






Basic information	
<p><b>2023/0455(COD)</b></p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p>	Procedure completed
<p>Re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals</p> <p>Amending Regulation 2002/178 <a href="#">2000/0286(COD)</a> Amending Regulation 2009/401 <a href="#">2007/0235(COD)</a> Amending Regulation 2017/745 <a href="#">2012/0266(COD)</a> Amending Regulation 2019/1021 <a href="#">2018/0070(COD)</a></p> <p><b>Subject</b></p> <p>3.40.01 Chemical industry, fertilizers, plastics 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)</p>	



Key players			
European Parliament	<b>Committee responsible</b>	<b>Rapporteur</b>	<b>Appointed</b>
	<a href="#">ENVI</a> Environment, Climate and Food Safety	TSIODRAS Dimitris (EPP)	07/08/2024
	<b>Former committee responsible</b>	<b>Former rapporteur</b>	<b>Appointed</b>
	<a href="#">ENVI</a> Environment, Climate and Food Safety	SPYRAKI Maria (EPP)	15/03/2024
	<b>Committee for opinion</b>	<b>Rapporteur for opinion</b>	<b>Appointed</b>
	<a href="#">AGRI</a> Agriculture and Rural Development	The committee decided not to give an opinion.	
	<b>Former committee for opinion</b>	<b>Former rapporteur for opinion</b>	<b>Appointed</b>
	<a href="#">BUDG</a> Budgets	VAN OVERTVELDT Johan (ECR)	13/12/2023
	<a href="#">ITRE</a> Industry, Research and Energy	The committee decided not to give an opinion.	
	<a href="#">AGRI</a> Agriculture and Rural Development	LINS Norbert (EPP)	24/01/2024
		<b>Rapporteur for budgetary</b>	

	<b>Committee for budgetary assessment</b>	<b>assessment</b>	<b>Appointed</b>
	<span style="border: 1px solid red; padding: 2px;">BUDG</span> Budgets	The committee decided not to give an opinion.	
Council of the European Union			
European Commission	<b>Commission DG</b>	<b>Commissioner</b>	
	Environment	SINKEVIČIUS Virginijus	
European Economic and Social Committee			
European Committee of the Regions			

<b>Key events</b>			
<b>Date</b>	<b>Event</b>	<b>Reference</b>	<b>Summary</b>
07/12/2023	Legislative proposal published	COM(2023)0783 	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	A10-0020/2025	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	GEDA/A/(2025)003065 PE775.540	
20/10/2025	Debate in Parliament		
21/10/2025	Decision by Parliament, 1st reading	T10-0237/2025	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		

<b>Technical information</b>

Procedure reference	2023/0455(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Regulation 2002/178 <a href="#">2000/0286(COD)</a> Amending Regulation 2009/401 <a href="#">2007/0235(COD)</a> Amending Regulation 2017/745 <a href="#">2012/0266(COD)</a> Amending Regulation 2019/1021 <a href="#">2018/0070(COD)</a>
Legal basis	Rules of Procedure EP 58 Treaty on the Functioning of the European Union TFEU 168-p4 Treaty on the Functioning of the European Union TFEU 207 Treaty on the Functioning of the European Union TFEU 114 Treaty on the Functioning of the European Union TFEU 043 Treaty on the Functioning of the European Union TFEU 192-p1
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	<a href="#">European Economic and Social Committee</a> <a href="#">European Committee of the Regions</a>
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/10/00306

Documentation gateway				
<b>European Parliament</b>				
Document type	Committee	Reference	Date	Summary
Committee draft report		<a href="#">PE763.253</a>	23/10/2024	
Amendments tabled in committee		<a href="#">PE766.688</a>	05/12/2024	
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A10-0020/2025</a>	25/02/2025	<a href="#">Summary</a>
Text adopted by Parliament, partial vote at 1st reading /single reading		<a href="#">T10-0047/2025</a>	01/04/2025	<a href="#">Summary</a>
Text agreed during interinstitutional negotiations		<a href="#">PE775.540</a>	25/06/2025	
Text adopted by Parliament, 1st reading/single reading		<a href="#">T10-0237/2025</a>	21/10/2025	<a href="#">Summary</a>
<b>Council of the EU</b>				
Document type		Reference	Date	Summary
Coreper letter confirming interinstitutional agreement		<a href="#">GEDA/A/(2025)003065</a>	25/06/2025	
Draft final act		<a href="#">00026/2025/LEX</a>	20/11/2025	
<b>European Commission</b>				
Document type		Reference	Date	Summary
Legislative proposal		<a href="#">COM(2023)0783</a>	07/12/2023	<a href="#">Summary</a>
Document attached to the procedure		<a href="#">SWD(2023)0850</a>	07/12/2023	

