

Basic information		
2023/0453(COD)		Procedure completed
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation		
Common data platform on chemicals, establishing a monitoring and outlook framework for chemicals		

Key players		
European Parliament	<p><b>Committee responsible</b></p> <p><span style="border: 1px solid red; padding: 2px;">ENVI</span> Environment, Climate and Food Safety</p>	<p><b>Rapporteur</b></p> <p>TSIODRAS Dimitris (EPP)</p> <p><b>Appointed</b></p> <p>07/08/2024</p>
		<p>Shadow rapporteur</p> <p>CLERGEAU Christophe (S&amp;D)</p> <p>TIMGREN Beatrice (ECR)</p> <p>HOJSÍK Martin (Renew)</p> <p>PAULUS Jutta (Greens/EFA)</p> <p>HAZEKAMP Anja (The Left)</p>
	<p><b>Former committee responsible</b></p> <p><span style="border: 1px solid red; padding: 2px;">ENVI</span> Environment, Climate and Food Safety</p>	<p><b>Former rapporteur</b></p> <p>SPYRAKI Maria (EPP)</p> <p><b>Appointed</b></p> <p>15/03/2024</p>
	<p><b>Former committee for opinion</b></p> <p><span style="border: 1px solid red; padding: 2px;">BUDG</span> Budgets</p>	<p><b>Former rapporteur for opinion</b></p> <p>VAN OVERTVELDT Johan (ECR)</p> <p><b>Appointed</b></p> <p>13/12/2023</p>
	<p><span style="border: 1px solid red; padding: 2px;">ITRE</span> Industry, Research and Energy</p>	<p>The committee decided not to give an opinion.</p>
	<p><b>Committee for budgetary assessment</b></p>	<p><b>Rapporteur for budgetary assessment</b></p> <p><b>Appointed</b></p>

	BUDG Budgets	The committee decided not to give an opinion.
Council of the European Union		
European Commission	Commission DG	Commissioner
	Environment	SINKEVIČIUS Virginijus
European Economic and Social Committee		

Key events			
Date	Event	Reference	Summary
07/12/2023	Legislative proposal published	COM(2023)0779 	Summary
29/02/2024	Committee referral announced in Parliament, 1st reading		
13/11/2024	Committee referral announced in Parliament, 1st reading		
18/02/2025	Vote in committee, 1st reading		
25/02/2025	Committee report tabled for plenary, 1st reading	A10-0018/2025	Summary 
31/03/2025	Debate in Parliament		
01/04/2025	Results of vote in Parliament		
01/04/2025	Decision by Parliament		
01/04/2025	Matter referred back to the committee responsible for interinstitutional negotiations		
03/07/2025	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE775.500 GEDA/A/(2025)003065	
20/10/2025	Debate in Parliament		
21/10/2025	Decision by Parliament, 1st reading	T10-0235/2025	Summary
21/10/2025	Results of vote in Parliament		
13/11/2025	Act adopted by Council after Parliament's 1st reading		
26/11/2025	Final act signed		
12/12/2025	Final act published in Official Journal		

Technical information	
Procedure reference	2023/0453(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation

<b>Legislative instrument</b>	Regulation
<b>Legal basis</b>	Rules of Procedure EP 58 Treaty on the Functioning of the EU TFEU 114-p1
<b>Other legal basis</b>	Rules of Procedure EP 165
<b>Mandatory consultation of other institutions</b>	European Economic and Social Committee
<b>Stage reached in procedure</b>	Procedure completed
<b>Committee dossier</b>	ENVI/10/00312

