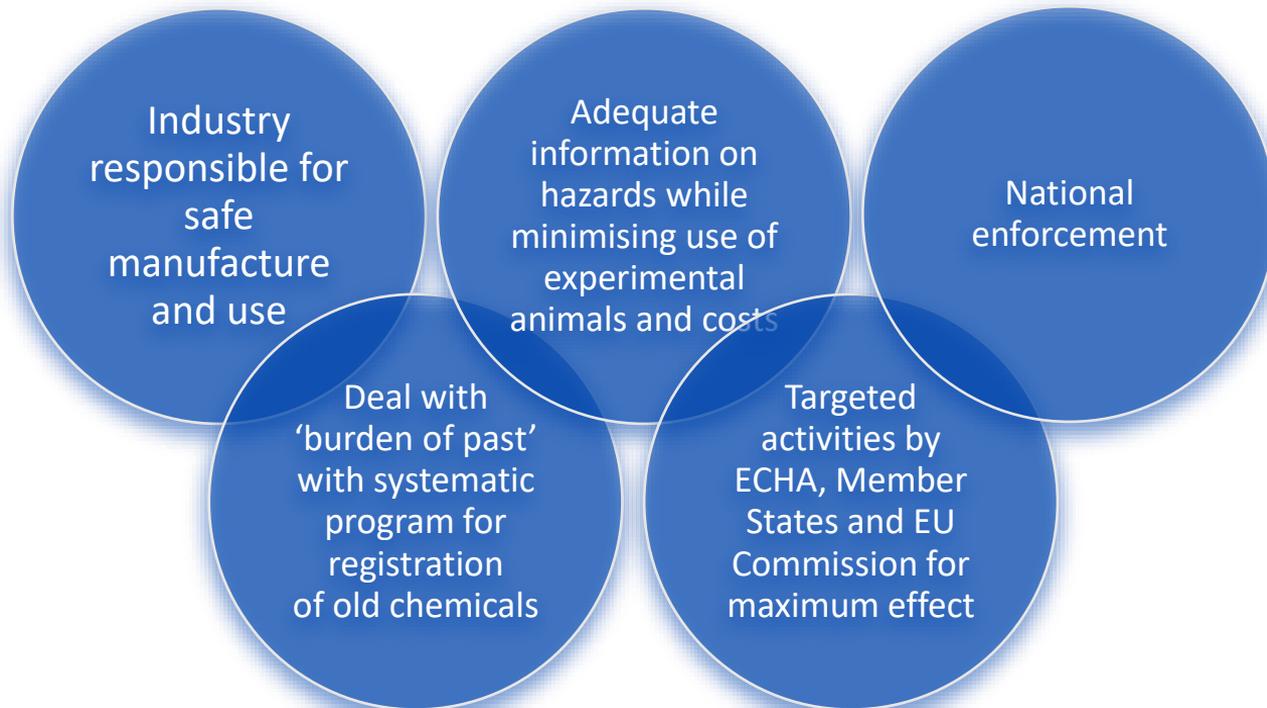
Challenges

- 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

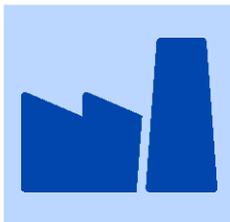
REACH



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

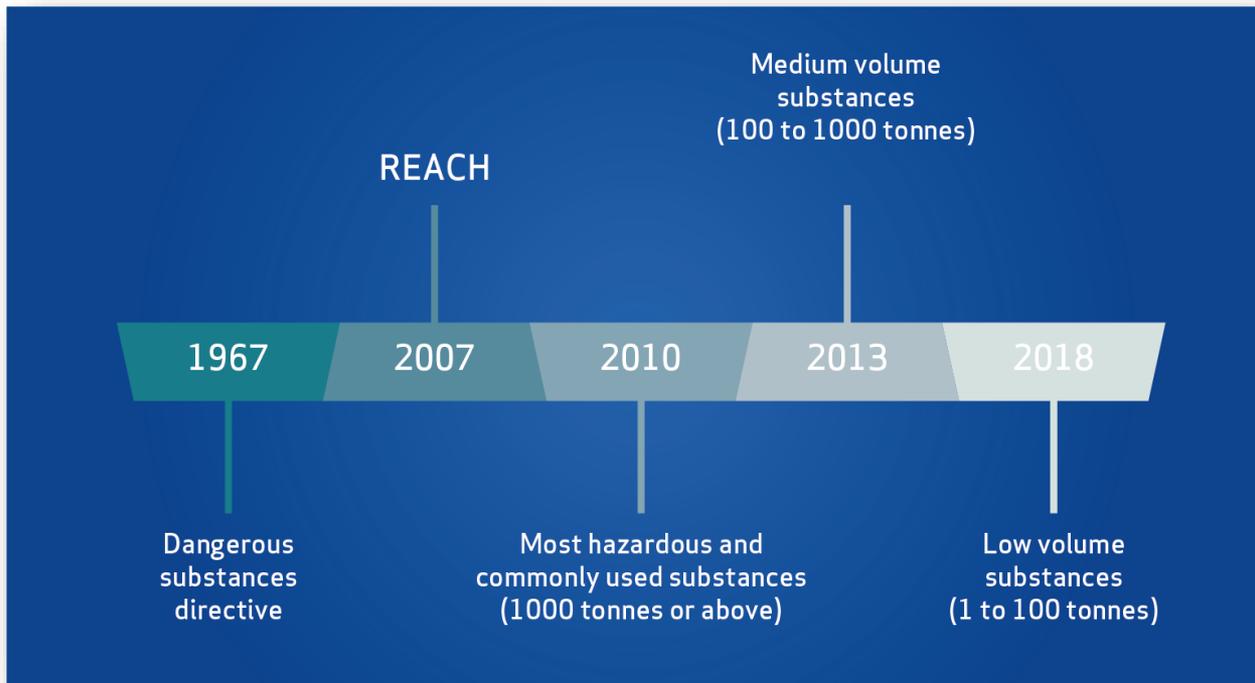


EU-wide risk management

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

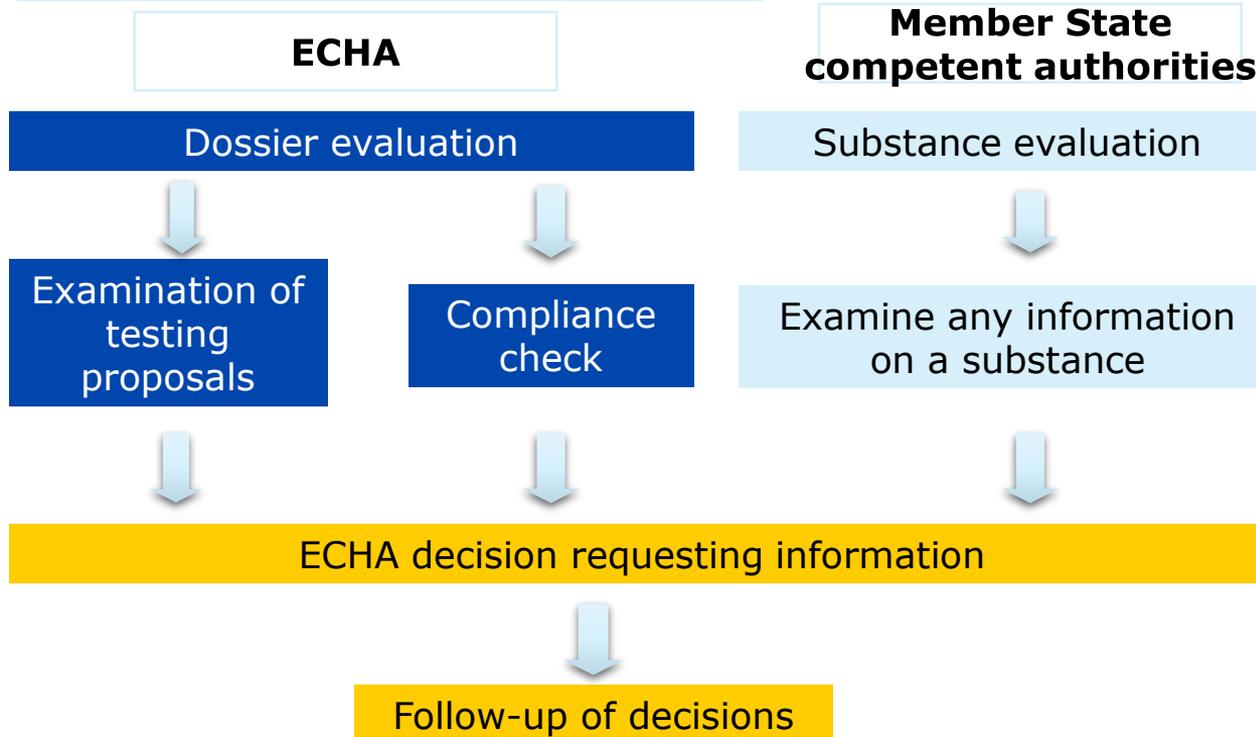


Registration journey





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



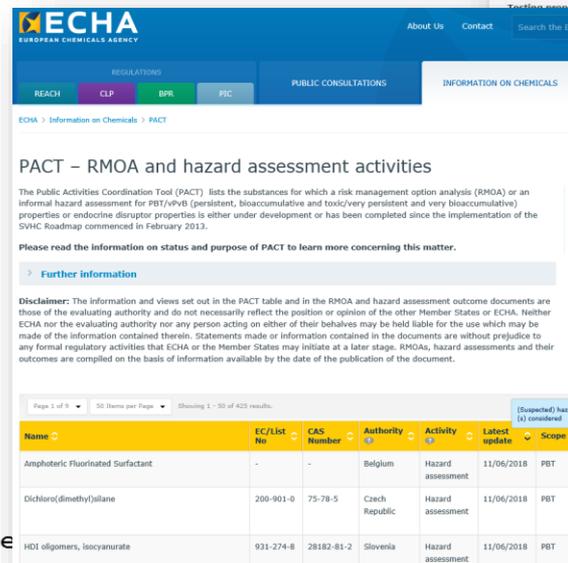
Transparent decision making process

- 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 website's 'Public consultations' section. It features a navigation bar with 'REACH', 'CLP', 'BPR', and 'PIC' tabs. 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	Activity	Start Date	Deadline
REACH	Substances: 1	02/05/2018	18/06/2018
	Substances: 1	21/05/2018	03/08/2018
	Restrictions	20/12/2017	20/06/2018
CLP	CLH proposals: 3	23/04/2018	22/06/2018
	CLH proposals: 1	03/05/2018	02/07/2018
BPR	CLH proposals: 3	21/05/2018	20/07/2018
	CLH proposals: 2	04/06/2018	03/08/2018



The screenshot shows the 'PACT - RMOA and hazard assessment activities' page. It includes a disclaimer and a table of substances under assessment. The table has columns for Name, EC/List No, CAS Number, Authority, Activity, Latest update, and Scope.

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>About this substance ?</p> <p>This substance is manufactured and/or imported in the European Economic Area in 1 000 000 - 10 000 000 tonnes per year.</p> <p>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).</p> <p>This substance is used for the manufacture of: chemicals.</p> <p>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.</p>		<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.

