

REGULATION (EU) 2017/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

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) 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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C , , p. .

² OJ C , , p. .

Whereas:

- (1) Mercury is a *very* 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.
- (1a) *The use of mercury in production processes should be phased out and, to that end, incentives should be provided for research into alternative substances to mercury with characteristics that are innocuous, or in any case, less dangerous for the environment and for health.*
- (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 Council¹ 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.

¹ **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).

- (4) The Communication from the Commission to the European Parliament and the Council 'Community Strategy Concerning Mercury'¹ ("the Strategy"), as reviewed in 2010², 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.
- (6a) *In order to reflect the current scientific understanding of risks from methylmercury, the Commission should evaluate the current health-based intakes and should establish new mercury health benchmarks, when undertaking the review of this Regulation.***

¹ Communication of 28 January 2005 from the Commission to the Council and the European Parliament "Community Strategy Concerning Mercury", COM(2005) 20 final.

² 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.

- (7) The Union and 26 Member States have signed **■** the Minamata Convention on Mercury ("the Convention")¹. ***The two Member States that did not sign the Convention, Estonia and Portugal, have expressed their commitment to ratify it.*** The Union and all its Member States are therefore committed to its conclusion, transposition and implementation **■** .
- (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. ***Further action undertaken by the Union, going beyond the Convention requirements, would lead the way, as it was the case with Regulation (EC) No 1102/2008 of the European Parliament and of the Council***², ***for mercury-free products and processes.***
- (9) **■** This Regulation should **■** 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.

¹ <https://treaties.un.org>

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).***

- (10) The mercury export ban set out in Regulation (EC) No 1102/2008 of the European Parliament and of the Council ■ should be complemented by restrictions on the import of mercury depending on the source, the intended use and the place of origin of mercury. *It is appropriate to clarify that the provisions of Regulation (EC) No 1013/2006 of the European Parliament and the Council¹ continue to apply as regards imports of mercury waste, particularly as regards the powers of the competent authorities under that Regulation.*
- (10a) *The provisions of this Regulation on the import into the Union of mercury and of mixtures of mercury ensure the fulfilment by the Union and the Member States of the provisions of the Convention on trade of mercury.*
- (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.

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¹ *Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste (OJ L 190, 12.7.2006, p. 1).*

- (13) This Regulation applies without prejudice to the provisions of the applicable Union *acquis* that set stricter requirements for *mercury-added* products, including in terms of their maximum content of mercury.
- (13a) *In accordance with Article 193 of the Treaty on the Functioning of the European Union (TFEU), this Regulation should not prevent Member States from maintaining or introducing more stringent protective measures, provided that such measures are compatible with the Treaties and the Commission has been notified.*
- (13b) *Regulation (EC) No 1907/2006 of the European Parliament and the Council¹, as amended, prohibits, as from 10 October 2017, the manufacture, placing on the market and use of the five phenylmercury compounds known to be used, especially as catalysts, for the production of polyurethane. The use of other mercury-containing catalysts in such production should also be prohibited by [10 October 2017 or the date of application of this Regulation whichever is the later].*

¹ *Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restrictions of chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).*

- (14) ***The production of alcoholates involving the use of mercury as an electrode should be phased out and replacement by feasible mercury-free production processes should take place as soon as possible.*** 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. ***Measures should be taken to reduce the use of mercury aiming at the phase out of this use in such production as fast as possible and within 10 years of the entry into force of the Convention.***
- (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 *or* health benefits ***and pose no significant risks either to the environment or to human health*** and that no technically *practicable* 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 *with negative effects both for the local communities and at global level*, and should therefore be *prohibited under this Regulation and regulated at international level. Without prejudice to the prohibition of such use under this Regulation and in addition to the implementation of effective, proportionate and dissuasive penalties by Member States in respect of infringements of this Regulation, it is also appropriate to provide for a national plan in the event of more than isolated cases of non-compliance, to tackle the problem of artisanal and small-scale gold mining and processing in which mercury amalgamation has been used to extract gold from ore.*
- (16a) *Dental amalgam is the largest use of mercury in the Union and a significant source of pollution of the environment. The use of dental amalgam should therefore be phased down in accordance with the Convention and with national plans based notably upon the measures listed in Annex A, Part II, to the Convention. The Commission should assess and report on the feasibility of a phase out of the use of dental amalgam in the long term, and preferably by 2030, taking into account national plans required by this Regulation and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care. Furthermore, particular measures of preventive health protection should be taken for vulnerable members of the population, such as children and pregnant and breastfeeding women.*

