Council of the European Union

Brussels, 18 July 2023
(OR. en)

Interinstitutional File: 2023/0272(COD)

11960/23
ADD 4

ENV 871
COMER 95
MI 632
ONU 50
SAN 460
IND 401
CODEC 1391

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	14 July 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2023) 397 final
Subject:	COMMISSION STAFF WORKING DOCUMENT Subsidiarity Grid *Accompanying the document* 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

Delegations will find attached document SWD(2023) 397 final.

Encl.: SWD(2023) 397 final

EUROPEAN
COMMISSION

Brussels, 14.7.2023
SWD(2023) 397 final

COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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

{COM(2023) 395 final} - {SEC(2023) 395 final} - {SWD(2023) 395 final} - {SWD(2023) 396 final}

Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The legal basis for this proposal is Article 192 TFEU. In accordance with Article 192(1) TFEU, the European Union shall contribute to the pursuit, inter alia, of the following objectives: preserving, protecting and improving the quality of the environment; promoting measures at international level to deal with regional or worldwide environmental problems, and combating climate change.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In the case of environment, the Union's competence is shared, in accordance with Article 4 of the TFEU.
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[1]:
The Commission's proposal to revise Regulation (EU) 2017/852 on mercury is supported by an impact assessment prepared in accordance with the Commission's prevailing guidelines and reviewed by the independent Regulatory Scrutiny Board. The impact assessment addresses the issues of subsidiarity and proportionality, economic, social and environmental impacts and documents the extensive consultation activities undertaken. The consultation process included a variety of different consultation activities aimed at gathering the views of all stakeholders and ensuring that the view of different organisations and stakeholder types were presented and considered. - Feedback was invited on the Inception Impact Assessment published via the Commission's 'Have Your Say' interactive portal. This was followed by a web-based Public Consultation open to all. The survey contained 66 questions, covering the three areas of interest (dental amalgam, mercury emissions from crematoria and mercury-added products). - A targeted stakeholder survey (TSS) took place from 15 December 2021 to 15 April 2022 which contained specialised questions in the above-mentioned three areas of interest. - Follow-up interviews, two consultation workshops and a focus group, to engage stakeholders in deeper discussion on key themes. - The TSS included consultation of national, regional and local stakeholders specifically regarding crematoria as this sector has in the past been largely publicly-run. As this is changing and more private companies are managing crematoria, both public and private operators of crematoria were consulted. In line with the Commission's commitment to better regulation, this proposal has been prepared inclusively, based on full transparency and continuous engagement with stakeholders with due regard to avoiding unnecessary burdens. It is based on the best

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

available evidence, referenced in the Impact Assessment accompanying this proposal, and expert knowledge taking into account the external feedback.

The proposal respects fundamental rights, in particular those in the Charter of Fundamental Rights of the European Union. It also contributes to the right to a high level of environmental protection in line with the principle of sustainable development, as laid down in Article 37 of the Charter.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The explanatory memorandum accompanying the Commission's proposal presents a summary of the Commission's analysis included in its impact assessment and covering elements on subsidiarity and proportionality.

Mercury is a pollutant which can travel long distances in the atmosphere once released and collective (global) action is needed to address its release and control and so Union action is justified to achieve a high level of environmental and human health protection.

The 2020 Review Report (COM2020/378) concluded on the necessity of EU action to, inter alia, establish a complete EU phase-out of the use of dental amalgam and to align Union legislation on products containing mercury (MAPs), as it would ensure more effective and efficient implementation than what could be achieved at the Member States' level.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

The objectives of the proposed action cannot be achieved sufficiently by the Member States acting alone.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

Mercury pollution is transboundary, travelling across national borders, both between Member States and across the frontiers of the EU. Hence appropriate and effective pollution control can be achieved more quickly and efficiently at Union level compared to Member States acting alone in an uncoordinated manner.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[2] or significantly damage the interests of other Member States?

In the absence of a common EU approach for restricting the last remaining intentional uses of mercury phasing out, specifically the use of dental amalgam and prohibiting the manufacture and export of mercury-containing lamps, risks impeding the Union's effort in pursuing the objective set out in Flagship 8 of the Zero Pollution Action Plan i.e., minimising the EU's pollution footprint. Non-action would also risk hindering the Treaty objectives of achieving a high level of environmental and human health protection.

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

[2] https://europa.eu/european-union/about-eu/eu-in-brief_en

The provisions of the Regulation will be directly applicable in the Member States. Member States take appropriate national administrative and legal measures to implement and enforce these EU provisions.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
The impact assessment documents the status of the progress achieved by individual Member States in tackling mercury emissions from the last remaining intentional uses of mercury in the EU (the use of dental amalgam and the manufacture and export of mercury-containing lamps). However, progress is heterogeneous in phasing out completely the use of mercury in dental amalgam and other products, despite mercury-free alternatives being available and accessible.
(e) Is the problem widespread across the EU or limited to a few Member States?
Although mercury pollution is a problem widespread across the EU due to its transboundary nature, national differences are observed in the use of dental amalgam for dental treatments, mercury emissions from crematoria and the manufacture of mercury-containing lamps.
(f) Are Member States overstretched in achieving the objectives of the planned measure?
Regulation (EU) 2017/852 on mercury is the main EU instrument regulating mercury and covers the entire lifecycle of mercury from mining to final disposal. The Regulation was adopted in 2016 and is based on a Commission proposal repealing Regulation (EC) No 1102/2008. The Mercury Regulation entered into force on 13 June 2017. This means that the EU legislative framework on mercury is already well embedded in the national legislative frameworks of Member States, not least because of their commitments under the Minamata Convention, to which they are Parties. Therefore. the current revision builds on the ongoing phase-out of mercury.
(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
Considering the toxicity of mercury and the harmful impacts it has on the environment and human health, there is a widespread view at national, regional and local levels that a robust and comprehensive EU legislative framework is necessary to eliminate or reduce those negative impacts; and that further improvements are required to make it fully consistent with objectives set out under the European Green Deal (COM/2019/640), the Zero Pollution Ambition Flagship 8 of minimising the EU's pollution footprint and the Sustainable Chemicals Strategy.
2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?
The objectives of the proposed action can be better achieved at Union level by reasons of scale and uniformity of that action.
(a) Are there clear benefits from EU level action?
Concerning the use of dental amalgam, EU level action through a complete phase-out provides for a more consistent/comprehensive tool to eliminate the last remaining intentional uses of mercury, the negative impacts of mercury emissions, including transboundary

