

## MERCURY REGULATION INFORMATION NOTE

### **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 manufacturing, import, and export restrictions**

**Cabinet Office, July 2024**

#### *Summary*

1. This information note relates to Regulation (EU) 2024/1849 amending Regulation (EU) 2017/852 (“the EU Mercury Regulation”). The EU Mercury Regulation is included in Annex 2 of the Windsor Framework and consequently any amendments will be applied under Article 13(3) of the Framework and will be directly applicable in Northern Ireland, subject to the processes set out in Article 13(3a) of the Framework.
2. Our assessment is that some particular elements of the regulation, notably the ban of the use of dental amalgam from 1 January 2025, could have impacts on service delivery and health outcomes in Northern Ireland, particularly given the limited length of time for Northern Ireland dentistry to prepare for the phase out. Other parts of the regulation, such as the prohibition on several additional mercury added products, are not expected to cause any issues for industry. The UK Government continues to engage with the European Union on dental amalgam to discuss how the implications can be handled in a way that reflects Northern Ireland’s unique circumstances.

#### *Subject matter*

3. On 10 July 2024, 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, was published in the Official Journal of the EU. This follows an initial proposal from the European Commission published in July 2023.
4. The EU Mercury Regulation implements the provisions of the Minamata Convention on Mercury, but also goes further in pursuing the aims of the Convention. The Minamata Convention is an international environmental agreement with an objective to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. The UK is a party to the Minamata Convention and implements the decisions adopted under Minamata domestically.
5. The EU Mercury Regulation 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); and the management of mercury waste. It applies directly in Northern Ireland under the terms

of the Windsor Framework. The EU Mercury Regulation was also assimilated into UK domestic law and therefore applies in Great Britain in its assimilated form.

6. Regulation 2024/1849 (amending the EU Mercury Regulation) will deliver on recommendations included in the European Commission's 2020 report on the use of mercury in dental amalgam and products. The amendments will also align the EU Mercury Regulation with wider EU law on the Restriction of Hazardous Substances (RoHS).
7. Specifically, the amendments will:
  - a. Prohibit the use of dental amalgam in the EU from 1 January 2025, whilst retaining dental practitioners' discretion to still use it when dental amalgam is deemed strictly necessary for addressing the specific medical needs of an individual patient;
  - b. Provide a derogation until 30 June 2026 for the use of dental amalgam in Member States where dental amalgam is the only reimbursed dental restoration material and this is reimbursed at a rate of at least 90%.
  - c. Prohibit the export of dental amalgam from the EU from 1 January 2025 and prohibit the import and manufacturing of dental amalgam from 1 July 2026. The import and manufacturing of dental amalgam will be permitted for specific medical needs, as per section (a).
  - d. Prohibit the manufacture, import and export of six additional mercury-added products (MAPs) by listing them in Annex II to the EU Mercury Regulation.
8. An explanatory memorandum (EM) to the UK Parliament for this proposed legislation (COM(223)395 and C(23)4683) was published on 1 November 2023. The November EM details the background of dental amalgam and should be read in conjunction with this note.
9. Subject to the processes set out in Schedule 6B of the Northern Ireland Act 1998 and Article 13(3a) of the Windsor Framework, the Mercury Regulation will directly apply in Northern Ireland under Article 13(3) of the Windsor Framework.

### **Scrutiny history**

10. The Parliamentary scrutiny history relevant to this Information Note is contained in Annex A.

### **Ministerial responsibility**

11. The Secretary of State for Environment, Food and Rural Affairs has responsibility in relation to the Minamata Convention on Mercury with management and enforcement of mercury policy being devolved. Northern Ireland's Department of Agriculture, Environment and Rural Affairs (DAERA) is responsible for implementing the amendments to the EU Mercury Regulation in Northern Ireland.

12. With regards to dental amalgam, as most health matters in the UK are devolved, the Secretary of State for Health and Social Care is responsible for dental amalgam policy in England, while the Northern Ireland Minister for Health is responsible for dental amalgam policy in Northern Ireland.

### **Interest of the Devolved Governments (DGs)**

13. The EU Mercury Regulation will directly apply in Northern Ireland under the terms of the Windsor Framework, subject to the processes set out in Article 13(3a) of the Framework and Schedule 6B of the Northern Ireland Act 1998. Defra, DHSC and Cabinet Office officials consulted with officials in the Devolved Governments in producing this information note and will continue to do so in considering this regulation.