- (17) The use of dental amalgam in an encapsulated form and the *use* of amalgam separators *by operators of dental facilities using dental amalgam or removing dental amalgam fillings or teeth containing such fillings*, should be made mandatory to protect dental practitioners and patients from mercury exposure and to ensure that resulting mercury waste *is, under no circumstance*, released into the environment, but *is* collected and subjected to sound waste management. *Hence, the use of mercury in bulk form by practitioners should be prohibited. Amalgam capsules such as described in European standards [EN ISO 13897:2004 and EN ISO 24234:2015] are suitable for use by dentists. Furthermore, minimum retention efficiency of amalgam separators should be set. Compliance of amalgam separators should be based on relevant standards, such as European standard EN ISO 11143:2008.* Given the size of the *economic operators* from the dentistry sector concerned by this change, it is appropriate to provide sufficient time to adapt to the new provision.
- (17a) *The training of students and dentists on the use of mercury-free alternatives, in particular for vulnerable groups such as pregnant and breastfeeding women and children, as well as the carrying out of oral health research and innovation in order to improve knowledge of existing materials and restoration techniques, and to develop new materials, can help in reducing the use of mercury.*

- (18) *Over 6000 tonnes of metallic mercury waste will be generated in the Union by 2017, mainly as a result of the mandatory decommissioning of mercury cells in the chlor-alkali industry in accordance with Commission Implementing Decision 2013/732/EU¹. Given the limited available capacity for undertaking the conversion of liquid mercury waste, the temporary storage of liquid mercury waste should still be allowed under this Regulation, in accordance with the requirements for such storage set out in Council Directive 1999/31/EC², for a period of time sufficient for ensuring the conversion and, if applicable, solidification, of all such waste produced.*

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- (18a) The permanent storage without pre-treatment of metallic mercury that is considered waste should be ruled out owing to the risks that such disposal poses, as it is an extremely hazardous substance in its liquid form. Prior to the permanent storage of mercury waste, the relevant conversion, and if applicable, solidification operations should be carried out in accordance with this Regulation. For that purpose, Member States may apply the technical guidelines on mercury of the Basel Convention (UNEP/CHW.12/5/Add.8/Rev.1) in order to reduce these risks.*
- (18b) In order to ensure proper implementation of the provisions on waste of this Regulation, measures should be taken to ensure an effective traceability system throughout the whole mercury waste management chain whereby the producers of mercury waste and the operators of waste management facilities that store and treat such waste should be under the obligation to establish an information register, as part of the record keeping required under Article 35 of Directive 2008/98/EC of the European Parliament and of the Council.*

(18c) *The Minamata Convention on Mercury requires Parties to endeavour to develop strategies for identifying and assessing sites contaminated by mercury or mercury compounds. Directive 2010/75/EU of the European Parliament and of the Council requires operators of industrial installations to address soil contamination. Furthermore, Directive 2000/60/EC of the European Parliament and of the Council requires Member States to address soil contamination where it adversely affects the status of a water body. Therefore an exchange of information between the Commission and the Member States should take place to share experience on the initiatives and measures undertaken at national level.*

- (19) In order to align Union legislation with Decisions of the Conference of the Parties of the Convention supported by the Union ***by means of a Council Decision adopted in accordance with Article 218(9) TFEU***, 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 regarding an extension of the period allowed for the temporary storage of mercury waste*** ■ . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, ***and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.***

- (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, *setting technical requirements for environmentally sound interim storage of mercury, mercury compounds and mixtures of mercury* 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 Council¹.
- (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.

¹ **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).**

- (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 *and objective*

This Regulation establishes measures and conditions concerning the trade, manufacture, use and storage of mercury, mercury compounds *and* mixtures, mercury-added products and the management of mercury waste *in order to ensure a high level of protection of human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds*.

Where appropriate, Member States may apply stricter requirements than those laid down in this Regulation, in accordance with the Treaty.

Article 2

Definitions

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

1. 'mercury' means metallic mercury (Hg, CAS RN 7439-97-6);

- 1a.** *'mercury compound' means any substance consisting of atoms of mercury and one or more atoms of other chemical elements that can be separated into different components only by chemical reactions;*
2. 'mercury-added product' means a product or product component that contains mercury and/or mercury compounds that were intentionally added;
- 2a.** *'mixture' means a mixture or solution composed of two or more substances;*
3. 'mercury waste' means **metallic** mercury that qualifies as waste, in accordance with Article 3(1), of Directive 2008/98/EC of the European Parliament and of the Council¹;
4. 'export' means any of the following:
- (a) the permanent or temporary export of **mercury, mercury compounds, mixtures of mercury and mercury-added products** meeting the conditions of Article 28(2) of the Treaty on the Functioning of the European Union;
 - (b) the re-export of **mercury, mercury compounds, mixtures of mercury and mercury-added products** 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;

¹ 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).

