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COVER NOTE

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Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT *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) 395 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

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

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EXECUTIVE SUMMARY

Policy context

Mercury is a hazardous substance which poses a threat to the environment and to human health. Following signature of the Minamata Convention on Mercury in 2013, the EU established Regulation (EU) 2017/852 on Mercury, setting limits on the use of mercury in a range of products and prohibiting the export of metallic mercury from the EU. Article 19(1) of the Regulation required the Commission to report on the outcome of its review for three focal areas:

- Feasibility of a phase out of the use of dental amalgam, preferably by 2030;
- Emissions of mercury and mercury compounds from crematoria; and
- Environmental benefits and feasibility of a further alignment of Annex II with relevant Union legislation regulating the placing on the market of mercury-added products (MAPs).

This report concluded that the phase out of dental amalgam is technically and economically feasible before 2030 and that the evidence base for mercury emissions from crematoria is highly uncertain, requiring further work. It also called for further work to assess the need to prohibit the placing on the market, manufacture and export of certain MAPs. This study will support the Commission in further assessment of these problem areas, with the aim of supporting a revision of the Regulation. This work and any subsequent legislative proposal will contribute to the Zero pollution ambition for a toxic-free environment announced in the European Green Deal (EGD), the Zero Pollution Action Plan (ZPAP) and the Chemicals Strategy for Sustainability (CSS).

Aims and objectives of the study

The overall aim of this study was to investigate the three Article 19(1) problem areas in further detail to support a revision of Regulation (EU) 2017/852 on Mercury. This will close remaining gaps in EU legislation, to contribute to the objectives of the Minimata Convention and the EGD. The specific policy objectives for each of the three problem areas are:

Problem 1 – To assess if and when a dental amalgam phase-out could be achieved (earlier than 2030), building on the commitment made in Article 10 of the Regulation (EU) 2017/852 on Mercury to phasing down dental amalgam use.

Problem 2 – To reduce emissions from crematoria to levels not considered significant to human health and the environment, in line with ambition to create a toxic-free environment as set in the ZPAP.

Problem 3 – To reduce entry into circulation of mercury in society by cutting supply and demand of mercury in products for all supply chains originating in the EU. This is in line with the ZPAP and CSS commitment to reduce the EU's external pollution footprint and restricting exports of products not allowed in the EU market.

Approach

In order to further assess these three areas, the problem was defined (including key drivers and impacts), data sources were identified and the policy objectives were defined for each problem area. A baseline was then developed for each problem area, forming the benchmark by which the policy options will be compared against and outlining what would happen under

a ‘no change’ scenario. A long list of policy measures was identified based on the Article 19(1) Review Report and input from Member States and stakeholders. These measures were then screened, with selected measures retained and the economic, social and environmental impacts were assessed in comparison to the baseline, in line with the Better Regulation Guidelines. Six policy options were retained (with sub-options) which were then compared and a preferred policy package was identified. An overarching componment of the study was an depth programme of stakeholder consultation. The consultation strategy included an open public consultation, a targeted consultation survey, targeted interviews, a focus group and two consultation workshops.

Problem definition

Problem 1 – Dental Amalgam

Dental amalgam is used as a filling material to restore tooth surfaces and is the largest remaining intentional use of mercury in the EU. Use of dental amalgam can result in emissions of mercury, during placement/removal by dental practitioners, via excretion or through cremation or burial of people with dental amalgam restorations. These emissions in turn lead to adverse human health effects. Limited exposure may also occur during the lifetime of a restoration. Use of dental amalgam varies considerably across Members States, for example Sweden has completely phased out dental amalgam use, but eight Member States used dental amalgam for over 50% of restorations in 2019. Its continued use can be motivated by a lack of communication/awareness of mercury-free alternatives, lack of training of practitioners to use such alternatives and in some cases higher costs for reimbursement of mercury-free alternatives.