### **Legal and procedural issues**

14. The EU's legal basis for this amendment is the Treaty on the Functioning of the European Union, and in particular Article 192(1). The voting procedure used was qualified majority voting. It was formally adopted by both the Council of Member States (30 May 2024) and the European Parliament (10 April 2024). After being signed by the President of the European Parliament and the President of the Council, the regulation was published in the Official Journal on 10 July 2024 and will enter into force 20 days after its publication.
15. The measure falls within Article 13(3) of the Windsor Framework. This is subject to the processes set out in Article 13(3a) of the Framework and Schedule 6B of the Northern Ireland Act 1998.

### **Policy implications: dental amalgam**

16. Regulation (EU) 2024/1849 includes amendments to phase out dental amalgam and prohibit the manufacturing, import, and export of a number of mercury-added products.
17. Under the regulation, dental amalgam will no longer be able to be used in the EU from 1 January 2025, unless deemed strictly necessary by the dental practitioner based on the medical needs of the patient. The export of dental amalgam will also be prohibited from 1 January 2025, whereas the manufacturing and import into the EU will be banned from 1 July 2026. Subject to the processes set out in Article 13(3a) of the Windsor Framework, this will also apply in Northern Ireland.

### *UK policy on dental amalgam*

18. The UK is a Party to the Minamata Convention. The Minamata Convention is an international environmental agreement and its objective is to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. The Convention requires Parties to implement measures to

phase down the use of dental amalgam, taking into account the Party's domestic circumstances and relevant international guidance. These measures can include national objectives aimed at dental cavities prevention and health promotion to minimise the need for dental restoration, and promoting research and development of quality mercury-free materials for dental restoration.

19. Amalgam policy is devolved in the UK and every nation has phase down plans in place, which were published in 2019. These include measures to minimise environmental discharge, improve collection of amalgam waste and changes in service delivery and support for alternative materials. Neither the UK Government nor any of the Devolved Governments currently have any plans to fully phase out amalgam, and amalgam continues to be widely used across the UK due to its important role in patient care and the relative speed and ease of its use, which impacts on treatment times.

*Summary of the impact on the proposal on Northern Ireland*

20. Under the updated Mercury Regulation, dental amalgam will need to be phased out in Northern Ireland by 1 January 2025. This will have implications on dental health inequalities and for patients in terms of access to dental treatment and associated costs. This will also impact the costs for the National Health Service and impact the dental sector more broadly, including costs, dental workforce training and delivery of dental care.
21. The prevalence of oral health issues in Northern Ireland is an important factor in how the updated regulations would affect dental care in Northern Ireland. Northern Ireland 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 oral health. Dental decay disproportionately affects those living in areas of deprivation and least able to pay for dental care and treatment. In 2022/23, General Dental Practitioners in Northern Ireland undertook approximately 201,000 treatments with amalgam, and 437,000 using non-amalgam materials. 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.
22. Our assessment is that the amendments would have implications for Northern Ireland's dentistry provision and patient care. The UK Government continues to engage with the European Commission on this issue.

*Treatment times*

23. The amended EU Mercury Regulation will likely lead to longer treatment times and delays in dental treatment in Northern Ireland. The British Dental Association estimates that the treatment times of alternative materials are over 50% higher than those of amalgam for cases involving more than one surface (37.5% when involving

one surface).<sup>1</sup> In the context of oral health outcomes in Northern Ireland, the effect of these alternatives may be to place additional time pressures on the delivery of dental services in Northern Ireland and extend overall waiting lists.

24. Longer treatment times are likely to be most acutely felt in particularly vulnerable groups, such as elderly people, patients with high treatment needs and patients with conditions such as excess saliva or low gag reflex during treatment - who benefit from the quicker, less complex, amalgam treatment. High-needs patients may see teeth extracted that could otherwise be treated with amalgam, given the increased costs associated with alternative materials.
25. The amended EU Mercury Regulation may also lead to further resourcing pressures as upskilling and postgraduate training adjustments would need to be required to accommodate higher rates of non-amalgam restoration.

#### *Industry and Health Practitioners*

26. Industry representatives have expressed concern about the impacts of the legislation and raised these concerns with the EU via a consultation. The British Dental Association (BDA), the UK trade union for dentists, also gave evidence in a Windsor Framework Democratic Scrutiny Committee session on 13 March. The BDA expressed concern that the regulations could have significant contractual and financial implications for dental practices and affect the dentistry service delivery in Northern Ireland due to dentists reducing public dentistry health services or going private entirely. Drawing on its own survey data, the BDA have estimated that 90% of dentists would reduce service, and up to 50% would no longer provide Health Service dentistry.
27. The BDA also provided a position paper with further detail on oral health implications, impacts on service delivery and feasibility of alternative materials to the Windsor Framework Democratic Scrutiny Committee.

