PROPOSED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

DSC REF:

Proposed Replacement EU Act

Amendment of 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: Proposal to amend Regulation (EU) 2017/852 on mercury.

Summary of the Act

The existing Regulation implements in EU law the provisions of the Minamata Convention on Mercury and establishes conditions concerning:

- the use, storage, and trade in mercury, mercury compounds and mixtures of mercury
- the manufacture, use of and trade in mercury-added products (including dental amalgam)
- the management of mercury waste.

The amendment to the Regulation proposes to deliver on the recommendations included in the 2020 report by the Commission on the feasibility of further phasing out the use of mercury in dental amalgam and other products. The proposed amendments will also align the Regulation with wider EU law on the Restriction of Hazardous Substances (RoHS) and implement a decision on prohibiting further Mercury Added Products adopted by Parties at the fourth meeting of the Conference of the Parties (the Minamata Convention COP) in March 2022.

Specifically, the proposed amendments will:

- Prohibit the use of dental amalgam in the EU from 1st January 2025, whilst safeguarding the right of the dental practitioners to still use it when deemed strictly necessary for addressing specific medical needs of the patient.
- Prohibit the manufacture of dental amalgam in the EU, and export of dental amalgam from the EU from 1st January 2025. (Import and manufacturing of dental amalgam should continue to be possible only if the use of such amalgam is necessary to cover specific medical needs).
- Prohibit the manufacture, import and export of additional Mercury Added Products (MAPs) by listing them in Annex II to the Regulation.

The EU Mercury Regulation applies directly in Northern Ireland under the terms of the Windsor Framework. The pre-amendment Regulation has also been retained in UK domestic law, with retained Regulation (EU) 2017/852 (the Retained Mercury Regulation) applying in Great Britain. The UK is also a party to the Minamata Convention on mercury.

Department(s) Responsible

- Lead Department DAERA - Minister Andrew Muir
- DoH – Minister Robin Swann

Initial Assessment of Impact

Does it appear likely that the application of the proposed replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

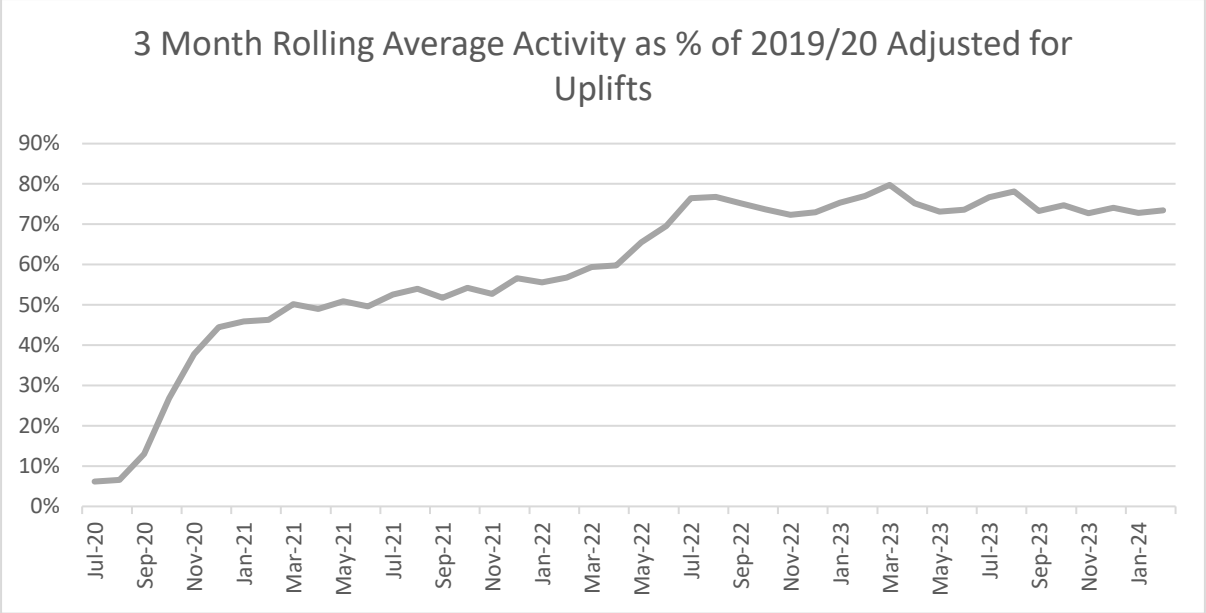
Yes

Does it appear likely that not applying the proposed replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

No

The Department of Health, on 20 March 2024, via the Executive Office, provided the Committee with our account of the impact in Northern Ireland of the proposed regulation on Dental Amalgam. The salient points are listed below for consideration.

