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Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL****on mercury, and repealing Regulation (EC) No 1102/2008**

(Text with EEA relevance)

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EXPLANATORY MEMORANDUM**1. CONTEXT OF THE PROPOSAL**

General context – Grounds for and objectives of the proposal

The Union and twenty-six Member States signed a new International Convention on Mercury ¹, negotiated under the auspices of UNEP. The Convention is named the "Minamata Convention" (hereafter, "Minamata Convention" or "the Convention"), after the name of the town where the worst ever case of mercury pollution occurred between 1950 and 1960. The signature marked the successful end of a negotiation process, involving five sessions of an Intergovernmental Negotiating Committee. All Member States are committed to ratifying the Convention.

The Convention addresses the whole life-cycle of mercury, from

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primary mercury mining to the management of mercury waste, with the objective to protect human health and the environment from anthropogenic emissions of mercury and mercury compounds to air, water and land. In particular, it sets restrictions on primary mining of mercury and on international trade of mercury, prohibits the manufacture, import and export of a wide range of mercury-added products, foresees prohibitions or operating conditions for several manufacturing processes using mercury, calls for discouraging new uses of mercury in products and industrial processes and measures to be taken to reduce mercury emissions from artisanal and small-scale gold mining (hereafter, "ASGM") and industrial activities, including through the use of best available techniques and requires interim storage of mercury and management of mercury waste to occur in an environmentally sound manner.

Much of the Minamata Convention is already covered by Union legislation. Regulation (EC) No 1102/2008 ² sets an export prohibition on mercury and on several mercury compounds, qualifies mercury from certain sources as waste and establishes rules on the storage of mercury. Other EU instruments contain ad hoc provisions on mercury and mercury compounds, including Regulation (EU) No 649/2012 ³ that sets a notification system applicable inter alia, to imports of mercury and Regulations (EC) 396/2005 ⁴, 1907/2006 ⁵, 1223/2009 ⁶ and Directives 2006/66/EC ⁷ and 2011/65/EU ⁸, which address the placing on the Union market of a range of mercury-added products and set maximum levels of mercury content. Additionally, Directives 2010/75/EU ⁹, 2012/18/EU ¹⁰, 2008/98/EC ¹¹ and 1999/31/EC ¹² aim at controlling, reducing and, when mercury-free alternatives exist, eliminating point sources and diffuse emissions of mercury, mercury compounds and mercury waste into the environment.

The assessment of the Union acquis has identified a limited number of regulatory gaps that need to be filled in to ensure the full alignment of Union legislation with the Convention. ¹³ This proposal seeks to address those gaps, which concern the following issues:

- the import of mercury;
- the export of certain mercury-added products;
- the use of mercury in certain manufacturing processes;
- new mercury uses in products and manufacturing processes;
- mercury use in ASGM and
- mercury use in dental amalgam.

In the interest of legal clarity, the obligations resulting from the

Convention that are not yet transposed into EU law should be integrated into a single legal act.

For that purpose, Regulation (EC) No 1102/2008, as the only dedicated Union legal act on mercury to date, should serve as the basis for doing so. Yet, given the nature and extent of the necessary modifications to Regulation (EC) No 1102/2008 and the need to enhance consistency and legal clarity, this proposal should repeal and replace it while taking over its substantive obligations whenever still needed.

Consistency with other policies and objectives of the Union

This initiative is consistent with the seventh Environment Action Programme¹⁴ that establishes the long-term objective of a non-toxic environment and that stipulates, for that purpose, that action is needed to ensure the minimisation of significant adverse effects of chemicals on human health and the environment by 2020.

The objectives of this initiative are also consistent with the Europe 2020 objectives on smart, inclusive, and sustainable growth, by stimulating innovation in terms of the development of mercury-free products and manufacturing processes. This proposal, by promoting ratifications of the Convention and its entry into force, will contribute to levelling the global playing-field for industrial processes using or unintentionally emitting mercury and mercury compounds and the manufacturing and trading of mercury-added products, thereby promoting the competitiveness of Union industry, all the more as most its provisions mirror the Union acquis.

Additionally, simplification and clarification of the acquis to enable better implementation is pursued where possible.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

Consultations with interested parties

Member State authorities and stakeholders were consulted within the framework of two studies conducted by the Commission¹⁵,¹⁶ and at a workshop held in Brussels on 7 July 2014 following which a request for additional information on specific issues was also published¹⁷. All written contributions received were made publicly available on the Commission's website¹⁸. A broad on-line public consultation was also run from 14 August 2014 until 14 November 2014 and publicised on the basis of a questionnaire¹⁹ on the "Your voice in Europe" webpage²⁰. The objective of this survey was to get a better understanding of the views of the public stakeholders and Member States concerning the

ratification of the Convention and specific issues related to its transposition and implementation, in particular in relation to the areas where Union legislation needs to be aligned with the Convention. The target groups were citizens, public authorities, research organisations, academia, non-profit/non-governmental organisations, consultancies and private companies and their representative organisations. There was broad consensus among stakeholders and the public in general that the Union should ratify the Minamata Convention. Specific issues raised by stakeholders were taken into account in the preparation of this proposal.