<b>Documentation gateway</b>				
<b>European Parliament</b>				
Document type	Committee	Reference	Date	Summary
Committee draft report		PE763.255	28/10/2024	
Amendments tabled in committee		PE766.686	04/12/2024	
Amendments tabled in committee		PE766.784	04/12/2024	
Amendments tabled in committee		PE766.765	05/12/2024	
Amendments tabled in committee		PE766.879	12/12/2024	
Committee report tabled for plenary, 1st reading/single reading		A10-0018/2025	25/02/2025	Summary
Text adopted by Parliament, partial vote at 1st reading /single reading		T10-0045/2025	01/04/2025	Summary
Text agreed during interinstitutional negotiations		PE775.500	25/06/2025	
Text adopted by Parliament, 1st reading/single reading		T10-0235/2025	21/10/2025	Summary
<b>Council of the EU</b>				
Document type	Reference	Date	Summary	
Coreper letter confirming interinstitutional agreement	GEDA/A/(2025)003065	25/06/2025		
Draft final act	00024/2025/LEX	20/11/2025		
<b>European Commission</b>				
Document type	Reference	Date	Summary	
Legislative proposal	COM(2023)0779 	07/12/2023	Summary	
Document attached to the procedure	SWD(2023)0855 	07/12/2023		
Commission response to text adopted in plenary	SP(2026)01-28	28/01/2026		
<b>National parliaments</b>				
Document type	Parliament /Chamber	Reference	Date	Summary

Contribution	IT_CHAMBER	COM(2023)0779	12/04/2024	
Contribution	CZ_SENATE	COM(2023)0779	22/04/2024	
Contribution	IT_SENATE	COM(2023)0779	08/05/2024	

#### Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES5710/2023	20/03/2024	

#### Additional information

Source	Document	Date
European Commission	EUR-Lex	

### Meetings with interest representatives published in line with the Rules of Procedure

#### Rapporteurs, Shadow Rapporteurs and Committee Chairs

Transparency				
Name	Role	Committee	Date	Interest representatives
HOJSÍK Martin	Shadow rapporteur	ENVI	23/01/2025	European Chemical Industry Council
TIMGREN Beatrice	Shadow rapporteur	ENVI	04/12/2024	ECHA
CLERGEAU Christophe	Shadow rapporteur	ENVI	28/11/2024	Eurogroup for Animals
TIMGREN Beatrice	Shadow rapporteur	ENVI	20/11/2024	AstraZeneca PLC
CLERGEAU Christophe	Shadow rapporteur	ENVI	20/11/2024	European Environmental Bureau
HOJSÍK Martin	Shadow rapporteur	ENVI	20/11/2024	European Environmental Bureau
HOJSÍK Martin	Shadow rapporteur	ENVI	15/11/2024	Zimmer Biomet Holdings
TIMGREN Beatrice	Shadow rapporteur	ENVI	07/11/2024	IKEM - Innovations- och kemiindustrierna i Sverige AB (556865-4650)
TIMGREN Beatrice	Shadow rapporteur	ENVI	06/11/2024	Svenskt Näringsliv
CLERGEAU Christophe	Shadow rapporteur	ENVI	17/10/2024	European Chemical Industry Council
HOJSÍK Martin	Shadow rapporteur	ENVI	17/10/2024	European Chemical Industry Council
TSIODRAS Dimitris	Rapporteur	ENVI	15/10/2024	EFPIA
CLERGEAU Christophe	Shadow rapporteur	ENVI	17/09/2024	ClientEarth AISBL
SPYRAKI Maria	Rapporteur	ENVI	19/03/2024	ECHA

## Other Members

Transparency		
Name	Date	Interest representatives
RADTKE Dennis	23/01/2025	Verband der deutschen Lack- und Druckfarbenindustrie e. V.
WÖLKEN Tiemo	15/01/2025	Novo Nordisk A/S
HANSEN Niels Flemming	19/11/2024	Novo Nordisk A/S

Final act
Regulation 2025/2455 OJ OJ L 12.12.2025

# Common data platform on chemicals, establishing a monitoring and outlook framework for chemicals

2023/0453(COD) - 21/10/2025 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 471 votes to 123, with 48 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

Parliament adopted its position at first reading by amending the proposal as follows:

### ***Purpose and scope of application***

This Regulation aims to ensure the efficient delivery of consistent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, in order to:

- achieve a high level of protection of human health and the environment,
- enable the development and use of safe and sustainable chemicals,
- ensure the proper functioning of the single market for chemicals,
- improve the Union's citizens' knowledge about, and trust in, the scientific basis for the decisions taken under Union legal acts on chemicals,
- contribute to the replacement and reduction of animal testing wherever possible.