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

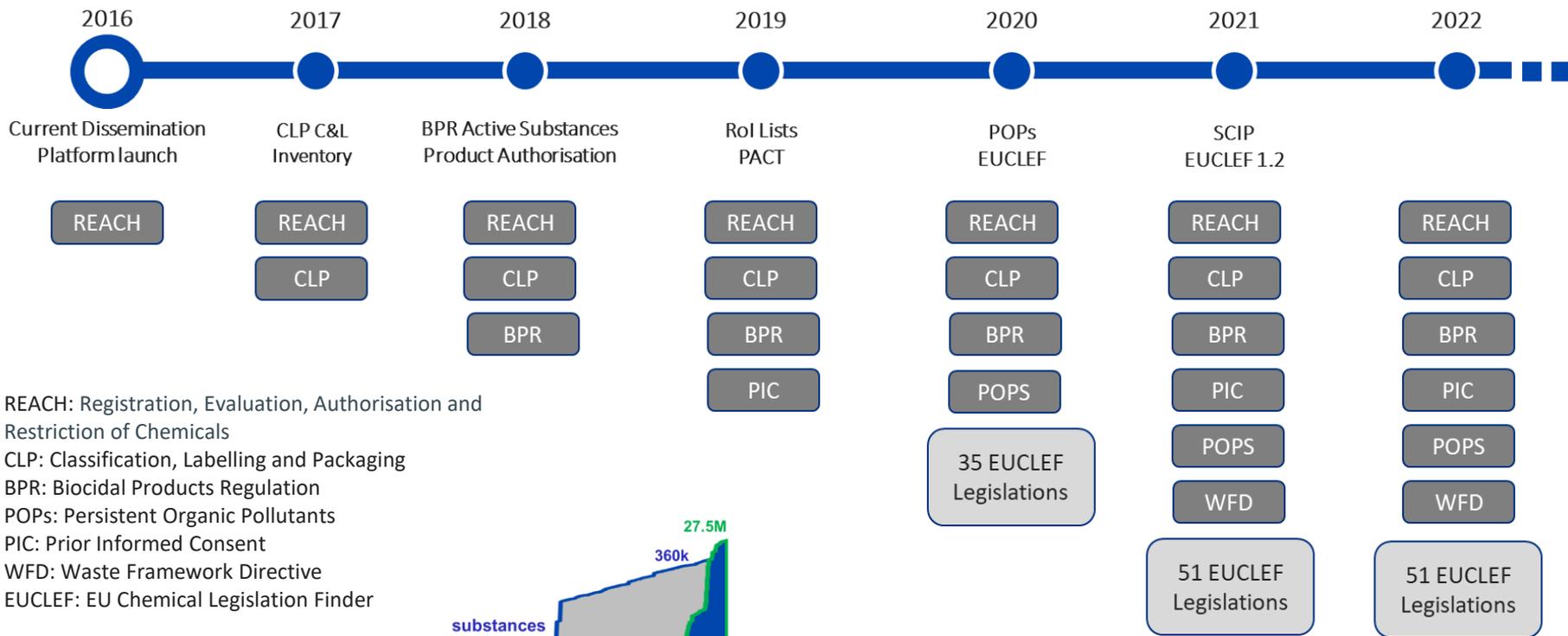
ECHA's data availability activities

- 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

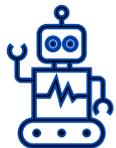
ECHA CHEMICALS DATABASE

2024

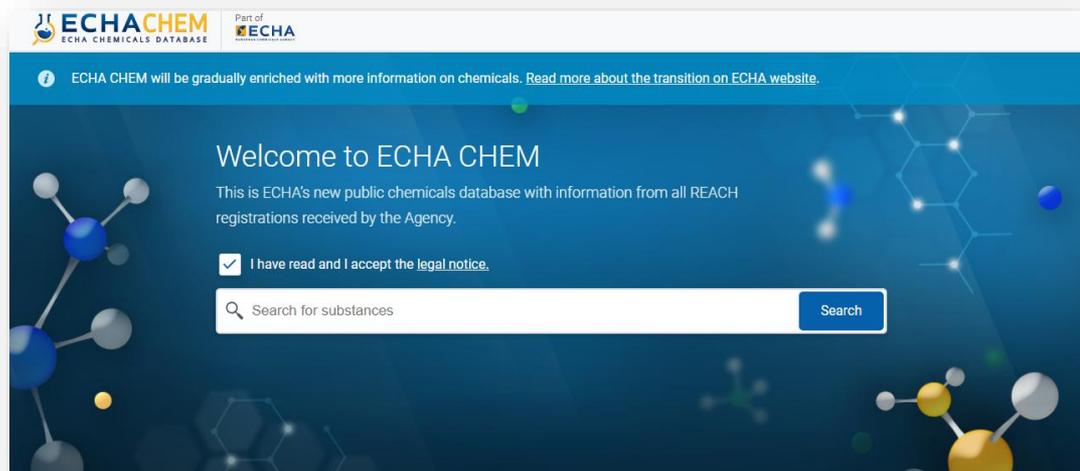
- rolling out ECHA's new strategic priorities & IT principles



