



Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Distr.: General

24 May 2024

Original: English

Chemical Review Committee

Twentieth meeting

Rome, 17–20 September 2024

Item 4 (a) (ii) of the provisional agenda*

**Technical work: consideration of draft decision guidance
documents: mercury**

Draft decision guidance document for mercury

Note by the Secretariat

I. Introduction

1. At its nineteenth meeting, the Chemical Review Committee reviewed notifications of final regulatory action for mercury submitted by Colombia and the European Union, together with the supporting documentation referred to therein, and concluded that the notifications met all the criteria of Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.
2. In decision CRC-19/4, the Committee adopted the rationale for its conclusion related to the notifications from Colombia and the European Union and recommended, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list mercury in Annex III to the Convention as an industrial chemical. By paragraph 4 of that decision, the Committee decided, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for mercury.
3. Pursuant to decision CRC-19/4 and the workplan for the preparation of draft decision guidance documents adopted by the Committee (UNEP/FAO/RC/CRC.19/14, annex III), the intersessional drafting group established at the nineteenth meeting has prepared a draft decision guidance document for mercury, which is set out in the annex to the present note, without formal editing. A compilation of comments relating to the draft decision guidance document received from Committee members and observers, including information on how those comments were addressed, is set out in document UNEP/FAO/RC/CRC.20/INF/5.

II. Proposed action

4. The Committee may wish to finalize the draft decision guidance document and to forward it, together with its recommendation to list mercury in Annex III to the Convention as an industrial chemical, for consideration by the Conference of the Parties at its twelfth meeting.

* UNEP/FAO/RC/CRC.20/1.

Annex

Draft Decision Guidance Document

Mercury

Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals



**Secretariat of the Rotterdam Convention
on the Prior Informed Consent Procedure for
Certain Hazardous Chemicals and Pesticides in
International Trade**



Table of Contents

Introduction.....	4
Standard core set of abbreviations	6
1. Identification and uses (see Annex 1 for further details).....	8
2. Reasons for inclusion in the PIC procedure	9
2.1 Final regulatory action (see Annex 2 for further details).....	9
2.2 Risk evaluation (see Annex 1 for further details).....	9
3. Protective measures that have been applied concerning the chemical	11
3.1 Regulatory measures to reduce exposure.....	11
3.2 Other measures to reduce exposure	12
3.3 Alternatives.....	12
3.4 Socio-economic effects.....	12
4. Hazards and risks to human health and the environment ¹	12
4.1 Hazard Classification.....	12
4.2 Exposure limits.....	13
4.3 Packaging and labelling.....	13
4.4 First aid.....	15
4.5 Waste management.....	15
5. References.....	15
5.1 Regulatory actions	15
5.2 Supporting Documentation.....	16
5.3 Other Documents.....	16
Annex 1 to the decision guidance document: Further information on the substance	18
1. Physico-chemical properties	18
2. Toxicological properties	18
3. Human exposure/risk evaluation.....	23
4. Environmental fate and effects	25
5. Environmental exposure/risk evaluation.....	26
Annex 2 to the decision guidance document: Details on final regulatory actions reported	28
Annex 3 to the decision guidance document: Addresses of designated national authorities.....	35

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals¹ for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties² in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion in the PIC procedure does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its [...] meeting, held in [...] on [...], the Conference of the Parties agreed to list [chemical name] in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on [...], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

¹ According to the Convention, the term “chemical” means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

² According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

Standard core set of abbreviations

<	Less than
≤	Less than or equal to
>	Greater than
≥	Greater than or equal to
µg	Microgram
µm	Micrometre
ARfD	Acute reference dose
a.i.	Active ingredient
ADI	Acceptable daily intake
AOEL	Acceptable operator exposure level
b.p.	Boiling point
bw	Body weight
°C	Degree Celsius (centigrade)
CAS	Chemical Abstracts Service
cc	Cubic centimetre
cm	Centimetre
DNA	Deoxyribonucleic acid
DT ₅₀	Dissipation time 50%
EC ₅₀	Median effective concentration
ED ₅₀	Median effective dose
ECHA	European Chemicals Agency
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	Gram
h	Hour
ha	Hectare
i.m.	Intramuscular
i.p.	Intraperitoneal
IARC	International Agency for Research on Cancer
IC ₅₀	Median inhibitory concentration
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
kg	Kilogram
K _{oc}	Soil organic partition coefficient.
K _{ow}	Octanol–water partition coefficient
kPa	Kilopascal
L	Litre
LC ₅₀	Median lethal concentration
LD ₅₀	Median lethal dose

LOAEL	lowest-observed-adverse-effect level
LOEL	Lowest-observed-effect level
m	Metre
m.p.	Melting point
mg	Milligram
ml	Millilitre
mPa	Millipascal
MRL	Maximum residue limit
MTD	Maximum Tolerated Dose
ng	Nanogram
NOAEC	No-observed-adverse-effect concentration
NOAEL	No-observed-adverse-effect level
NOEC	No-observed-effect concentration
NOEL	No-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	Predicted environmental concentration
Pow	Octanol-water partition coefficient, also referred to as Kow
PPE	Personal protective equipment
ppm	Parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	Reference dose (for chronic oral exposure; comparable to ADI)
SMR	Standard(ized) mortality ratio
STEL	Short-term exposure limit
TER	Toxicity exposure ratio
TLV	Threshold limit value
TWA	Time-weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
VOC	Volatile organic compound
w/w	Weight for weight
WHO	World Health Organization
wt	Weight

Decision guidance document for a banned or severely restricted chemical

Mercury**Published:**

1. Identification and uses (see Annex 1 for further details)

Common name	Mercury
Chemical name and other names or synonyms	Mercury
Molecular formula	Hg
Chemical structure	Hg
CAS No.	7439-97-6
Harmonized System Customs Code	2805.40
Other numbers	EC number 231-106-7
Category	Industrial
Regulated category	Industrial
Use(s) in regulated category	<p>In Colombia, mercury was used in mining, chlor-alkali industry, production of fluorescent lamps and in the manufacture of dental amalgams. The final regulatory action prohibited the marketing and use of mercury in the different industrial activities on July 15, 2013, the use of mercury in mining activities from July 15, 2018, and all other industrial activities including the manufacture of dental amalgams from July 15, 2023.</p> <p>In the European Union, mercury was used in mining, chlor-alkali industry, the production of lamps, electrical and electronic devices. The final regulatory action notified by the European Union severely restricts the industrial use of mercury in several sectors through different Directives and Regulations.</p> <p>The Minamata Convention on Mercury aims to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. The Convention addresses all aspects of the life cycle of mercury, including:</p> <ul style="list-style-type: none"> • the direct mining of mercury, its export and import, its safe storage and its disposal once it becomes waste, • the reduction and where feasible the elimination of the use and release of mercury from artisanal and small-scale gold mining, • the control of mercury air emissions from coal-fired power plants, coal-fired industrial boilers, certain non-ferrous metals production operations, waste incineration and cement production, • the phase-out or reduction of mercury use in certain products such as batteries, switches, lights, cosmetics, pesticides and measuring devices, and creating initiatives to reduce the use of mercury in dental amalgam, and • the phase out or reduction of the use of mercury in manufacturing processes such as chlor-alkali production, vinyl chloride monomer production, and acetaldehyde production
Trade names	Colloidal mercury, Quicksilver, Liquid silver, Hydrargyrum. <i>This is an indicative list. It is not intended to be exhaustive.</i>
Formulation types	Elemental Mercury
Uses in other categories	Use as a chemical intermediate in the manufacture of various industrial chemicals and processes (UNEP 2017).

Basic manufacturers Avantor, Inc. (Thermo Fisher Scientific), AHSA, Aldrett Hermanos SA de CV., Merck KGaA. *This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

Mercury is included in the PIC procedure as an industrial chemical. It has been listed on the basis of the final regulatory actions to severely restrict its use, notified by Colombia and the European Union. Contact details of the designated national authorities of these two Parties are set out in annex 3 to the decision guidance document.

2.1 Final regulatory action (see Annex 2 for further details)

Colombia

Based on Law 1658 of 15 July 2013, the government of Colombia prohibited the marketing and use of mercury. The regulation eradicates the use of mercury in the national territory in: 1) all industrial and production processes within a period not exceeding 10 years (until 15 July 2023), and 2) for mining within a maximum period of 5 years (until 15 July 2018). The deadline for industrial uses other than mining has not been met; this is the reason why the use of mercury in the production of dental amalgam will continued until 15 July 2023.

Reason: Human Health and Environment

European Union

The use of mercury as an industrial chemical is severely restricted in the European Union pursuant to Regulation (EU) 2017/852 on mercury, Regulation (EC) 1907/2006 (REACH), Directive 2011/65/EU (RoHS) and Directive 2006/66/EC (batteries and accumulators). More specifically:

- (a) In 2006, Directive 2006/66/EC introduced a prohibition on the placing on the market of batteries and accumulators containing mercury;
- (b) In 2007, Directive 2007/51/EC introduced a restriction under Directive 76/769/EEC on the placing on the market of mercury in fever thermometers and in other measuring devices intended for sale to the general public;
- (c) Regulation (EC) No 1907/2006 (REACH) repealed Directive 76/769/EEC. Commission Regulation (EC) No 552/2009 amended Annex XVII to REACH by incorporating in entry 18.a the restrictions on certain measuring devices containing mercury that was adopted under Directive 2007/51/EC;
- (d) In 2011, Directive 2011/65/EU (RoHS) established a restriction on the placing on the market of electric and electronic equipment to a maximum concentration value of 0.1% of mercury, allowing exemptions for certain applications for a limited time period;
- (e) Commission Regulation (EU) No 847/2012 amended Annex XVII to REACH by incorporating in entry 18.a a restriction on the placing on the market of mercury-containing and mercury- using measuring devices intended for industrial and professional uses. The restriction started to apply from 10 April 2014.