### ***Common data platform on chemicals***

The Regulation establishes a common data platform on chemicals managed by the European Chemicals Agency (ECHA), which will provide access to all data on chemicals, including data provided on a voluntary basis by Member States or other parties, including national agencies, research institutes and third-country organisations, and held or accepted by the ECHA, the EEA, the EFSA, EU-OSHA or the Commission.

Each chemical or material hosted on the common data platform must be identified by means of a **unique chemical identifier** and a chemical notation specifying, if possible, its molecular structure, without prejudice to the confidentiality requirements contained in the original act.

The common data platform will contain appropriate **background and explanatory information** in order to make it easier for the Authorities and the public to use those data in an informed manner. The Authorities and the public will have easy access, **free of charge**, to the data contained in the common data platform.

### ***Stepwise approach***

Taking due account of the administrative work for the European Medicines Agency (EMA) from the adaptation of such data to an appropriate format for incorporation in the common data platform, the amended text provides for a stepwise approach and to include during the first stage only chemicals data for active substances which are submitted to the EMA in the context of the relevant procedures that are finalised after the entry into force of this

Regulation. No later than **six years after the entry into force of this Regulation**, the EMA will also start incorporating chemicals data on active substances resulting from procedures concluded before the entry into force of this Regulation.

#### ***Governance***

No later than six months from the date of entry into force of the Regulation, the Commission will adopt, by means of an implementing act, an **implementation plan** setting out the datasets on chemicals to be included in the common data platform and a timeline for their inclusion. The Commission will establish and manage, by means of an implementing act, a **steering committee** for the platform comprising at least one representative from each of the agencies and as many representatives of the Commission as representatives of all the agencies combined.

The ECHA will host and maintain occurrence data related to workplace monitoring, including occupational human biomonitoring data.

#### ***Human biomonitoring data***

The Agencies and the Commission will be able to **process human biomonitoring data** constituting personal data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to assess the need for regulatory action and prioritise such action, to monitor the impact of regulatory action, and to support policy making and the development of legislation, including by carrying out scientific research for those purposes.

#### ***Confidentiality of study notification elements***

Where the Commission or one of the Agencies makes the corresponding registration, application, notification or other relevant regulatory dossier available to the ECHA, it will indicate which elements of the study notification are to be confidential when it is included in the common data platform.

To enhance the visibility of the available data, the ECHA will establish and manage a database containing data on **chemicals** in articles or products. It will also establish and manage a repository with data on **alternatives** to potential substances of concern.

#### ***Notification of studies***

Business operators will notify to the database of study notifications, without delay, any studies that generate chemicals data and that they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products that business operators commission as part of a risk or safety assessment under the Union legal acts listed in Annex I, Part 1, to this Regulation.

The obligation to notify studies will not begin to apply until **22 months** after the date of entry into force of the regulation.

## **Common data platform on chemicals, establishing a monitoring and outlook framework for chemicals**

2023/0453(COD) - 07/12/2023 - Legislative proposal

**PURPOSE:** to establish a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

**PROPOSED ACT:** Regulation of the European Parliament and of the Council.

**ROLE OF THE EUROPEAN PARLIAMENT:** the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

**BACKGROUND:** the European Green Deal sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability is a crucial delivery of this zero-pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, 'safe and sustainable by design' criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.

**CONTENT:** the Commission is presenting this draft Regulation which aims to implement the above-mentioned objectives.

#### ***Subject matter and scope***

The proposed Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.

To achieve the objectives, this proposal contains measures to:

- bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;

- keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;
- establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;
- establish an early warning and action system for emerging chemical risks.

#### ***Common data platform on chemicals***

The proposal aims to establish a common data platform on chemicals to be managed by the European Chemicals Agency (ECHA). The common data platform is a **digital infrastructure** that brings together data on chemicals and information generated under the EU chemicals acquis and held by EU agencies, namely ECHA, the European Environment Agency (EEA), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Agency for Safety and Health at Work (EU-OSHA). This includes data on hazards, physico-chemical properties, presence in the environment, emissions, uses, environmental sustainability of chemical substances and current regulatory procedures.