Result of the impact assessment

The impact assessment (hereafter: "IA") concluded that the ratification and implementation of the Minamata Convention will provide the EU with significant environmental and human health benefits, mainly due to the expected reduction of mercury emissions originating in other parts of the world. In particular:

- Once implemented, important provisions of the Convention concerning among others the application of the best available techniques (hereafter, "BAT") to abate emissions from large industrial plants, the phase out of existing primary mining combined with the prohibition of new primary mining or the establishment of restrictions on ASGM are expected to have a great positive environmental impact both globally and for the Union. Such activities practically do not exist within the EU or are already regulated. This will allow the Union to meet its objectives on the protection of the environment and human health, as outlined in the 2005 Community Strategy Concerning Mercury ('the Strategy')²¹.
- By implementing the Convention, third countries will apply similar standards as those currently in force within the Union to many industrial activities. This will help address potential competitive advantages benefitting companies in non-EU Member States that are subject to less strict (or even non-existing) environmental standards and possibly open new markets for Union companies specialising in environmental technology. As an illustrative example, the provisions of the Convention on mercury emissions from certain industrial activities will make numerous industrial facilities emitting mercury on the global scale subject to the use of BAT that are already applied by the Union industry.
- The IA examined different policy options to address the above-listed six regulatory gaps affecting EU law: a baseline option corresponding to "No EU action", and at least two different options for each of the relevant policy areas, i.e. one option consisting in transposing the obligations set out in the

Convention and one option consisting in laying down requirements going beyond what is required by the Convention.

With regard to the use of dental amalgam, the IA assessed the need for measures and their potential impacts:

- Commission Decision 2000/532/EC²² characterises amalgam waste from dental care as hazardous waste, it is therefore subject to the provisions of the Waste Framework Directive²³. Mercury emissions from dental cabinets are also subject to Union water legislation. Mercury is classified as priority hazardous substance according to Annex X of the Water Framework Directive²⁴ and hence the release of this substance to water has to be drastically reduced. As amalgam is the second biggest use of mercury within the Union with an estimated pollution potential of about 75t of mercury per year and a long-term pollution potential of more than 1000t²⁵, specific measures addressing this source are necessary.
- The IA concludes, in the light of the available scientific information, that a prohibition of the use of dental amalgam would not be proportionate as the health risks of dental amalgam are not clearly demonstrated and the cost of a prohibition would be high. Furthermore, the assessment shows that two measures included in the list of measures proposed in the Convention, and from which Parties should take at least two, would deliver environmental and health benefits at a low cost, i.e. the restriction of the use of dental amalgam to its encapsulated form and the promotion of the use of best environmental practices in dental facilities. Such measures are in line with Action 4 of the Mercury Strategy that was confirmed as a priority area for further action by the review of the Strategy in 2010. They would reduce exposure of dentists and patients to mercury emissions and ensure a drastic reduction of mercury releases to sewage systems and to the environment via urban wastewater treatment plants. Furthermore, the generation of new jobs is expected in companies involved in the manufacturing, installation and maintenance of amalgam separators and in companies specialising in the collection and treatment of mercury-containing waste.
- Although the majority of the businesses concerned would qualify as microenterprises, they would not be disproportionately affected by the proposed measures as (1) given the type of activity they would not suffer from competition with larger undertakings, (2) the implementation cost of the measure is limited and would require only low

investment, and (3) no jobs loss is expected in the dentistry sector. Furthermore, those measures are good practice promoted²⁶ by the Council of European Dentists and the majority have already implemented them. However, as such undertakings would need time to adapt to the obligations set out in this Regulation, the compliance date proposed for these measures is one year later than for the other measures covered in this Regulation. Finally, the requirement to use amalgam in an encapsulated form would not cause any additional burden to dentists who have opted out from using dental amalgam.

With regard to the other gaps, the analysis carried out in the IA concludes as follows:

- Import restrictions on mercury: trade restrictions that would go beyond the requirements of the Convention, i.e. to set an unconditional mercury import prohibition (rather than allowing imports of mercury under certain conditions related to the place of origin and to the source of the imported mercury) would not be justified as they would be more costly for Union industry and would not have any significant environmental benefits.
- Export restrictions on certain mercury-added products: trade restrictions that would go beyond the ones established in the Convention, i.e. to prohibit the export of mercury-added products subject to stricter Union rules regarding their mercury content than those laid down in the Convention (rather than prohibiting only exports of mercury-added products that do not meet the requirements of the Convention) would not be justified given that mercury input and releases into the environment would remain largely unchanged and that mercury emissions could, as a consequence of such a prohibition, increase in third countries.
- To restrict the use of mercury in certain manufacturing processes: the establishment of an absolute prohibition on the use of mercury for the production of sodium or potassium ethylate or methylate (instead of requirements limiting mercury use and emissions as foreseen in the Convention) would not be justified given the need for industry to be supplied with certain chemicals for which the availability of mercury-free production processes could not be demonstrated.
- To restrict mercury use in new manufacturing processes and products: the Convention provides only for Parties to take measures to discourage the development of new manufacturing processes using mercury and the production and placing on the market of new mercury-added products. Setting up a conditional prohibition applicable to those

processes and products would result in the best environmental and economic outcome as it would have a strong signal value and thus reduce the risk that economic operators engage in costly development of such products or processes that would likely be subsequently prohibited.