emissions. Furthermore, an ambitious phase-out date (2025) will lead to more omitted mercury pollution and reduced potential risk.

Regarding mercury-added products, action at Union level will allow establishing a more consistent and clearer legal framework by addressing all sides of the issue from manufacturing to export. Clear and precise EU-wide rules will enable concerned individuals and legal persons to ascertain the full extent of their rights and obligations.

The EU legal framework is increasingly being used by third countries, thereby also promoting an international level playing field.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

Uniform action to phase out the use of dental amalgam and other mercury-added products, specifically mercury-containing lamps, will reduce the potential risk of mercury pollution across and beyond the EU; lead to a more efficient functioning of the EU market for mercury-added products as well as more effective compliance/enforcement across the EU. Furthermore, uniform action is necessary in order to align the Mercury Regulation with already existing legislative framework e.g., the Directive on the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS).

Overall, the proposal strengthens the existing mercury legislative framework that equips the EU to address the significant environmental challenges expected in the next decade from intentional mercury uses.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

The current Mercury Regulation needs to be adapted, in line with Article 19, to more comprehensively integrate the objectives set out in the Zero Pollution Ambition and Sustainable Chemicals Strategy. The Commission's proposal to review the Mercury Regulation aims to address the last remaining intentional uses of mercury, taking into account the availability and accessibility of mercury-free alternatives. Furthermore, uniform action to phase out the use of dental amalgam and other mercury-added products will reduce the potential risk of mercury pollution and lead to a more efficient functioning of the EU market for such products as well as more effective compliance/enforcement across the EU.

This initiative will contribute to overall pollution reductions both within and outside the EU, delivering healthier ecosystems and improved human health. In parallel, this will support EU companies in becoming first movers and developing more mercury-free alternatives.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

A loss of competence of Member States is limited as this proposal strengthens and improves an already existing legislative framework aiming at further alignment with other EU legislation e.g., the Directive on the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS). Overall, benefits of the initiative outweigh any such possible loss of competence of Member States and local and regional authorities.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes, as the proposal will allow establishing a more consistent and clearer legal framework by addressing all sides of the issue from manufacturing to export. Clear and precise EU-wide rules will enable concerned individuals and legal persons to ascertain the full extent of their rights and obligations.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The explanatory memorandum summarises the analysis of the supporting impact assessment which contains an environmental, economic and social assessment of each policy option including an assessment of proportionality. The content of this proposal takes full account of the outcome of this analysis.

The proposed phase-out of the use, manufacture and export of dental amalgam and the proposed prohibition on the manufacture, import and export of relevant mercury-containing lamps are deemed to be proportionate and timely. By providing for the above-mentioned phase-out and prohibition, this proposal does not go beyond what is necessary to achieve the environmental objective being pursued, i.e., a mercury-free Europe, which will no longer export mercury-added products for which toxic-free and more energy-efficient alternatives are available.

The option of a legally binding obligation for Member States to install best available technologies for the abatement of mercury emissions in crematoria was not chosen for the reasons of proportionality.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed action constitutes an appropriate way to achieve the intended objectives.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The initiative is limited to those aspects that Member State cannot achieve satisfactorily on their own, and where the Union can do better.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

The objectives of this proposal can be best pursued through a Regulation, which is the most appropriate instrument to amend an existing Regulation. It is as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued.

A Regulation is a legal act that applies directly and uniformly to all EU Member States as

soon as it enters into force. Member States do not need to create their own legislation to bring this legal act into force.
(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)
The legal basis for this proposal is Article 192 TFEU. In accordance with Article 192(1) TFEU, the European Union shall contribute to the pursuit, inter alia, of the following objectives: preserving, protecting and improving the quality of the environment; promoting measures at international level to deal with regional or worldwide environmental problems, and combating climate change. Furthermore, Article 19(3) of the Mercury Regulation stipulates that the Commission shall, if appropriate, present a legislative proposal together with its report referred to in Article 19(1). However, action taken at EU level concerning mercury emissions from crematoria raised issues around proportionality. Hence, the development of non-binding EU guidance would allow Member States to implement control measures on a voluntary basis and at the discretion of national or regional authorities.
(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The initiative creates costs that are provided in the answer to question 3.1 above, which also shows that these costs are proportionate.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
The proposal contains a provision on a derogation, enabling under certain conditions and at the discretion of medical practitioners taking into account of special circumstances, while respecting the Union law.