INVENTORY OF EXISTING MERCURY-ADDED PRODUCTS AND MANUFACTURING PROCESSES INVOLVING THE USE OF MERCURY OR MERCURY COMPOUNDS

EXPLANATORY TEXT

In accordance with Article 8(7) of Regulation (EU) 2017/852 on mercury¹ ('Mercury Regulation'), the Commission shall make publicly available on the internet by 30 June 2018 an inventory of existing manufacturing processes involving the use of mercury or mercury compounds ('processes') and of existing mercury-added products (MAPs) as well as any applicable marketing restrictions.

The inventory is an indicative non-exhaustive living document and will accordingly be regularly updated when additional information on existing MAPs and processes are made available to the Commission Services² or when new or amended provisions of EU law affect existing MAPs and processes.

Revision 1 includes an amendment of section V. 2 Medical Products, Part A of the inventory table on existing mercury-added products.

1. Legal context

Art. 8 sets a regulatory regime under which the manufacturing and placing on the market of new MAPs and the use of new processes are prohibited unless authorised by the Commission under its Art. 8(6)³ or under Art. 4(6) of the RoHS Directive.⁴

For a new MAP or a new process to be authorised, the concerned economic operator must first provide the relevant national competent authorities with a notification containing the information listed in Art. 8(3). Where these authorities consider based on their own assessment that the criteria referred to Art. 8(6)(1st sub-§)⁵ are met, they forward the notification to the Commission for final decision.

The Commission adopts a decision⁶ specifying whether the manufacturing and/or placing on the market of the new MAP or the use of the new process is authorised.

Art. 8(1)(1st sub-§) concerns new uses of mercury. A new MAP is accordingly defined under Art. 8(1) as one that was not being manufactured prior to 1 January 2018 whilst a new

Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1).

Additional information on existing mercury-added products and processes listed in the inventory should be addressed to the Commission Services via the mailbox: ENV-MERCURY@ec.europa.eu.

Articles and annexes referred to in this text are articles and annexes to Regulation (EU) 2017/852 on mercury, unless specified otherwise.

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.

Provision of significant environmental or health benefits, no significant risks to the environment or to human health and no technically practicable mercury-free alternatives providing such environmental and health benefits.

By means of Implementing Acts adopted in accordance with the examination procedure by the Mercury Committee established under Art. 22.

process is defined under Art. 8(2) as one that was not being used prior to 1 January 2018. This seeks to discourage the emergence of new products or industrial processes in which the mercury or mercury compound fulfils a novel function.

A number of exemptions to the prohibition of new uses are provided for under Art. $8(1)(2^{nd} \text{ sub-}\S)(a)$ and (b) and $(2)(2^{nd} \text{ sub-}\S)$:

- 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;
- Equipment designed to be sent into space;
- Processes that manufacture or use a MAP, the manufacturing of which and its placing on the market is not prohibited.

In addition, in accordance with Art. 8(1)(2nd sub-§)(c), existing MAPs being manufactured or placed on the market prior to 1 January 2018 also fall under Art. 8 when they undergo technical improvements or redesign that do not lead to less mercury being used in those products. This implies that existing MAPs fall under the authorisation obligation foreseen under Art. 8(6) when technical improvements or redesign affect the function of the mercury/mercury compound or the way it is used to fulfil its function in the product and this does not lead to less mercury being used in the product.

2. Purpose of the inventory

The inventory is a publicly available list of existing MEPs and manufacturing processes involving the use of mercury or mercury-compounds. It will serve as a useful reference for determining whether a given MAP or a given process is to be considered as an existing MAP or process within the meaning of Art. 8(1) and (2).

MAPs⁷ contain intentionally-added mercury or mercury compounds that allow the product to fulfil the function for which it is manufactured and marketed. Accordingly, the inventory annexed refers to existing MAPs by addressing the functional purpose or role played by mercury and/or mercury compounds therein.⁸ For instance:

- Mercury-containing batteries are defined in the inventory as mercury batteries using a reaction between mercuric oxide and zinc electrodes or cadmium in an alkaline electrolyte;
- Mercury-containing switches or relays are defined in the inventory as an electrical switch opening and closing a circuit or as a relay using mercury as the switching element.

This also allows using the inventory when assessing the applicability of Art. $8(1)(2^{nd} \text{ sub-} \$)(c)$. For example, an existing mercury-containing hydrometer undergoing a design change would fall under the exemption foreseen in Art. $8(1)(2^{nd} \text{ sub-} \$)(c)$ if that redesign does not affect the function of the mercury/mercury compound or the manner it performs its function.