- To restrict mercury use in ASGM: as the only Member State concerned, France, has already taken measures to prohibit the use of mercury in ASGM, it is therefore sufficient for the Union to simply transpose the obligation to develop and review a national action plan in accordance with the Convention.

Economically-wise, the total cost of above-mentioned options, that have been singled out in the IA as the preferred ones ranges between 13-135 million EUR/y, mainly reflecting the costs of measures relating to the use of mercury in manufacturing processes and dental amalgam.

3. LEGAL ELEMENTS OF THE PROPOSAL

Summary of the proposed action

While Regulation (EC) No 1102/2008 constitutes the starting point for this Proposal, it is appropriate to repeal and replace it for the sake of legal clarity. Annex IV contains the correlation table.

Articles 1 and 2 specify the subject-matter of the proposal and provide definitions of key terms used therein.

Article 3 read in combination with Annex I sets a prohibition on the export from the Union of mercury, of several mercury compounds and of mixtures of mercury with other substances, save in respect of those mercury compounds that can still be exported when aimed at laboratory-scale research. This prohibition is already established since March 2011 in accordance with Article 1 of Regulation (EC) No 1102/2008 and complements the one provided for in Regulation (EU) No 649/2012. It transposes Article 3 (6), of the Minamata Convention read in combination with its Article 3 (1) ((a) and (b)), and (2) (a).

Article 4 prohibits the import into the Union of mercury when intended for ASGM and puts up a conditional prohibition on the import into the Union of mercury and of mixtures when planned for other uses. Such a prohibition does not apply to imports of mercury and of mixtures for final disposal as waste, to imports of mercury from countries that are Parties to the Minamata Convention when it originates from a primary mining source that is still allowed under Article 3(4) of the Convention, to imports of mercury from countries that are not Parties to the Convention provided that imported mercury is neither from primary mining nor from the chlor-alkali sector and that an import written

consent has been granted. For the purpose of streamlining administrative activity and preventing an increased administrative burden, Article 4(3) specifies that the national competent authorities designated under Regulation (EU) No 649/2012 shall also be those in charge of the implementation and control of such a prohibition.

Article 5 read in combination with Annex II transposes Article 4(1) and Annex A (Part I) of the Minamata Convention. It sets a prohibition, which shall start on 1st January 2021, on the export, import and manufacturing of a range of mercury-added products. Article 5 applies both as a complement and without prejudice to provisions of the EU acquis that establish already restrictions on the placing on the market and that set stricter requirements in terms, for instance, of the maximum mercury content of these products, as laid down, among others, in Directive 2006/66/EC.

Article 6 foresees the possible adoption of Commission Implementing Decisions specifying the trade forms to be used by the Member States' competent authorities to implement Articles 3 and 4, as a follow up of Decisions that will be adopted by the Conference of the parties of the Minamata Convention ('CoP') in accordance with Article 3(12) of the Convention.

Article 7 read in combination with Annex III transposes Article 5 (2 and 3) and Annex B of the Convention. It prohibits the use of mercury and mercury compounds as catalyst for the production of acetaldehyde and of vinyl chloride monomer as from 1st January 2019. Regarding installations producing sodium or potassium methylate or ethylate using a mercury-based process, it establishes restrictions on the use of mercury from primary mining and on releases of mercury and mercury compounds to the environment while prohibiting, as from the date of entry into force of this Regulation, any increase of production capacity or new establishment of installations. Article 7(3) foresees the possible adoption of Commission Delegated Acts as a means to transpose Decisions of the CoP establishing requirements for the interim storage of mercury and mercury compounds when supported by the Union, thereby maintaining the application of the ordinary legislative procedure in the absence of a Union position in favour of the concerned CoP decision or when the Union would have opposed to it.

Article 8 transposes Articles 4(6 and 7) and 5(4 and 9) of the Convention. It sets a prohibition on the manufacturing and placing on the market of mercury-added products not covered by any known use prior to the date of application of this proposal and on the implementation of manufacturing processes that did not exist prior to this date. Article 8(3 and 4) establishes a mechanism by which such new mercury-added products and manufacturing processes could still be allowed by means of a Commission Implementing Act taken on the basis of an assessment of their environmental and human health benefits

and of the availability of mercury-free alternatives that are technically and economically feasible.

In accordance with Article 7 of the Convention, Article 9 read in combination with Annex IV provides that Member States where ASGM occurs shall take steps to reduce, and where feasible eliminate, the use and emissions of mercury and mercury compounds resulting from such an activity and shall develop and implement a relevant national plan.

Article 10 transposes Article 4(3) and Annex A (Part II) of the Minamata Convention. It requires that dental amalgam be used only in an encapsulated form and that dental facilities be equipped with amalgam separators to retain and collect mercury-containing amalgam residues, as from 1st January 2019. It calls upon Member States to make use of relevant EN standards, as last updated, including EN ISO 138987 ²⁷, EN ISO 24234 ²⁸ and EN 1641:2009 ²⁹ or of any other national or international standards ensuring an equivalent level of amalgam residue retention and quality of amalgam capsules.