5. 'import' means the physical introduction into the customs territory of the Union of ***mercury, mercury compounds, mixtures of mercury and mercury-added products*** 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;
- 5a. ***'disposal' means disposal as defined in Article 3(19) of Directive 2008/98/EC;***
6. 'primary mercury mining' means mining in which the principal material sought is mercury;
- 6a. ***'placing on the market' means supplying or making available, to a third party, whether in return for payment or free of charge. Import shall be deemed to be placing on the market;***
- 6b. ***'conversion' means the chemical transformation of the physical state of mercury from a liquid state to mercury sulfide or a comparable chemical compound which is equally or more stable and equally or less soluble in water and that presents no greater environmental or health hazard than mercury sulfide.***

Chapter II

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

Article 3

Export restrictions

1. The export of mercury ■ shall be prohibited.
2. The ■ export of the mercury compounds *and of mixtures of mercury* listed in Annex I *shall be prohibited as from the dates set out therein.*
3. *By way of derogation from paragraph 1, the export of the mercury compounds listed in Annex I for the purposes of laboratory-scale research or laboratory analysis shall be allowed.*
4. The export of *mercury compounds and* mixtures of mercury *that do not fall under paragraph 1* for the *purpose of reclaiming* mercury shall be prohibited.

Article 4

Import restrictions

1. The import of mercury and *the import* of mixtures *of mercury* listed in Annex I, *including mercury waste from large sources referred to in Article 11*, for uses other than disposal as waste shall be prohibited.

Without prejudice to Article 11 and by way of derogation from the first subparagraph, import *for a use allowed in a Member State* shall be allowed *where the importing Member State concerned has granted its written consent to the import* in *either* of the following circumstances:

- a) the exporting country is a Party to the Convention and the exported mercury is not from primary mercury mining *which is prohibited under* Article 3(3) and (4), of *the* Convention; *or*
- b) the exporting country not being a Party to the Convention has provided certification that the mercury is not from primary mercury mining ■ .

A use allowed pursuant to Union legislation shall be deemed to be a use allowed in a Member State for the purposes of this paragraph, without prejudice to national measures adopted in accordance with the Treaty.

The import for disposal as waste shall only be allowed where the exporting country has no access to available conversion capacity within its own territory.

- 1a. The import of mixtures of mercury that do not fall under paragraph 1 and of mercury compounds, for the purpose of reclaiming mercury, shall be prohibited.*
- 1b. Where the import of mercury waste is allowed, Regulation (EC) No 1013/2006 shall continue to apply in addition to the requirements of this Regulation.*
2. The import of mercury for use in artisanal and small-scale gold mining shall be prohibited.

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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 *as from **the dates specified therein***.
2. The prohibition laid down in paragraph 1 shall not apply to the following mercury-added products:
 - a)* products essential for civil protection and military uses;
 - b)* products for research, calibration of instrumentation, *or* for use as *a* 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 **shall be** 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 **subject to** the conditions set out therein.
3. Interim storage of mercury and **of the** mercury compounds **and mixtures of mercury listed in Annex I** shall be carried out in an environmentally sound manner, **in accordance with the thresholds and requirements set out in Directive 2012/18/EU of the European Parliament and of the Council¹ and Directive 2010/75/EU of the European Parliament and of the Council².**

¹ **Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances (OJ L197 of 24.7.2012, p. 1).**

² **Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions (OJ L 334 of 17.12.2010, p. 17).**

In order to ensure the uniform application of this requirement, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 18 in order to set out requirements for environmentally sound interim storage of mercury, mercury compounds and mixtures of mercury in line with decisions adopted by the Conference of the Parties to the Convention in accordance with Article 10(3) and Article 27 of the Convention, where the Union has supported the Decision concerned by means of a Council Decision adopted in accordance with Article 218(9) TFEU.

Article 8

New mercury-added products and new manufacturing processes

1. ***Economic operators shall not manufacture or place on the market mercury-added products that were not being manufactured prior to 1 January 2018 unless allowed to do so by means of a decision in accordance with paragraph 4a or pursuant to Directive 2011/65/EU.***

This paragraph shall not apply to:

- a) equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;*
- b) equipment designed to be sent into space; and*
- c) technical improvements or the redesign of existing mercury-added products provided that such improvements or redesign leads to less mercury used in those products.*

2. *Economic operators shall not use manufacturing processes involving the use of mercury ■ or mercury compounds that were not used prior to 1 January 2018 unless allowed to do so by means of a decision in accordance with paragraph 4a.*

This paragraph shall not apply to processes manufacturing ■ 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 **■** or place on the market a new mercury-added product or to operate a new manufacturing process *involving the use of mercury or mercury compounds, that would provide significant environmental or health benefits, pose no significant risks either to the environment or to human health and where no technically practicable mercury-free alternatives providing such benefits are available*, the *economic* operator shall notify the competent authorities of the Member State concerned and provide them, with the following:
- a) a technical description of the product or process concerned;
 - b) an assessment of its environmental and health risks *and benefits*;
 - c) *evidence demonstrating the absence of technically practicable mercury-free alternatives providing significant environmental or health benefits*;
 - d) a detailed explanation of the manner in which such product or process *is to* be manufactured, used, operated *and disposed of after use as waste in order* to ensure a high level of protection of the environment and of human health.