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⁷ 'Mercury-added product' is defined in Art. 3(4) as 'a product or component of a product that contains mercury or a mercury compound that was intentionally added'.

Note: There are cases where products contain mercury or mercury compounds that are residues from the manufacturing process, but that do not fulfil a particular useful function in the product itself. Hence, for the purpose of Art. 8, such cases are addressed under Part B of the inventory concerning existing manufacturing processes involving the use of mercury or mercury compounds.

Similarly, the part of the inventory on existing processes involving the use of mercury or mercury compounds describes those processes in such a manner as to reflect the function fulfilled by the mercury or mercury compounds in the production process.

3. Content of the inventory

Uses of mercury and mercury compounds are listed in either Part A or in Part B of the inventory, depending on whether mercury and mercury compounds fulfil a function in a MAP or in a process.

The inventory is not restricted to MAPs and to processes that are still currently being manufactured or placed on the EU market or operated or that are explicitly authorised or allowed under EU law. Rather, it covers all identified 'existing' MAPs and processes within the meaning of Art. 8(1)1st paragraph) and (2) i.e. those that were manufactured or placed on the EU market or operated any time prior to 1 January 2018.

3.1 Indicative non-exhaustive list of MAPs and of manufacturing processes

Part A of the inventory

The left column of Part A of the inventory contains entries listing MAPs (e.g. lamps, switches) irrespective of whether they are individual products or components of larger products, installations or equipment (e.g. lamps or switches in medical devices). For instance, whereas the inventory lists mercury-containing lamps, it does not list products that contain mercury-containing lamps.

A MAP is 'a product or product component that contains mercury or a mercury compound that was intentionally added' (Art. 2(4)). Hence, Part A of the inventory neither lists products that make use of mercury or mercury compounds, but do not contain them (e.g. porosimeters, pycnometers and metering devices for the determination of the softening point) nor mercury or mercury compounds used on their own (e.g. use of mercury sulphate for water analysis).

Part B of the inventory

The left column of Part B of the inventory contains entries on manufacturing processes 'involving the use of mercury or mercury compounds' (Art. 8(2)).

In light of Art. 8(2)(2nd sub-§), the inventory does not list processes manufacturing or using MAPs where mercury or mercury compounds do not exert a function in the manufacturing process itself in addition to the function exerted in the MAPs.

3.2 Indicative non-exhaustive list of relevant EU legal instruments

The right column of Parts A and B of the inventory contains an indicative non-exhaustive list of EU legal instruments directly or indirectly covering existing MAPs or processes.

As the inventory seeks to list all existing MAPs and processes manufactured or placed on the EU market or operated prior to 1 January 2018 irrespective of their legal status under EU law or current use, there may be cases where the left column refers to a given MAP or process that is not concerned by any of the EU instruments listed in the corresponding right column.

In addition, the fact that a given MAP or process is listed in the inventory does not mean that those uses are currently allowed under EU law.

INVENTORY TABLE

PART A:

EXISTING MERCURY-ADDED PRODUCTS9/10

Indicative non-exhaustive list of existing Mercury-added products	INDICATIVE NON-EXHAUSTIVE LIST OF RELEVANT EU INSTRUMENTS
 I. BATTERIES / ACCUMULATORS 1) Mercury-containing batteries using a reaction between mercuric oxide and zinc electrodes or cadmium in an alkaline electrolyte, including, e.g.: a) Mercuric oxide batteries b) Button cell & silver oxide or zinc air or mercuric oxide or zinc carbon c) Alkaline manganese 	 Regulation (EU) 2017/852 on mercury (Art. 5 and Annex II (Part A)) Directive (EC) 2006/66 on batteries and accumulators (Art. 2 and 4(1)(a))

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The left column contains an indicative non-exhaustive list of MAPs that were manufactured and placed on the market prior to 1 January 2018, irrespective of whether they are subject to EU law, authorised, allowed or prohibited under EU law or still manufactured or placed on the market. Hence, there may be MAPs listed in the left column that is not concerned by any of the EU legal instrument listed in the right column.

Devices that do not contain mercury or mercury compounds but that make use of mercury or mercury compounds when operating, such as porosimeters and permeters, are not included in the inventory since they do not qualify as mercury-added products within the meaning of Art. 2(4) of the Mercury Regulation.