Article 11 reproduces Article 2 of Regulation (EC) 1102/2008 by providing that mercury that is no longer used in the chlor-alkali industry or generated from the cleaning of natural gas or from non-ferrous metals mining and smelting or extracted from cinnabar ore qualifies as waste that must be disposed of.

Article 12 is based upon Article 6 of Regulation (EC) 1102/2008 and provides that the companies operating activities referred to in Article 11 shall have to provide annually to national competent authorities information regarding notably the amount of mercury stored within each installation concerned and the amount of mercury sent to temporary or permanent mercury waste storage facilities. Article 12(2) provides that information must be reported by using the relevant waste category and NACE codes, as established in Regulation (EC) No 2150/2002 ³⁰. Article 12(3) specifies that installations producing chlor-alkali using mercury cells shall cease reporting once all those cells will have been decommissioned in accordance with Commission Implementing Decision 2013/732/EU ³¹ and all mercury waste has been transferred to a storage facility.

Article 13 provides that mercury waste can be temporarily or permanently stored in underground storage facilities and temporarily stored in above-ground storage facilities and specifies, for that purpose what requirements established in Council Directive 1999/31/EC for the temporary storage of mercury waste are applicable to the permanent storage of mercury waste in underground storage facilities.

Articles 14 and 20 lay down the provisions on penalties applicable to breaches of this proposal and on its entry into force and date of application.

Article 15 transposes Article 21 of the Minamata Convention by providing for an obligation for Member States to prepare, update and publish a report containing all relevant information on the implementation of this proposal, information that needs to be reported to comply with above-cited Article 21, a summary of the information gathered under Article 12 of this proposal on mercury waste from large sources and information on the significant individual stocks of mercury that may exist on the territory of each Member State. This provision specifies that the Commission must be informed of such a report and updates within one month of their publication. Article 15(2) provides for the adoption by the Commission of an Implementing Act establishing questionnaires to assist Member States to report relevant information to the Commission by specifying what precise information will have to be submitted, including information on key performance indicators, under what format and by when.

Article 16 foresees the possible adoption by the Commission of delegated acts that would amend Annexes I to IV of this proposal in order to transpose relevant Decisions adopted by the CoP when supported by the Union, thereby maintaining the application of the ordinary legislative procedure in the absence of a Union position in favour of the concerned CoP decision or when the Union would have opposed to it.

Articles 17 and 18 are standard texts for the exercise of the delegation granted to the Commission under Articles 7(3) and 16 and for the Committee procedure as a means to adopt Implementing Acts under Articles 6, 8(4) and 15(2).

Article 19 stipulates that Regulation (EC) No 1102/2008 will be replaced and repealed by 1st January 2018, date where this proposal shall start to apply and that references to Regulation (EC) No 1102/2008 shall be construed as references to this proposal.

Legal basis

Alike Regulation (EC) No 1102/2008, this proposal seeks both to protect the environment and human health and to ensure uniformity in respect of its trade aspects (export and import prohibition and restrictions affecting mercury, mercury compounds and mercury-added products). Accordingly, this proposal has a twofold legal basis, i.e. Articles 192(1) and 207 of the Treaty on the Functioning of the European Union.

Subsidiarity and proportionality principles and choice of instrument

This proposal aims at transposing into the Union acquis the provisions of the Minamata Convention that are not yet covered by EU legal requirements in order to enable the Union and the Member States to

ratify and implement that Convention.

In this respect, the subsidiarity principle applies insofar as this proposal does not entirely fall under the exclusive competence of the Union.

The objectives of this proposal cannot be sufficiently achieved by the Member States. To address the issue of mercury pollution and exposure in the Union, each Member State must inter alia implement an export prohibition on mercury and several mercury compounds and on certain mercury-added products and a conditional import prohibition applicable to mercury. Such trade-related measures can only be transposed and implemented on the basis of Union provisions as measures in the field of common commercial policy fall within the exclusive competence of the Union in accordance with Article 3(e) of the Treaty on the Functioning of the European Union.

Regarding the non-trade provisions of this proposal on the use of mercury in existing and new manufacturing processes and in new products, on the control of mercury emissions into the environment and on the storage of mercury and management of mercury waste, they belong to the category of the shared competence between the Union and the Member States, i.e. environmental and human health protection. Considering, as specified above, that the protection of the environment and of human health from mercury pollution and exposure is already extensively regulated at Union level, action by the Union is justified. As to the provisions of the Convention on ASGM, this proposal provides the concerned Member State with the choice of the optimum combination of measures to implement to achieve the relevant requirements.

This proposal therefore respects the subsidiarity principle.

The chosen legal instrument is a Regulation as the proposal lays down provisions on e.g. trade and mercury-added products, which require uniform implementation across the Union, while leaving sufficient flexibility to the Member States as regards the choice of measures for compliance with provisions on manufacturing processes and ASGM and their detailed implementation. The proposal therefore complies with the proportionality principle.