Regulation (EU) 2017/852 on mercury was adopted in May 2017. This regulation complements the European Union *acquis* and lays down the provisions that are needed to ensure the complete alignment of the European Union *acquis* with the Minamata Convention on Mercury establishing measures and conditions concerning the use and storage of and trade in mercury, mercury compounds and mixtures of mercury, and the manufacture and use of and trade in mercury-added products, and the management of mercury waste.

Reason: Human Health and Environment

2.2 Risk evaluation (see Annex 1 for further details)

Colombia

According to the evaluation related to human health and the environment, the following information was identified:

- (a) Data in the Colombian notification includes extensive neuro-epidemiological studies in exposed populations (occupational and general population) and studies of mercury level in different environmental compartments (freshwater, soil, sediment, biota, etc.) and food (fish). These data were used to determine the risk to human health and environment and provide technical evidence to support regulatory actions to address the identified risks. Mercury measurements have been made in humans, mainly in workers and communities surrounding mining activities or adjacent to riverine areas;
- (b) The evaluation established that mercury is a toxic substance, that when present in the human body produces disorders, mainly targeting the central nervous system. The presence of mercury in the air, water, soil and food (mainly fish) in concentrations above the allowed limit has caused a serious public health problem in

Colombia. Regions such as the Northeast of Antioquia, the South of Bolívar, Chocó, Santander, Nariño, Caldas, Vaupés, among others, carry out artisanal gold mining using mercury for the final extraction of gold from ore. Its use occurs in an indiscriminate and poorly controlled way, a situation that has caused environmental contamination and has affected people's health. Exposure to mercury is also increased in industrial areas that use this substance;

- (c) Studies conducted by the Government of Antioquia in the municipalities of Segovia and Remedios, in the Northeast of the department, found a concentration of mercury of approximately 340 µg/m³ in the air (300 times higher than the guideline of the World Health Organization for public maximum exposure to vapour of mercury). Approximately 26 to 6,118 ppm of Hg is discharged into rivers by miners in the region. Additionally, the main food of these communities is fish, which has been shown to be affected by the emission of mercury. Studies completed by Corantioquia, the University of Antioquia, and the University of Cartagena have revealed a concentration above 1.06 µg Hg/g in most of the species found in the rivers of the surrounding area;
- (d) Mercury contamination in Colombia is mostly caused by its use in the extraction of gold from ore. In this process, elemental mercury is added to gold containing ores and minerals to form a gold amalgam. Mercury used this way may spill into water bodies and the environment. Subsequently, the gold amalgam recovered is burned in the open air to extract the gold, which releases the toxic mercury vapours into the atmosphere. All these activities are performed very close to the miners' households, in such a way that families breathe a large part of the volatilized mercury vapour. Even remote populations can be affected by the mobilization of this substance (Protocol for Surveillance and Control of Acute Mercury Poisoning);
- (e) Studies on populations with known exposures to mercury, including occupational and general population exposures, show a link between exposure and adverse health effects (Fawer et al 1983, Piikivi 1989, Marh et al 1987). The neuroepidemiological and toxicological study of the Suratá river pollutants carried out in the mining population of that region (Santander, 1992) raised the possible relationship of chronic exposure to mercury with the presence of neurological diseases. Tirado et al (2000) suggest that this form of exposure can cause neuropsychological and behavioural deficits in the population. In 1995, Olivero et al reported that the inhabitants of southern Bolívar presented signs of mercury intoxication such as hand tremors, neurological disorders and visual problems, among others. In this region, frequent cases of congenital malformations have also been reported, although without evidence of association with mercury exposure;
- (f) According to National Public Health Surveillance System - SIVIGILA, during 2010 and in the first half of 2011, 201 cases of mercury poisoning were reported in Colombia- 96% of the cases were of occupational or accidental origin as follows: 85% (n = 171) occupational, 11% (n = 22) accidental.
- (g) Occupational exposure is the highest reported cause of mercury poisoning in Colombia. Mining and quarrying occupations have the highest number of cases due to the use of mercury in gold mining. The most frequent notifiers of poisoning cases during the review period were the regions of Antioquia, followed by Bogotá, Bolívar, Risaralda, Santander and Valle del Cauca. The highest percentage of intoxications reported were occupational, predominately miners or quarryers, with inhalation being the most frequent route of exposure (Scientific, Regulatory and Technical Evidence on the Mercury Problem at the Level National and International Health Sector and Other Related Sectors);
- (h) The evaluation identified some population groups may need special consideration in relation to exposure to mercury, since they have a greater probability of exposure to dangerous levels, or effects are exacerbated by underlying medical conditions:
 - (i) Workers exposed to mercury;
 - (ii) General population next to sources of mercury contamination (mines, industries);
 - (iii) Populations in areas contaminated by mercury, especially indigenous and riverine, whose main source of proteins is fish;
 - (iv) People using mercury-containing medications for a long time;
 - (v) People with central nervous system diseases, patients with chronic kidney and bronco pulmonary failure;
 - (vi) Pregnant women and toddlers.

European Union

According to the evaluation related to human health and the environment, the following information was identified:

- (a) While this risk assessment was conducted in the context of the restriction on mercury-containing measuring devices intended for industrial and professional uses, it includes information on the risks associated with

mercury that is not limited to those measuring devices and that could support the other Directives and Regulations that comprise the final regulatory action notified by the European Union.

- (b) According to the ECHA Committee for Risk Assessment (RAC) Opinion and its background document, mercury and its compounds are highly toxic to humans, ecosystems and wildlife, with amongst others serious chronic irreversible adverse neurotoxic and neurodevelopmental effects. The RAC opinion includes a PBT assessment for mercury-methylmercury concluding an equivalent level of concern in terms of persistency, due to mercury cycling and methylation *versus* demethylation rates under anaerobic conditions, as well as the clear potential for bioaccumulation and toxicity identified for methylmercury.
- (c) The hazard and fate of mercury and its compounds are described in numerous peer-reviewed reports, which were referenced in the Documentation provided:
 - (i) ‘Global Mercury Assessment’, published by UNEP in 2002 (and UNEP 2008a and b);
 - (ii) ‘Methylmercury’ (WHO, 1990);
 - (iii) ‘Risks to Health and the Environment Related to the Use of Mercury Products’ prepared for the Commission by RPA in 2002.
- (d) It is estimated that 3.5–7.6 tonnes of mercury are placed on the market in mercury containing measuring devices in 2010. These amounts are used to estimate the maximum potential for mercury emissions to the environment that might ultimately occur. This assumption is considered appropriate because of an estimated low separate collection rate of mercury waste and resulting inadequate waste treatment of a substantial part of the devices. This inappropriate waste collection leads in the long term to a relatively high share of mercury used in these devices being released to the environment. For measuring equipment using mercury (porosimeters, mercury probes used for capacitance-voltage determinations and mercury electrodes used in voltammeters) the total use is 5–15 tonnes per year (mostly porosimeters 5–14 tonnes per year). It should be noted that these figures are the amount of mercury the laboratories purchase and cannot be used to estimate maximum potential for emission as is the case for the measuring equipment containing mercury. To estimate emissions several additional factors need to be considered. These include number of measurements carried out, practices to purify and regenerated used mercury and the risk management measures and operational conditions applied to control the emissions and exposures.
- (e) The total mercury consumption in Europe was in 2007 estimated to be 320–530 tonnes. 160–190 tonnes of the total amount were used in the chlor-alkali production and 90–110 were used in dental amalgams. The amount used in mercury measuring devices thus equals about 4% of the total, while the restricted devices will be lower due to the large use in porosimeters.
- (f) Once released to the environment, mercury persists in the environment, where it circulates between air, water, sediments, soil and biota in various forms. Mercury can be transformed to methylmercury, the most toxic form, which biomagnifies especially in the aquatic food chain, making populations and wildlife with a high intake of fish and seafood particularly vulnerable.
- (g) Several existing pieces of legislation in the European Union abate the risks arising from mercury in different stages of the life cycle of measuring devices. However, none of the measures currently in place is sufficient to remove the concern fully, although there is a difference between their observed effectiveness with regard to measuring devices containing mercury and measuring devices using mercury.
- (h) The emissions from mercury measuring devices, although relatively small, contribute to the overall emissions of mercury to the environment and thereby also to the exposure of species and of humans via the environment. Therefore, measuring devices containing or using mercury are of concern.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Colombia

The government of Colombia prohibited the marketing and use of mercury in the different industrial activities under Law 1658 on July 15, 2013, the use of mercury in mining activities from 15 July 2018, and all other industrial activities including the manufacture of dental amalgams from 15 July 2023.