*Modular,
expandable,
scalable
architecture*



*Modern technology
& high automation*



*User experience,
stakeholder input*



*Findable, inter-
operable and
accessible data*



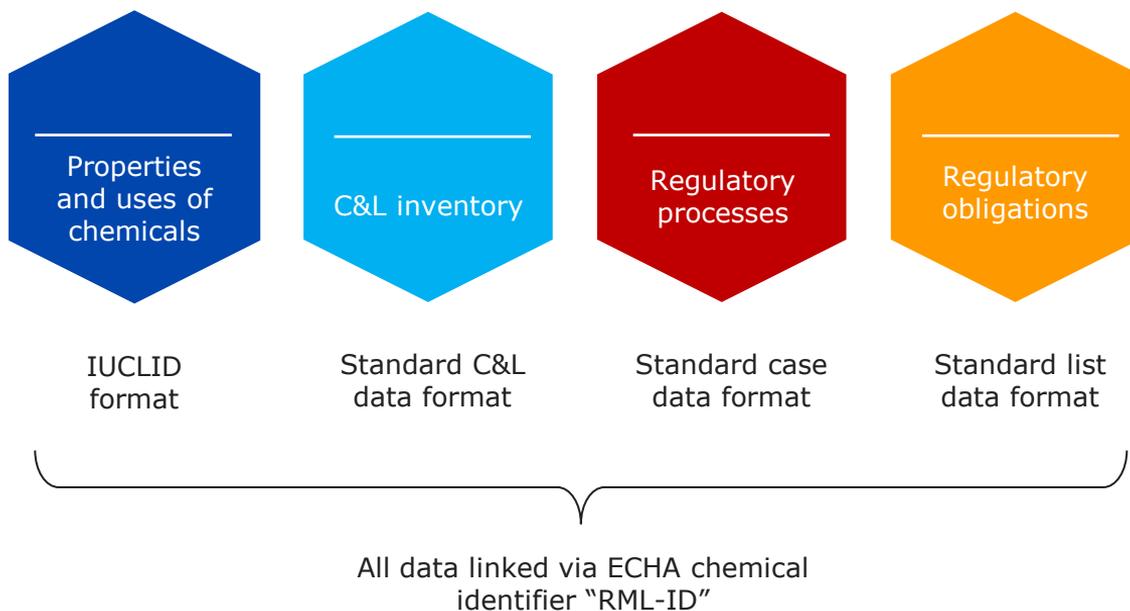
Cloud-based



*Agile,
incremental
development*

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