4. BUDGETARY IMPLICATION

This legislative Proposal has no budgetary implications.

2016/0023
(COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on mercury, and repealing Regulation (EC) No 1102/2008

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,
and in particular Article 192(1) and Article 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social
Committee ³²,

Having regard to the opinion of the Committee of the Regions ³³,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Mercury is a highly toxic substance which represents a global and major threat to human health, including by methylmercury in fish and seafood resources, the ecosystems and wildlife. Due to the transboundary nature of mercury pollution, between 40% and 80% of total mercury deposition in the Union originates from outside of the Union and therefore warrants action at local, regional, national and international levels.
- (2) Most mercury emissions and associated exposure risks result from anthropogenic activities, including primary mercury mining and processing, the use of mercury in products, industrial processes and artisanal and small-scale gold mining ("ASGM") and mercury emissions originating in particular from coal combustion and the management of mercury waste.
- (3) The seventh Environment Action Programme adopted by Decision No 1386/2013/EU of the European Parliament and of the Council ³⁴ establishes the long-term objective of a non-toxic environment and, for that purpose, stipulates that action is needed to ensure the minimisation of significant adverse effects

of chemicals on human health and the environment by 2020.

- (4) The Communication from the Commission to the European Parliament and the Council 'Community Strategy Concerning Mercury'³⁵ ("the Strategy"), as reviewed in 2010³⁶, aims at minimising and, where feasible, ultimately eliminating global anthropogenic mercury releases to air, water and land.
- (5) Significant progress has been achieved in the Union in the past 10 years in the field of mercury management following the adoption of the Strategy and of a wide range of measures concerning mercury emissions, supply, demand and use and the management of mercury surplus and stocks.
- (6) The Strategy establishes that the negotiation and conclusion of an international legally-binding instrument should be a priority as Union action alone cannot guarantee effective protection of the citizens of the Union against the negative health effects of mercury.
- (7) The Union and 26 Member States have signed in Kumamoto on 11 October 2013 the Minamata Convention on Mercury ("the Convention").³⁷ The Union and all its Member States are therefore committed to its conclusion, transposition and implementation³⁸.
- (8) Swift ratification of the Convention by the Union and its Member States will encourage major global mercury users and emitters, that are signatories of the Convention, to ratify and implement it.
- (9) As Union legislation already transposes many of the obligations of the Convention, this Regulation should only lay down provisions that complement the Union acquis and that are needed to ensure its full alignment with the Convention and, accordingly, to enable the Union and its Member States to ratify and implement it.
- (10) The mercury export ban set out in Regulation (EC) No 1102/2008 of the European Parliament and of the Council³⁹ should be complemented by restrictions on the import of mercury depending on the source, the intended use and the place of origin of mercury. The national authorities designated in accordance with Regulation (EU) No 649/2012 of the European Parliament and of the Council⁴⁰ should perform the administrative functions linked to the implementation of such restrictions.
- (11) The export, import and manufacturing of a range of mercury-added products accounting for a significant share of the use of

mercury and mercury compounds within the Union and globally should be prohibited.

- (12) This Regulation should therefore have a twofold legal basis, Articles 192(1) and 207 of the TFEU, as it seeks to protect both the environment and human health and to ensure uniformity in respect of its trade aspects through the export and import prohibition and restrictions affecting mercury, mercury compounds and mercury-added products.
- (13) This Regulation applies without prejudice to the provisions of the applicable Union acquis that set stricter requirements for such products, including in terms of their maximum content of mercury.
- (14) In the absence of relevant available mercury-free production processes, operating conditions for the production of sodium or potassium methylate or ethylate involving the use of mercury should be set.
- (15) The manufacturing and placing on the market of new mercury-added products and the establishment of new mercury-based manufacturing processes would increase the use of mercury and of mercury compounds and mercury emissions within the Union. Such new activities should therefore be prohibited unless an assessment demonstrates that these uses would provide significant environmental and health benefits and that no technically and economically feasible mercury-free alternatives providing such benefits are available.
- (16) The use of mercury and mercury compounds in ASGM accounts for a significant share of mercury use and emissions worldwide, and should therefore be regulated.
- (17) The use of dental amalgam in an encapsulated form and the implementation of amalgam separators should be made mandatory to protect dental practitioners and patients from mercury exposure and to ensure that resulting mercury waste are not released into the environment, but are collected and subjected to sound waste management. Given the size of the undertakings from the dentistry sector concerned by this change, it is appropriate to provide sufficient time to adapt to the new provision.
- (18) Most of the criteria established in Council Directive 1999/31/EC⁴¹ for the temporary storage of mercury waste should apply to the permanent storage of mercury waste in underground storage facilities. The applicability of some of those criteria should depend on the specific characteristics of each underground storage facility, as determined by the

competent authorities of the Member States in charge of the implementation of Directive 1999/31/EC.

