








Procedure file

Basic information	
<p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p> <p>2023/0272(COD)</p>	Awaiting Council's 1st reading position
<p>Mercury: dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions</p> <p>Amending Regulation 2017/852 2016/0023(COD)</p> <p>Subject</p> <p>3.60.01 Solid fuels, coal mining, mining industry</p> <p>3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)</p> <p>6.20.02 Export/import control, trade defence, trade barriers</p>	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<p> Environment, Public Health and Food Safety</p>	<p> MORTLER Marlene</p> <p>Shadow rapporteur</p> <p> FRITZON Helène</p> <p> AMALRIC Catherine</p> <p> METZ Tilly</p> <p> VONDRA Alexandr</p> <p> VILLUMSEN Nikolaj</p>	23/08/2023
Council of the European Union	Commission DG	Commissioner	
European Commission	Environment	SINKEVIČIUS Virginijus	
European Economic and Social Committee			
European Committee of the Regions			

Key events			
14/07/2023	Legislative proposal published	COM(2023)0395	Summary
11/09/2023	Committee referral announced in Parliament, 1st reading		

11/01/2024	Vote in committee, 1st reading		
12/01/2024	Committee report tabled for plenary, 1st reading	A9-0002/2024	Summary
17/01/2024	Decision by Parliament, 1st reading	T9-0019/2024	Summary
17/01/2024	Matter referred back to the committee responsible		
11/03/2024	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	GEDA/A/(2024)001159	
10/04/2024	Decision by Parliament, 1st reading	T9-0191/2024	Summary

Technical information

Procedure reference	2023/0272(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2017/852 2016/0023(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 192-p1
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	ENVI/9/12728

Documentation gateway

Legislative proposal	COM(2023)0395	14/07/2023	EC	Summary
Document attached to the procedure	SEC(2023)0395	14/07/2023	EC	
Document attached to the procedure	SWD(2023)0395	14/07/2023	EC	
Document attached to the procedure	SWD(2023)0396	14/07/2023	EC	
Document attached to the procedure	SWD(2023)0397	14/07/2023	EC	
Committee draft report	PE753.554	24/10/2023	EP	
Amendments tabled in committee	PE756.167	28/11/2023	EP	
Amendments tabled in committee	PE756.274	28/11/2023	EP	
Amendments tabled in committee	PE757.033	19/12/2023	EP	
Committee report tabled for plenary, 1st reading/single reading	A9-0002/2024	12/01/2024	EP	Summary
Text adopted by Parliament, partial vote at 1st reading/single reading	T9-0019/2024	17/01/2024	EP	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2024)001159	21/02/2024	CSL	

Mercury: dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions

PURPOSE: to phase out the use of dental amalgam and to restrict the manufacture and export of certain mercury-containing lamps.

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: mercury is a highly toxic element and a major risk to the environment and human health. Dental amalgam is the largest remaining intentional use of mercury in the Union estimated at around 40 t in 2019. Considering the risk posed by mercury to both human health and the environment, the Commission developed in 2005 a dedicated Mercury Strategy as reviewed in 2010³ inviting the Union to address all facets of mercury, including its use in products.

According to the review clause established in [Regulation \(EU\) 2017/852](#) (the Mercury Regulation), the Commission is asked to report to the European Parliament and to the Council on the outcome of its assessment regarding:

- the feasibility of a total phase-out of the use of dental amalgam preferably by 2030 and the need for the EU to regulate associated mercury emissions from crematoria;
- the environmental benefits and the feasibility of prohibiting the manufacturing, import and export of other remaining mercury-added products, which are already or will soon be banned from being placed on the market in accordance with other Union instruments.

The Commission adopted in August 2020 its Review Report on the feasibility of phasing out the use of mercury in dental amalgam and other products. Both this report and the subsequent Commissions impact assessment pointed to the appropriateness of presenting a legislative proposal to phase out the use of dental amalgam and to restrict the manufacture and export of certain mercury-containing lamps.

This initiative contributes to implementing the 2020 EU Chemicals Strategy for Sustainability and 2021 EU Zero Pollution Action Plan adopted under the European Green Deal.

