

**EXPLANATORY MEMORANDUM FOR EUROPEAN UNION
LEGISLATION/DOCUMENTS WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL
AGREEMENT AND THE WINDSOR FRAMEWORK**

COM(23)395 + ANNEX

SEC(23)395

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C(23)4683 + 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**

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**

Submitted by the Department for Environment, Food and Rural Affairs

01 November 2023

SUBJECT MATTER

1. The European Commission has published both a legislative proposal and a Commission Delegated Regulation to amend Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on Mercury (the EU Mercury Regulation). The existing Regulation implements in EU law the provisions of the Minamata Convention on Mercury and establishes conditions concerning:
 - a. the use, storage, and trade in mercury, mercury compounds and mixtures of mercury
 - b. the manufacture, use of and trade in mercury-added products (including dental amalgam)
 - c. the management of mercury waste.

2. Under Article 19 of the EU Mercury Regulation, the Commission published a report in August 2020 on the feasibility of further phasing out the use of mercury in dental amalgam and other products. The legislative proposal, accompanied by the Commission Delegated Regulation to be adopted in parallel, sets out amendments to the EU's Mercury Regulation to deliver on the recommendations included in the 2020 report. 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.
3. Specifically, the proposed amendments will:
 - a. 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.
 - b. Prohibit the manufacture of dental amalgam in the EU, and export of dental amalgam from the EU from 1st January 2025.
 - c. Prohibit the manufacture, import and export of additional Mercury Added Products (MAPs) by listing them in Annex II to the Regulation.
4. The EU Mercury Regulation applies directly in Northern Ireland under the terms of the Windsor Framework. This 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.

SCRUTINY HISTORY

5. The Parliamentary scrutiny history relevant to this Explanatory Memorandum is contained in Annex A.

MINISTERIAL RESPONSIBILITY

6. The Secretary of State for Environment, Food and Rural Affairs has responsibility for policy on mercury and the Secretary of State for Health and the Northern Ireland Executive Ministers are responsible for policy on dental amalgam.

INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)

7. The management and enforcement of the Retained Mercury Regulation and the EU Mercury Regulation is devolved. Northern Ireland's Department of Agriculture, Environment and Rural Affairs (DAERA) is responsible for implementing the proposed changes to the EU Mercury Regulation in Northern Ireland. Scottish Government Ministers, Welsh Government Ministers, the Secretary of State for Health and Social Care, and the Secretary of State for Environment, Food and

Rural Affairs have an interest as the Retained EU Mercury Regulation applies in Great Britain.

8. Defra and DHSC officials consulted with officials in the Devolved Governments in producing this EM. We will continue to engage with the DGs to assess the impact of possible divergence identified.

LEGAL AND PROCEDURAL ISSUES

9.

i. Legal Base:

The legal basis for this proposal is the Treaty on the Functioning of the European Union, and in particular Article 192(1).

The legal basis for the Commission Delegated Regulation is the Treaty on the Functioning of the European Union, having regard to Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008, and in particular Article 20 thereof.

ii. Voting Procedure:

Qualified Majority Voting.

iii. Timetable for adoption and implementation:

The proposal will be considered by the European Parliament and the Council of the European Union according to the Ordinary Legislative Procedure (OLP). Defra expects negotiations under the OLP process to take 12 months to complete. The Commission Delegated Regulation will come into force on 14 September 2023, unless an objection is raised by the European Parliament, or by the Council.

POLICY AND LEGAL IMPLICATIONS

10. This EU legislative proposal, if adopted, will amend the EU Mercury Regulation, which is listed in the Windsor Framework and therefore applies in Northern Ireland.

Mercury Added Products (MAPs)

11. The Commission Delegated Regulation implements a decision adopted at the Minamata Convention COP in March 2022 to prohibit the manufacture, import and export of nine further MAPs from 31 December 2025. These have been listed in Table 1 of Annex B. Defra intends to lay equivalent legislation to amend the Retained Mercury Regulation to implement the Minamata Convention decision in

respect of Great Britain for these products. There will therefore be no significant difference in approach in Great Britain and Northern Ireland.