	Indicative non-exhaustive list of existing Mercury-added products	Indicative non-exhaustive list of relevant EU instruments
11) 1) 2)	Mercury switches as an electrical switch opening and closing a circuit or as a relay using mercury as the switching element, including e.g.: a) Tilt / vibration / float / pressure / temperature switch b) Displacement relay, wetted reed relay, contact relay Electrode using mercury as an electrical conductor to make contact with a non-metallic part of a circuit (e.g. semiconductor, electrolyte), including e.g.: a) Reference electrode (calomel) / saturated calomel electrode b) Reference electrode (mercury-mercurous sulphate electrode) c) Liquid mercury cathode d) Hanging mercury drop electrode e) Dropping mercury electrode f) Static mercury drop electrode, or SMDE	 Regulation (EU) 2017/852 on mercury (Art. 5 and Annex II) Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Art. 2(4), 4, 5 and Annex IV).
7)	Mercury vacuum pump using mercury to trap air Infrared light detectors using mercury-containing semiconductors Tensiometer using mercury to measure the surface tension of liquids or surfaces, soil moisture tension or the tension in a wire, fibre or beam Melt pressure transducers, transmitters and sensors using a capillary system filled with mercury to transfer pressure from the measuring point the electronic sensor Mercury target systems for the spallation neutron source using mercury as target material Seam-welding machines, gyroscopes and wetted slip rings using mercury as a lubricant to fill the space between the stator and the rotor	

Indicative non-exhaustive list of existing Mercury-added products	Indicative non-exhaustive list of relevant EU instruments
 Non-Electrical/Electronic Devices Devices using mercury to measure pressure, including e.g.: a) Barometer b) Pressure gauges (e.g. manometer) c) Sphygmomanometer Devices using mercury to measure temperature, including e.g.: a) Thermometer and other non-electrical thermometric applications b) Pyrometer Devices using mercury to measure humidity (hygrometer) Devices using mercury to measure speed/velocity (psychrometer) Devices using mercury to measure fluxes/flows (flow meter) Devices using mercury to measure density (hydrometer) Devices using mercury to measure volume change of part of a body (strain gauge to be used with plethysmographs) Devices using mercury to measure molecular motion (mercury molecular motion device / tube) Devices using mercury to measure gas pressure and volume (mercury gas law apparatus) Triple point cells using mercury-filled cells for the calibration of e.g. thermometers Spectrum tubes using mercury vapour to observe mercury gas spectral lines 	 Regulation (EU) 2017/852 on mercury (Art. 5 and Annex II (Part A)) Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Art. 67 and Annex XVII (18a)) Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Art. 2(4), 4, 5 and Annex IV)¹¹

Non-electrical/electronic mercury-containing devices used as components in finished electrical and electronic equipment that fall under the scope of application of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), must meet the substance restrictions established under that Directive.

Indicative non-exhaustive list of existing Mercury-added products	Indicative non-exhaustive list of relevant EU instruments
 IV. LAMPS Gas discharge lamps that use an electric arc through vaporized mercury to produce light, including e.g.: Fluorescent lamps (e.g. U-tube, non-linear and linear fluorescent lamps (LFL), bug zappers, certain ultraviolet lights (e.g. tanning lamps, black lights), halophosphate lamps, induction lamps, cold cathode fluorescent lamps (CCFL), compact fluorescent lamps (CFL), external electrode fluorescent lamps (EEFL)) Non-fluorescent low discharge pressure lamps (e.g. ultraviolet lamps without phosphor coating such as germicidal lamps) Metal halide lamps (e.g. shop or stage lighting) High pressure lamps for special purposes (e.g. projector, industrial and entertainment lamps High pressure sodium lamps (e.g. horticulture lighting) Mercury vapour lamps (e.g. UV curing lamps) Mercury short-arc lamps (e.g. UV curing lamps) Low, medium and high-pressure UV lamps Components used for the production of discharge lamps and its components (e.g. discharge tubes, burners, dosing units) Liquid mercury floats/baths used in lighthouses to support and rotate lenses and reduce friction 	 Regulation (EU) 2017/852 on mercury (Art. 5 and Annex II) Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Art. 2(4), 4(1) and (3), 5(2) and Annex III) Directive 2000/53/EC on end-of-life vehicles (Art. 3(1), 4(2) and Annex II(15b))