3a. *The Member State concerned shall forward to the Commission the notification received from the economic operator, if it considers on the basis of its own assessment of the information provided therein that the criteria referred to in the first subparagraph of paragraph 4a are fulfilled.*

The Member States shall inform the Commission of cases where they have considered the criteria to have not been fulfilled.

4. *In the event that the Member State forwards the notification referred to in paragraph 3a, the Commission shall immediately make the notification available to the Committee referred to in Article 18.*

4a. *The Commission shall examine the notification received and assess whether it has been demonstrated that the new mercury-added product or new manufacturing process would provide significant environmental or health benefits, pose no significant risks either to the environment or to human health and that no technically practicable mercury-free alternatives providing such benefits are available. Member States shall be informed of the outcome of the assessment.*

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).

- 4b. By 30 June 2018, the Commission shall make publicly available on the internet an inventory of manufacturing processes involving the use of mercury and mercury-compounds that were used and mercury-added products which were being manufactured before the date of application of this Regulation and applicable marketing restrictions.***

Article 9

Artisanal and small-scale gold mining

1. ***Artisanal and small-scale gold mining and processing in which mercury amalgamation is used to extract gold from ore is prohibited.***
2. ***Without prejudice to paragraph 1 of this Article and Article 14, where there is evidence of more than isolated cases of non-compliance with this prohibition, the competent authority of the Member State shall develop and implement a national plan in accordance with Annex IV.***

Article 10

Dental amalgam

1. From 1 January 2019 **█** dental amalgam shall only be used in *pre-dosed* encapsulated form.
The use of mercury in bulk form by the practitioner is prohibited.
- 1a. *From 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, children under 15 years and pregnant or breastfeeding women, except when strictly deemed necessary by the practitioner on the ground of specific medical needs of the patient.*
- 1b. *By 1 July 2019, the Member States shall set out a national plan on the measures they intend to implement to phase down the use of dental amalgam.*
Member States shall make their national plans electronically available to the public and shall transmit them to the Commission within one month following their adoption.

2. From 1 January 2019 *operators of dental facilities using dental amalgam or removing dental amalgam fillings or teeth containing such fillings*, shall *ensure that their facilities are* equipped with amalgam separators *to retain and collect* amalgam particles, *including those contained in used water*.

Operators shall ensure that their amalgam separators comply with the following conditions:

- a) *Separators put into service after the date of application of this Regulation shall ensure a retention of at least 95% of the amalgam particles.*
- b) *From 1 January 2021, all separators in use shall ensure the retention level specified in paragraph (a).*

█ Separators shall be maintained *in accordance with manufacturer's instructions* to ensure *the highest practicable* level of retention.

3. Capsules and amalgam separators complying with *European* 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.

3a. *Dental practitioners shall ensure that their amalgam waste, including amalgam residues, particles and fillings and teeth, or part of them, contaminated by dental amalgam, is handled and collected by an authorised waste management establishment or undertaking.*

Dental practitioners shall not release directly or indirectly such amalgam waste into the environment under any circumstance.

Chapter IV

■ Disposal of mercury waste

Article 11

■ Waste

Without prejudice to *Article 2 point 3, mercury and mercury compounds, whether in pure form or in mixtures, from* the following *large sources* 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) ■ the chlor-alkali industry;
- (b) ■ the cleaning of natural gas;
- (c) ■ non-ferrous mining and smelting operations;
- (d) *extraction in the Union* from cinnabar ore ■ .

Such disposal shall not lead to any form of reclamation of mercury.

Article 12

Reporting on ■ large sources

1. The *economic operators* within the industry sectors referred to in points (a), (b) and (c) of Article 11 shall send, each year by 31 May, ***the following*** to the competent authorities of the Member States concerned:
 - a) data related to the total amount of mercury waste stored in each installation;
 - b) ***data related to the total amount of mercury waste*** sent to individual ■ facilities ***undertaking the temporary storage, the conversion and, if applicable, solidification or the permanent storage of mercury waste;***
 - c) ■ the location and contact details of those facilities;
 - d) ***a copy of the certificate provided by the operator undertaking the temporary storage of mercury waste, in accordance with Article 13a(1);***
 - e) ***a copy of the certificate provided by the operator undertaking the conversion, and if applicable, the solidification of mercury waste, in accordance with Article 13a(2);***
 - f) ***a copy of the certificate provided by the operator undertaking the permanent storage of mercury waste that underwent conversion and, if applicable, solidification, in accordance with Article 13a(3).***

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 Council¹.
3. The obligation established in paragraphs 1 and 2 shall cease to apply to ***an economic operator*** operating chlor-alkali installations ***after one year from the date that*** all mercury cells ***operated by the economic operator*** will have been decommissioned in accordance with Commission Implementing Decision 2013/732/EU² and all mercury has been handed over to waste management facilities.

