

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to share any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	Revision of Regulation (EU) 2017/852 of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008
LEAD DG – RESPONSIBLE UNIT	DG ENV Unit C.4
LIKELY TYPE OF INITIATIVE	Legislative proposal
INDICATIVE PLANNING	2022
ADDITIONAL INFORMATION	Community Strategy concerning Mercury in 2005 European Green Deal Assessment of the feasibility of phasing-out dental amalgam

The Inception Impact Assessment is provided for information purposes only. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception Impact Assessment, including its timing, are subject to change.

A. Context, problem definition and subsidiarity check

Context

The EU has one of the most comprehensive and far-reaching bodies of legislation worldwide regulating mercury to protect human health and the environment. Regulation (EU) 2017/852 on mercury has restricted the use of mercury in most mercury-added products (MAPs); however, significant amounts of mercury are still used in the EU. That Regulation is one of the key EU instruments transposing the Minamata Convention, which covers the whole mercury life-cycle, from primary mercury mining to final disposal of mercury waste.

In its report [COM\(2020\)378](#) to the European Parliament and the Council on the reviews required under Article 19 (1) of Regulation 2017/852 ('the Regulation'), the Commission informed the EU legislator that:

- (a) The phase-out of the largest remaining intentional use of mercury in the EU, dental amalgam, is technically and economically feasible before 2030.
- (b) The Commission will assess the need for further work at EU level to prohibit not only the placing on the market, but also the manufacture and export of certain MAPs through an amendment to Annex II of the Regulation, taking into account progress made during international negotiations under the Minamata Convention to prohibit the use of mercury in MAPs.

This initiative contributes to the Zero Pollution ambition for a toxic-free environment announced in the European Green Deal.

Problem the initiative aims to tackle

Mercury is a major risk to the environment and human health. Exposure to mercury can cause permanent brain and kidney damage in adults and negatively affect foetal and early childhood development. It is bio-accumulative and, via the food webs and transboundary transport of air pollution, travels around the globe. Mercury in the air deposits on land and water. Pollution by mercury is persistent. Hence, a build-up of mercury in the environment leads to mercury accumulating in the fauna, flora and biotopes and to excessive amounts of mercury in fish and seafood consumed by humans.

Despite much progress since the adoption of the Community Strategy Concerning Mercury in 2005, significant amounts of mercury are still used in the EU, mainly in dental amalgam and MAPs such as lamps and measuring devices. Furthermore, larger amounts of dental amalgam and other MAPs are used worldwide. Such continued use of mercury contributes to the adding to the existing stock of mercury in the environment in the EU and worldwide.

Progressive substitution of dental amalgam with mercury-free materials is occurring gradually without policy intervention as patients, in general, and increasingly dentists, prefer mercury-free fillings. Nevertheless, without further legislative action, significant amounts of dental amalgam are still expected to be used in the coming years in the EU.

Ongoing inter-sessional work of experts may result in the fourth meeting of the Conference of the Parties to the Minamata Convention (November 2021) agreeing to prohibit manufacturing and trade of further MAPs at international level. However, should such agreement in the view of the EU be insufficient, the EU may take more ambitious measures, by applying a manufacturing and trade prohibition to a more extensive list of MAPs.

Basis for EU intervention (legal basis and subsidiarity check)

The objective of the Regulation on mercury is to ensure a high level of protection of human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds from, *inter alia*, mercury-added products. Given the transboundary nature of mercury pollution and the nature of the measures to be taken, the abovementioned objectives can be better achieved at Union level. In addition, an individual action by Member States would lead to the single market fragmentation.

The Regulation already forbids the use of dental amalgam for treatment of teeth of children under 15 years and for pregnant or breastfeeding women and requires Member States to draw up plans to phase-down its use. Article 19(1)(b) also required the Commission to assess the feasibility of an EU-wide phase-out of the use of dental amalgam. The Commission concluded in [COM\(2020\)378](#) that such phase-out is technically and economically feasible and committed to present a respective legislative proposal in 2022.

The restriction on placing of MAPs on the internal market, as well as regulating international trade of such products, falls under exclusive EU competence (Article 3 of TFEU), and has already been largely regulated at EU level.

B. Objectives and policy options

This initiative aims at further restricting the use of mercury in products, including dental amalgam, at EU level and by doing this, setting an example and a strong basis for international negotiations under the Minamata Convention.

In accordance with Commission report [COM\(2020\)378](#) options will be assessed concerning:

- (a) Phasing-out the use of dental amalgam in the EU, and
- (b) Prohibiting, if needed, the manufacture and export of certain MAPs.

With regard to dental amalgam, the impact assessment will consider a phase-out over different timeframes and include the possibility of certain exceptions relating to specific categories of patients or medical specificities (also reflecting conclusions from the [assessment of the feasibility of phasing-out dental amalgam](#)).

In considering a phase-out of dental amalgam, the assessment will also address the implications a phase-out would have on mercury emission from crematoria and the potential need to regulate such emissions.

Regarding other MAPs, the preparatory work for the revision of the Mercury Regulation will seek to identify the most environmentally and economically effective manner of reducing and eliminating the presence on the international market. As set out in [COM\(2020\)378](#), this can be done by:

- (a) Unilaterally prohibiting the manufacturing and export from the EU of all MAPs that are prohibited from being placed on the EU market. This would be achieved by adding those products to Annex II to the Mercury Regulation;
- (b) Agreeing at global level on the prohibition of further products. This would be achieved in two steps by (i) a Decision of the Conference of the Parties of the Minamata Convention extending the list of MAPs contained in Annex A, and (ii) implementing such extension in Annex II to the Mercury Regulation.

