

PUBLISHED REPLACEMENT EU ACT INITIAL ASSESSMENT OF IMPACT

DSC REF: [12/2024]

Published Replacement EU Act:

REGULATION (EU) 2024/1849 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulation (EU) 2017/852 on mercury as regards dental amalgam and other mercury-added products subject to export, import and manufacturing restrictions.

Published 10 July 2024

AND

COMMISSION NOTICE - Application of Regulation (EU) 2024/1849 of the European Parliament and of the Council amending Regulation (EU) 2017/852 on mercury as regards dental amalgam and other mercury-added products subject to export, import and manufacturing restrictions to and in the United Kingdom in respect of Northern Ireland

Published 19 July 2024

[Regulation - 2024/1849 - EN - EUR-Lex \(europa.eu\)](#)
[EUR-Lex - C 202404675 - EN - EUR-Lex \(europa.eu\)](#)

This Regulation (and Commission Notice) replaces Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on Mercury (the EU Mercury Regulation) – Referenced in Article 13(3) of the Windsor Framework.

Summary of the Act

The amended Regulation and Commission Notice implements in EU law 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. However, the Commission Notice provides specific derogations regarding the application of the law in Northern Ireland.

The amendments 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 underrogated amendments were to put into law such that:

- From 1 January 2025, dental amalgam shall not be used for dental treatment in the EU, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.

- From 1 January 2025, the export of dental amalgam from the EU shall be prohibited.
- From 1 July 2026, the import and manufacturing of dental amalgam shall be prohibited except for use based on the specific medical needs of the patient.
- 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.

However, the derogation outlined in the Commission's Notice, enables the continued importation and use of dental amalgam for residents in Northern Ireland until 31 December 2034, provided a number of conditions are met. These conditions are that:

- a) We take the necessary measures to ensure regular and consistent progress towards full compliance of the Regulations by 31 December 2034 or until the date agreed by the Parties to the Minamata Convention on Mercury for phasing out the use of dental amalgam, whichever is earlier;
- b) dental amalgam is used for treatment of a UK resident and undertaken by a dental practitioner registered for that purpose in Northern Ireland;
- c) we implement and enforce a system to penalise operators who do not comply with the conditions of the Commission's Notice;
- d) we ensure that the imports of dental amalgam destined to dental practitioners in Northern Ireland are commensurate to their use of such material;
- e) we ensure that imports after 1 July 2026 comply with the new customs formalities; and
- f) we submit an annual report to the Commission regarding the importation and use of dental amalgam, and that we update the Northern Ireland Plan to phase down the use of dental amalgam

Department(s) Responsible

- Lead Department DAERA - Minister Andrew Muir
- DoH – Minister Mike Nesbitt

Initial Assessment of Impact

Does it appear likely that the application of the 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 significant and persisting impacts that had previously been advised to the Committee by the Department have been largely mitigated by the new derogation.

Does it appear likely that not applying the 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 18 April & 18 July 2024, attended the Windsor Framework Democratic Scrutiny Committee to provide a briefing on the impact in Northern Ireland of the proposed regulation on Dental Amalgam. Whilst noting that the clear and desirable direction of travel was the further reduction in use of dental amalgam, there were significant concerns around the timescales of the EU regulations, the ongoing uncertainty for practices and patients, and the impact on sector capacity and cost. This evidence has been provided to the Committee.

The key and most meaningful benefit from the derogation is that the deferral to phase out by 2035, rather than 2025, is much more in line with the current trajectory within the UK in terms of the longer term reduced usage of dental amalgam. The significant derogation also means that it is more likely that the Minamata global convention will be the mechanism that defines use in Northern Ireland, rather than the EU regulations.

The 10 year derogation means that the Department can better plan a more gradual phase out, working with practitioners in Northern Ireland to ensure that the conditions are met in a proportionate and effective manner.

The *immediate* increased costs that *would* have been felt from January 2025 have been mitigated. Whilst the more gradual transition to alternative materials may still incur costs in the longer term, the immediate impact on practices and service delivery is averted. Similarly, in respect of capacity, whilst the eventual destination will be the use of a material that takes longer to place, the derogation gives stakeholders the time to plan for these changes and absorb any benefits arising from improvements in materials and techniques in the meantime.

DOH and DAERA have undertaken an initial review of all the conditions outlined in the derogation and have concluded that none present a significant challenge in terms of implementation.

In addition, this derogation gives a significant period of time in which to effect change in overall population oral health, which in turn could reduce the overall use of restorative materials, including dental amalgam.

UK Government Explanatory Memorandum (EM)

The United Kingdom Government published a very limited EM in November 2023. 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 are advised that, in place of an EM, the UKG will be issuing a briefing note which will be provided as soon as possible for your consideration. The EM from November 2023 is still, therefore, the current version.

The Committee will wish to note, however, that this EM related to the non-derogated regulations.

Analysis by the European Commission on its Impact Assessment

[https://ec.europa.eu/transparency/documents-register/api/files/SWD\(2023\)396?ersIds=090166e5feabf75e](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;
- GPs 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 of Health 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).