EXPLANATORY MEMORANDUM TO

THE CONTROL OF MERCURY (ENFORCEMENT) (AMENDMENT) REGULATIONS 2025

2025 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Minister Hardy, Parliamentary Under-Secretary of State at the Department for Environment, Food and Rural Affairs, confirms that this Explanatory Memorandum meets the required standard.

2.2 Marc Casale, Deputy Director for mercury policy, at the Department for Environment, Food and Rural Affairs confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Chibi Takaya at the Department for Environment, Food and Rural Affairs, email: wastemovements@defra.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument implements changes made to Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on Mercury (the 'Mercury Regulation') which applies directly in Northern Ireland under the terms of the Windsor Framework. Regulation (EU) 2024/1849[1] of the European Parliament and of the Council of 13 June 2024 (the 'EU amending regulation'), which amends the Mercury Regulation, introduces a prohibition on the import, export, and manufacturing of specific mercury-added lamps.

4.2 The EU amending Regulation also introduces a prohibition on the use and export of dental amalgam from 1 January 2025, and the manufacture and import of dental amalgam from 1 July 2026. Separate arrangements have been granted in Northern Ireland, as per Commission Notice C/2024/4675[2] of 19 July 2024 ('the Commission Notice'), which recognises the specific circumstances of Northern Ireland, and as such allows for continued import and use of dental amalgam until 31 December 2034, unless an earlier date is agreed under the Minamata Convention on Mercury, to which both the UK and EU are Parties.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0852-20240730
[2] https://eur-lex.europa.eu/eli/C/2024/4675/oj/eng

4.3 The Control of Mercury (Enforcement) Regulations 2017[3] implements the Mercury Regulation in Northern Ireland, and the assimilated Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 (the 'assimilated Mercury Regulation') which applies in Great Britain. It establishes offences and penalties for non-compliance with the requirements set out in the relevant mercury regulations and identifies relevant UK enforcing authorities (Competent Authorities). The Department for Agriculture, Environment and Rural Affairs (DAERA) is designated as the Competent Authority for Northern Ireland.

4.4 The references to the Mercury Regulation in the Control of Mercury (Enforcement) Regulations are ambulatory references by virtue of Article 2A(2) of Schedule 8 of the EU (Withdrawal) Act 2018[4]. The Control of Mercury (Enforcement) Regulations 2017 currently refer to the provisions of the Mercury Regulations relating to mercury-added lamps and amendment is not required with respect to those lamps. However, the Control of Mercury (Enforcement) Regulations 2017 do not currently refer to the new provisions of the EU amending regulation relating to dental amalgam. This instrument will therefore amend The Control of Mercury (Enforcement) Regulations 2017 Regulations to ensure that the following provisions of the EU amending regulation, as modified by the Commission Notice, are enforceable in Northern Ireland:

(i) prohibitions on export and manufacture of dental amalgam, from December 2025 and 1 July 2026, respectively

(ii) restrictions on dental amalgam use, such that only patients that are resident in the UK and treated by dental practitioners registered in NI can be treated with dental amalgam as set out in the Commission Notice

(iii) prohibitions on dental amalgam imports as set out in the Commission Notice

(iv) additional reporting requirements for importers and manufacturers of dental amalgam.

Where does the legislation extend to, and apply?

4.5 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the United Kingdom.

4.6 The territorial application of this instrument (that is, where the instrument produces a practical effect) is Northern Ireland.

5. Policy Context

What is being done and why?

5.1 The instrument implements the amendments on dental amalgam in line with the EU amending regulation as those amendments are modified by the specific arrangements granted to Northern Ireland set out in the Commission Notice. Specifically, the instrument provides for enforcement of arrangements on dental amalgam trade (import and export), use and manufacture.

5.2 This instrument introduces the necessary powers to enforce the arrangements on dental amalgam applicable in Northern Ireland in line with the Windsor Framework, which maintains Northern Ireland's dual market access to the UK internal market and the EU single market.

[3] https://www.legislation.gov.uk/uksi/2017/1200/contents
[4] https://www.legislation.gov.uk/ukpga/2018/16

What was the previous policy, how is this different?

5.3 There is no change to the policy. The Control of Mercury (Enforcement) Regulations 2017 are the vehicle for implementing the Mercury Regulation in Northern Ireland. However, The Control of Mercury (Enforcement) Regulations 2017 need to be updated to implement recent amendments to the Mercury Regulation and the arrangements specific to Northern Ireland set out in the Commission Notice.

5.4 Prior to the EU amending regulation, Northern Ireland applied restrictions on dental amalgam use which have been in place for certain populations (persons with deciduous teeth, children under 15 years, pregnant or breastfeeding women except when deemed strictly necessary) since 1 July 2018. There has also been a requirement to use dental amalgam only in pre-dosed encapsulated form since 1 January 2019.

5.5 The instrument will amend the Control of Mercury (Enforcement) Regulations 2017 in relation to Northern Ireland, regarding the: import and use of dental amalgam as set out in the Commission Notice; and the export and manufacture of dental amalgam as set out in the Mercury Regulation.

6. Legislative and Legal Context

How has the law changed?