The proposal creates an obligation to ensure that data on chemicals held by these agencies or by the Commission is included in the common data platform. The common data platform will centralise and consolidate data on chemicals at EU level in one centrally accessible IT infrastructure.

The proposed Regulation will also establish dedicated services within the common data platform and lay down rules on the **accessibility and usability of the data contained in this platform**. It aims to create a common knowledge base on chemicals available to authorities to enable better, comprehensive, consistent and robust scientific assessments of chemicals and their impacts, as well as to ensure the best use of existing information for the implementation and development of EU chemicals legislation.

In addition, the proposed Regulation aims to provide a **one-stop-shop** on chemicals data and information in the Union accessible to the public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.

## **Common data platform on chemicals, establishing a monitoring and outlook framework for chemicals**

2023/0453(COD) - 01/04/2025 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 481 votes to 170, with 22 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

The matter was referred back to the relevant committee for interinstitutional negotiations.

The main amendments adopted in plenary concern the following points:

#### ***Subject matter***

By ensuring the effective delivery of coherent hazard and risk assessments of chemicals where such assessments are required by Union legal acts, the Regulation should (i) enable the development and use of **safe and sustainable chemicals**, (ii) enhance Union citizens' awareness of, and trust in, the scientific basis for decisions taken under Union legal acts in the field of chemicals, and (iii) contribute to the goal of **phasing out animal testing** wherever possible.

#### ***Common data platform on chemicals***

Each chemical or material hosted on the common data platform should be identified by a **unique chemical identifier** and a chemical notation specifying its molecular structure without prejudice to any confidentiality requirements in the original act or related legal obligations.

The Authorities and the general public should have **easy access, free of charge**, to the data contained in the common data platform. **Security** measures should be adopted by the relevant agencies in cooperation with the European Chemicals Agency (ECHA) to ensure the secure transmission of chemicals-related data to the common data platform.

#### ***Stepwise approach***

Taking due account of the administrative work for EMA coming from the adaptation of such data to an appropriate format for inclusion in the common data platform, Members suggested adopting a stepwise approach, and including during the first stage only chemical data for active substances which are submitted to the EMA in the context of the relevant procedures that are finalised after the entry into force of this Regulation. No later than **eight years** after the entry into force of this regulation, EMA should also include the chemical data on active substances from procedures concluded before the entry into force of this Regulation.

#### ***Data flows for the purposes of the common data platform***

The Commission and the agencies should indicate whether data or information included in the common data platform can be made publicly available or whether it is considered confidential. Members specified that ECHA should host and administer data on the presence of chemicals relevant for workplace monitoring, including human biomonitoring data in the workplace.

### **Human biomonitoring data**

The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission should be able to process human biomonitoring data constituting personal data. Since human biomonitoring personal data constitute a special category of personal data, namely, health data, the EEA, the Commission, the ECHA, the EFSA, the EU-OSHA and the EMA should process those data only where the processing is necessary for reasons of substantial public interest, and for scientific research. Members introduced amendments laying down the cases where there is such **substantial public interest** in processing human biomonitoring data constituting personal data.

### **Information on chemicals**

To enhance visibility on the availability of data, and to promote research and development activities as regards safer alternatives, ECHA should establish and manage a **repository** of information on chemicals in articles generated or submitted under Union acts listed in Annex I. In addition, ECHA should also establish and manage a database collecting available information from Agencies, Member States and business operators on **safer alternatives to substances of concern**.

### **Study notification database**

The ECHA should establish and operate a mechanism for cooperation and exchange of information with relevant **third countries' authorities** for the exchange of studies notified or submitted by business operators to those authorities to support an application, notification or regulatory dossier for a chemical no later than two years after the date of entry into force of the Regulation. Data in the study notification database should be considered **confidential** and should not be made public.

### **Notification of studies relating to chemicals**

Scientific studies that are conducted only for research purposes, that are not commissioned to support an application, notification or regulatory dossier notified or submitted to an Authority, or that are not part of a risk or safety assessment under Union acts listed in Annex I, do not need to be notified.

The obligation to notify studies should only start to apply **18 months** after the date of entry into force of this Regulation.