Indicative non-exhaustive list of existing Mercury-added products	INDICATIVE NON-EXHAUSTIVE LIST OF RELEVANT EU INSTRUMENTS
 V. MEDICINAL PRODUCTS 1) Vaccines for human or veterinary use in which mercury or mercury compounds, including thiomersal, are used as antimicrobial preservative in bulk antigen, bulk finished product before filling and finished product to prevent spoilage or other adverse effects caused by microbial contamination 2) Homeopathic medicinal products for human or veterinary use containing mercury or mercury compounds used as active ingredient, intermediate solution or starting material 3) Diuretics containing mercury or mercury compounds used as renal diuretic VI. DENTAL AMALGAM 	 Directive 2001/82/EC on the Community code relating to veterinary medicinal products Regulation (EU) 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (Annex, Table 1) Directive 2001/83/EC on the Community code relating to medicinal products for human use Regulation (EC) 726/2004 on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use Regulation (EU) 2019/6 on veterinary medicinal products (applicable from 28 January 2022) Regulation (EU) 2017/852 on mercury (Art. 10 and 19)
Capsules using mercury together with other metals to generate an alloy that hardens to produce a filling for dental restorations	- Regulation (EU) 2017/832 on melecury (Art. 10 and 19) - Directive 93/42/EC on medical devices
 VII. COSMETIC PRODUCTS 1) Skin lightening soaps and creams using mercury and mercury compounds that inhibit the formation of melanin to achieve a lighter skin tone (lightening or bleaching of skin) 2) Eye makeup, cleansing products and mascara using thiomersal as preservative 	 Regulation (EU) 2017/852 on mercury (Art. 5 and Annex II) Regulation (EC) 1223/2009 on cosmetic products (Art. 14(1)(a) and Annexes II (221) and V (entries 16 and 17)) Regulation (EU) 649/2012 concerning the export and import of hazardous chemicals (Art. 15(2) and Annex V (Part 2)).

	Indicative non-exhaustive list of existing Mercury-added products	INDICATIVE NON-EXHAUSTIVE LIST OF RELEVANT EU INSTRUMENTS
VIII 1) 2) 3)	Paints using mercury and mercury compounds as pigments (e.g. use of pigments from natural or synthetic cinnabar) Paints using mercury compounds as additives to impede bacteria formation (bactericide) and hinder fungus attacks (fungicide) Varnishes using mercury and mercury compounds to enhance look (e.g. gloss effect) and durability.	- Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Art. 67 and Annex XVII (18))
IX. 1)	BIOCIDES, INCLUDING PESTICIDES, AND PLANT PROTECTION PRODUCTS Biocidal products, including pesticide and plant protection products, containing mercury compounds as an active substance or anti-microbial agent to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism, including e.g.: a) Fungicides, herbicides, insecticides, algicides, molluscicides, miticides, slimicides b) Germicides, antifungals, antiparasites	 Regulation (EU) 2017/852 on mercury (Art. 5 and Annex II (Part A)) Regulation (EC) 1107/2009 on the placing of plant protection products on the market Regulation (EC) 528/2012 concerning the making available on the market and use of biocidal products.

	Indicative non-exhaustive list of existing Mercury-added products	INDICATIVE NON-EXHAUSTIVE LIST OF RELEVANT EU INSTRUMENTS
X. 1) 2) 3) 4) 5) 6) 7) 8) 9) 10) 11) 12) 13)	heating and cooling systems (used e.g. in district heating plants) Oesophageal dilators using mercury-filled dilators or bougies resulting in dilation and allowing treatment of oesophageal strictures Gastrointestinal tubes where mercury is used as a flexible weight to guide tube into place through gravity	 Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Art. 67). Directive 2001/95/EC of 3 December 2001 on general product safety Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Art. 2(4), 4, 5 and Annex IV)¹³ Directive 93/42/EEC on medical devices

12

Products containing polyurethane produced with a mercury compound-based catalyst are not listed in Part A of the inventory as the function met by the mercury compounds relates to the production of polyurethane *per se* and not to the product containing polyurethane (e.g. gym flooring, doming labels). Manufacturing processes producing polyurethane and using a mercury compound-based catalyst are therefore listed in Part B of the inventory.

Non-electrical/electronic mercury-containing devices used as components in finished electrical and electronic equipment that fall under the scope of application of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), must meet the substance restrictions established under that Directive.