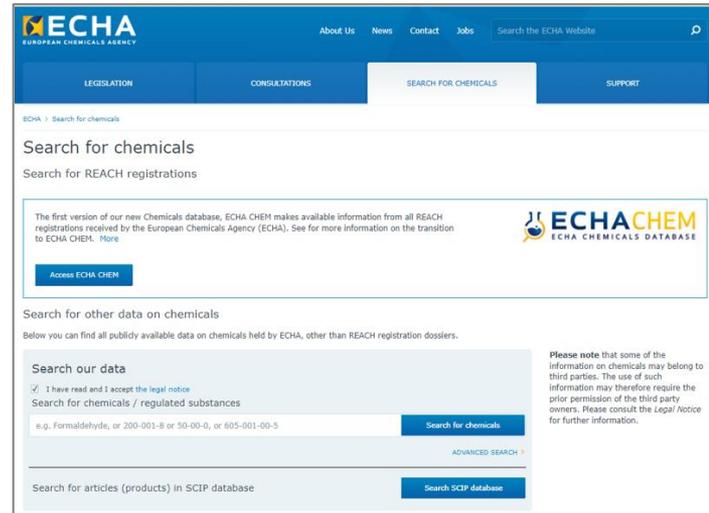
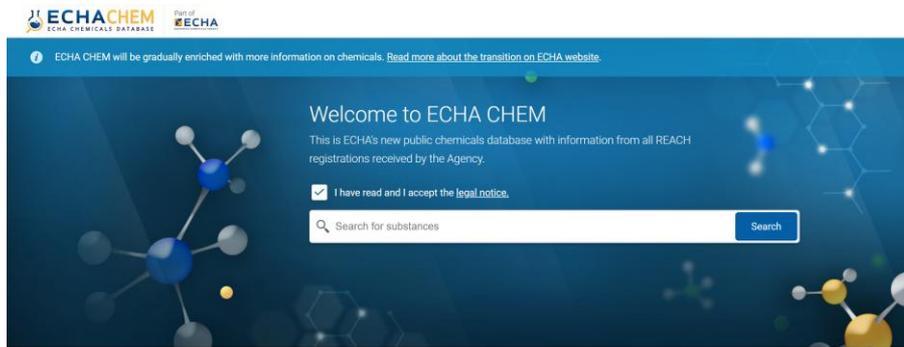


→ Support material prepared to guide users in this journey



Gradual transition

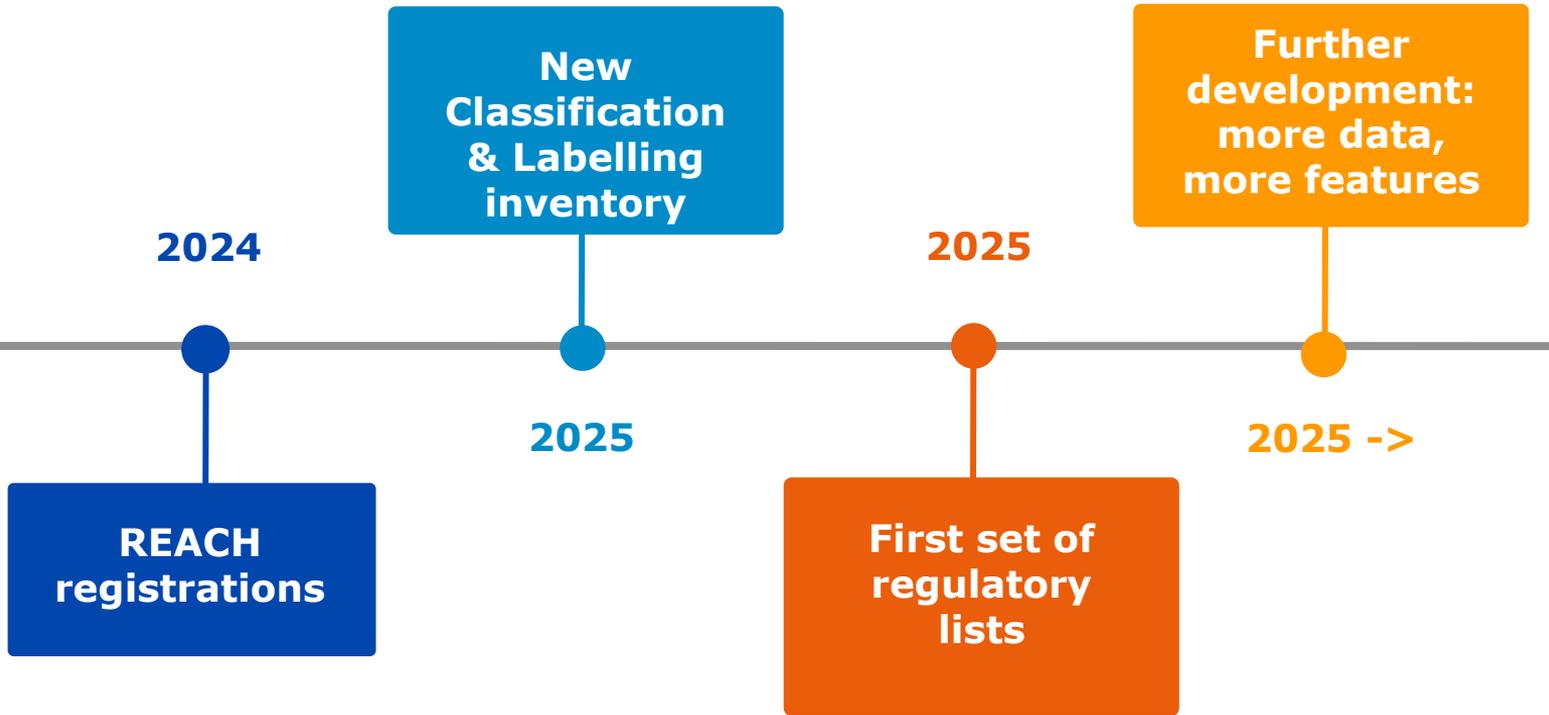
- First ECHA CHEM module was released in Q1/2024
- Two systems in parallel