European Union

The final regulatory action notified by the European Union severely restricts the industrial use of mercury in several sectors through different Directives and Regulations. More specifically:

- (a) In 2006, Directive 2006/66/EC introduced a prohibition on the placing on the market of batteries and accumulators containing mercury;

- (b) In 2007, Directive 2007/51/EC introduced a restriction under Directive 76/769/EEC on the placing on the market of mercury in fever thermometers and in other measuring devices intended for sale to the general public;
- (c) Regulation (EC) No 1907/2006 (REACH) repealed Directive 76/769/EEC. Commission Regulation (EC) No 552/2009 amended Annex XVII to REACH by incorporating in entry 18.a the restrictions on certain measuring devices containing mercury that was adopted under Directive 2007/51/EC; In 2011, Directive 2011/65/EU (RoHS) established a restriction on the placing on the market of electric and electronic equipment to a maximum concentration value of 0.1% of mercury, allowing exemptions for certain applications for a limited time period;
- (d) Commission Regulation (EU) No 847/2012 amended Annex XVII to REACH by incorporating in entry 18.a a restriction on the placing on the market of mercury-containing and mercury- using measuring devices intended for industrial and professional uses. The restriction started to apply from 10 April 2014;

Regulation (EU) 2017/852 on mercury was adopted in May 2017. This regulation complements the European Union *acquis* and lays down the provisions that are needed to ensure the complete alignment of the European Union *acquis* with the Minamata Convention on Mercury establishing measures and conditions concerning the use and storage of and trade in mercury, mercury compounds and mixtures of mercury, and the manufacture and use of and trade in mercury-added products, and the management of mercury waste.

3.2 Other measures to reduce exposure

Colombia

None reported.

European Union

None reported.

3.3 Alternatives

Colombia

No information was provided.

European Union

No information was provided.

General (relating to sections 3.2 and 3.3)

The Minamata Convention on Mercury addresses all aspects of the life cycle of mercury, including requiring controls and reductions across a range of products, processes and industries. Updated information on the phase out of products containing mercury and available alternatives to these products, including alternatives to the use of mercury in manufacturing processes and mining is available on the Convention's website at <https://minamataconvention.org>

3.4 Socio-economic effects

Colombia

No assessment of socio-economic effects was reported.

European Union

No assessment of socio-economic effects was reported.

4. Hazards and risks to human health and the environment¹

4.1 Hazard Classification

WHO / IPCS	Mercuric chloride, Class Ib Mercuric oxide, Class Ib Mercurous chloride, Class II
IARC	Group 3 (not classifiable as to their carcinogenicity to humans) Methylmercury, Group 2B (possibly carcinogenic to humans)

European Union	Acute Tox 2: H330 – fatal if inhaled. STOT RE 1: H372 – causes damage to organs through prolonged or repeated exposure. Aquatic Acute 1: H400 – very toxic to aquatic life. Aquatic Chronic 1: H410 – very toxic to aquatic life with long lasting effects. Repr. 1B: H360D – may damage the unborn child.
US EPA	Carcinogenicity classification: Mercury, elemental D (IRIS 1995a) Mercuric chloride C (IRIS 1995b) Methylmercury C (IRIS2001)

1: Elemental mercury is ionized and methylated in the environment and therefore this chapter includes information on hazard, exposure and risk of mercury compounds.

4.2 Exposure limits

WHO (2021)

In 2003 the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a tolerable intake of 1.6 µg/kg body weight per week for dietary exposure to methylmercury in order to protect the developing foetus from neurotoxic effects. In 2006, JECFA clarified that life stages other than the embryo and foetus may be less sensitive to the adverse effects of methylmercury. For adults, up to about twice the tolerable intake per week would not pose any risk of neurotoxicity. However, available data did not allow firm conclusions to be drawn for children (aged up to about 17 years), as they may be more sensitive than adults. Hence the tolerable intake established in 2003 applies also to children.

In 2010 JECFA established a provisional tolerable weekly intake for inorganic mercury of 4 µg/kg body weight, applicable to dietary exposure to total mercury from foods other than fish and shellfish.

Drinking water: 6 µg/litre for inorganic mercury.

Air: 1 µg/m³ (annual average).

WHO estimated a tolerable concentration of 0.2 µg/m³ for long-term inhalation exposure to elemental mercury vapour, and a tolerable intake of total mercury of 2 µg/kg body weight per day (17).

SCOEL/SUM/84 (2007)


Occupational exposure:

8-hour Total Weight Average (TWA): 0.02 mg mercury/m³

Biological limit values (BLV): 10 µg Hg/l blood; 30 µg Hg/g creatinine in urine

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:	
Hazard Class and Packing Group:	UN Hazard Class: 8 UN subsidiary risk: 6.1 UN pack Group III Source: ICSC 0056 - MERCURY (inchem.org)
UN shipping names	ADR/RID/IMDG: MERCURY

International Maritime Dangerous Goods (IMDG) Code	<p>According to UN GHS Criteria</p>  <p>DANGER</p> <p>H290: May be corrosive to metals H330: Fatal if inhaled H360: May damage fertility or the unborn child H730: Causes damage to central nervous system and kidneys H732: Causes damage to the central nervous system and the kidneys through prolonged or repeated exposure H410: Very toxic to aquatic life with long lasting effects</p>
Transport Emergency Card	<p>ICSC 0056 - MERCURY (inchem.org)</p>

4.4 First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

International Chemical Safety Cards (ICSCs): [ICSC 0056 - MERCURY \(inchem.org\)](https://www.inchem.org/icsc/0056)

Description of first aid measures

AVOID ALL CONTACT! IN ALL CASES CONSULT A DOCTOR!			
	SYMPTOMS	PREVENTION	FIRST AID
Inhalation	Cough. Sore throat. Shortness of breath. Fever. Vomiting. Diarrhoea. Abdominal pain. Headache. Weakness.	Use local exhaust or breathing protection.	Fresh air, rest. Artificial respiration may be needed. Refer immediately for medical attention.
Skin	MAY BE ABSORBED! Redness.	Protective gloves. Protective clothing.	Remove contaminated clothes. See Notes. Rinse and then wash skin with water and soap. Refer for medical attention.
Eyes		Wear face shield or eye protection in combination with breathing protection.	First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then refer for medical attention.
Ingestion		Do not eat, drink, or smoke during work. Wash hands before eating.	Refer for medical attention.

Fire-fighting measures

In case of fire in the surroundings, use appropriate extinguishing media. In case of fire: keep drums, etc., cool by spraying with water.

Spillage disposal

Evacuate danger area! Consult an expert! Personal protection: chemical protection suit and filter respirator for mercury adapted to the airborne concentration of the substance. Ventilation. DO NOT let this chemical enter the environment. Collect leaking and spilled liquid in sealable non-metallic containers as far as possible. Then store and dispose of according to local regulations.

Storage

Provision to contain effluent from fire extinguishing. Separated from food and feedstuffs. Well closed. Store in an area without drain or sewer access.

4.5 Waste management

Regulation (EU) 2017/852 on mercury was adopted in May 2017. This regulation complements the European Union *acquis* and lays down the provisions that are needed to ensure the complete alignment of the European Union *acquis* with the Minamata Convention on Mercury establishing measures and conditions concerning the use and storage of and trade in mercury, mercury compounds and mixtures of mercury, and the manufacture and use of and trade in mercury-added products, and the management of mercury waste.

Basel Technical guidelines on the environmentally sound management of wastes consisting of, containing or contaminated with mercury or mercury compounds are available - Adopted by COP-15, June 2022 ([Technical guidelines](#)).

5. References

5.1 Regulatory actions

Colombia

Ley 1658 de 2013 (Anexo I)

DIARIO OFICIAL AÑO CXCLIX. N. 48.852. 15, JULIO, PAG.6

<http://www.suin-juriscol.gov.co/viewDocument.asp?ruta=Leyes/1685943>

European Union

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.

<http://data.europa.eu/eli/dir/2006/66/2018-07-04>

Directive 2007/51/EC of the European Parliament and of the Council of 25 September 2007 amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury

<http://data.europa.eu/eli/dir/2007/51/oj>

Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII

<http://data.europa.eu/eli/reg/2009/552/oj>

Commission Regulation (EU) No 847/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury

<http://data.europa.eu/eli/reg/2012/847/oj>

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.

<http://data.europa.eu/eli/dir/2011/65/2020-09-01>

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.

<http://data.europa.eu/eli/reg/2017/852/oj>

5.2 Supporting Documentation

Mercury: notifications of final regulatory action. UNEP/FAO/RC/CRC.19/11

Supporting documentation provided by Columbia. UNEP/FAO/RC/CRC.19/INF/22

Supporting documentation provided by the European Unions. UNEP/FAO/RC/CRC.19/INF/24

5.3 Other Documents

ECHA registration dossier 5169 (Mercury), accessed at: <https://echa.europa.eu/registration-dossier/-/registered-dossier/5169>

IARC (1993), IARC Monographs on the Evaluation of Carcinogenic Risks to humans, Beryllium, Cadmium, Mercury and Exposures in Glass Manufacturing Industry, Volume 58.

<https://publications.iarc.fr/publications/media/download/1954/ed5ada49ff1536d1474abdb982ee69583dbf1bc2.pdf>

IRIS (1995a). Mercury elemental; CASRN 7439-97-6.

https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0370_summary.pdf

IRIS(1995b). Mercuric chloride (HgCl₂); CVASRN 787-94-7.

https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0692_summary.pdf

IRIS (2001). Methylmercury (MeHg); CASRN 22967-92-6.

https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0073_summary.pdf

SCOEL/SUM/84 (2007). Recommendation from the Scientific Committee on Occupational Exposure Limits for elemental mercury and inorganic divalent mercury compounds. May 2007.

