

Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on
mercury in measuring devices

ECHA/RAC/RES-O-0000001363-81-02/F

Adopted

8 June 2011

08 June 2011
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**Opinion of the Committee for Risk Assessment
on an Annex XV dossier proposing restrictions of the manufacture, placing
on the market or use of a substance within the Community**

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s): *Mercury*
EC No.: *231-106-7*
CAS No.: *7439-97-6*

This document presents the opinion adopted by RAC. The Background document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINIONS

EUROPEAN CHEMICALS AGENCY (ECHA) has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The dossier conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/consultations/restrictions/ongoing_consultations_en.asp on *24 September 2010*. Interested parties were invited to submit comments and contributions by *24 March 2011*.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: *Frank JENSEN*
Co-rapporteur, appointed by RAC: *Boguslaw BARANSKI*

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on *8 June 2011*.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted *by consensus*.

OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document (Annex I).

RAC considers that the proposed restriction on *Mercury in measuring devices* is the most appropriate Community wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the scope and/or conditions are modified.

Mercury, CAS number: 7439-97-6, EC number: 231-106-7

Conditions:

The following restrictions with derogations are proposed for mercury measuring devices in professional and industrial uses. They do not affect the existing restriction on mercury in measuring devices intended for sale to general public and on mercury in fever thermometers established in entry 18a of Annex XVII to the REACH Regulation.

1. Mercury containing barometers, hygrometers, manometers, sphygmomanometers, strain gauges to be used with plethysmographs, tensiometers, thermometers and other non-electrical thermometric applications shall not be placed on the market after [18 months of the entry into force]. This applies also to measuring devices placed on the market empty intended to be filled with mercury.
2. The restriction in paragraph 1 shall not apply to:
 - (a) Sphygmomanometers to be used (i) in epidemiological studies which are on-going at entry into force; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers.
 - (b) Thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until [5 years after the entry into force].
 - (c) Mercury triple point cells that are used for the calibration of platinum resistance thermometers.
3. Mercury pycnometers and mercury metering devices for determination of the softening point shall not be placed on the market after [18 months of the entry into force].
4. The restrictions in paragraphs 1 and 3 shall not apply to measuring devices which are to be displayed in exhibitions for cultural and historical purposes.

JUSTIFICATION FOR THE OPINION

The opinion covers restriction proposals for a number of mercury measuring devices¹, with the aim to reduce the amount of mercury in our society.

Restrictions without device specific derogations are proposed for the placing on the market of mercury containing barometers, hygrometers, manometers, tensiometers, strain gauges and of mercury using pycnometers and meters for the determination of the softening point.

Restrictions with limited derogations for the placing on the market are proposed for sphygmomanometers and thermometers, while no restrictions are proposed for mercury using porosimeters, mercury probes used for capacitance-voltage determinations and electrodes.

“Placing on the market” in these restrictions includes not only placing on the market for the first time, i. e. second-hand market is included. There is no proposal to restrict the use of mercury measuring devices that are already placed on the market.

Based on the information received during the public consultation on the Annex XV restriction report, RAC suggests that the proposed restriction would not apply to measuring devices which are to be displayed in exhibitions for cultural and historical purposes. This derogation would replace the proposed derogation in the Annex XV restriction report for measuring devices that are more than 50 years old on 3 October 2007.

Identified hazard and risk

Mercury is a very hazardous substance. Mercury is highly toxic to humans, ecosystems and wildlife, in particular when chemically converted to methylmercury. The nervous system and the developing brain are the most sensitive target organs.

Mercury is found both naturally and as an introduced contaminant in the environment. Anthropogenic emissions have widespread impacts on human and environmental health. Mercury is considered to be a global persistent pollutant; in the environment it cannot be broken down 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.

¹ The term “mercury measuring devices” is used throughout this document to cover both, measuring devices containing mercury and measuring devices using mercury.

According to the EU Community strategy concerning mercury most people in coastal areas of Mediterranean countries, and around 1-5% of the population in central and northern Europe, show bioindicators of exposure that are around internationally accepted safe levels for methylmercury and large numbers among Mediterranean fishing communities and the Arctic population exceed them significantly.