CONTENT: the objectives of this proposal amending Regulation (EU) 2017/852 on mercury are as follows:

(a) extend the prohibition to use dental amalgam to include all members of the population in the Union as from 1 January 2025 (total phase-out), whilst safeguarding the right of the dental practitioners to still use it when deemed strictly necessary for addressing specific medical needs of the patient (e.g., allergies, moisture control issues etc.);

(b) set a prohibition on the manufacturing in the Union and export of dental amalgam as from 1 January 2025;

(c) make the following six additional mercury-added products subject to a manufacturing, import and export prohibition by adding them to Annex II:

- compact fluorescent lamps (CFLs) for general lighting purposes, not yet covered by Annex II nor by the concomitant amendment to Annex II resulting from above-cited Delegated Act;
- triband phosphor linear fluorescent lamps (LFLs) for general lighting purposes not yet covered by Annex II;
- halophosphate phosphor LFLs for general lighting purposes not yet covered by Annex II;
- non-linear triband phosphor lamps for general lighting purposes;
- non-linear halophosphate phosphor lamps;
- high pressure sodium (vapour) lamps for general lighting purpose.

It should be noted that this proposal does not introduce an EU-wide obligation for Member States and operators to equip crematoria with mercury emissions abatement technology.

Mercury: dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions

The Committee on the Environment, Public Health and Food Safety adopted the report by Marlene MORTLER (EPP, DE) on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2017/852 of the European Parliament and of the Council on mercury as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions.

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:

Dental amalgam

The report stated that considering the availability of mercury-free alternatives, the affordability of alternative materials and the current transition to mercury-free fillings in many Member States, it is appropriate to prohibit the use of dental amalgam for dental treatment of all members of the population, whilst maintaining the possibility of using dental amalgam for patients with specific medical needs.

From 1 January 2025, dental amalgam should not be used for dental treatment of any member of the population, except when deemed strictly

necessary by the dental practitioner based on duly justified specific medical needs of the patient.

Waste

Mercury-added products that are still in circulation and that can no longer be used should be considered waste and should be collected separately and in an environmentally sound manner.

Restriction on the manufacture and export of certain mercury-added lamps

Mercury-added products such as linear triband phosphor lamps for general lighting purposes that are not already covered by Annex II, as well as non-linear triband phosphor lamps, should be subject to a ban on manufacture, import and export from 31.12.2025 (instead of 31.12.2027).

The report stated that significant co-benefits can be achieved by phasing out the export of mercury-added lamps as soon as possible, given that mercury-free alternatives are more energy-efficient and would therefore prevent tonnes of CO₂ emissions from being released.

Report and review

Members suggested that by 30 June 2024, and every two years thereafter, Member States should report to the Commission on planned and implemented measures to reduce mercury emissions and releases from crematoria. By 31 December 2025, the Commission should report to the European Parliament and to the Council on the reduction of mercury emissions and releases from crematoria on the basis of the reporting and, where appropriate, draft guidelines on the abatement technologies to control and reduce mercury emissions and releases from crematoria.

By 30 June 2026, the Commission should submit a report assessing the feasibility of withdrawing the exemptions for the use of dental amalgam, by 2030. That report should also outline the impact on the health of patients generally and patients dependent on amalgam fillings.

At the latest by 31 December 2026, the Commission should report to the European Parliament and to the Council on:

- the implementation and enforcement of the Convention including as regards the phase-out of mercury in cosmetics by 2025 by the Parties to the Convention and controlling and eliminating the manufacturing, import and export of mercury compounds for illegal practices within the Union and globally;
- the need to phase out remaining mercury uses, such as in lighthouses and porosimetry;
- the necessity to expand the list of mercury waste sources.

Mercury: dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions

The European Parliament adopted by 550 votes to 14, with 64 abstentions, amendments to the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions.

The matter was referred back to the committee responsible for inter-institutional negotiations.

The main amendments adopted in plenary relate to the following:

Dental amalgam

From 1 January 2025, dental amalgam should not be used for dental treatment of any member of the population, except when deemed strictly necessary by the dental practitioner based on duly justified specific medical needs of the patient.

Waste

Mercury-added products that are still in circulation and that can no longer be used should be considered waste and should be collected separately and in an environmentally sound manner.