- (19) In order to align Union legislation with Decisions of the Conference of the Parties of the Convention supported by the Union, the power to adopt acts in accordance with Article 290 of the TFEU should be delegated to the Commission in respect of amending the annexes to this Regulation and supplementing this Regulation with technical requirements for environmentally sound interim storage of mercury and mercury compounds. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.
- (20) In order to ensure uniform conditions for the implementation of this Regulation with regard to prohibiting or allowing new mercury using products and processes and reporting obligations, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and the Council ⁴² .
- (21) Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (22) Given the nature and extent of the modifications which need to be made to Regulation (EC) No 1102/2008/EC and to enhance legal certainty, clarity, transparency and legislative simplification, that Regulation should be replaced.
- (23) In order to allow for the competent authorities of the Member States and the economic operators concerned by this Regulation sufficient time to adapt to the new regime laid down by this Regulation, it should apply from 1 January 2018.
- (24) Since the objective of this Regulation, namely to ensure a high level of protection of human health and the environment from mercury, by means of a mercury and mercury-added product export and import prohibition, of restrictions on mercury use in manufacturing processes, products, ASGM and dental amalgam and of obligations applicable to mercury waste, cannot be sufficiently achieved by Member States, but can rather, by reason of the transboundary nature of mercury pollution and the nature of the measures to be taken, be better achieved at Union level, the Union may adopt measures in accordance with the

principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

Chapter I General provisions

Article 1

Subject matter

This Regulation establishes measures and conditions concerning the trade, manufacture, use and interim storage of mercury, mercury compounds, mixtures, mercury-added products and the management of mercury waste.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'mercury' means metallic mercury (Hg, CAS RN 7439-97-6);
2. 'mercury-added product' means a product or product component that contains mercury and/or mercury compounds that were intentionally added;
3. 'mercury waste' means mercury that qualifies as waste, in accordance with Article 3(1), of Directive 2008/98/EC of the European Parliament and of the Council ⁴³ ;
4. 'export' means any of the following:
 - (a) the permanent or temporary export of a chemical meeting the conditions of Article 28(2) of the Treaty on the Functioning of the European Union;
 - (b) the re-export of a chemical not meeting the conditions of Article 28(2) of the Treaty on the Functioning of the European Union which is placed under a customs

procedure other than the external Union transit procedure for movement of goods through the customs territory of the Union;

5. 'import' means the physical introduction into the customs territory of the Union of a chemical that is placed under a customs procedure other than the external Union transit procedure for movement of goods through the customs territory of the Union;
6. 'primary mercury mining' means mining in which the principal material sought is mercury.

Chapter II

Trade and manufacturing restrictions concerning mercury, mercury compounds and mercury-added products

Article 3

Export restrictions

1. The export of mercury and of the mercury compounds and of mixtures listed in Annex I shall be prohibited.

The first subparagraph shall not apply to the export of the mercury compounds listed in Annex I for laboratory-scale research.
2. The export of mixtures of mercury not listed in Annex I for the purposes of recovering the mercury shall be prohibited.

Article 4

Import restrictions

1. The import of mercury and of mixtures listed in Annex I for uses other than disposal as waste shall be prohibited.

By way of derogation from the first subparagraph, import shall be allowed in any of the following circumstances:

- the exporting country is a Party to the Convention and the exported mercury is not from primary mercury mining as set out in Article 3(3) and (4), of that Convention;

- the exporting country not being a Party to the Convention has provided certification that the mercury is not from primary mercury mining and not from the chlor-alkali industry, and the importing Member State has granted its written consent to the import.
2. The import of mercury for use in artisanal and small-scale gold mining shall be prohibited.
 3. The national authority or authorities designated in accordance with Article 4 of Regulation (EU) No 649/2012 shall carry out the administrative functions resulting from the requirements laid down in paragraphs 1 and 2 of this Article.

Article 5

Export, import and manufacturing of mercury-added products

1. Without prejudice to stricter requirements set out in other applicable Union legislation, the export, import and the manufacturing in the Union of the mercury-added products as set out in Annex II shall be prohibited from 1 January 2021.
2. The prohibition laid down in paragraph 1 shall not apply to the following mercury-added products:
 - products essential for civil protection and military uses;
 - products for research, calibration of instrumentation, for use as reference standard.

Article 6

Forms for Import and Export

The Commission shall adopt decisions, by means of implementing acts, to specify the forms to be used for the purpose of implementing Articles 3 and 4.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Chapter III

Restrictions on use and storage of mercury and mercury compounds

Article 7
Industrial activities

1. The use of mercury and mercury compounds in the manufacturing processes listed in Part I of Annex III is prohibited as from the dates indicated therein.
2. The use of mercury and mercury compounds in the manufacturing processes listed in Part II of Annex III shall only be allowed under the conditions set out therein.
3. Interim storage of mercury and mercury compounds shall be carried out in an environmentally sound manner.

The Commission shall be empowered to adopt delegated acts in accordance with Article 17 in order to set out requirements for environmentally sound interim storage of mercury and mercury compounds adopted by the Conference of the Parties to the Convention, where the Union has supported the Decision concerned.

Article 8
New mercury-added products and new manufacturing processes

1. The manufacture and placing on the market of mercury-added products not covered by any known use prior to 1 January 2018 shall be prohibited.
2. Manufacturing processes involving the use of mercury and/or mercury compounds that did not exist prior to 1 January 2018 shall be prohibited.