Access to General Dental Services (GDS) and dental activity has still not returned to pre-covid levels. In the last 6 months, activity within GDS has been relatively stable. This equates to approximately 73% of average activity over the same 6 months in 2019/20 adjusted for fee uplifts. The table below shows the ongoing impact on activity following the pandemic and showing a plateauing at around the 73% level.



In short, if implemented in NI, General Dental Practitioners (GDPs) would only be permitted to use amalgam fillings when there is a specific medical need. Alternative materials would need to be used in the vast majority of cases, such as composites and glass ionomers.

The impact would also be felt in Community Dental Services who manage many high needs and vulnerable patient groups.

Composite fillings are frequently used in NI and are already listed in the NI GDS Statement of Dental Remuneration, the list of permitted Health Services treatments. However amalgam is still a very popular, cost-effective and clinically appropriate treatment used by GDPs.

In 2022/23, GDPs undertook approximately 201k treatments with amalgam and 437k using non-amalgam materials. However, a significant number of the non-amalgam fillings would be small fillings, in anterior (front) teeth, compared to larger amalgam fillings in posterior (back) teeth. This is a very important distinction in terms of the amount of material being used, and associated costs. Chart 2 below attempts to estimate, as far as possible, the ratio in relation to material use in back teeth.

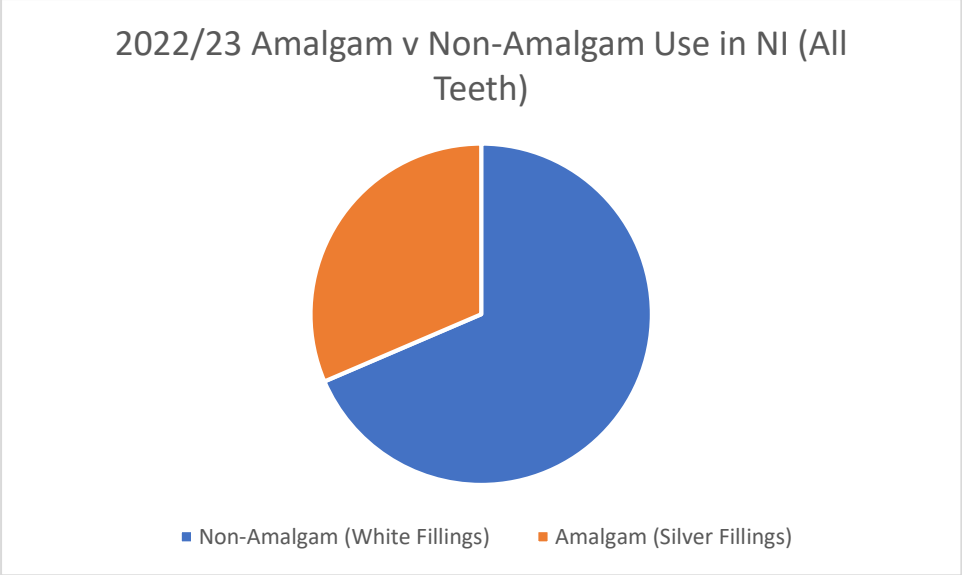


Chart 1

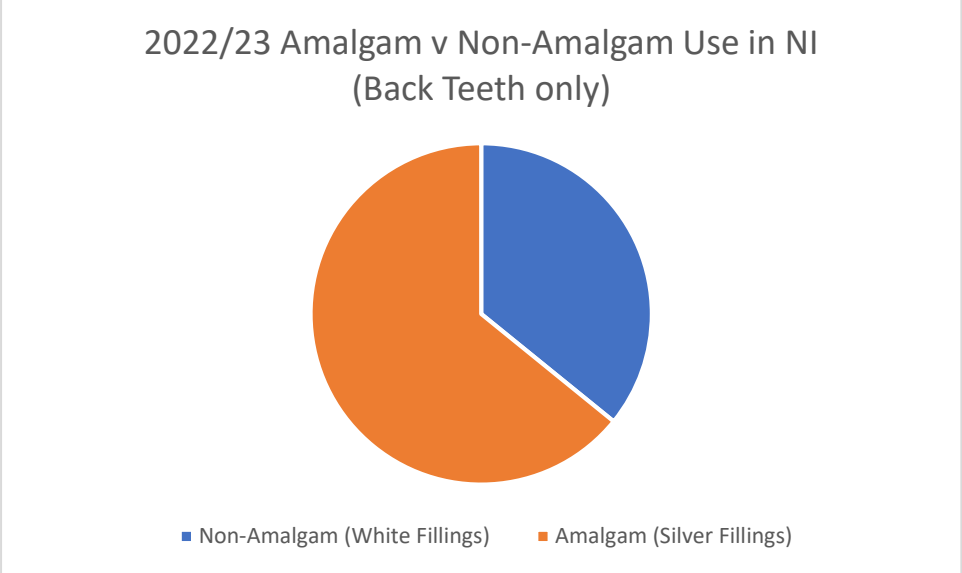


Chart 2

13. The key clinical impact, then, relates to how GDPs treat caries in back teeth.

Costs

It is estimated that replacing the 201k amalgam fillings with non-amalgam alternatives would cost in the region of £3.6m to the Department per annum, based on 2022/23 activity levels. However, there is also a notable increase in clinical time for non-amalgam fillings to be placed. The Department is concerned that both the increase in costs and in clinical time will erode the already reduced dental capacity in NI. The £3.6m is only the direct cost to the Department; patients that are not exempt from health service charges will also have to pay for the more expensive treatments, as alternatives are more expensive, are more technique sensitive and have reduced longevity, so may need to be replaced more often. The increased cost implication represents a 4% increase in the

Department of Health's (DoH) dental budget at a time of post-COVID pressure on the dental health system and significant pressure on public finances.