Restriction on the manufacture and export of certain mercury-added lamps

Mercury-added products such as linear triband phosphor lamps for general lighting purposes that are not already covered by Annex II, as well as non-linear triband phosphor lamps, should be subject to a ban on manufacture, import and export from 31.12.2025 (instead of 31.12.2027).

Report and review

Crematoria are a significant source of releases of mercury into the atmosphere and even with a phase-out of dental amalgam, crematoria will continue to contribute to mercury pollution of air, water, and soil.

Members suggested that by 30 June 2024, and every two years thereafter, Member States should report to the Commission on planned and implemented measures to reduce mercury emissions and releases from crematoria. By 31 December 2025, the Commission should report to the European Parliament and to the Council on the reduction of mercury emissions and releases from crematoria on the basis of the reporting and, where appropriate, draft guidelines on the abatement technologies to control and reduce mercury emissions and releases from crematoria.

By 30 June 2026, the Commission should submit a report assessing the feasibility of withdrawing the exemptions for the use of dental amalgam, by 2030. That report should also outline the impact on the health of patients generally and patients dependent on amalgam fillings.

At the latest by 31 December 2026, the Commission should report to the European Parliament and to the Council on:

- the implementation and enforcement of the Convention including as regards the phase-out of mercury in cosmetics by 2025 by the Parties to the Convention and controlling and eliminating the manufacturing, import and export of mercury compounds for illegal practices within the Union and globally;
- the need to phase out remaining mercury uses, such as in lighthouses and porosimetry;

- the necessity to expand the list of mercury waste sources.

In parallel, the Commission should, where appropriate, propose measures, such as a review of Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals and restrictions of exports of mercuric azanide chloride (HgNH₂Cl).

Mercury: dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions

The European Parliament adopted by 575 votes to 12, with 38 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2017/852 of the European Parliament and of the Council on mercury as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions.

The position adopted by the European Parliament at first reading under the ordinary legislative procedure is as follows:

Dental amalgam

The Regulation proposed that from 1 January 2025, dental amalgam should not be used for dental treatment in the Union, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.

Dental amalgam may be used for dental treatment until 30 June 2026 in order to limit the socio-economic impact of the phase-out of dental amalgam, in particular on low-income patients. Member States in which dental amalgam is the only publicly reimbursed material at a rate of at least 90 % under national law, and in which such reimbursement is not yet possible for mercury-free alternatives as of 1 January 2025. Member States should provide reasoned explanations for making use of the derogation.

From 1 January 2025, the export of dental amalgam should be prohibited. From 1 July 2026, the import and manufacturing of dental amalgam should be prohibited. By way of derogation, the import and manufacturing of dental amalgam should be allowed for specific medical needs.

By 31 May of a given calendar year, importers and manufacturers of dental amalgam should report to their competent authority for the preceding calendar year the amount of dental amalgam they imported or manufactured.

Restriction on the manufacture and export of certain mercury-added lamps

Mercury-added products such as linear triband phosphor lamps for general lighting purposes that are not already covered by Annex II, as well as non-linear triband phosphor lamps, should be subject to a ban on manufacture, import and export from 31.12.2026.

Review

By 31 December 2029, the Commission should report to the European Parliament and to the Council on:

- the implementation and impact of the guidance, developed by the Commission by 31 December 2025, on abatement technologies for emissions of mercury and mercury compounds from crematoria applied in Member States;
- the need to maintain the exemption from the prohibition on the use of dental amalgam;
- the developments under the Convention as regards the phase-out of illegal mercury use in cosmetics;
- the need to phase out remaining mercury uses;
- the need to expand the list of mercury waste sources;
- the need to expand the list of mercury compounds set out in Annex I, by adding, for example, mercuric azanide chloride (HgNH₂Cl).

Transparency				
METZ Tilly	Shadow rapporteur	ENVI	10/01/2024	European Network for Environmental Medicine gUG
VONDRA Alexandr	Shadow rapporteur	ENVI	10/01/2024	Arnika, z.s.
MORTLER Marlene	Rapporteur	ENVI	11/10/2023	European Network for Environmental Medicine gUG
MORTLER Marlene	Rapporteur	ENVI	12/09/2023	Bundeszahnärztekammer