<http://ec.europa.eu/social/BlobServlet?docId=3852&langId=en>

UNEP (2002): Global Mercury Assessment. UN Environment Programme, Chemicals Branch, Geneva, Switzerland.

<https://www.unep.org/globalmercurypartnership/resources/report/global-mercury-assessment-2002>

UNEP (2008): The Global Atmospheric Mercury Assessment: Sources, Emissions and Transport. UN Environment Programme, Chemicals Branch, Geneva, Switzerland.

<https://www.unep.org/globalmercurypartnership/resources/report/global-atmospheric-mercury-assessment-sources-emissions-and-transport-2008>.

UNEP (2013): Global Mercury Assessment 2013: Sources, Emissions, Releases and Environmental Transport. UNEP Chemicals Branch, Geneva, Switzerland. [Global Mercury Assessment 2013: Sources, emissions, releases, and environmental transport \(unep.org\)](https://www.unep.org/globalmercurypartnership/resources/report/global-mercury-assessment-2013-sources-emissions-releases-and-environmental-transport-unep.org)

UNEP (2017). Global mercury supply, trade and demand. United Nations Environment Programme, Chemicals and Health Branch. Geneva, Switzerland. <https://www.unep.org/resources/report/global-mercury-supply-trade-and-demand>

UNEP (2019): Global Mercury Assessment 2018. UN Environment Programme, Chemicals and Health Branch, Geneva, Switzerland. https://www.unep.org/resources/publication/global-mercury-assessment-2018?_ga=2.172454499.1370957274.1702051132-948088036.1661281591

WHO (2000). Air quality guidelines for Europe, 2nd ed.. World Health Organization. Regional Office for Europe. <https://iris.who.int/handle/10665/107335>

WHO (2003). Elemental mercury and inorganic mercury compounds: human health aspects, Concise International Chemical Assessment Document 50. World Health organization. <https://www.inchem.org/documents/cicads/cicads/cicad50.htm>

WHO (2021). Exposure to mercury: a major public health concern, second edition. Preventing disease through healthy environments. World Health Organization. <https://www.who.int/publications/i/item/9789240023567>

Annexes to the decision guidance document

- Annex 1: Further information on the substance
- Annex 2: Details on final regulatory action
- Annex 3: Address of designated national authorities

Annex 1 to the decision guidance document: Further information on the substance

The information presented in this annex reflects the conclusions of the notifying Parties: Colombia and the European Union. The notification from Colombia was published in PIC Circular LII of December 2020. The notification from the European Union was published in PIC Circular LVI of December 2022. This information has been taken from the notifications of the final regulatory actions to ban mercury and the supporting documents.

The toxicity of mercury is very well documented internationally and only a brief summary of data to supplement information provided in the notifications is included in this annex. This annex is not meant to be a comprehensive review of the toxicological profile of mercury.

More detailed information is available in the following UNEP Mercury Assessments:

- (a) Global Mercury Assessment 2002;
- (b) The Global Atmospheric Mercury Atmospheric Assessment 2008: Sources, Emissions and Transport;
- (c) Global Mercury Assessment 2013: Sources, emissions, releases, and environmental transport;
- (d) Global Mercury Assessment 2018.

The global lifecycle of mercury is addressed under the Minamata Convention on Mercury.

1. Physico-chemical properties

1.1	Identity	Mercury
1.2	Formula	Hg
1.3	Molecular weight	200.6 g/mol
1.4	Colour and Texture	Silver-white liquid at room temperature
1.5	Melting point	Melting point: -39°C (at 101,325 Pa)
1.6	Boiling point	Boiling point: 357°C (at 101,325 Pa)
1.7	Density	13.5 g/cm ³ at 25°C
1.8	Solubility in water	none
1.9	Vapour density	(air=1) 6.93
1.10	Vapour pressure	0.26 Pa at 20°C
1.11	Viscosity	1.55 mPa s at 20°C
1.12	Relative density vapour/air-mixture	1.009 (ait=1) at 20°C

2. Toxicological properties

2.1 General

European Union

Mercury is a chemical of global concern owing to its long-range atmospheric transport, its persistence in the environment once anthropogenically introduced, its ability to bioaccumulate in ecosystems and its significant negative effects on human health, which include significant adverse neurological and other health effects, with particular concerns expressed about its harmful effects on infants and unborn children.

Mercury can be transformed to methylmercury, the most toxic form, which biomagnifies especially in the aquatic food chain, making populations and wildlife with a high intake of fish and seafood particularly vulnerable.

2.1.1 Mode of Action

European Union

Elemental mercury is very toxic to humans via inhalation. About 80 percent of inhaled vapours are absorbed by the lung tissues. This vapour easily penetrates the blood-brain barrier and is a well documented

neurotoxicant causing neurological and behavioural disorders in humans when inhaled. Specific symptoms include tremors, emotional lability, insomnia, memory loss, neuromuscular changes, and headaches. Intestinal absorption of elemental mercury is low.

WHO (2003)

At high levels of exposure, elemental mercury induces adverse effects in most organ systems in the body. Respiratory failure, cardiac arrest, and cerebral oedema are the causes of death in fatal cases.

The central nervous system is the most sensitive target for elemental mercury vapour exposure. Similar effects are seen following all durations of exposure, but their severity increases as exposure duration and/or concentration increase. Long-term exposure to elemental mercury may lead to changes in renal function.

2.1.2 Symptoms of poisoning

WHO (2003)

Prominent symptoms include tremors, emotional lability, insomnia, memory loss, neuromuscular changes, headaches, polyneuropathy, and performance deficits in tests of cognitive or motor function.

2.1.3 Absorption, distribution, excretion and metabolism in mammals

WHO (2003)

Inhalation is the primary route of entry into the body for elemental mercury, while oral exposure is the primary route for inorganic mercury salts. Dermal penetration is usually not a significant route of exposure to inorganic mercury.

Approximately 80% of inhaled elemental mercury is absorbed through the lungs by rapid diffusion. In contrast, only 0.01% of elemental mercury is absorbed through the gastrointestinal tract, possibly because of its enterogastric conversion to divalent mercury and subsequent binding to sulfhydryl groups. Dermal absorption of elemental mercury is limited. Dermal absorption is estimated to contribute approximately 2.6% of the absorbed mercury following exposure to elemental mercury vapour in the air; the other 97.4% occurs through inhalation.

The absorption, blood levels, and excretion of mercury evaluated in nine healthy volunteers (two males, seven females) exposed to mercury vapour in air at 400 µg/m³ for 15 min corresponded to a dose of 5.5 nmol mercury/kg body weight. Samples of exhaled air, blood, and urine were collected for 30 days after exposure. The median retention of elemental mercury after 30 days was 69% of the inhaled dose. This corresponds to the estimated half-life of approximately 60 days for elemental mercury.

The lipophilic nature of elemental mercury results in its distribution throughout the body. Elemental mercury dissolves in the blood upon inhalation, and some remains unchanged. Elemental mercury in the blood is oxidized to its divalent form in the red blood cells. The divalent cation exists as a diffusible or non-diffusible form. The non-diffusible form exists as mercuric ions that bind to protein and are held in high-molecular-weight complexes, existing in equilibrium with the diffusible form. In the plasma, the mercuric ion is predominantly non-diffusible and binds to albumin and globulins.

The high lipophilicity of elemental mercury in solution in the body allows it to readily cross the blood–brain and placental barriers. In mice, the uptake of mercury across the placenta appears to increase as gestation progresses. Levels of mercury in the foetus are approximately 4 times higher after exposure to elemental mercury vapour than after mercuric chloride administration for mice and 10–40 times higher for rats. The transport of the mercuric ion is limited at the placental barrier by the presence of high-affinity binding sites.

Mercury distributes to all tissues and reaches peak levels within 24 h, except in the brain, where peak levels are achieved within 23 days. The longest retention of mercury after inhalation of mercury vapour occurs in

the brain. Japanese workers who died 10 years after their last exposure to elemental mercury vapours still had high residual levels of mercury in their brains.

While the primary organs of mercury deposition following inhalation exposure to elemental mercury vapours are the brain and kidney, the extent of deposition is dependent upon the duration of exposure and, to a greater extent, the concentration to which the organism is exposed.

The available evidence indicates that the metabolism of all forms of inorganic mercury is similar for humans and laboratory mammals. Once absorbed, elemental and inorganic mercury enter an oxidation–reduction cycle. Elemental mercury is oxidized to the divalent inorganic cation in the red blood cells and lungs. Evidence from animal studies suggests the liver as an additional site of oxidation. Absorbed divalent cation from exposure to mercuric mercury compounds can, in turn, be reduced to the metallic or monovalent form and released as exhaled elemental mercury vapour.

Elimination of mercury occurs primarily through the urine and faeces, with the expired air, sweat, and saliva contributing to a much lesser extent.

2.2 Toxicology studies

2.2.1 Acute toxicity

ECHA Registration Dossier 5169

In an acute oral toxicity study in rats of different age groups, the highest oral toxicity was found in the youngest group of rats (two-week-old sucklings) as indicated by the lowest LD₅₀ value of 35 mg/kg bw mercury chloride (26 mg Hg/kg bw). In six-week-old animals, a LD₅₀ of about 92 mg/kg bw HgCl₂ (78 mg Hg/kg bw) was determined, and in older animals (up to 54 weeks) the LD₅₀ values were only about 1.4 times higher than in sucklings (50 mg/kg bw HgCl₂ corresponding to 37 mg Hg/kg bw).