Problem 2 – Mercury emissions from crematoria

Crematoria continue to be an important source of mercury emissions in the EU, originating from mercury amalgam fillings in human remains. The number and size of crematoria in the EU vary significantly by Member State, for example Spain has the highest number of crematoria in the EU but most carry out less than 350 cremations a year, whereas in Croatia the average crematorium carries out 5000 cremations a year. A 38% increase in annual cremation numbers were experienced in the EU between 2010 and 2019, and cremation is estimated to continue to increase across the EU up to 2030. Emissions of mercury from crematoria can be avoided through the use of abatement techniques. There are currently no EU-wide regulations on the use of such techniques, although use is expected to increase and abatement techniques are recommended by OSPAR and HELCOM Commissions. As dental amalgam fillings last on average 15-20 years, emissions from crematoria will still continue even after a phase out of dental amalgam.

Problem 3 – Manufacture of mercury-added products for export to third countries

Various laws are in place to prohibit the placing on the market and import into the EU of MAPs, however, there are MAPs which continue to be manufactured in the EU and exported to third countries despite being prohibited for placing on the EU market. This is a significant cause of mercury pollution in third countries, where EU-made products add to the national burden of hazardous products. In many cases, MAPs can end up in landfill or are incinerated in some cases. This weakens the position of the EU as a global leader and threatens its ability to meet its objectives of reducing the EU’s external pollution footprint. The relevant MAPs considered in this study include dental amalgam and various types of lamps, which are either

currently or soon to be banned on the internal market but continue to be manufactured and exported.

Policy options

A longlist of potential measures was identified based on the Commission Article 19(1) Review Report and input from Member States and stakeholders. These measures were then screened, in line with Better Regulation Tool #16, to identify those which should be analysed further, and the remaining thirteen measures were then retained for further analysis (three for dental amalgam, six for crematoria, four for MAPs). These measures were assessed for their impacts, and six policy options were retained. The retained policy options for each problem are laid out below:

The table below lists the shortlisted policy options.

Policy Option
PO1 – Dental health communication campaigns
PO2 – Establish a legally binding end date for the use of dental amalgam in the EU
PO3 – Publication of EU guidance on emissions abatement in crematoria
PO4 – Mandatory application of emissions abatement in crematoria
PO5 – Global agreement to ban the manufacture and trade of mercury-containing lamps
PO6 – EU ban on the manufacture and export of MAPs

Comparison of options

Problem 1 - Dental Amalgam

While the costs of PO1 are likely to be limited, it will likely also yield minimal social and environmental benefits and robust quantification of impacts is not possible due to uncertainties surrounding the campaign type and implementation. Several Member States also already organise such campaigns so additional campaigns may not have much impact. In comparison, PO2 will realise significant social and environmental benefits but also would incur more costs. An EU wide phase-out of the use of dental amalgam would ensure a uniform phase-out across all Member States. The extent of which these costs and benefits are incurred depends on the date by which phase-out comes into force (phase-out by 2025 leading to the greatest benefits). For this reason, PO2a is the preferred option.

Problem 2 – Emissions from crematoria

The phase-out date selected under PO2 subsequently effects the extent to which emissions from crematoria are reduced and will decrease the effectiveness and cost-benefit ratio of PO3 and PO4 (as less mercury to abate). PO3 (EU guidance on abatement use) will be much lower cost than PO4 but with corresponding smaller environmental and human health benefits. For PO4a (mandatory uptake of abatement technology for all crematoria), the costs are high in comparison to the benefits, in particular for SMEs. If dental amalgam is phased out by 2025 (as in preferred option PO2a), emissions will be lower by 2030 so the cost effectiveness of this option decreases. However, under PO4b (large crematoria only) the cost benefit ratio becomes positive.

Problem 3 – Mercury-added products

PO5 is considered to be the preferable option to achieve the maximum reduction of product-related mercury use but is associated with a high level of uncertainty as Parties to the Minamata Convention may fail to reach an agreement at COP5 or subsequent COPs. PO6 would allow the EU to take immediate action on this issue, lowering its external footprint and setting a political signal in the international domain. The risk of net negative impacts decreases if more time is planned between the adoption of the initiative and entry into force of a ban and no negative impacts would be expected if this is followed by a global ban. Therefore, a ban by 2025 for dental amalgam, and 2026/28 for relevant lamps are preferred under PO6, but both PO5 and PO6 are retained as preferred options.