14) Colour photographic paper containing mercury or mercury compounds used to stabilize the final image

INVENTORY TABLE

PART B:

EXISTING MANUFACTURING PROCESSES INVOLVING THE USE OF MERCURY OR MERCURY COMPOUNDS

EXISTING MANUFACTURING PROCESSES INVOLVING THE USE OF MERCURY AND MERCURY COMPOUNDS	INDICATIVE NON-EXHAUSTIVE LIST OF RELEVANT EU INSTRUMENTS ¹⁴
 MANUFACTURING PROCESSES IN WHICH MERCURY OR MERCURY COMPOUNDS ARE USED AS A CATALYST Production of vinyl chloride monomer Production of polyurethane¹⁵ Production of acetaldehyde Production of 1-aminoanthraquinone and anthaquinone derivates Production of vinyl acetate 	Manufacturing processes using mercury or mercury compounds as a catalysts are prohibited with the exception of vinyl chloride monomer production involving the use of mercury or mercury compounds and for which a specific phase-out date (01/01/2022) is set: - Regulation (EU) 2017/852 on mercury (Art. 7(1) and Annex III (Part I)) - Directive 2010/75/EU on industrial emissions - Commission Implementing Decision (EU) 2017/2117 establishing best available techniques (BAT) conclusions for the production of large volume organic chemicals - Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Art. 67 and Annex XVII (62))

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See footnote (12).

	EXISTING MANUFACTURING PROCESSES INVOLVING THE USE OF MERCURY AND MERCURY COMPOUNDS	INDICATIVE NON-EXHAUSTIVE LIST OF RELEVANT EU INSTRUMENTS
1) 2) 3) 4)	MANUFACTURING PROCESSES IN WHICH MERCURY OR MERCURY COMPOUNDS ARE USED AS AN ELECTRODE: Production of chlor-alkali Production of sodium or potassium methylate or ethylate Production of sodium dithionite/hydrosulfite Production of alkali metal	Manufacturing processes using mercury or mercury compounds as an electrode are prohibited with the exception of sodium and potassium ethylate and methylate production involving the use of mercury or mercury compounds and for which a specific phase-out date (01/01/2028) is set: - Regulation (EU) 2017/852 on mercury (Art. 7(1), 24 and Annex III (Parts I and II) - Directive 2010/75/EU on industrial emissions - Commission Implementing Decision (EU) 2017/2117 establishing best available techniques (BAT) conclusions for the production of large volume organic chemicals and Commission Implementing Decision (EU) 2013/732 establishing best available techniques (BAT) conclusions for the production of chlor-alkali (Art. 1 and Annex (BAT. 1 and 2)).
1) 2)	USE OF THIOMERSAL AS ANTIMICROBIAL PRESERVATIVE OR AN INACTIVATING AGENT IN THE PRODUCTION OF VACCINES Antimicrobial preservative in bulk antigen harvests to prevent replication of the bioburden and the subsequent build-up of bacterial/fungal extraneous cellular components in the bulk fluids. Agent used to inactivate certain organisms that are sensitive to thiomersal	- Manufacturing processes using mercury or mercury compounds as an antimicrobial preservative or an inactivating agent are regulated by <i>Directive 2010/75/EU on industrial emissions</i> when the relevant conditions are met (e.g. production on an industrial scale by chemical or biological processing). ¹⁶

Regarding the manufacturing process for human vaccines, see also the general guidance on the reduction, elimination and substitution of thiomersal (CPMP/BWP/2517/00) and the warning statement EMEA/CHMP/VWP/19541/2007. Concerning the manufacturing process for veterinary vaccines, see also the European Pharmacopoeia's General Monograph 'Vaccines for veterinary use' (01/2017, section 'Antimicrobial preservatives', Ph. Eur. 0062 Vaccines for veterinary use) and the Guideline on requirements for the production and control of immunological veterinary medicinal products (EMA/CVMP/IWP/206555/2010 Rev. 1.).

	EXISTING MANUFACTURING PROCESSES INVOLVING THE USE OF MERCURY AND MERCURY COMPOUNDS	Indicative non-exhaustive list of relevant EU instruments
IV.	OTHER MANUFACTURING PROCESSES IN WHICH MERCURY OR MERCURY COMPOUNDS ARE USED	Manufacturing processes using mercury or mercury compounds other than those mentioned in other categories of part II to this inventory may be regulated by <i>Directive 2010/75/EU on industrial emissions</i> when the
1) 2)	Isotope separation, in particular lithium-6 and lithium-7 (e.g. COLEX process) Production e.g. of tetraethyl lead, y-keto acids and vitamin B-2	relevant conditions are met (e.g. production on an industrial scale by chemical or biological processing).
3)	Fire gilding and mercury silvering	