- 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.

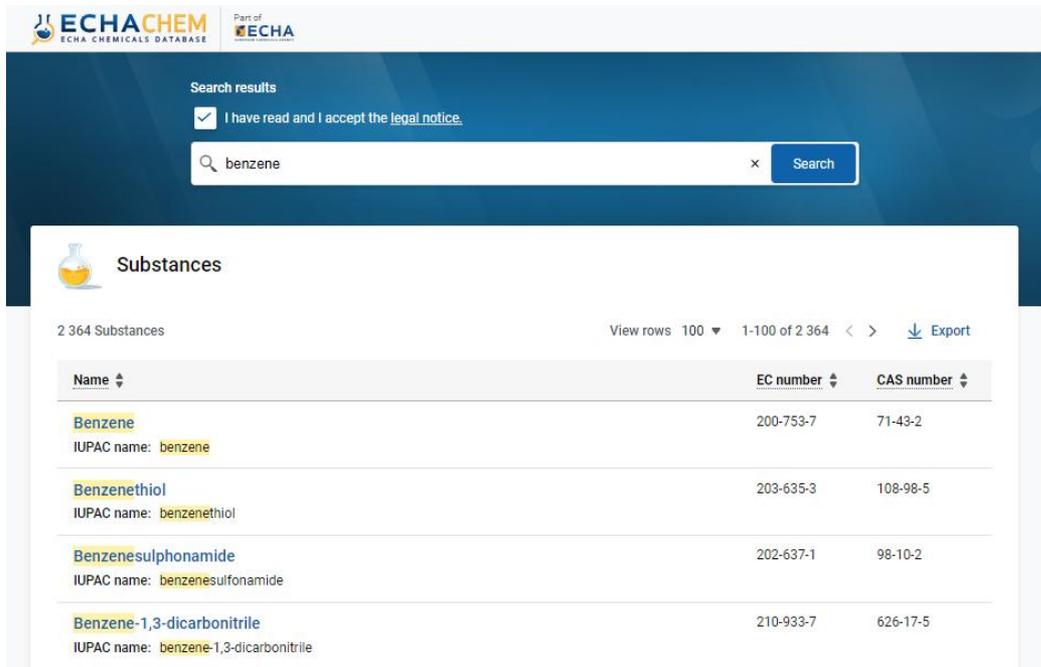
ECHA CHEM Release Timeline



Current status: REACH
registrations

ECHA CHEM: released in January 2024!

→ Substance centric approach



The screenshot shows the ECHA CHEM search interface. At the top, there is a search bar with the text 'benzene' and a 'Search' button. Below the search bar, there is a section titled 'Substances' with a flask icon. It indicates '2 364 Substances' and provides options for 'View rows' (set to 100), '1-100 of 2 364', and an 'Export' button. A table lists the search results for 'benzene'.