There are also likely to be impacts to the price of dental amalgam, increased in line with reduced availability, and in relation to the price of alternative materials, with demand increasing sharply across the EU. These impacts will be felt not only in NI but across the UK and discussions are ongoing with the Department of Health and Social Care (DHSC) in relation to better examining these impacts. So whilst the costs can be estimated, there are a range of variables at play.

We would also want to explore any additional training requirements, to offer dental professionals across all sectors refresher training on the placement of non-amalgam posterior restorations. Upskilling the dental team and postgraduate training adjustments would also be required to accommodate higher rates of non-amalgam restoration. This will lead to some less significant resourcing pressures across the GDS and HSC Trust dental services.

There is an extant process in place to bid to Treasury for such EU Exit Divergence cost pressures, and the Department intends to develop a robust case to seek to recover any additional costs.

NI has the highest rates of tooth filling in the UK at 47,000 per 100,000 in 2019/20, compared with 22,000 per 100,000 in England, reflecting higher reliance on dental amalgam and poorer overall oral health. In terms of losing further capacity in GDS, we are concerned that this will impact low-income patients and families the most, further increasing already evidenced health inequalities. Dental decay disproportionally affects those living in areas of deprivation and least able to pay for dental care and treatment.

Dental amalgam is still widely considered as the material of choice for specific procedures, such as the replacement of existing amalgam restorations in complex cavities and in deep cavities where moisture control is challenging. Vulnerable patient groups, including older people, will have had amalgam fillings placed and replaced over many years and would be most affected by a ban. Amalgam is also the almost appropriate material for patients who have difficulty tolerating longer dental treatment times, including older persons and others with physical health issues.

Alternate tooth-coloured restorative filling materials, while offering the opportunity to adopt a minimum intervention approach, are regarded as being more costly, require more time for placement and may suffer increased failure rates. This presents challenges for the existing service, which is already under significant pressure, as well as patient safety and effectiveness of treatment concerns.