6.1 The Mercury Regulation establishes rules for the use, storage and trade of mercury, and the management of mercury waste, aiming to protect human health and the environment by reducing mercury pollution and its harmful effects. The Mercury Regulation also implements the provisions of the Minamata Convention, an international agreement aimed at protecting health and the environment from the harmful effects of mercury. The Mercury Regulation applies directly in Northern Ireland under the terms of the Windsor Framework while the assimilated Mercury Regulation applies in Great Britain.

6.2 Article 10 of the Mercury Regulation specifically outlines restrictions and requirements regarding dental amalgam use and handling, while Articles 3, 5 and 8 outline restrictions on mercury-containing products. Parts A and B of Annex II list various lamps containing mercury that are prohibited from export, import, or manufacturing after specific dates.

6.3 The Control of Mercury (Enforcement) Regulations 2017 provide for enforcement of the Mercury Regulation across the UK by establishing enforcing authorities, civil sanctions and offences related to breaches of relevant provisions of the EU and assimilated Mercury Regulation.

6.4 Schedule 1 of The Control of Mercury (Enforcement) Regulations 2017 lists the prohibitions and requirements detailed in the Mercury Regulation and assimilated Mercury Regulation in relation to exports, imports, use, and manufacturing of mercury, mercury compounds, and mercury-added products. Enforcement powers are available with respect to the listed prohibitions and requirements.

6.5 The proposed instrument aims to amend the Control of Mercury (Enforcement) Regulations 2017 in relation to NI to ensure that the provisions of the EU amending regulation, as modified by the Commission Notice, are enforceable in Northern Ireland.

Why was this approach taken to change the law?

6.6 The Control of Mercury (Enforcement) Regulations 2017 are the appropriate domestic legislation to implement the EU amendments as modified by the Commission Notice.

7. Consultation

Summary of consultation outcome and methodology

7.1 Northern Ireland's Department of Agriculture, Environment and Rural Affairs (DAERA), NI Environment Agency (NIEA) and Department of Health (DoH) were consulted on the approach taken during the drafting of this instrument and were given the opportunity to propose amendments to the text.

8. Applicable Guidance

8.1 The enforcement provisions of the instrument will be administered by DAERA in cooperation with NIEA and the Department of Health. Guidance developed by Northern Ireland's Department of Health has been circulated to dental practitioners.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the impact to business is currently considered to be low. However, a de minimis assessment has been prepared.

9.2 The amendment allows Northern Ireland businesses to use and import dental amalgam until 31 December 2034 or until the date agreed under the framework of the Minamata Convention, whichever is earlier. This gradual approach to phasing out amalgam avoids disruption to dental services that could result from an immediate ban. Non-amalgam alternatives, such as composite fillings generally require longer treatment times which could strain dental service capacity.

9.3 The amendment introduces minor compliance costs for businesses, including familiarisation with the new regulations and new reporting requirements. However, these costs are outweighed by the benefits of avoided service disruption. In addition, since both the Government and patients bear the cost of dental treatments, the continued use of more affordable amalgam material will also benefit them. Overall, the policy is expected to deliver net benefits estimated at £24 million over a 10-year period.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring of this legislation is that Defra, as well as the Devolved Governments in relation to devolved matters, will monitor and review the impact of this instrument as part of their standard policy-making procedures.

10.2 As this instrument is made under the European Union Withdrawal Act 2018, no review clause is required.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 The Parliamentary Under-Secretary of State for the Environment, Emma Hardy MP, has made the following statement regarding Human Rights:

"In my view the provisions of the Control of Mercury (Enforcement) (Amendment) Regulations 2025 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is made under section 8C(1) of the European Union (Withdrawal) Act 2018 and therefore relates to the withdrawal of the United Kingdom from the European Union.

14. Appropriateness statement

14.1 The Parliamentary Under Secretary of State for the Environment, Emma Hardy MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Control of Mercury (Enforcement) (Amendment) Regulations 2025 does no more than is appropriate".

14.2 This is the case because the instrument implements the amendments on dental amalgam in line with the Mercury Regulation and the specific arrangements for Northern Ireland set out in the Commission Notice, as necessary.

15. Good reasons

15.1 The Parliamentary Under Secretary of State for the Environment, Emma Hardy MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action."

15.2 These are: that without the instrument, the UK would not be compliant with the Windsor Framework, and it is appropriate for UK authorities to exercise the required legislative functions.

16. Equalities

16.1 The Parliamentary Under Secretary of State for the Environment, Emma Hardy MP, has made the following statement(s):

"The instrument does not amend, repeal, or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.

16.2 The Parliamentary Under Secretary of State for the Environment, Emma Hardy MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Emma Hardy, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

16.3 The amendments made by this instrument do not raise any issues relevant to the public sector equality duty under section 149(1) Equality Act 2010 because they do not alter the operation of the underlying schemes or impose any new liabilities or obligations on any relevant persons.

17. Criminal offences

17.1 Criminal offences will be created but these will be brought into scope of the existing penalty provisions in the Control of Mercury (Enforcement) (Amendment) Regulations 2025.

17.2 The Parliamentary Under Secretary of State for the Environment, Emma Hardy, made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the creation of a criminal offence and for the penalty in respect of it in the Control of Mercury (Enforcement) (Amendment) Regulations 2025."

17.3 These are: to provide a clear enforcement mechanism and to deter non-compliance.