Article 13

Storage of mercury waste

1. By way of derogation from point (a) of Article 5(3) of Directive 1999/31/EC, mercury waste may be ***temporarily*** stored in ***liquid form provided that the specific requirements for the temporary storage of mercury waste as laid down in Annexes I, II and III to that Directive are complied with and that such storage occurs in*** █ above-ground facilities dedicated to and equipped for the temporary storage of mercury ***waste***.

The derogation set out in the first subparagraph shall cease to apply 5 years after the date of application of this Regulation.

¹ **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).

² 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).

- 1a. *The Commission shall be empowered to adopt delegated acts in accordance with Article 17 to extend the period allowed for temporary storage of mercury waste referred to in paragraph 1 by up to 3 years.*
2. *Mercury waste shall be permanently disposed of once it has undergone conversion and, if applicable, solidification and shall only be disposed of in the following permanent storage facilities licensed for disposal of hazardous waste:*
 - a) *salt mines that are adapted for the permanent storage of mercury waste that underwent conversion, or deep underground hard rock formations providing a level of safety and confinement equivalent to or higher than that of such salt mines; or*

- b) above-ground facilities dedicated to and equipped for the permanent storage of mercury waste that underwent conversion and solidification and that provide a level of safety and confinement equivalent to or higher than that of facilities referred to under (a).*

Operators of permanent storage facilities shall make sure that mercury waste that underwent conversion and, if applicable, solidification, is placed separately from other waste and in disposal batches in a storage chamber that is sealed, and that the requirements set out in Council Directive 1999/31/EC, including those established in the third and fifth indents of Section 8 of Annex I and of Annex II to that Directive are complied with.

Article 13a

Traceability

- 1. Operators of installations undertaking the temporary storage of mercury waste shall establish a register including the following:**
 - a) for each shipment of mercury waste received:**
 - i) the origin and amount of mercury waste received;**
 - ii) the name and contact details of the supplier and the owner of the temporarily stored mercury waste;**
 - b) for each shipment of mercury waste leaving the installation:**
 - i) the amount of mercury waste and its mercury content;**
 - ii) the destination and intended disposal operation of the mercury waste;**
 - iii) a copy of the certificate provided by the operator undertaking the conversion of the mercury waste as referred to in paragraph 2;**

iv) *a copy of the certificate provided by the operator undertaking the permanent storage of the mercury waste that underwent conversion as referred to in paragraph 3;*

c) *the amount of mercury waste stored at the installation at the end of each month.*

Operators of installations undertaking the temporary storage of mercury waste shall, as soon as the mercury waste is taken out of temporary storage, issue a certificate that the mercury waste was sent to a facility undertaking disposal operations covered by this Article.

Once a certificate referred to in the second subparagraph of this paragraph is issued, a copy thereof shall be transmitted without delay to the concerned operators referred to in Article 12.

2. *Operators of installations undertaking the conversion and, if applicable, the solidification of mercury waste shall establish a register including the following:*

a) *for each shipment of mercury waste received:*

i) *the origin and amount of mercury waste received;*

ii) *the name and contact details of the supplier and the owner of the mercury waste to be converted;*

- b) for each shipment of mercury waste that underwent conversion leaving the installation:*
- i) the amount of mercury waste that underwent conversion and, if applicable, solidification and its mercury content;*
 - ii) the destination and intended disposal operation of the mercury waste that underwent conversion and, if applicable, solidification;*
 - iii) a copy of the certificate provided by the operator undertaking the permanent storage of the mercury waste that underwent conversion and, if applicable, solidification as referred to in paragraph 3;*
- c) the amount of mercury waste stored at the installation at the end of each month.*

Operators of installations undertaking the conversion and, if applicable, the solidification of mercury waste shall, as soon as the conversion and, if applicable, the solidification operation of the entire shipment is completed, issue a certificate that the entire shipment of mercury waste has been converted and, if applicable, the solidification.

Once a certificate referred to in the second subparagraph of this paragraph is issued, a copy thereof shall be transmitted without delay to the operators of the installations referred to in paragraph 1 of this Article and to the concerned operators referred to in Article 12.