UK Government Explanatory Memorandum

The United Kingdom Government published a very limited EM in November 2023 – link below.

https://assets.publishing.service.gov.uk/media/6543a0ad1f1a60000d360ca8/EM_COM_23_395_C_23_4683_-_Mercury_Regulation_amendment.pdf

The EM merely advised that the UKG were discussing impacts with colleagues in NI departments to fully understand the potential impacts to inform future engagement with the EU. Regarding any financial implications, the EM stated that there was ongoing engagement with DOH to assess the cost. The outcome of this process has informed the impact assessment provided above.

The Committee should note that a revised EM is being prepared by the UKG and will be provided as soon as possible for your consideration.

Analysis by the European Commission on its Impact Assessment

https://ec.europa.eu/transparency/documents-register/api/files/SWD(2023)396?ersIds=090166e5feabf75e

The Commission published their Impact Assessment (IA) in July 2023 that covered the dental amalgam issue, as well as emissions of from crematoria and the manufacture of Mercury Added Products. The pertinent 'policy option' that impacts on the remit of DOH is Policy Option 2 – establishing a legally binding end date for the use of amalgam in the EU.

The Commission IA notes that:

- six of the nine mercury manufacturers have already (or will soon) discontinue the production of dental amalgam;
- the associated costs of phase-out are considered to be negligible as costs are passed on to patients (or in some cases Member States (MS));
- the variation in dental restoration costs varies across the EU, with some MSs experiencing very low cost differentials, with €6 being regarded as a representative cost differential;
- that the total cost to EU consumers would be €208m in the first year of implementation;
- the estimated financial impact in the UK, nor NI, was clearly not referenced, but, by way of comparison, the cost to Ireland was estimated to be €6.7m in the first year.

The British Dental Association responded to the initial roadmap consultation in 2021 advising that:

- they remain supportive of a phase down approach in the UK;
- GDPs should continue to have a full range of materials to use and are best placed to recommend which is most appropriate;
- the impact of the pandemic has exacerbated pre-existing inequalities;

- phase down remains the only viable option that does not risk destabilising healthcare systems under strain; and
- there were considerable factual issues with the Commission's IA.

It does not appear that the Commission has taken such comments on board in terms of the outcome of their deliberations.

Departmental Engagement

The Department worked with DHSC and the other Devolved Nations on a joint CDO letter to the BDA that was issued on 15 December 2023 that outlined a recommitment to the phase down, rather than phase out of amalgam, and exceeding the requirements in the Minamata Convention. The letter also pointed to the existing arrangements at UK Government level to engage on matters of divergence, including the issue of dental amalgam. Cabinet Office have been responsible for engaging with the EU on this matter.

Both DOH and DAERA worked with DEFRA on the Control of Mercury (Amendment) (EU Exit) Regulations 2020 to ensure it remains operable as retained EU law at the end of the implementation period and to implement the requirements of the Northern Ireland Protocol. This was approved the Executive, as it was cross-cutting in nature, and was not commented on by the respective AERA and Health Committees.

DOH contributed to the public UK policy position on dental amalgam in the run up to the fifth meeting of the Conference of the Parties to the Minamata Convention on Mercury (COP-5) late 2023. This UK policy position (continuation to phase down rather than phase out) was at odds with a proposal submitted by Botswana and Burkina Faso to adopt 2030 as the phase-out. The decision at COP-5 was to uphold the phase-down approach and defer a decision on the phase out of dental amalgam to the next COP in 2025.

DOH and DAERA officials have been in regular communication with DHSC in particular since the proposal was published in July 2023, but also with Cabinet Office, Defra, official counterparts in the Republic of Ireland and the NI Office in Brussels to assess impacts, monitor the progress of the EU legislation and scenario plan for the potential need to implement in January 2025.

The Department have been engaging with the BDA on the matter since August 2023 to ensure that patient and clinical views are front and centre in our approach. The matter was discussed formally at meetings on 16 November 2023 (with the Permanent Secretary), 24 January 2024, 29 February 2024 and most recently on 27 March 2024 (with the Minister).