Commission response to text adopted in plenary	SP(2026)01-28	28/01/2026	
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### National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_CHAMBER	COM(2023)0783	12/04/2024	
Contribution	CZ_SENATE	COM(2023)0783	22/04/2024	
Contribution	IT_SENATE	COM(2023)0783	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	13/02/2024	European Chemical Industry Council (Cefic)
HOJSÍK Martin	Shadow rapporteur	ENVI	13/02/2024	European Chemical Industry Council (Cefic)

### Other Members

Transparency		
Name	Date	Interest representatives
SMIT Sander	07/02/2025	EuropeanCoordination Committee of the Radiological, Electromedical and Healthcare IT Industry.

### Final act

Regulation 2025/2457  
OJ OJ L 12.12.2025

# Re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

2023/0455(COD) - 01/04/2025 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 486 votes to 171, with 18 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) No 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals.

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

The main amendments adopted in plenary concern the following issues:

## *Divergent scientific opinions*

Differences in assessment methodologies resulting in divergent opinions will be duly justified, especially regarding the protection of **vulnerable groups**.

Members specify that the Authority and the body concerned must cooperate to resolve the divergence, with the aim of ensuring the highest level of health and environmental protection. Priority should be given to the most protective opinion to safeguard vulnerable groups.

Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, **the Authority and the national body will be obliged to cooperate** with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. That document will be made public.

In cases where a divergence is identified, and the Authority requests additional information from the other Union or Member State authority, the period within which the relevant authorities are required to adopt their respective output, or the joint output may be extended.

## *Agency's resources*

The proposed Regulation expands the tasks, workload and remit of the scientific committees of the European Chemicals Agency. Support and thorough scientific evaluations, appropriate and stable resources, capacity and governance of the scientific committees should be ensured.

In this regard, the Commission will monitor the situation regarding the resources of the European Chemicals Agency and tasks, workload and remit of the scientific committees of the European Chemicals Agency and present, where necessary, a **legislative proposal** to reflect any needs of the European Chemicals Agency stemming from tasks introduced by this Regulation and to improve the governance of its scientific committees.

## *Persistent organic pollutants*

Lastly, Parliament introduces amendments to Annex IV of Regulation (EU) 2019/1021 on persistent organic pollutants (list of substances subject to waste management provisions). These amendments stipulate that the Commission will review the concentration limits for certain substances and, if necessary, adopt a legislative proposal to lower certain values by 30 December 2027.

# Re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

2023/0455(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 amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) No 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of 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:

## *Divergent scientific opinions*

Members specify that the Authority and the body concerned must cooperate to resolve the divergence, with the aim of ensuring the highest level of health and environmental protection. Priority should be given to the **most protective opinion to safeguard vulnerable groups**.

When a substantive divergence on scientific issues has been identified and the body concerned is a Member State body, the Authority and the national body must be required to cooperate either to resolve the divergence or to prepare a joint report clarifying the contentious scientific issues, identify the relevant uncertainties in the data and the possible causes for the diverging opinions, including on methodological differences. This document must be made publicly available.

## *Agency's resources*

The Commission will monitor the situation regarding the resources of the European Chemicals Agency and tasks, workload and remit of the scientific committees of the European Chemicals Agency and present, where necessary, a **legislative proposal** to reflect any needs of the European Chemicals Agency stemming from tasks introduced by this Regulation and to improve the governance of its scientific committees.

Lastly, the report introduces amendments to Annex IV of Regulation (EU) 2019/1021 on **persistent organic pollutants** (list of substances subject to waste management provisions). These amendments stipulate that the Commission will review the concentration limits for certain substances and, if necessary, adopt a legislative proposal to lower certain values by 30 December 2027.

## Re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

2023/0455(COD) - 07/12/2023 - Legislative proposal

**PURPOSE:** to amend Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of 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 Commission has, in its Communication 'European Green Deal', set an objective that chemical safety assessments should move towards a process of 'one-substance, one-assessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions.

To achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources.