3. *Operators of installations undertaking the permanent storage of mercury waste that underwent conversion and, if applicable, solidification shall, as soon as the disposal operation of the entire shipment is completed, issue a certificate that the entire shipment of mercury waste that underwent conversion and, if applicable, solidification has been placed into permanent storage in accordance with Directive 1999/31/EC, including information on the storage location.*

Once a certificate referred to in the first subparagraph of this paragraph is issued, a copy thereof shall be transmitted without delay to the operators of the installations referred to in paragraphs 1 and 2 of this Article as well as to the concerned operators referred to in Article 12.

4. *Each year by 31 January the operators of the installations referred to in paragraphs 1 and 2 shall transmit the register for the previous calendar year to the authority designated by the Member State. Subsequently, each register shall be communicated annually to the Commission by the national authority.*

Article 13b

Contaminated sites

- 1. The Commission shall organise an exchange of information with the Member States regarding the measures taken at national level to identify and assess sites contaminated by mercury and mercury compounds and to address the significant risks such contamination may pose to human health and the environment.*
- 2. By three years at the latest from the date of application of this Regulation, the Commission shall make the information gathered under paragraph 1 electronically available to the public, including an inventory of sites contaminated by mercury and mercury compounds.*

Chapter V
Penalties and reporting

Article 14

Penalties

Member States shall lay down the rules on penalties applicable to infringements of **■** this Regulation and shall take all measures necessary to ensure that they are ***implemented***. The penalties provided for ***shall*** be effective, proportionate and dissuasive. **■** Member States shall, ***by the respective dates of application of the relevant provisions of this Regulation***, notify ***the Commission of those rules and of those measures*** and shall notify it, without delay, of any subsequent amendment affecting them.

Article 14a

Competent authorities

Member States shall designate the competent authorities responsible for carrying out the obligations arising from this Regulation.

Article 15

Report

1. ***By ... [two years after the date of application referred to in Article 20] for the first time and at appropriate intervals thereafter***, Member States shall prepare, ***provide to the Commission*** and publish online a report with the following ***content***:
 - (a) information concerning the implementation of this Regulation;
 - (b) information needed for the fulfilment by the Union ■ of its reporting obligation established under Article 21 of the ■ Convention;
 - (c) a summary of the information gathered in accordance with Article 12;
 - (d) ***information regarding mercury*** ■ located in their ***territories***:
 - i) ***a list of sites where stocks of more than 50 metric tonnes of mercury other than mercury waste are located as well as the amount of mercury at each site***;
 - ii) ***a list of sites where more than 50 metric tonnes of mercury waste is accumulated as well as the amount of mercury at each site***; and

e) where Member States are made aware, a list of sources *supplying more than 10 metric tonnes of mercury per year*.

Member States may decide not to make information public on any of the grounds mentioned in Article 4 of Directive 2003/4/EC, subject to the second sub-paragraph thereof.

2. *For the purposes of the reporting referred to in paragraph 1, the Commission shall make an electronic reporting tool available to Member States.*

The Commission shall adopt *implementing acts to establish* appropriate questionnaires in order to specify the content, the information and the key performance indicators to *meet the requirements* referred to in paragraph 1 as well as the format *and the frequency* of this report **■**. *These questionnaires shall not duplicate reporting obligations of the Parties to the Convention.*

█
█
The implementing acts *referred to in this paragraph* shall be adopted in accordance with the examination procedure referred to in Article 18(2).

- 2a. *The Member States shall without delay make available to the Commission reports they have provided to the Secretariat of the Convention.*

Article 15a

Review

1. *By 30 June 2020, the Commission shall report to the European Parliament and to the Council on the outcome of its assessment regarding:*
- a) *the need for the Union to regulate emissions of mercury and mercury compounds from crematoria;*

- b) the feasibility of a phase out of dental amalgam use in the long term, and preferably by 2030, taking into account the national plans referred to in Article 10(1b) and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care; and*
 - c) the environmental benefits and the feasibility of a further alignment of Annex II to this Regulation to relevant Union legislation regulating the placing of mercury-added products on the internal market.*
- 2. By 31 December 2024, the Commission shall report to the European Parliament and to the Council on the implementation and the review of this Regulation, inter alia, in the light of the effectiveness evaluation undertaken by the Conference of the Parties of the Convention and of the implementation reports established by the Member States in accordance with Article 15 of this Regulation and Article 21 of the Convention.*
 - 3. The Commission shall, if appropriate, present a legislative proposal together with the reports referred to in paragraphs 1 and 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 *align them with* Decisions adopted by the Conference of the Parties to the Convention *in accordance with Article 27 of the Convention*, where the Union has supported the Decision concerned *by means of a Council Decision adopted in accordance with Article 218(9) TFEU*.