This paragraph shall not apply to processes manufacturing and/or using mercury-added products others than those falling under paragraph 1.

3. By way of derogation from paragraphs 1 and 2, where an economic operator intends to manufacture and/or place on the market a new mercury-added product or to operate a new manufacturing process, the operator shall notify the competent authorities of the Member State concerned and provide them, with the following:
 - a technical description of the product or process concerned;
 - an assessment of its environmental and health risks;
 - a detailed explanation of the manner in which such

product or process must be manufactured, used and operated to ensure a high level of protection of the environment and of human health.

4. Upon notification by the Member State concerned, the Commission shall verify in particular whether it has been demonstrated that the new mercury-added product or new manufacturing process would provide significant environmental and health benefits and that no technically and economically feasible mercury-free alternatives providing such benefits are available.

The Commission shall adopt decisions, by means of implementing acts, in view of specifying whether the relevant new mercury-added product or new manufacturing process is allowed.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Article 9

Artisanal and small-scale gold mining

Member States on the territory of which more than insignificant artisanal and small-scale gold mining and processing activities are carried out shall:

- take steps to reduce, and where feasible eliminate, the use of mercury and mercury compounds in, and the emissions and releases to the environment of mercury from, such mining and processing;
- develop and implement a national plan in accordance with Annex IV.

Article 10

Dental amalgam

1. From 1 January 2019 onwards dental amalgam shall only be used in an encapsulated form.
2. From 1 January 2019 onwards dental facilities shall be equipped with amalgam separators aimed at retaining and collecting amalgam particles. Those separators shall be maintained as required to ensure a high level of retention.
3. Capsules and amalgam separators complying with harmonised

EN standards or with other national or international standards that ensure an equivalent level of quality and of level retention shall be presumed to satisfy the requirement set out under paragraphs 1 and 2.

Chapter IV

Storage and disposal of mercury waste

Article 11

Mercury waste

Without prejudice to Commission Decision 2000/532/EC ⁴⁴ , the following shall be considered as waste and be disposed of without endangering human health or harming the environment in accordance with Directive 2008/98/EC:

- (a) mercury that is no longer used in the chlor-alkali industry;
- (b) mercury generated from the cleaning of natural gas;
- (c) mercury generated through non-ferrous mining and smelting operations;
- (d) mercury extracted from cinnabar ore in the Union.

Article 12

Reporting on mercury waste from large sources

1. The companies operating within the industry sectors referred to in points (a), (b) and (c) of Article 11 shall send each year by 31 May to the competent authorities of the Member States concerned data related to the total amount of mercury waste stored in each installation and sent to individual temporary or permanent storage facilities as well as the location and contact details of those facilities.
2. The data referred to in paragraph 1 shall be expressed using the codes laid down in Regulation (EC) No 2150/2002 of the European Parliament and of the Council ⁴⁵ .
3. The obligation established in paragraphs 1 and 2 shall cease to apply to companies operating chlor-alkali installations the year after all mercury cells will have been decommissioned in accordance with Commission Implementing Decision 2013/732/EU ⁴⁶ and all mercury has been handed over to

waste management facilities.

Article 13
Disposal of mercury waste

1. By way of derogation from point (a) of Article 5(3) of Directive 1999/31/EC, mercury waste may be stored in one of the following ways:
 - (a) temporarily stored for more than one year or permanently stored in salt mines that are adapted for the disposal of mercury, or in deep underground hard rock formations providing a level of safety and confinement equivalent to that of those salt mines;
 - (b) temporarily stored in above-ground facilities dedicated to and equipped for the temporary storage of mercury.
2. The specific requirements for the temporary storage of mercury waste, as laid down in Annexes I, II and III to Directive 1999/31/EC shall apply to the permanent storage facilities referred to in point (a) of paragraph 1 of this Article under the following conditions laid down in the following Annexes to that Directive:
 - (a) Annex I, Section 8 (first, third and fifth indents) and Annex II to Directive 1999/31/EC shall apply;
 - (b) Annex I, Section 8 (second, fourth and sixth indents) and Annex III, Section 6, to Directive 1999/31/EC shall only apply where deemed appropriate by the competent authorities of the Member States in charge of implementing that Directive.

Chapter V
Penalties and reporting

Article 14
Penalties

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are applied. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by [xxx]

and shall notify it without delay of any subsequent amendment affecting them.

Article 15 *Report*

1. Member States shall prepare, update and publish online a report with the following information:
 - (a) information concerning the implementation of this Regulation;
 - (b) information needed for the fulfilment by the Union and by the Member States of its reporting obligation established under Article 21 of the Minamata Convention;
 - (c) a summary of the information gathered in accordance with Article 12;
 - (d) a list of individual stocks of mercury exceeding 50 metric tonnes, which are located in their territory and, where Member States are made aware, a list of sources of mercury supply generating annual stocks of mercury exceeding 10 metric tonnes.

Member States shall inform the Commission of their report and of their updates within one month of their publication.