The LD₅₀ (rats) was higher than 2000 mg/kg for the test item MISCELA HY-TQS. Since only about 24.8% of mercury are included in the test item, this can be recalculated to > 496 mg/kg mercury.

A concentration level of 27 mg/m³ Hg was lethal in the majority of animals exposed by inhalation for 2 hours, but no death occurred in animals exposed only for 1 hour.

Limited information on acute dermal toxicity in rabbits indicated lethality after application of high dermal doses of mercury from ointments.

Mild to moderate morphological changes were observed in the kidneys of rats at lower oral dose levels in the range of 10.0 and 12.5 mg/kg bw (7.4 and 9.2 mg Hg/kg bw/d). Morphological changes in kidneys were also found in animals treated dermally with high doses of mercury.

Biochemistry revealed decreased levels of lactate dehydrogenase (LDH) activity and an increase in serum cholesterol and phosphorus, and hematology showed decreases in red blood cell parameters in the oral study.

2.2.2 Short term toxicity

ECHA Registration Dossier 5169

Repeated dose toxicity, oral:

Data on repeated dose toxicity by the oral route in animals are available. In a NTP study, mice and rats were administered orally by gavage for 2 weeks, 26 weeks or 2 years. The lowest LOAEL of 0.312 mg HgCl₂/kg bw/d (0.23 mg Hg/kg bw/d) was identified in the 26-week NTP study in rats based on effects on kidney weights and nephropathy. Results from the subsequent 2-year carcinogenicity study in rats revealed the lowest dose level of 2.5 mg/kg bw/d HgCl₂ (1.9 mg Hg/kg bw/d) representing also only a LOAEL based on morphological changes of nephropathy.

Repeated dose toxicity, dermal:

There is almost no information available on systemic toxicity resulting from repeated dermal exposure of animals. The evaluation of human

literature revealed some information about clinical findings in subjects using skin lightening creams containing mercuric ammonium chloride. It could be concluded that a urinary mercury concentration of 29 µg/l (range 0 -90 µg/l) must be regarded as a LOAEL based on established mercury induced nephrotic syndrome.

However, absorption through the skin is very limited [“... a very small amount of mercury (about 2% of what is taken up by the lungs) enters the body through the skin”], and thus systemic toxicity following repeated dermal exposure appears to be not of major concern.

Repeated dose toxicity, inhalation:

The biological effects of long-time low to moderate exposures to metallic mercury vapours under occupational settings were evaluated in depth by EuroChlor (2009):

It was concluded that with the exception of urinary excretion of N-acetyl-beta-D-glucosamidase (NAG) from the proximal tubular kidney cells, it seems from the review of scientific literature that effects on the central nervous system are the most sensitive indicator of Hg toxicity. It is considered that the toxic effects from high level exposure are sufficiently well known. Sufficient knowledge for defining reasonably tenable occupational exposure limits also seems to be in place. This is based on recent epidemiological studies on cohorts under current or historical low-level exposures. The conclusion of the author of this review, putting a particular emphasis on the latest Ellingsen et al studies encompassing the magnitude of reversibility after cessation or reduction of exposure, there are reasons to support a NOAEL (no adverse effect level) of 30 µg Hg/g creatinine.

2.2.3 Genotoxicity (including mutagenicity)

ECHA Registration Dossier 5169

In vitro and *in vivo* genotoxicity studies showed equivocal results.

2.2.4 Long term toxicity and carcinogenicity

ECHA Registration Dossier 5169

The evidence for a mutagenic or carcinogenic potential of Hg in both animal (oral exposure) and epidemiological studies (occupational inhalation exposure) is equivocal, and it is so far lacking in humans at low exposure concentrations < 50 µg/g creatinine in urine. The mutagenic or carcinogenic potential of Hg seems to be related to metal induced oxidative stress and thus, if a potential is present in humans, a threshold effects is hypothetically possible.

IARC (1993)

Metallic mercury is not classifiable as to its carcinogenicity to humans (Group 3)

2.2.5 Effects on reproduction

ECHA Registration Dossier 5169

Toxicokinetic animal data has shown that mercury does penetrate the placental barrier and accumulates in the foetus when the mother is exposed to metallic Hg vapour. Even though there are inter-species differences, limited epidemiological studies in humans show that there is a transfer from mother to foetus during Hg vapour exposure. Only a few epidemiological studies have been performed and these were mostly in the field of dentistry. As a whole, the limited data presently available provide no conclusive evidence for occupational exposure to mercury vapour being harmful to reproduction. There is no link to an increase in teratogenic or other adverse pregnancy outcomes.

2.2.6 Neurotoxicity/ delayed neurotoxicity, Special studies where available

European Union

Methylmercury is highly toxic especially to the nervous system. Methylmercury toxicity has been demonstrated at low exposure levels. In adults, the first effects at the lowest doses are nonspecific symptoms such as paresthesia, malaise and blurred vision. This may progress to cerebellar

ataxia (clumsiness or unsteadiness), dysarthria (speech disorder), constriction of the visual fields and loss of hearing. With increasing exposure there are signs such as constriction of the visual field, deafness, dysarthria and ataxia, and ultimately leading to coma and death.

Methylmercury exhibits severe neurodevelopmental effects. It passes both the placental barrier and the blood-brain barrier. The developing nervous system in unborn and newborn children is the most sensitive target organ. The effects can take place even at exposure levels where the mother remains healthy or suffers only minor symptoms due to mercury exposure. At lower exposure levels, the effects may only become apparent later during the development as psychomotor and mental impairment and persistent pathological reflexes. In infants exposed to high levels of methylmercury during mothers pregnancy, the clinical picture can be indistinguishable from cerebral palsy caused by other factors, the main pattern being microcephaly, hyperreflexia and gross motor and mental impairment, and in rare cases, blindness or deafness. Some studies suggest even small increases in methylmercury exposures may cause adverse effects on the cardiovascular system, thereby leading to increased mortality.

The examples of mercury poisoning in Japan and Iraq have shown on a population scale the severe neurological effects of methylmercury to humans.

ECHA Registration Dossier 5169

Marked cellular degeneration and widespread necrosis were observed in the brains of rabbits following exposures to elemental mercury vapour at 28.8 mg/m³ for durations ranging from 2 to 30 h, whereas exposure of rabbits to mercury vapour at 6 mg/m³ for periods ranging from 1 to 11 weeks produced effects ranging from mild, unspecified pathological changes to marked cellular degeneration and some necrosis in the brain. More serious degenerative changes were observed at longer exposure durations (i.e., 8 and 11 weeks). Mild to moderate pathological changes were observed in the brains after exposure to 0.86 mg/m³ for 12 weeks. Slight tremors and clonus were observed in two of six rabbits exposed for 13 weeks to an elemental mercury vapour concentration of 4 mg/m³. Neurobehavioural deficits were also observed in the offspring of mother monkeys and rats that were exposed to mercury vapours during gestation. Exposure of neonatal rats to elemental mercury vapour at 0.05 mg/m³ for 1 or 4 h/day for 1 week during a period of rapid brain growth (postpartum days 11–17) resulted in subtle behavioural changes when the rats were tested at 4 and 6 months of age. The severity of effect was directly related to the duration of individual exposures.

2.2.7 Summary of mammalian toxicity and overall evaluation

WHO 2021

Elemental mercury and methylmercury are toxic to the central and peripheral nervous system. The inhalation of mercury vapour can produce harmful effects on the nervous, digestive and immune systems, lungs and kidneys, and may be fatal. The inorganic salts of mercury are corrosive to the skin, eyes and gastrointestinal tract, and may induce kidney toxicity if ingested. Neurological and behavioural disorders may be observed after inhalation, ingestion or dermal application of different mercury compounds. Symptoms include tremors, insomnia, memory loss, neuromuscular effects, headaches and cognitive and motor dysfunction. Mild subclinical signs of central nervous system toxicity can be seen in workers exposed to an elemental mercury level in the air of 20 µg/m³ or more for several years. Kidney and immune effects have been reported. There is no conclusive evidence linking mercury exposure to cancer in humans. Children are especially vulnerable and may be exposed directly by eating contaminated fish. Methylmercury bioaccumulated in fish and consumed by pregnant women may lead to neurodevelopmental problems in the developing foetus. Transplacental exposure is the most dangerous,

as the fetal brain is very sensitive. Neurological symptoms include intellectual disability, seizures, vision and hearing loss, delayed development, language disorders and memory loss. In infants and young children, a condition called acrodynia (or “pink disease”), characterized by red and painful extremities with local swelling and intense itching, and which can be accompanied by insomnia, irritability, and sensitivity to light, has been reported to result from chronic mercury exposure

3. Human exposure/risk evaluation

3.1 Food

WHO (2003)

Eating contaminated fish and shellfish is the main source of methylmercury exposure, especially in populations that rely heavily on consumption of predatory fish. Cooking does not eliminate mercury from fish. FAO and WHO guidance exists for national food safety authorities to assess the net health benefits or risks of fish consumption, taking into account the existing information on the benefits of eating fish

3.2 Air

Colombia

Studies conducted in Colombia by the Government of Antioquia in the municipalities of Segovia and Remedios, in the Northeast of the department, found a concentration of mercury of approximately 340 µg/m³ in the air (300 times higher than the guideline of the World Health Organization for public maximum exposure to vapour of mercury).