**CONTENT:** this proposal proposes **targeted amendments** to attribute tasks in Regulation (EU) 2019/1021 on persistent organic pollutants, and Regulation (EU) 2017/745 on medical devices. The proposal also amends Regulation (EC) No 401/2009 establishing the European Environmental Agency and Regulation (EC) No 178/2002 laying down the general principles and requirements of food law and establishing the European Food Safety Authority. These amendments will ensure good cooperation among EU agencies on all aspects involving the consistency and efficiency of chemical assessments. These include the development of methodologies, data exchanges and reconciling divergence in scientific output.

The proposal:

- amends Regulation (EC) No 178/2002 (General Food Law Regulation). It includes provisions **enabling EFSA to better cooperate and coordinate with ECHA, EMA and EEA**. This cooperation would lead to **more consistent scientific assessments of chemicals** and encourage the agencies to develop consistent scientific opinions and methodologies, taking into account specific sectoral characteristics. The provisions on data and information exchange would bring the EU a step closer to the one substance, one assessment goals. These provisions make greater interoperability possible and scientific processes more robust;

- amends Regulation (EC) No 401/2009 (the EEA Founding Regulation). It includes streamlining obligations on the EEA to **promote and coordinate the development of assessment methodologies** and places cooperation obligations on the EEA;

- amends Annex I of Regulation (EU) 2017/745 (the Medical Devices Regulation) to task ECHA with **updating existing guidelines** on conducting the risk-benefit assessment of the presence of phthalates in medical devices. The agency will also develop guidelines for other substances, which are classified as either carcinogenic, mutagenic or toxic to reproduction, of category 1A or 1B or have endocrine disrupting properties for human health of Category 1;

- amends Regulation (EU) No 2019/1021 by giving the Commission the possibility to request ECHA to develop a report **analysing the human health, environmental, social, and economic impact of introducing or modifying concentration limit values** specified in Annexes IV and V to Regulation (EU) No 2019/1021 (POPs Regulation).

Considering the highly technical nature of the amendments, this provision also introduces the adoption of amendments to Annexes IV and V by means of a delegated act. To promote the development of a comprehensive chemical exposure and toxicity knowledge base, as well as streamline data flows in line with the one substance, one assessment policy target, the provision also **diverts data flows** on the presence of persistent organic pollutant substances in the environment to EEA, which is the agency responsible for collecting occurrence data on chemicals in the environment.

## Re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

2023/0455(COD) - 21/10/2025 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 469 votes to 126, with 50 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) No 2019/1021 of the European

Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals.

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

#### ***Divergent scientific opinions***

This Regulation aims to address possible discrepancies between scientific opinions delivered by the European Food Safety Authority (EFSA) and those delivered by other bodies, taking into account the objective of ensuring **a high level of protection of the environment and human health, including for vulnerable groups**.

The Authority will take the necessary and appropriate measures to ensure the monitoring and rapid identification of potential sources of divergence between its scientific opinions and the scientific opinions of other bodies carrying out a similar mission.

The Authority and the other body will cooperate to resolve any divergence, taking into account the objective of ensuring a high level of protection of health and the environment. If the Authority and the other body are unable to resolve the divergence, they will prepare a joint report. The report will clearly outline the contentious scientific issues, identify any relevant uncertainties in the data and give the underlying reasons for the divergence of opinions, including reasons related to methodological differences. The report will be made publicly available.

#### ***Cooperation***

The European Environment Agency will actively seek cooperation from the Commission, other Union bodies and programmes, including the Joint Research Centre, the Statistical Office of the European Union (Eurostat), the European Chemicals Agency, the European Food Safety Authority, the European Medicines Agency and Union's environmental research and development programmes.

Cooperation with the European Chemicals Agency, the European Food Safety Authority and the European Medicines Agency will relate to the exchange of data and information on chemical substances.

#### ***European Chemicals Agency Resources***

The proposed regulation expands the tasks, increases the workload, and extends the remit of the European Chemicals Agency's scientific committees, including the Committee for Socio-Economic Analysis. In order to provide adequate expertise and support, thorough scientific assessments, and appropriate and stable resources, the amended text emphasises the need to ensure the capacity and governance of the scientific committees.

#### ***Review***

Taking due account of any regulatory developments concerning the status of resources and governance of the Scientific Committees of the European Chemicals Agency, the Commission will monitor the situation regarding the tasks, workload and remit of the Scientific Committees and, if appropriate, submit a **legislative proposal** to amend this Regulation accordingly.

The concentration limit values specified in Annex IV will be reviewed by the Commission by 30 December 2027.