#### *Costs*

28. In terms of quantifiable costs, the amended regulation would result in increased costs for the Northern Ireland Executive. It is estimated that replacing the 201,000 annual amalgam fillings with non-amalgam alternatives would cost in the region of £3.6m to the Department of Health (DoH) 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 increased cost implication represents a 4% increase in the DoH's dental budget at a time of post-COVID pressure on the dental health system and significant pressure on public finances. There are also potential unquantifiable costs in relation to treatment times, increased waiting lists and wider pressures on NI dentistry services.

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<sup>1</sup> January 2024, British Dental Association, 'Government failure on amalgam ban could break NHS dentistry'. [\[Link\]](#)

### **Policy implications: mercury-added products (MAPs)**

29. The EU amendments will restrict the manufacture, import and export of six types of mercury-added lamps by listing them in Annex II to the EU Mercury Regulation, with phase out dates ranging from 2025 to 2026.
30. At the Minamata Convention Conference of the Parties (COP) held in October-November 2023, the Parties adopted amendments to Annex A of the Convention to prohibit the manufacture, export and import of five of the six mercury added lamps contained in the amended EU Mercury Regulation, but with phase out dates ranging from 2026 to 2027. The amended EU Regulation therefore goes further than the Convention by including earlier phase out dates for the five lamps restricted under the Convention, and also restricting one further type of lamp.
31. The UK, as a Party to the Minamata Convention, intends to implement the decisions taken at the most recent Minamata COP in due course concerning the five mercury added lamps. We expect this will limit any divergence between the UK and amended EU Mercury Regulations concerning the phase out dates for these five lamps, and we will continue to monitor policy concerning the additional type of lamp (high pressure mercury sodium (vapour) lamps for general lighting purposes). Please see Table 1 in Annex B for mercury added lamps prohibited by Regulation (EU) 2024/1849.
32. However, all the lamps to be prohibited by the EU are already listed in the UK Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Regulations 2012 (as amended). Recent Minamata and EU decisions are therefore, to a large extent, consistent with existing UK legislation and policy. These Regulations prohibit the import and placing on the market of listed equipment. Therefore the possible divergence is limited only to the manufacture and export of the relevant lamps. Defra officials have engaged with representatives from the Lighting Industry Association on the issue but no concerns have been raised regarding the impact of possible divergence, as Defra officials understand that these six lamps are no longer manufactured in the UK.

### **Consultation**

33. Defra officials have consulted with representatives from the Lighting Industry Association concerning the Mercury Added Products aspect of Regulation (EU) 2024/1849.
34. Defra and DHSC officials have consulted the Devolved Governments on areas of their respective devolved policy.

### **Financial implications**

35. No financial implications are currently anticipated in relation to the addition of MAPs to Annex II of the EU Mercury Regulation.
36. Due to the application of the Article 10 amendment in Northern Ireland, concerning dental amalgam, it is estimated that replacing the 201,000 annual amalgam fillings with non-amalgam alternatives would cost in the region of £3.6m to the Department of Health (DoH) per annum, based on 2022/23 activity levels, and £2.75m for fee-paying patients.

**PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO:**

**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 manufacturing, import, and export restrictions**

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**COM(23)395 + ANNEX: 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**

**WITH**

**SEC(23)395: OPINION OF THE REGULATORY SCRUTINY BOARD  
SWD(23)395: EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT  
SWD(23)396: IMPACT ASSESSMENT  
SWD(23)397: SUBSIDIARITY GRID**

**C(23)4683 + ANNEX: COMMISSION DELEGATED REGULATION (EU) /... AMENDING REGULATION (EU) 2017/852 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS MERCURY-ADDED PRODUCTS SUBJECT TO MANUFACTURING, IMPORT AND EXPORT PROHIBITIONS**

**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**

**OPINION OF THE REGULATORY SCRUTINY BOARD**

**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT**

**IMPACT ASSESSMENT**

**SUBSIDIARITY GRID**

**COMMISSION DELEGATED REGULATION (EU) /... AMENDING REGULATION (EU) 2017/852 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS**