WHO (2000)

The atmosphere and dental amalgam are the sole sources of exposure to mercury vapour, whereas the diet is the dominant source of methylmercury compounds.

Current levels of mercury in outdoor air, except for regional “hot spots”, are typically in the order of 0.005–0.010 µg/m³ and thus are marginal compared to exposure from dental amalgam. The exposure to mercury from outdoor air at these air levels is not expected to have direct effects on human health.

The LOAELs for mercury vapour are around 15–30 µg/m³.

Applying an uncertainty factor of 20 (10 for uncertainty due to variable sensitivities in higher risk populations and, on the basis of dose–response information, a factor of 2 to extrapolate from a LOAEL to a likely NOAEL), a guideline for inorganic mercury vapour of 1 µg/m³ as an annual average has been established. Since cationic inorganic mercury is retained only half as much as the vapour, the guideline also protects against mild renal effects caused by cationic inorganic mercury. Present knowledge suggests, however, that effects on the immune system at lower exposures cannot be excluded.

3.3 Water

Colombia

Studies conducted in Colombia by the Government of Antioquia in the municipalities of Segovia and Remedios, in the Northeast of the department, reported that approximately 26 to 6,118 ppm of Hg is discharged into rivers by miners in the region. Additionally, the main food of these communities is fish, which has been shown to be affected by the emission of mercury. Studies completed by Corantioquia, the University of Antioquia, and the University of Cartagena have revealed a concentration above 1.06 µg Hg/g in most of the species found in the rivers of the surrounding area.

3.4 Occupational exposure

Colombia

Occupational exposure is the most reported cause of mercury poisoning in Colombia, mining and quarrying occupations have the highest number of cases due to the use of mercury in gold mining. The most frequent notifiers of poisoning cases during the review period were Antioquia,

followed by Bogotá, Bolívar, Risaralda, Santander and Valle del Cauca. The highest percentage of intoxications reported were occupational, predominantly miners or stonemasons, with inhalation being the most frequent route of exposure.

3.5 Medical data contributing to regulatory decision

Colombia

According to the National Public Health Surveillance System - SIVIGILA, during 2010 and in the first half of 2011, 201 cases of mercury poisoning were reported in Colombia- 96% of the cases were of occupational or accidental origin as follows: 85% (n = 171) occupational, 11% (n = 22) accidental.

3.6 Public exposure

Colombia

Studies on populations with known exposures to mercury, including occupational and general population exposures, show a link between exposure and adverse health effects. The neuroepidemiological and toxicological study of the Surata river pollutants carried out in the mining population of that region raised the possible relationship of chronic exposure to mercury with the presence of neurological diseases. It was further reported that the inhabitants of southern Bolívar presented signs of mercury intoxication such as hand tremors, neurological disorders and visual problems, among others. In this region, frequent cases of congenital malformations have also been reported, although without evidence of association with mercury exposure.

3.7 Summary-overall risk evaluation

Colombia

Data in the Colombian notification includes extensive neuro-epidemiological studies in exposed populations (occupational and general population) and studies in different environmental compartments (freshwater, soil, sediment, biota, etc.) and food (fish). Mercury measurements have been made in humans, mainly in workers and communities surrounding mining activities or adjacent to riverine areas.

The evaluation established that mercury is a toxic substance, that when entering the human body produces disorders, mainly at the central nervous system level. The presence of mercury in the air, water, soil and food (mainly fish) in concentrations above the allowed limit has caused a serious public health problem in Colombia. Regions such as the Northeast of Antioquia, the South of Bolívar, Chocó, Santander, Nariño, Caldas, Vaupés carry out artisanal gold mining using mercury for the final extraction of gold from ore. Its use occurs in an indiscriminate and poorly controlled way that has caused environmental contamination and has affected people's health. Exposure to mercury is also increased in industrial areas that use this substance.

European Union

While the European Union's risk assessment was conducted in the context of the restriction on mercury-containing measuring devices intended for industrial and professional uses, it includes information on the risks associated with mercury that is not limited to those measuring devices and that could support the other Directives and Regulations that comprise the final regulatory action notified by the European Union.

According to the ECHA Committee for Risk Assessment (RAC) Opinion and its background document, mercury and its compounds are highly toxic to humans, ecosystems and wildlife, with amongst others serious chronic irreversible adverse neurotoxic and neurodevelopmental effects. The RAC opinion includes a PBT assessment for mercury-methylmercury concluding and equivalent level of concern in terms of persistency, due to mercury cycling and methylation versus demethylation rates under anaerobic conditions, as well as the clear potential for bioaccumulation and toxicity identified for methylmercury.

4. Environmental fate and effects

- | | | |
|--------------|--|--|
| 4.1 | Fate | European Union |
| | | Once released to the environment, mercury persists in the environment, where it circulates between air, water, sediments, soil and biota in various forms. Mercury can be transformed to methylmercury, the most toxic form, which biomagnifies especially in the aquatic food chain. |
| 4.1.1 | Soil | European Union |
| | | Mercury in soil is mostly bound to bulk organic matter and is susceptible to wash out in runoff only when attached to suspended soil or humus. Mercury has a long retention time in soil and as a result, the mercury accumulated in soil may continue to be released to surface waters and other media for long period of time, possibly hundreds of years. |
| 4.1.2 | Water | UNEP (2002) |
| | | From open ocean studies, it is apparent that elemental mercury, dimethylmercury and, to a lesser extent, methylmercury are common constituents of the dissolved mercury pool in deep ocean waters. In open ocean surface waters dimethylmercury is lacking, maybe as a result of decomposition in the presence of light and an additional potential loss via evaporation from the water surface. Results suggest that low oxygen conditions are not necessary for the formation of dimethylmercury in the open oceans. This contrasts with temperate lake waters where methylmercury is more commonly occurring than dimethylmercury. Studies in freshwater and estuarine environments have shown that methylation of mercury is primarily taking place under low oxygen conditions and mainly by sulphate-reducing bacteria. Here methylmercury is the product of methylation of ionic mercury. |
| 4.1.3 | Air | European Union |
| | | Once released into the atmosphere, mercury can undergo long-range atmospheric transport, hence the atmosphere is the most important pathway for the worldwide dispersion and transport of mercury in the environment. Elemental mercury in the atmosphere can undergo transformation into inorganic mercury forms, providing a significant pathway for deposition of emitted elemental mercury. Mercury vapour has an atmospheric residence time that is between 0.4 and 3 years. Emitted mercury vapour is converted to soluble forms, these soluble forms have residence times of a few weeks. Soluble forms of mercury are deposited by rain into soil and water. |
| 4.1.4 | Bioconcentration | European Union |
| | | The bioconcentration factor (BCF) of methylmercury in fish can range from 8140 to 85 700. Methylmercury' biomagnification is very high with a typical increase of more than 1 log unit between trophic levels, and the bioaccumulation factor BAF can reach values 10^7 times higher than the concentration measured in water. |
| 4.1.5 | Persistence | European Union |
| | | Elemental mercury can be considered persistent, as it is not removed from the environment through degradation processes and will always be potentially available for cycling into methylmercury (through complex processes under appropriate conditions, even at equilibrium there is a near constant level of methylmercury in sediment). Any increase in the environmental pool of inorganic mercury will provide an additional source of methylmercury, and this source will persist for many years. |
| 4.2 | Effects on non-target organisms | N/A |
| 4.2.1 | Terrestrial vertebrates | European Union |

As in humans, mercury exposure of animals may result in severe neurological effects. These effects were clearly seen in the Minamata poisoning, where birds experienced severe difficulties in flying, and domestic animals, especially cats, showed signs of severe neurological intoxication. In birds, methylmercury has been associated with eggshell thinning in the 1950's and 1960's. Methylmercury was used as a fungicidal seed dressing, and severe poisoning of wildlife was observed in Scandinavia and North America. Populations of pheasants and other seed-eating birds, as well as birds of prey were drastically reduced and, in some areas, nearly disappeared. Adverse effects of mercury on reproduction can occur at egg concentrations as low as 0.05 to 2.0 mg/kg (wet weight). Eggs of certain Canadian species were reported to be in this range, and concentrations in the eggs of several other Canadian species were said to continue to increase and were approaching these levels.

4.2.2 Aquatic species

European Union

To adult fish, direct exposure to methylmercury from the surrounding water is generally not a serious concern. However, evidence suggests that mercury exposure to early life stages of some fish can affect growth, development and hormonal status at levels within a factor of 10 of levels encountered in "pristine" lakes. Effects from indirect exposure via dietary uptake and maternal transfer of methylmercury to eggs and developing embryos might be of concern.

4.2.3 Honeybees and other arthropods

A bioassay conducted with the worm *Eisenia foetida*, to determine the toxicity of mercury, added as methyl mercury, reported a NOEC of 2.3 mg/kg dry wt (nominal result). This NOEC could be considered as being a NOEC for inorganic mercury due to the long test duration, the volatility of methyl mercury and the data on the behaviour of mercury in the soil.

4.2.4 Earthworms

Not available

4.2.5 Soil microorganisms

European Union

Mercury is toxic to micro-organisms and has long been used to inhibit the growth of bacteria in laboratory experiments. Evidence suggests that mercury is responsible for a reduction of micro-biological activity vital to the terrestrial food chain in soils over large parts of Europe – and potentially in many other places in the world with similar soil characteristics.