12. In addition, the EU legislative proposal will amend the EU Mercury Regulation to restrict the manufacture, import and export of six further types of mercury added lamp by 2025, by listing them in Annex II to the Regulation (please see Table 2 in Annex B). This will align the EU Mercury Regulation with the EU's Restriction of Hazardous Substances Directive 2011/65/EU (EU RoHS Directive) which already restricts placing on the market and import of these mercury containing lamps.
13. The upcoming Minamata Convention COP in October-November 2023 will consider a decision to prohibit the manufacture, export and import of three of the six types of mercury added lamp discussed above. A decision on the associated phase out deadline will also be proposed for adoption at the COP.
14. This means that the EU proposal will:
 - (a) prohibit the manufacture, import and export of three MAPs irrespective of the decision taken at the Minamata Convention COP in October-November 2023. It also includes the most ambitious phase-out dates for these three MAPs to be considered at the Minamata Convention COP to ensure that the Regulation at a minimum aligns with the prospective decision;
 - (b) go further by prohibiting the manufacture, import and export of the three additional MAPs not being considered at the Minamata Convention COP in October-November 2023.
15. In summary, as the UK and EU are both parties to the Minamata Convention, changes to the EU Mercury Regulation in line with decisions taken at the Minamata Convention will not result in significant divergence between Great Britain and Northern Ireland for these products (listed in Annex B, Table 1). Where the EU are proposing additional measures on six MAPs, two will be considered at the Minamata Convention in October-November 2023 and a further four will not. As a result, there may be future divergence between Great Britain and Northern Ireland concerning the export and manufacture of these six MAPs (depending on the outcome of the Minamata Convention COP this may be reduced). But as Great Britain and Northern Ireland are aligned in terms of the RoHS regimes, these six MAPs are already prohibited from being imported or placed on the market in both Great Britain and Northern Ireland. Defra officials will continue to work with the Devolved Administrations to assess the impact of any divergence, but if there is any impact it is expected to be minimal.

Dental Amalgam

16. Dental amalgam is a dental filling material used to fill cavities caused by tooth decay. It is a mixture of metals, consisting of liquid mercury and a powdered alloy

composed of silver, tin and copper. In Great Britain, the Retained Mercury Regulation applies. Whilst dental amalgam is currently widely used across both Northern Ireland and Great Britain, the UK's current position is to phase down but not yet phase out dental amalgam in accordance with Great Britain's current regulations. This includes restrictions on the use of dental amalgam on the treatment of deciduous teeth; in children under 15 years; or pregnant or breastfeeding women, except when strictly deemed necessary by the practitioner on the ground of specific medical needs of the patient.

17. The EU proposal, and the Commission Delegated Regulation, will amend the EU Mercury Regulation to prohibit the use of dental amalgam from 1 January 2025 for dental treatments for all members of the population, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient. Such instances could include, for example, where a patient may be allergic to alternative options for example, composite filling, and special care dentistry where patients may produce a lot of saliva, where composite alternatives would not be suitable as they require a dry environment, unlike dental amalgam. The proposal also prohibits the manufacture and export of dental amalgam from 1 January 2025. Were this EU proposal to apply in Northern Ireland, it would therefore prohibit the use, manufacture and export of dental amalgam in Northern Ireland.

18. This proposal is at an early stage and the UK will be discussing it in further detail with the EU using the governance forums set up under the Windsor Framework to manage these types of issues and find solutions. Initial discussions have taken place with colleagues in Northern Ireland and we are working with the Department of Health in Northern Ireland to fully understand the potential impacts of this proposal and next steps. This will inform further engagement with the EU about these proposals. The Government's priority is that everyone seeking NHS dental care can receive it when they need it.

19. The upcoming Minamata Convention COP in October-November 2023 will consider a proposal to prohibit the manufacture, import or export of dental amalgam by 2030.

CONSULTATION

20. There has been no external consultation undertaken with stakeholders outside His Majesty's Government.

FINANCIAL IMPLICATIONS

21. No financial implications are currently anticipated in relation to the addition of MAPs to Annex II of the EU Mercury Regulation.

22. Should the Article 10 amendment concerning dental amalgam apply in Northern Ireland, we do anticipate financial impacts and we are working with the Department of Health in Northern Ireland to fully cost the proposals.

A handwritten signature in blue ink, appearing to read 'Rebecca Pow', is positioned above the printed name.