The outcome of ongoing international negotiations under the Minamata Convention as well as developments in relevant EU policy and legislation will be taken into account in the impact assessment, in particular in the design of policy options. These options will be assessed and reviewed for individual product categories.

C. Preliminary assessment of expected impacts

Likely economic impacts

The progressive substitution of dental amalgam with mercury-free materials (such as e.g. composite resins, ceramics, and glass ionomer cements) is already taking place. The overwhelming majority of EU dental filling manufacturers (95%) produce mercury-free materials, which represent a major share of the market. A regulatory requirement to phase-out dental amalgam would accelerate the declining trend and require manufacturers to shift towards producing alternative materials. The few remaining dentists using only dental amalgam would have to invest in equipment and training needed to use alternative materials.

A phase-out of dental amalgam could however affect certain costs that are borne by dentists, patients or healthcare systems depending on different national approaches in various Member States.

The production in the EU of MAPs prohibited on the internal market is limited. Therefore, applying manufacturing and export prohibitions would have direct economic impacts only where such products (e.g. certain categories of mercury lamps) are still produced in the EU.

Likely social impacts

There are a number of potential social impacts associated with phasing-out the use of mercury in dental amalgam and other products i.e. employment, health (and access to it) and healthcare systems. A prohibition of dental amalgam would present a solution to the concerns of patients and dentists about health risks dental amalgam. However, adjustment of the reimbursement schemes in certain Member States might be necessary to avoid possible negative impacts on low-income households.

Concerning other MAPs, shifting to mercury-free products would reward R&I activities, and promote opportunities for job creation. However, with regard to certain mercury lamps, a prohibition of EU export could affect a limited number of the EU's lamps manufacturers.

Intake of (methyl)mercury from food, especially by unborn and young children, may lead to serious neurological and developmental effects, including significant reduction of IQ. This in turn can lead to substantial damage costs to society (health care, mortality rates, ability to learn and labour productivity, etc.). Reducing the amount of mercury emissions to the environment would reduce such damage costs and have a beneficial impact on human health, as this contributes to limiting mercury accumulation in the food chain.

Likely environmental impacts

Dental amalgam and MAPs (throughout their entire life cycle) cause significant emissions of mercury to air, water and soil. A phase-out of certain MAPs, including dental amalgam, would eliminate these emissions and thus their contribution to the stock of mercury that already circulates in the environment, which would result in incremental environmental and health benefits. However, fewer data are available on the environmental impacts, safety profile and biocompatibility of mercury-free alternatives, some of which contain Bisphenol A (BPA) and nano-sized particles. It must also be noted that a phase-out of dental amalgam would not address existing fillings i.e. historical dental amalgam, which will continue to enter the environment.

Likely impacts on fundamental rights

No negative impact on fundamental rights is expected.

Likely impacts on simplification and/or administrative burden

The further alignment of Annex II to Regulation 2017/852 (ban on manufacturing, import and export) with relevant EU internal market legislation (ban on placing on the EU internal market and import) would contribute to a simplified regulatory environment at EU level.

D. Evidence base, data collection and better regulation instruments

Impact assessment

An impact assessment will be carried out to support the preparation of this initiative and to inform the Commission's decision-making. The impact assessment will look at all economic, social and environmental impacts, and be supported by a contractor who will thoroughly review literature, gather stakeholder views and analyse the implications of different options. The Commission will in particular seek to gather information covering all Member States and, where not possible, develop a robust methodology for bridging data gaps.

Evidence base and data collection

A large amount of evidence has recently been gathered by the Scientific Committees (SCHER/SCENHIR) and in two Commission studies, which were conducted to provide an information basis, *inter alia*, for the Commission report to the European Parliament and to the Council in accordance with Article 19(1) of Regulation 2017/852.

- a) A [study on the use of dental amalgam in the EU](#). Extensive data collection included the review of scientific articles and reports, EU-wide data collection through an online survey and interviews. A workshop gathering experts from Member States and stakeholders (dentistry organisations, NGOs) validated the preliminary findings of the study, whilst providing additional input to improve the modelling and conclusions.
- b) A [study on mercury-added products and their alternatives providing the analysis and necessary documents to support the review of Annexes A and B of the Minamata Convention](#). This study included a review of the regulatory gaps between EU legislation and the Minamata Convention provisions and produced individual product fiches containing information on mercury-free alternatives as well as their technical, economic and environmental feasibility.

Additional information for this impact assessment will also be gathered through a support contract.

Consultation of citizens and stakeholders

A consultation strategy will be prepared to map relevant stakeholders and to decide on relevant consultation tools. As a minimum, the following consultation activities will be carried out to allow the public and all stakeholders to provide evidence and give views on the best options to enhance the EU's Mercury Regulation:

- A public consultation based on a questionnaire posted on the Commission's "Have Your Say" portal will run for a minimum of 12 weeks.
- A separate targeted consultation for key stakeholders in a form of questionnaire(s).
- Stakeholder meetings will be organised to: (1) present and discuss the main issues and options under consideration, and (2) present and discuss the main conclusions of the impact assessment.

The main stakeholder groups expected to be consulted are: Member States authorities, business associations (in particular mercury-added products industries), non-governmental/civil society organisations, individuals, workers associations and trade unions.

Consultation results will be published on the Commission's "Have Your Say" portal once all the activities are completed.

Will an implementation plan be established?

Given the nature of this initiative, it is not envisaged that an implementation plan is needed.