Name	EC number	CAS number
Benzen 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
Benzen -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

ECHA CHEM
ECHA CHEMICALS DATABASE

Part of
ECHA
EUROPEAN CHEMICALS AGENCY

←  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	C6H6
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	View Dossier
Active	Article 18 - intermediate	Individual		29-Jun-2010	9-Dec-2011	View Dossier
Active	Article 18 - intermediate	Member (joint submission)		4-Nov-2010	18-Apr-2024	View Dossier
Active	Article 18 - intermediate	Member (joint submission)		4-Oct-2010	19-Dec-2023	View Dossier
Active	Article 18 - intermediate	Member (joint submission)		21-Jul-2010	12-Oct-2023	View Dossier
Active	Article 18 - intermediate	Member (joint submission)		21-Jul-2010	11-Jul-2023	View Dossier
Active	Article 18 - intermediate	Member (joint submission)		22-Oct-2010	2-Mar-2023	View Dossier

REACH Registrations

→ Information on substances follows the IUCLID structure

The screenshot displays the ECHA Chem database interface for Benzene (EC number 200-753-7, CAS number 71-43-2). The left sidebar shows a tree view of the dossier publication, with 'Physical and chemical properties' expanded to 'Boiling point'. The main content area shows the following details:

- Boiling point**: The boiling point of benzene is 80.09 °C at standard pressure.
- Administrative data**:
 - Confidentiality: [Empty]
 - Justification: [Empty]
 - Use restricted to selected regulatory programmes: [Empty]
- 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.

On the right side, there is a 'Hide empty fields' toggle and a 'Jump to' menu with options: Administrative data, Link to relevant study record(s), Description of key information, Key value for chemical safety assessment, and 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

The screenshot displays the ECHA CHEM landing page. At the top, it says "Welcome to ECHA CHEM" and "This is ECHA's new public chemicals database with information from all REACH registrations received by the Agency." Below this is a checkbox for "I have read and I accept the legal notice." and a search bar with the placeholder "Search for substances" and a "Search" button. The page is divided into two main sections: "Legal obligations" and "Regulatory activities".

Legal obligations (View all obligations →)

- Restriction list
 - REACH ↗
- Candidate list
 - REACH ↗
- Authorisation list
 - REACH ↗

Regulatory activities (View all activities →)

- Restriction process
 - REACH ↗
- Identification of substances of very high concern (SVHC)
 - REACH ↗
- Recommendations for inclusion in the Authorisation list
 - REACH ↗

Separate sections for

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

Access by substance: Search → Substance overview

ECHACHEM Part of **ECHA**
ECHA CHEMICALS DATABASE

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

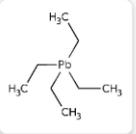
Overview

- 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



Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs...

EC number 272-712-1 • CAS number 68909-77-3



Regulatory activities

4 activities

View rows 100 ▾

1-4 of 4 < >

 Export

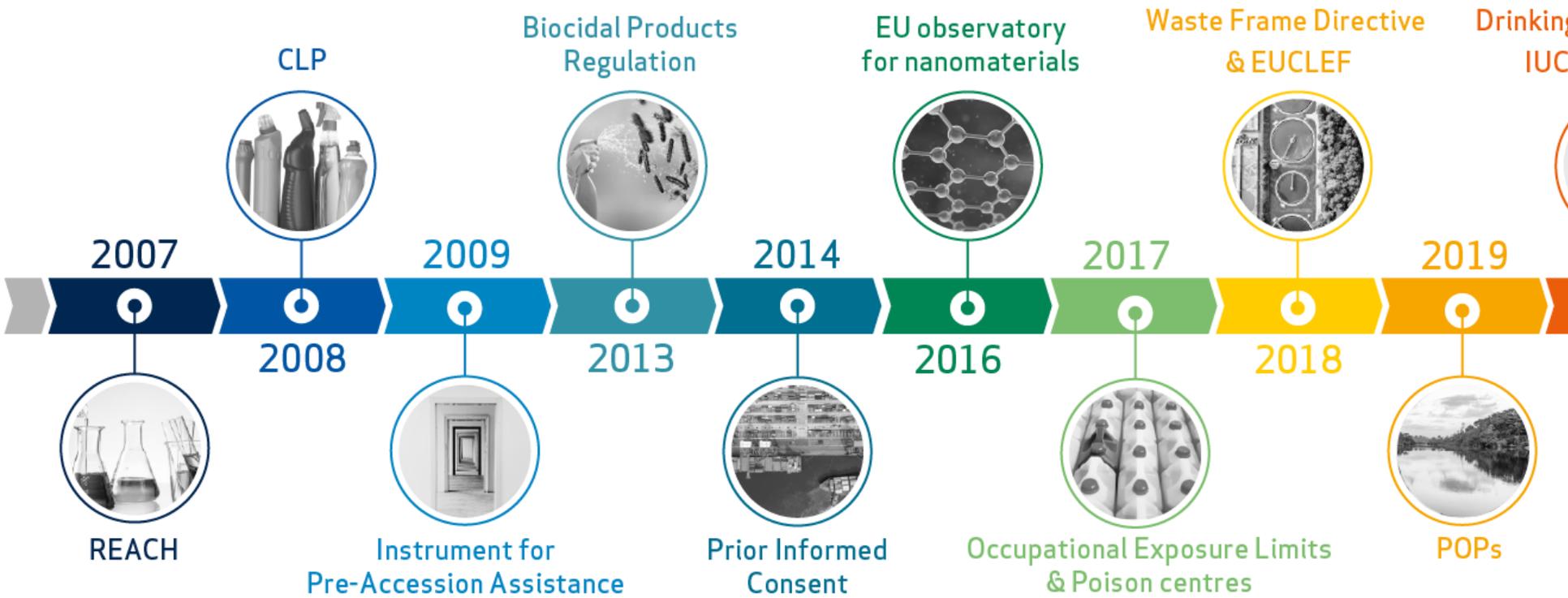
Regulatory activity ▾	Status ▾	Current stage ▾	Current stage date ▾	Relevant legislation ▾	View activity details
Restriction process	Ongoing	Start consultation on restriction proposal	22 May 2023	REACH 	
Recommendations for inclusion in the Authorisation list	Ongoing	Annex XIV end of consultation	21-May-2023	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 	