2. The Commission shall adopt appropriate questionnaires in order to specify the content, the information and the key performance indicators to be included in the report referred to in paragraph 1 as well as the format of this report and the timing of its publication and of its updates.

The questionnaires may also organise reporting in such a way as to enable the Union to provide the Secretariat of the Convention with a single report submitted on behalf of the Union and its Member States.

The Commission shall adopt decisions, by means of implementing acts, to provide a template for those questionnaires and to make an electronic reporting tool available to the Member States.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Chapter VI

Delegated and implementing powers

Article 16

Amendment of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 17 in order to amend Annexes I, II, III and IV to transpose Decisions adopted by the Conference of the Parties to the Convention, where the Union has supported the Decision concerned.

Article 17

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of powers referred to in Articles 7(3) and 16 shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.
3. The delegation of power referred to in Articles 7(3) and 16 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 7(3) and 16 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

Article 18
Committee procedure

1. For the adoption of forms for import and export under Article 6, of a decision under Article 8(4), and of questionnaires in accordance with Article 15(2) the Commission shall be assisted by a Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Chapter VII
Final provisions

Article 19
Repeal

Regulation (EC) No 1102/2008 is hereby repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 20
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 1st January 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*The President
The
President*

*For the
European
Parliament
For the
Council
The President
The
President*

-
- (1) Portugal and Estonia did not sign the Minamata Convention.
 - (2) Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury (OJ L 304, 14.11.2008, p. 75).
 - (3) Regulation (EU) 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60).
 - (4)

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).
 - (5)

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).
 - (6)

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).
 - (7) Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (OJ L 266 of 26.9.2006, p. 1).
 - (8) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174 of 1.7.2011, p. 88).
 - (9) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on Industrial Emissions (OJ L 334 of 17.12.2010, p. 17).
 - (10) Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197 of 24.7.2012, p. 1).
 - (11) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312 of 22.11.2008, p. 3).
 - (12) Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182 of 16.7.1999, p. 1).

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- (13) Commission Staff Working Document, Impact Assessment Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008 and Proposal for a Council Decision on the conclusion of the Minamata Convention on Mercury, SWD [2016] 17 final.
- (14) Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' (OJ L 354, 28.12.2013, p. 171).
- (15) ICF, COWI, BiPRO, Garrigues (2015). [Study on EU Implementation of the Minamata Convention on Mercury](#) (March 2015)
- (16) COWI, BiPRO (2015). [Ratification of the Minamata Convention by the EU - Complementary Assessment of the Mercury Export Ban](#) (June 2015).
- (17) <http://ec.europa.eu/environment/chemicals/mercury/pdf/InfoRequest.pdf>
- (18) http://ec.europa.eu/environment/chemicals/mercury/ratification_en.htm
- (19) Questionnaire available at: <http://ec.europa.eu/environment/consultations/pdf/MinamataConvention.pdf>
- (20) <http://ec.europa.eu/yourvoice/consultations>
- (21) Communication of 28 January 2005 from the Commission to the Council and the European Parliament "Community Strategy Concerning Mercury", COM(2005) 20 final.
- (22) Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3).0
- (23) Supra, No 11.
- (24) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327 of 22.12.2000, p. 1).
- (25) Quantity of mercury estimated in people's mouths in the form of dental amalgam within the EU.
- (26) [CED resolution on responsible practice](#) (2011).
- (27) European standard EN ISO 13897, Dentistry – Amalgam capsules (ISO 1397:2003), May 2004.
- (28) European standard EN ISO 24234:2015, Dentistry – Dental amalgam (ISO 24234:2015), January 2015.
- (29) European standard EN 1641:2009, Dentistry – Medical devices for dentistry – Materials, October 2009.
- (30) Regulation (EC) No 2150/2002 of the European Parliament and of the Council of 25 November 2002 on waste statistics (OJ L 332, 9.12.2002, p. 1).
- (31) Commission implementing Decision 2013/732/EU of 9 December 2013 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for the production of chlor-alkali (OJ L 332, 11.12.2013, p. 34).
- (32) OJ C , , p. .
- (33) OJ C , , p. .
- (34) Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' (OJ L 354, 28.12.2013, p. 171).
- (35) Communication of 28 January 2005 from the Commission to the Council and the European Parliament "Community Strategy Concerning Mercury", COM(2005) 20 final.
- (36) Communication of 7 December 2010 from the Commission to the European Parliament and the Council "Review of the Community Strategy Concerning Mercury", COM(2010) 723 final.
- (37) <https://treaties.un.org>
- (38) Council Decision XXX of XX/XX/XX on the conclusion of the Minamata Convention on Mercury (OJ L , , p.).
- (39) Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury (OJ L 304, 14.11.2008, p. 75).
- (40) Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60).
- (41) Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182 of 16.7.1999, p. 1).
- (42) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (43) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312 of 22.11.2008, p. 3).
- (44) Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3).
- (45) Regulation (EC) No 2150/2002 of the European Parliament and of the Council of 25 November 2002 on waste statistics (OJ L 332, 9.12.2002, p.1).
- (46) Commission implementing Decision 2013/732/EU of 9 December 2013 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for the production of chlor-alkali (OJ L 332, 11.12.2013, p. 34).