4.2.6 Terrestrial plants

UNEP (2002)

Terrestrial plants are fairly insensitive to the toxic effects of mercury compounds. Mercury is, however, accumulated in higher plants, especially in perennials. The primary effect observed in plants is associated with root tips.

5. Environmental exposure/risk evaluation

5.1 Terrestrial vertebrates

UNEP (2002)

On the global scale, the Arctic region has been in focus because of mercury's particular tendency to long-range transport. It is important to acknowledge, however, that impacts of mercury are by no means restricted to the Arctic region. The same food web characteristics and similar dependence on a mercury contaminated food source are found in specific ecosystems and human communities in many countries around the world, particularly where a fish diet is predominant. Consequently, fish-eating birds and mammals are more highly exposed to mercury than any other known denizens of the aquatic ecosystem.

5.2 Aquatic species

European Union

The elimination of methylmercury from fish is very slow, which causes fish to accumulate methylmercury over time. Moreover, methylmercury biomagnifies throughout the many aquatic trophic levels. The highest

		levels in the aquatic food web are found in fish that are apical predators of older age (such as king mackerel, pike, shark, swordfish, walleye, barracuda, large tuna, scabbard, and marlin) and fish-consuming mammals such as seals and toothed whales.
5.3	Honeybees	Not available
5.4	Earthworms	Not available
5.5	Soil microorganisms	Not available
5.6	Summary – overall risk evaluation	<p>European Union</p> <p>Mercury occurs both naturally and as an introduced contaminant in the environment. Anthropogenic emissions have widespread impacts on human and environmental health.</p> <p>Mercury is a global pollutant that cannot be broken down in the environment to any harmless form. Once emitted, mercury enters the complex biogeochemical cycle. After intensive use of mercury over many years mercury can be found in almost all environmental compartments, like the atmosphere, soil and water systems and in biota all over the world. The formation of methylmercury and subsequent biomagnification in food chains considerably increases risks posed by mercury causing, among others, chronic intoxications of people, although it is difficult to determine the proportion of mercury contaminating the environment, which is turned into methylmercury. Therefore, it is necessary to reduce the risk of exposure to mercury for humans and the environment. The key, long term benefit of reducing mercury emissions will be decreased levels of mercury in the environment. This, in turn, will lead to lower levels of human exposure to mercury, including methylmercury in fish, with resultant health benefits. It will also reduce the impacts of mercury on soils and biodiversity.</p>

Annex 2 to the decision guidance document: Details on final regulatory actions reported

Colombia

1. **Effective date(s) of entry into force of actions** 15 July 2013

Reference to the regulatory document Ley 1658 de 2013 (Anexo I)
DIARIO OFICIAL AÑO CXCLIX. N. 48.852. 15, JULIO, PAG.6
<http://www.suin-juriscol.gov.co/viewDocument.asp?ruta=Leyes/1685943>
2. **Succinct details of the final regulatory action(s)** Based on Law 1658 of 15 July 2013, the government of Colombia prohibited the marketing and use of mercury. The regulation eradicates the use of mercury in the national territory in: 1) all industrial and production processes within a period not exceeding 10 years (till 15 July 2023), and 2) for mining within a maximum period of 5 years (till 15 July 2018). Currently the deadline for industrial uses other than mining has not been met; this is the reason why the use of mercury in the production of dental amalgam will continue until 15 July 2023.
3. **Reasons for action** The government of Colombia prohibited the marketing and use of mercury under Law 1658 of 15 July 2013. It was determined that in order to protect and safeguard the human health and preserve renewable natural resources and the environment, the use, import, production, marketing, handling, transportation, storage, final disposal and release into the environment of mercury in industrial activities, whatever they may be, must be regulated throughout the national territory.

Specifically, Article 3 of the law establishes the measures to reduce and eliminate the use of mercury in the country as follows: "Article 3. Reduction and elimination of the use of mercury. The Ministries of Environment and Sustainable Development; Mines and Energy; Health and Social Protection and Work, will establish the necessary regulatory measures that will allow to reduce and eliminate, in a safe and sustainable way, the use of mercury in the different industrial activities of the country. Eradicate the use of mercury throughout the national territory, in all industrial and productive processes within a period not exceeding ten (10) years and for mining within a maximum period of five (5) years.
4. **Basis for inclusion into Annex III** The final regulatory action was taken to protect human health and the environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in Colombia.
- 4.1 **Risk evaluation** According to the evaluation related to human health and the environment, the following information was identified (UNEP/FAO/RC/CRC.19/11 and UNEP/FAO/RC/CRC.19/INF/24):
 - (a) The data includes extensive neuro-epidemiological studies in exposed populations (occupational and general population) and studies in different environmental compartments (freshwater, soil, sediment, biota, etc.), food (fish), with a view of establishing the levels of mercury and the perception of risk, and generating scientific, regulatory and technical evidence on the mercury problem both at the national and international level of the health sector and other related sector. Mercury measurements have been made in humans, mainly in workers and communities surrounding mining activities or adjacent to riverine areas.
 - (b) The evaluation conducted establish that mercury is a toxic substance, that when entering the human body produces disorders, mainly at the central nervous system level. The presence of mercury in the air, water, soil and food (mainly fish) in concentrations above the allowed limit has caused a serious public health problem in Colombia. Regions such as the Northeast of Antioquia, the South of Bolívar, Chocó, Santander, Nariño, Caldas, Vaupés, among others, carry out artisanal gold mining and for the final extraction of this precious metal, mercury is used. Its use occurs in an indiscriminate and poorly controlled way, a situation that has caused environmental

contamination and has affected people's health. Exposure to mercury is also increased in industrial areas that use this substance.

- (c) Studies conducted by the Government of Antioquia in the municipalities of Segovia and Remedios, in the Northeast of the department, found a concentration of mercury of approximately 340 µg/m³ in the air (300 times higher than the guideline of the World Health Organization for public maximum exposure to vapour of mercury).
- (d) Approximately 26 to 6,118 ppm of Hg is discharged into rivers by miners in the region. Additionally, the main food of these communities is fish, which has been shown to be affected by the emission of mercury. Studies completed by Corantioquia, the University of Antioquia, and the University of Cartagena have revealed a concentration above 1.06 µg Hg/g in most of the species found in the rivers of the surrounding area.
- (e) Mercury contamination in Colombia is mostly caused by its use in the extraction of gold from ore. In this process, elemental mercury is added to gold containing ores and minerals to form a gold amalgam. Mercury used this way may spill into water bodies and the environment. Subsequently, the gold amalgam is recovered and burned in the open air to extract the gold, which release toxic mercury vapours into the atmosphere. All these activities are performed very close to the miners' households, in such a way that families breathe a large part of the volatilized mercury vapour. Even remote populations can be affected by the mobilization of this substance (Protocol for Surveillance and Control of Acute Mercury Poisoning. INF/30, Annex III).
- (f) Studies on populations with known exposures to mercury, including occupational and general population exposures, show a link between exposure and adverse health effects (Fawer et al 1983, Piikivi 1989, Marh et al 1987). The neuroepidemiological and toxicological study of the Suratá river pollutants carried out in the mining population of that region (Santander, 1992) raised the possible relationship of chronic exposure to mercury with the presence of neurological diseases. Tirado et al (2000) suggest that this form of exposure can cause neuropsychological and behavioural deficits in the population. In 1995, Olivero et al reported that the inhabitants of southern Bolívar presented signs of mercury intoxication such as hand tremors, neurological disorders and visual problems, among others. In this region, frequent cases of congenital malformations have also been reported, although without evidence of association with mercury exposure.
- (g) According to National Public Health Surveillance System - SIVIGILA, during 2010 and in the first half of 2011, 201 cases of mercury poisoning were reported in Colombia- 96% of the cases were of occupational or accidental causes as follows: 85% (n = 171) occupational, 11% (n = 22) accidental.
- (h) Occupational exposure is the most reported cause of mercury poisoning in Colombia. Mining and quarrying occupations have the highest number of cases due to the use of mercury in gold mining. The most frequent notifiers of poisoning cases during the review period were Antioquia, followed by Bogotá, Bolívar, Risaralda, Santander and Valle del Cauca. The highest percentage of intoxications reported were occupational, predominately miners or stonemasons, with inhalation being the most frequent route of exposure (Scientific, Regulatory and Technical Evidence on the Mercury Problem at the Level National and International Health Sector and Other Related Sectors. Revision Systematics of Literature, INF/30, Annex IV).
- (i) Some population groups may need special consideration in relation to exposure to mercury, since they have a greater probability of exposure to dangerous levels, or because carriers of disease, the intoxication effects can be exacerbated:
 - (i) Workers exposed to mercury;

- (ii) General population next to sources of mercury contamination (mines, industries);
 - (iii) Populations in areas contaminated by mercury, especially indigenous and riverine, whose main source of proteins is fish;
 - (iv) People using mercury-containing medications for a long time;
 - (v) People with central nervous system diseases, patients with chronic kidney and bronco pulmonary failure;
 - (vi) Pregnant women and toddlers.
- 4.2 Criteria used** Risks to human health and the environment.
- Relevance to other States and Region** The notification states that mercury can be used in other countries for the manufacture of products with added mercury and in gold extraction, mainly in developing countries. Therefore, the considerations leading to the final regulatory action being taken are expected to be applicable to other geographical area where mercury is used in similar conditions.
- 5. Alternatives** None reported
- 6. Waste management** None reported
- 7. Other** None reported