**REGARDS MERCURY-ADDED PRODUCTS SUBJECT TO MANUFACTURING, IMPORT AND EXPORT PROHIBITIONS**

**DEFRA SUBMITTED AN EM DATED 02 NOVEMBER 2023**

**SCRUTINY COMMITTEES' RECOMMENDATIONS:**

<b>COMMONS</b>	<b>LORDS</b>
SCRUTINY NOT COMPLETED (AGENDA 5 13/12/23) CLEARED FROM SCRUTINY (OUTCOME AGENDA 3, 29/11/23)	CLEARED SENT FOR INFORMATION TO THE ATTENTION OF THE PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE (AT CHAIR'S SIFT NO 42; 9/11/23)

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**COM (2020) 378: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL ON THE REVIEWS REQUIRED UNDER ARTICLE 19 (1) OF REGULATION 2017/852 ON THE USE OF MERCURY IN DENTAL AMALGAM AND PRODUCTS**

**DEFRA SUBMITTED AN EM DATED 16 SEPTEMBER 2020**

**SCRUTINY COMMITTEES' RECOMMENDATIONS:**

<b>COMMONS</b>	<b>LORDS</b>
SCRUTINY CONCLUDED (ESC OUTCOME AGENDA 25 No.27, 19-21) 4/11/2020 SCRUTINY NOT CONCLUDED (ESC OUTCOME AGENDA 20 No.23, 19-21) 1/10/2020	NOT SIFTED FOR SCRUTINY (EU ENVIRONMENT SUB COM) AT CHAIR'S SIFT 27 23/9/2020

## Annex B

**List of Mercury Containing Lamps Prohibited by the Minamata Convention COP-5 and the EU's Text**

Mercury Containing Lamps whose manufacture, import and export will be prohibited		
No.	Minamata COP 5 Decision MC-5/4 ( <a href="#">found here</a> )*	EU Text ( <a href="#">found here</a> ) ( <a href="#">found here</a> )
1.	Compact fluorescent lamps (CFLs) for general lighting purposes that are > 30 watts <i>Phase out date: 2026</i>	All other compact fluorescent lamps (CFLs) for general lighting purposes not already covered by entries 3 and 3a <i>Phase out date: 31.12.2025</i>
	Compact fluorescent lamps with a non-integrated ballast (CFL.ni) for general lighting purposes that are ≤ 30 watts with a mercury content not exceeding 5 mg per lamp burner <i>Phase out date: 2026</i>	
2.	Linear fluorescent lamps (LFLs) for general lighting purposes: (a) Halophosphate phosphor ≤ 40 watts with a mercury content not exceeding 10 mg per lamp (b) Halophosphate phosphor > 40 watts <i>Phase out date: 2026</i>	Halophosphate phosphor lamps for general lighting purposes that are not included in entry 4, point (b) <i>Phase out date: 31.12.2025</i>
3.	Linear fluorescent lamps (LFLs) for general lighting purposes: (a) Triband phosphor < 60 watts with a mercury content not exceeding 5 mg/lamp (b) Triband phosphor ≥ 60 watts with a mercury content not exceeding 5 mg per lamp (c) Triband phosphor ≥ 60 watts with a mercury content exceeding 5 mg per lamp <i>Phase out date: 2027</i>	Triband phosphor lamps for general lighting purposes that are not included in entry 4, point (a) <i>Phase out date: 31.12.2026</i>

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4.	Non-linear fluorescent lamps (NFLs) (e.g., U-bend and circular) for general lighting purposes: a. Triband phosphor, all wattages <i>Phase out date: 2027</i>	Non-linear triband phosphor lamps <i>Phase out date: 31.12.2026</i>
5.	b. Halophosphate phosphor, all wattages <i>Phase out date: 2026</i>	Non-linear halophosphate phosphor lamps <i>Phase out date: 31.12.2025</i>
6.	<i>Not considered</i>	High pressure sodium (vapour) lamps (HPS) for general lighting purposes with: (a) $P \leq 105 \text{ W}$ exceeding 16 mg Hg; (b) $105 \text{ W} < P \leq 155 \text{ W}$ exceeding 20 mg Hg; (c) $P > 155 \text{ W}$ exceeding 25 mg Hg <i>Phase out date: 31.12.2025*</i>
<i>Total No.</i>	5	6

\*- Phase out dates represent the dates after which the manufacture, import or export of the product shall not be allowed – e.g. a phase out date of 2025 means 1 January 2026 in practice for implementation.