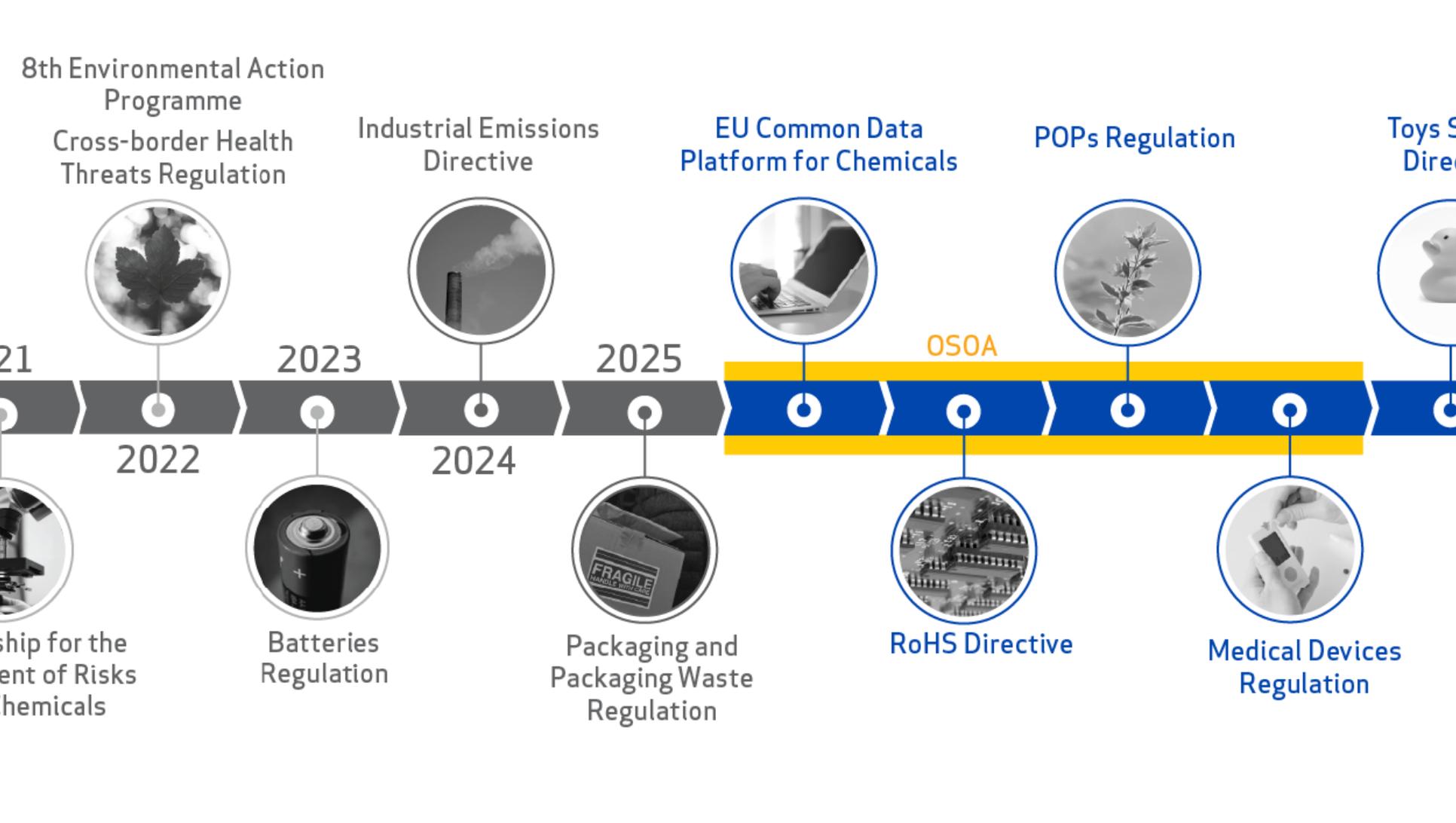
DRAFT

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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