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 *13(1a)* and 16 shall be conferred on the Commission for a **■** period of *five years* from the date of entry into force of this Regulation.

The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles *13(1a)* 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.

- 3a. *Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.*
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 *13(1a)* 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 technical requirements for environmentally sound interim storage of mercury, mercury compounds or mixtures of mercury under Article 7(3)***, of a decision under Article 8(4a), 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.
- 2a. ***Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.***

Chapter VII
Final provisions

Article 19

Repeal

Regulation (EC) No 1102/2008 is ■ repealed *as from the date of application set out in Article 20*.

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 *except the following provisions*:

- a) *Part I, letter bc) of Annex III shall apply from [10 October 2017 or from the date of application of this Regulation whichever is the latest];*
- b) *Part I, letter bd)(new) of Annex III shall apply from 11 December 2017.*

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Mercury compounds and mixtures subject to Articles 3, 4 *and* 7(3)

Mercury compounds *prohibited for export from the date of application of this Regulation:*

Mercury (I) chloride (Hg_2Cl_2 , CAS RN 10112-91-1)

Mercury (II) oxide (HgO , CAS RN 21908-53-2)

Cinnabar ore

Mercury sulfide (HgS , CAS RN 1344-48-5)

Mercury compounds prohibited for export from 1 January 2020:

Mercury sulphate (HgSO_4 , CAS RN 7783-35-9)

Mercury nitrate ($\text{Hg}(\text{NO}_3)_2$, CAS RN 10045-94-0)

Mixtures prohibited for export and import from the date of application of this Regulation:

Mixtures of mercury with other substances, including alloys of mercury, with a mercury concentration of at least 95 % weight by weight.

ANNEX II

Mercury-added products referred to in Article 5

Part A - Mercury-added products

<i>Mercury-added products</i>	<i>Date after which the manufacture, import and export of the mercury-added product shall be prohibited</i>
1. Batteries <i>or accumulators that contain more than 0,0005% of mercury by weight.</i>	31.12.2020
2. Switches and relays, except very high accuracy capacitance and loss measurement bridges and high frequency radio frequency switches and relays in monitoring and control instruments with a maximum mercury content of 20 mg per bridge, switch or relay.	31.12.2020
3. Compact fluorescent lamps (<i>CFL</i>) for general lighting purposes: (a) <i>CFL.i</i> ≤ 30 watts with a mercury content exceeding 2.5 mg per lamp burner. (b) <i>CFL.ni</i> ≤ 30 watts with a mercury content exceeding 3.5 mg per lamp burner.	31.12.2018

<p>4. The following linear fluorescent lamps (LFLs) for general lighting purposes:</p> <p>(a) Triband phosphor < 60 watts with a mercury content exceeding 5 mg per lamp;</p> <p>(b) Halophosphate phosphor ≤ 40 watts with a mercury content exceeding 10 mg per lamp.</p>	<p>31.12.2018</p>
<p>5. High pressure mercury vapour lamps (HPMV) for general lighting purposes.</p>	<p>31.12.2018</p>
<p>6. The following mercury added cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for electronic displays:</p> <p>(a) short length (≤ 500 mm) with mercury content exceeding 3.5 mg per lamp;</p> <p>(b) medium length (> 500 mm and ≤ 1 500 mm) with mercury content exceeding 5 mg per lamp;</p> <p>(c) long length (> 1 500 mm) with mercury content exceeding 13 mg per lamp.</p>	<p>31.12.2018</p>
<p>7. Cosmetics with mercury and mercury compounds, except those special cases included in Annex V <i>entries 16 and 17</i> of Regulation (EC) No 1223/2009 of the European Parliament and of the Council¹.</p>	<p>31.12.2020</p>

¹ **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).**

<p>8. Pesticides, biocides and topical antiseptics.</p>	<p>31.12.2020</p>
<p>9. The following non-electronic measuring devices ■ :</p> <ul style="list-style-type: none"> (a) barometers; (b) hygrometers; (c) manometers; (d) thermometers <i>and other non-electrical thermometric applications</i>; (e) sphygmomanometers; <i>(ea) strain gauges to be used with plythysmographs</i>; <i>(eb) mercury pycnometers</i>; <i>(ec) mercury metering devices for determination of the softening point</i>; <p>This entry does not cover the following measuring devices:</p> <ul style="list-style-type: none"> (a) non-electronic measuring devices installed in large-scale equipment or those used for high precision measurement <i>where no suitable mercury-free alternative is available</i>; (b) measuring devices more than 50 years old on 3 October 2007; (c) measuring devices, which are to be displayed in public exhibitions for cultural and historical purposes. 	<p>31.12.2020</p>

Part B - Additional products excluded from the list in Part A of this Annex

Switches and relays, cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for electronic displays and measuring devices, when they are used to replace a component of a larger equipment and provided that no feasible mercury-free alternative for that component is available, in accordance with Directive 2000/53/EC of the European Parliament and of the Council¹ and Directive 2011/65/EU of the European Parliament and of the Council².