**REBECCA POW MP
MINISTER FOR ENVIRONMENTAL QUALITY AND RESILIENCE
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS**

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A:

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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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:

COMMONS	LORDS
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 the EU's proposed Mercury-Added Products

Table 1. List of Mercury-Added Products (MAPs) whose manufacture, import and export will be prohibited after 2025 in accordance with Minamata Convention Conference of the Parties (COP) Decision in 2022			
S/N	Category	Minamata COP Decision MC-4/3 (UNEP/MC/COP.4/Dec.3) on MAPs whose manufacture, import or export shall not be allowed after 2025	EU approach (via Commission Delegated Regulation)
1	Lamp	Compact fluorescent lamps with an integrated ballast (CFL.i) for general lighting purposes that are ≤ 30 watts with a mercury content not exceeding <u>5 mg</u> per lamp burner	Compact fluorescent lamps with an integrated ballast (CFL.i) for general lighting purposes that are ≤30 watts with a mercury content not exceeding <u>2.5 mg</u> per lamp burner
2	Lamp	<p>Cold cathode fluorescent lamps (CCFL) and external electrode fluorescent lamps (EEFL) of all lengths for electronic displays, not included in the listing below:</p> <ul style="list-style-type: none"> • short length (≤ 500 mm) with mercury content exceeding 3.5 mg per lamp • medium length (>500 mm and ≤1,500 mm) with mercury content exceeding 5 mg per lamp • long length (>1,500 mm) with mercury content exceeding 13 mg per lamp 	To align with Minamata Convention COP Decision
3	Sensors	Strain gauges to be used in plethysmographs	Not applicable as already prohibited (from 2020) in EU Mercury Regulation
4	Electrical and electronic measuring device	<p>The following electrical and electronic measuring devices, except those installed in large-scale equipment or those used for high precision measurement, where no suitable mercury-free alternative is available:</p> <ul style="list-style-type: none"> • Melt pressure transducers 	To align with Minamata Convention COP Decision

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S/N	Category	Minamata COP Decision MC-4/3 (UNEP/MC/COP.4/Dec.3) on MAPs whose manufacture, import or export shall not be allowed after 2025	EU approach (via Commission Delegated Regulation)
		<ul style="list-style-type: none"> • Melt pressure transmitters • Melt pressure sensor 	
5	Other mercury products	Mercury vacuum pumps	
6	Other mercury products	Tyre balancers and wheel weights	
7	Other mercury products	Photographic film and paper	
8	Other mercury products	Propellant for satellites and spacecraft	

Table 2. List of EU proposed mercury-added lamps whose manufacture, import and export will be prohibited after 2025 in accordance with EU Restriction of Hazardous Substances Directive (EU RoHS Directive)

S/N	Mercury-added lamps under consideration for prohibition by the EU	Next steps under the Minamata Convention
1	Triband phosphor Linear Fluorescent Lamps (LFLs) for general lighting purposes not yet covered by Annex II	To be considered at Minamata COP-5 (Oct/Nov 2023) – potential phase out dates of 2027 or 2030. (Decision UNEP/MC/COP.4/Dec.3)
2	Halophosphate phosphor lamps for general lighting purposes not yet covered by Annex II	To be considered at Minamata COP-5 (Oct/Nov 2023) – potential phase out dates of 2025, 2027 or 2030: Halophosphate phosphor lamps ≤ 40 watts (Under Decision UNEP/MC/COP.4/Dec.3)
3	Halophosphate phosphor lamps for general lighting purposes not yet covered by Annex II	To be considered at Minamata COP-5 (Oct/Nov 2023) – potential phase out dates of 2025, 2027 or 2030: Halophosphate phosphor lamps > 40 watts (Decision UNEP/MC/COP.4/Dec.3)
4	All other compact fluorescent lamps (CLFs) for general lighting purposes not already covered by entries 3 and 3a of Annex II nor by the concomitant amendment to Annex II to Regulation (EU) 2017/852. Those covered in entries 3 and 3a of Annex II of Regulation (EU) 2017/852 are: CFL.i ≤ 30 watts with a mercury content exceeding 2,5 mg per lamp burner and CFL.ni ≤ 30 watts with a mercury content exceeding 3,5 mg per lamp burner	
5	Non-linear halophosphate and triband phosphor lamps	
6	High pressure mercury sodium (vapour) lamps (HPS) for general lighting purposes	