Where the Commission or any of the Agencies makes available to the ECHA, a registration, application, notification, it should indicate which elements of the study notifications are confidential when included in the common data platform.

### **Research data**

Members stressed the need to **structure and make transparent** the assessment of research data in order to increase their use in the regulatory assessment of chemicals. No later than four years after the date of entry into force of the regulation, the Commission should assess the feasibility of harmonised reporting requirements and of enabling the integrating of relevant content from scientific journals and publications into the common data platform, in order to increase further the uptake of research data into the hazard and risk assessment of chemicals.

## **Common data platform on chemicals, establishing a monitoring and outlook framework for chemicals**

2023/0453(COD) - 25/02/2025 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Climate and Food Safety adopted the report by Dimitris TSIODRAS (EPP, EL) on the proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

### **Subject matter**

The Regulation aims to:

- enable the development and use of safe and sustainable chemicals;
- improve the Union's citizens' knowledge of, and trust in, the scientific base for the decisions taken under Union legal acts on chemicals, and to **contribute to the goal of phasing out animal testing** wherever possible.

### **Common data platform on chemicals**

Each chemical or material hosted on the common data platform should be identified by a **unique chemical identifier** and a chemical notation specifying its molecular structure without prejudice to any confidentiality requirements in the original act or related legal obligations.

The Authorities and the general public should have **easy access, free of charge**, to the data contained in the common data platform.

The common data platform should also include terms and conditions, particularly regarding the respect of intellectual property rights and other related rights.

### **Stepwise approach**

Taking due account of the administrative work for EMA coming from the adaptation of such data to an appropriate format for inclusion in the common data platform, Members suggested adopting a stepwise approach, and including during the first stage only chemical data for active substances which are submitted to the EMA in the context of the relevant procedures that are finalised after the entry into force of this Regulation. No later than **eight years** after the entry into force of this regulation, EMA should also include the chemical data on active substances from procedures concluded before the entry into force of this Regulation.

### **Governance**

The Commission should establish and manage, by means of an implementing act, a **platform steering committee**, comprising at least one representative from each Union agency required to submit chemicals-related data to the common data platform and as many representatives of the Commission as representatives of all Union agencies combined.

The governance scheme should describe: (i) the organisation and operation of cooperation and information exchange mechanisms with databases and similar platforms in third countries and at internationally; (ii) the operating, reporting requirements, and transparency obligations of the steering committee itself.

The Commission and the agencies should indicate whether the data or information included in the common data platform may be made publicly available or whether it is considered confidential. Members specify that ECHA should host and administer data on the presence of chemicals relevant for **workplace monitoring**, including human biomonitoring data in the workplace.

### **Human biomonitoring data**

Human biomonitoring data that constitute personal should be processed by the EEA for the following purposes: providing support to policymaking and legislative processes at EU level; creating a '**chemical exposure index**' for each EU region; and facilitating processing by the Commission, ECHA, EFSA, EMA, and EU-OSHA.

The Commission, ECHA, EFSA, EMA, and EU-OSHA should process human biomonitoring data that constitute personal data only for certain purposes (e.g., scientific research for policymaking; assessing the impact of chemicals on human health and the environment; conducting chemical assessments).

The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission should define the storage period, and carry out any review thereof, for the human biomonitoring data constituting personal data that they hold as well as the criteria used to define the storage period.

### **Information on chemicals**

To enhance visibility on the availability of data, and to promote research and development activities as regards safer alternatives, ECHA should establish and manage a **repository of information** on chemicals in articles generated or submitted under Union acts listed in Annex I. In addition, ECHA should also establish and manage a database collecting available information from Agencies, Member States and business operators on **safer alternatives to substances of concern**.

### **Notification of studies relating to chemicals**

Scientific studies that are conducted only for research purposes, that are not commissioned to support an application, notification or regulatory dossier notified or submitted to an Authority, or that are not part of a risk or safety assessment under Union acts listed in Annex I, do not need to be notified.

The obligation to notify studies should only start to apply **18 months** after the date of entry into force of this Regulation.

Where the Commission or any of the Agencies makes available to the ECHA, a registration, application, notification, it should indicate which elements of the study notifications are confidential when included in the common data platform.