European Union

- 1. Effective date(s) of entry into force of actions**
- (a) Directive 2006/66/EC entered into force on 26 September 2006;
 - (b) Directive 2007/51/EC started to apply on 3 April 2009;
 - (c) Commission Regulation (EC) No 552/2009 entered into force 27 June 2009;
 - (d) Directive 2011/65/EU entered into force 21 July 2011;
 - (e) Commission Regulation (EU) No 847/2012 started to apply on 10 April 2014;
 - (f) Regulation (EU) 2017/852 entered into force on 13 June 2017.
- Reference to the regulatory document**
- 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.
<http://data.europa.eu/eli/dir/2006/66/2018-07-04>
- Directive 2007/51/EC of the European Parliament and of the Council of 25 September 2007 amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury.
<http://data.europa.eu/eli/dir/2007/51/oj>
- Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII.
<http://data.europa.eu/eli/reg/2009/552/oj>
- Commission Regulation (EU) No 847/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury.
<http://data.europa.eu/eli/reg/2012/847/oj>
- 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.
<http://data.europa.eu/eli/dir/2011/65/2020-09-01>
- 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.
<http://data.europa.eu/eli/reg/2017/852/oj>
- Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009L0048>
- 2. Succinct details of the final regulatory action(s)**
- The use of mercury as an industrial chemical is severely restricted in the European Union pursuant to Regulation (EU) 2017/852 on mercury, Regulation (EC) 1907/2006 (REACH), Directive 2011/65/EU (RoHS) and Directive 2006/66/EC (batteries and accumulators). More specifically:
- (a) In 2006, Directive 2006/66/EC introduced a prohibition on the placing on the market of batteries and accumulators containing mercury;
 - (b) In 2007, Directive 2007/51/EC introduced a restriction under Directive 76/769/EEC on the placing on the market of mercury in fever thermometers and in other measuring devices intended for sale to the general public;
 - (c) Regulation (EC) No 1907/2006 (REACH) repealed Directive 76/769/EEC. Commission Regulation (EC) No 552/2009 amended Annex XVII to REACH by incorporating in entry 18.a the restrictions on certain

measuring devices containing mercury that was adopted under Directive 2007/51/EC;

- (d) In 2011, Directive 2011/65/EU (RoHS) established a restriction on the placing on the market of electric and electronic equipment to a maximum concentration value of 0.1% of mercury, allowing exemptions for certain applications for a limited time period;
- (e) Commission Regulation (EU) No 847/2012 amended Annex XVII to REACH by incorporating in entry 18.a. a restriction on the placing on the market of mercury-containing and mercury- using measuring devices intended for industrial and professional uses. The restriction started to apply from 10 April 2014;
- (f) Regulation (EU) 2017/852 on mercury was adopted in May 2017. This regulation complements the European Union *acquis* and lays down the provisions that are needed to ensure the complete alignment of the European Union *acquis* with the Minamata Convention on Mercury establishing measures and conditions concerning the use and storage of and trade in mercury, mercury compounds and mixtures of mercury, and the manufacture and use of and trade in mercury-added products, and the management of mercury waste.
- (g) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. Toys must be designed and constructed so that there is no risk of harmful effects on human health due to exposure to substances, including mercury, of which the toys are made or which are contained in them.

- 3. Reasons for action** The final regulatory action has been taken in order to protect human health and the environment and further explains that mercury is a chemical of global concern owing to its long-range atmospheric transport, its persistence in the environment once anthropogenically introduced, its ability to bioaccumulate in ecosystems and its significant negative effects on the environment and on human health, which include significant adverse neurological and other health effects, with particular concerns expressed about its harmful effects on infants and unborn children. Mercury can be transformed to methylmercury, the most toxic form, which biomagnifies especially in the aquatic food chain, making populations and wildlife with a high intake of fish and seafood particularly vulnerable.
- 4. Basis for inclusion into Annex III** The final regulatory action was taken to protect human health and the environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions of use of mercury in the European Union.
- 4.1 Risk evaluation** According to the evaluation related to human health and the environment, the following information was identified (UNEP/FAO/RC/CRC.19/11 and UNEP/FAO/RC/CRC.19/INF/22):
- (a) While this risk assessment was conducted in the context of the restriction on mercury-containing measuring devices intended for industrial and professional uses, it includes information on the risks associated with mercury that is not limited to those measuring devices and that could support the other Directives and Regulations that comprise the final regulatory action notified by the European Union;
 - (b) According to the ECHA Committee for Risk Assessment (RAC) Opinion and its background document, mercury and its compounds are highly toxic to humans, ecosystems and wildlife, with amongst others serious chronic irreversible adverse neurotoxic and neurodevelopmental effects. The RAC opinion does not explicitly conduct a PBT assessment for mercury-methylmercury, but it does note that it should be considered with an equivalent level of concern in terms of persistency, due to mercury cycling and methylation versus demethylation rates under anaerobic conditions, as well as the clear potential for bioaccumulation and toxicity identified for methylmercury;

- (c) The hazard and fate of mercury and its compounds are described in numerous peer-reviewed reports, which were referenced in the Documentation provided:
- (i) 'Global Mercury Assessment', published by UNEP in 2002 (and UNEP 2008a and b);
 - (ii) 'Methylmercury' (WHO, 1990);
 - (iii) 'Risks to Health and the Environment Related to the Use of Mercury Products' prepared for the Commission by RPA in 2002;
- (d) It is estimated that 3.5–7.6 tonnes of mercury are placed on the market in mercury containing measuring devices in 2010. These amounts are used to estimate the maximum potential for mercury emissions to the environment that might ultimately occur. This assumption is considered appropriate because of an estimated low separate collection rate of mercury waste and resulting inadequate waste treatment of a substantial part of the devices. This inappropriate waste collection leads in the long term to a relatively high share of mercury used in these devices being released to the environment. For measuring equipment using mercury (porosimeters, mercury probes used for capacitance-voltage determinations and mercury electrodes used in voltmeters) the total use is 5–15 tonnes per year (mostly porosimeters 5–14 tonnes per year). It should be noted that these figures are the amount of mercury the laboratories purchase and cannot be used to estimate maximum potential for emission as is the case for the measuring equipment containing mercury. To estimate emissions several additional factors need to be considered. These include number of measurements carried out, practices to purify and regenerated used mercury and the risk management measures and operational conditions applied to control the emissions and exposures;
- (e) The total mercury consumption in Europe was in 2007 estimated to be 320–530 tonnes. 160–190 tonnes of the total amount were used in the chlor-alkali production and 90–110 were used in dental amalgams. The amount used in mercury measuring devices thus equals about 4% of the total, while the restricted devices will be lower due to the large use in porosimeters;
- (f) Once released to the environment, mercury persists in the environment, where it circulates between air, water, sediments, soil and biota in various forms. Mercury can be transformed to methylmercury, the most toxic form, which biomagnifies especially in the aquatic food chain, making populations and wildlife with a high intake of fish and seafood particularly vulnerable;
- (g) Several existing pieces of legislation in the European Union abate the risks arising from mercury in different stages of the life cycle of measuring devices. However, none of the measures currently in place is sufficient to remove the concern fully, although there is a difference between their observed effectiveness with regard to measuring devices containing mercury and measuring devices using mercury;
- (h) The emissions from mercury measuring devices, although relatively small, contribute to the overall emissions of mercury to the environment and thereby also to the exposure of species and of humans via the environment. Therefore, measuring devices containing or using mercury are of concern.

4.2	Criteria used	Risks to human health and the environment
	Relevance to other States and Region	The notification states that similar human health and environmental problems are likely to be encountered in other regions where the substance is used, particularly in developing countries and especially for women and children, and, through them, future generations.
5.	Alternatives	None reported.

- 6. Waste management** Regulation (EU) 2017/852 on mercury was adopted in May 2017. This regulation complements the European Union *acquis* and lays down the provisions that are needed to ensure the complete alignment of the European Union *acquis* with the Minamata Convention on Mercury establishing measures and conditions concerning the use and storage of and trade in mercury, mercury compounds and mixtures of mercury, and the manufacture and use of and trade in mercury-added products, and the management of mercury waste.
- 7. Other** None reported.

Annex 3 to the decision guidance document: Addresses of designated national authorities

Colombia

<p>Rotterdam Convention Designated national authority for industrial chemicals (DNA C)</p> <p>Name: Ms. Andrea Patricia Soler Galindo Job title: Coordinadora Grupo Desarrollo y Salud Department: Subdirección de Salud Ambiental Institution: Ministerio de Salud y Protección Social</p>	<p>Postal address: Carrera 13 # 32 - 76 Piso 14, Edificio Urano Bogotá D.C. Colombia Phone: +57 1 330 5000 ext. 1241 Email: asoler@minsalud.gov.co; jhernandez@minsalud.gov.co</p>
--	--

European Union

<p>Rotterdam Convention Designated national authority for industrial chemicals and pesticides (DNA CP), Rotterdam Convention Official contact point (OCP).</p> <p>Name: Mr. Juergen Helbig Job title: International Chemicals Policy Coordinator Department: DG Environment, Unit ENV.B2 - Safe and Sustainable Chemicals Institution: European Commission</p>	<p>Postal address: 1049 Brussels Belgium Phone: +32 2 298 8521 Fax: +32 2 298 8874 Email: juergen.helbig@ec.europa.eu</p>
---	---

C Industrial chemicals

CP Pesticides and industrial chemicals

P Pesticides