# **Basic information**

# 2023/0455(COD)

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation

Chemicals: re-attribution of scientific and technical tasks and improving cooperation among Union agencies

Amending Regulation 2002/178 2000/0286(COD) Amending Regulation 2009/401 2007/0235(COD) Amending Regulation 2017/745 2012/0266(COD) Amending Regulation 2019/1021 2018/0070(COD)

## Subject

3.40.01 Chemical industry, fertilizers, plastics 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)

Awaiting Parliament's position in 1st reading

## **Key players**

### European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Climate and Food Safety	TSIODRAS Dimitris (EPP)	07/08/2024
	Shadow rapporteur	
	CLERGEAU Christophe (S&D)	
	TIMGREN Beatrice (ECR)	
	HOJSÍK Martin (Renew)	
	PAULUS Jutta (Greens/EFA)	
	HAZEKAMP Anja (The Left)	

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Climate and Food Safety	SPYRAKI Maria (EPP)	15/03/2024

Committee for opinion	Rapporteur for opinion	Appointed
AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	

Former committee for opinion	Former rapporteur for opinion	Appointed
BUDG Budgets	VAN OVERTVELDT Johan (ECR)	13/12/2023

			The committee decided not to give an opinion.		
	AGRI Agriculture and Rural Development		LINS Norbert (EPP)	24/01/2024	
			Rapporteur for budgetary assessment	Appointed	
			The committee decided not to give an opinion.		
Council of the European Union					
European	Commission DG	Commissioner			
Commission	Environment	Environment SINKEVIIUS Virgin			
European Economic	c and Social Committee				

Key events				
Date	Event	Reference	Summary	
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		

Forecasts	
31/03/2025	Indicative plenary sitting date, 1st reading

Technical information		
Procedure reference	2023/0455(COD)	
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)	
Procedure subtype	Legislation	
Legislative instrument Regulation		
	Amending Regulation 2002/178 2000/0286(COD) Amending Regulation 2009/401 2007/0235(COD) Amending Regulation 2017/745 2012/0266(COD) Amending Regulation 2019/1021 2018/0070(COD)	
Legal basis	Treaty on the Functioning of the EU TFEU 207 Treaty on the Functioning of the EU TFEU 168-p4	

	Treaty on the Functioning of the EU TFEU 192-p1 Treaty on the Functioning of the EU TFEU 043 Treaty on the Functioning of the EU TFEU 114
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Awaiting Parliament's position in 1st reading
Committee dossier	ENVI/10/00306

# **Documentation gateway**

#### **European Parliament**

Document type	Committee	Reference	Date	Summary
Committee draft report		PE763.253	23/10/2024	
Amendments tabled in committee		PE766.688	05/12/2024	
Committee report tabled for plenary, 1st reading/single reading		A10-0020/2025	25/02/2025	

## **European Commission**

Document type	Reference	Date	Summary
Document attached to the procedure	SWD(2023)0850	07/12/2023	
Legislative proposal	COM(2023)0783	07/12/2023	Summary

### **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	

## Other institutions and bodies

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

# Chemicals: re-attribution of scientific and technical tasks and improving cooperation among Union agencies

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.