¹ Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles (OJ L 269, 21.10.2000, p. 34).

² **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, 1.7.2011, p. 88).

ANNEX III

Mercury-related requirements applicable to manufacturing processes *referred to in Article 7(1) and (2)*

Part I: Prohibited use of mercury or mercury compounds, *whether in pure form or in mixtures*, in manufacturing processes

- (a) from 1 January 2018: *where mercury is used as a catalyst;*
- (b) from ... *[four years after the date of application of this Regulation]: where mercury is used as an electrode;*
- (ba) *By way of derogation from point (a) of Part I, the production of vinyl chloride monomer shall be allowed for a period of four years from ... [the date of application of this Regulation].*
- (bb) *By way of derogation from point (b) of Part I, the production of potassium and sodium methylate or ethylate shall be allowed for a period of ten years from ... [the date of application of this Regulation].*
- (bc) *from [10 October 2017 or the date of application of this Regulation whichever is the latest]: polyurethane production, to the extent not already restricted or prohibited in accordance with entry 62 of Annex XVII to Regulation (EC) No 1907/2006, as amended.*
- (bd) *by way of derogation from point b of Part I, from 11 December 2017: for the chlor-alkali production where mercury is used as an electrode.*

Part II: Manufacturing processes subject to restrictions on use and releases of mercury and mercury compounds

Production of sodium or potassium methylate or ethylate

The production of sodium or potassium methylate or ethylate shall be carried out in accordance with ***point (b) of Part I and*** the following requirements:

- No use of mercury from primary mining;
- Reduction of direct and indirect release of mercury and of mercury compounds into air, water and land in terms of per ***unit production*** by 50% by 2020 as compared to 2010; ■
- ***supporting research and development in respect of mercury-free processes; and***
- At the date of entry into force of this Regulation, the capacity of installations using mercury and mercury compounds for the production of sodium or potassium methylate or ethylate that were in operation before that date shall not be increased and no new installations shall be allowed.

ANNEX IV

Content of the national plan on artisanal and small-scale gold mining referred to in Article 9

The national plan shall include the following information:

- (a) national objectives and reduction targets *to eliminate the use of mercury and mercury compounds*;
- (b) actions to eliminate:
 - (i) whole ore amalgamation;
 - (ii) open burning of amalgam or processed amalgam;
 - (iii) burning of amalgam in residential areas; and
 - (iv) cyanide leaching in sediment, ore or tailings to which mercury has been added without first removing the mercury;
- (c) steps to facilitate the formalization or regulation of the artisanal and small-scale gold mining sector;
- (d) baseline estimates of the quantities of mercury used and the practices employed in artisanal and small-scale gold mining and processing within its territory;

- (e) strategies for promoting the reduction of emissions and releases of, and exposure to, mercury in artisanal and small-scale gold mining and processing, including mercury-free methods;
- (f) strategies for managing trade and preventing the diversion of mercury and mercury compounds from both foreign and domestic sources to use in artisanal and small scale gold mining and processing;
- (g) strategies for involving stakeholders in the implementation and continuing development of the national action plan;
- (h) a public health strategy on the exposure of artisanal and small-scale gold miners and their communities to mercury which shall include, inter alia, the gathering of health data, training for health-care workers and awareness-raising through health facilities;
- (i) strategies to prevent the exposure of vulnerable populations, particularly children and women of child-bearing age, especially pregnant women, to mercury used in artisanal and small-scale gold mining;
- (j) strategies for providing information to artisanal and small-scale gold miners and affected communities;
- (k) a schedule for the implementation of the national action plan.

ANNEX V
Correlation table

Regulation (EC) No 1102/2008	This Regulation
Article 1(1)	Article 3(1)(first subparagraph)
Article 1(2)	Article 3(1)(second subparagraph)
Article 1(3)	Article 3(2)
Article 2	Article 11
Article 3(1), first subparagraph	Article 13(1)
Article 3(1), second subparagraph	–
Article 3(2)	–
Article 4(1)	–
Article 4(2)	–
Article 4(3)	–
Article 5(1)	–
Article 5(2)	–
Article 5(3)	–
Article 6(1)	Article 12(1)
Article 6(2)	Article 12(1)
Article 6(3)	Article 12(1)
Article 6(4)	–
Article 7	Article 14
Article 8(1)	–

Article 8(2)	-
Article 8(3)	-
Article 8(4)	-
Article 8(5)	-
Article 9	-