Although the Background Document to this Opinion underlines that mercury as an element is persistent and that methylmercury bioaccumulates, biomagnifies, and is highly toxic, it does not explicitly compare these properties of mercury with the PBT criteria of Annex XIII to REACH. However, the following comparison is made in the Opinion document on phenylmercury compounds²

The inorganic form of mercury is not covered by Annex XIII. Elemental mercury is by definition 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. It is therefore not relevant to compare half-life data with the Annex XIII “P” criterion. Mercury cycling itself represents an equivalent level of concern for persistence (or even “very persistent”). Furthermore, rate of demethylation can be under anaerobic conditions lower than methylation.

The “B” criterion of Annex XIII is met by methylmercury as the bioconcentration factor (BCF) in fish can range from 8140 to 85 700 and is thus higher than the threshold value for bioaccumulative and very bioaccumulative. Methylmercury’ biomagnification is very high with a typical increase of more than 1 log unit between trophic levels, and bioaccumulation factor BAF can reach values 10^7 times higher than the concentration measured in water (Hill *et al.*, 1996; Weiner *et al.*, 2003).

The “T” criterion of Annex XIII is met by methylmercury which NOEC is 0.26 µg Hg /l which is 2 orders of magnitude below the threshold value of 10 µg/l. The classification of methylmercury and mercury for reproductive toxicity category 1B and 1A respectively also confirm this criterion.

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. The Arctic is believed to be a global sink of mercury due to a set of extraordinary circumstances occurring during Polar spring. Certain indigenous communities, for example in the Arctic, have been shown to be particularly vulnerable due to high levels of deposition and accumulation of methylmercury in their traditional foods (even though they use and emit virtually no mercury).

The global threat from mercury releases warrants action at local, national, regional and global level. There is now a world-wide common effort to reduce both demand and supply of mercury. In 2009, the UN Environment Governing Council agreed to take steps towards a global legally binding instrument to control uses and emissions of mercury. The Council of the European Union supports this step towards an international treaty.

² http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp

The European Union has launched an EU mercury strategy in 2005. It contains 20 measures to reduce mercury emissions, cut supply and demand. Two of the measures are:

“Action 7. The Commission intends to propose in 2005 an amendment to Directive 76/769/EEC to restrict the marketing for consumer use and healthcare of non-electrical or electronic measuring and control equipment containing mercury

Action 8. The Commission will further study in the short term the few remaining products and applications in the EU that use small amounts of mercury. In the medium to longer term, any remaining uses may be subject to authorisation and consideration of substitution under the proposed REACH Regulation, once adopted”.

The Strategy has resulted in restrictions on the placing on the market for the general public of measuring devices containing mercury. In this restriction (Annex XVII, entry 18a, of the REACH Regulation) there is a review clause which states: *“[The Commission] shall carry out a review of the availability of reliable safer alternatives that are technically and economically feasible.”*

The current proposal of restriction of mercury in measuring devices and present Annex XV dossier is the result of this review clause.

RAC recognises this as unusual starting point for an opinion. Therefore the proposal and therefore also this opinion has focussed on the technical feasibility of the alternatives with their hazards, exposures and risks being compared with those of mercury in semi-quantitative and qualitative terms.

It is estimated that 3.5 to 7.6 tonnes of mercury is 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.

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.

Justification that action is required on a Community-wide basis

RAC considers that it is justified that the proposed restriction needs to be on a Community-wide basis.

The mercury measuring devices containing mercury are used widespread across the EU countries. Emissions come from daily use and waste handling. Mercury is volatile at low temperature and can easily be transported over long distances both through air and biota.

The main reason to act on a Community-wide basis is the cross-boundary human health and environmental problem. Furthermore, the fact that the goods need to circulate freely within the EU stresses the importance of the Community-wide action, as some Member States have already national restrictions for mercury measuring devices. Thus, the use of mercury in these devices needs to be controlled also at the EU level. In addition, acting at Community level strengthens the possibilities to address the adverse impacts of mercury at worldwide level.

Justification that the suggested restriction is the most appropriate Community-wide measure

Restriction of use of mercury in selected measuring devices is a part of EU strategy to reduce use of mercury, particularly it is a result of the action undertaken in response to a review clause built into the current entry 18a for mercury in Annex XVII to REACH.

RAC considers the proposed community wide restrictions to be necessary and appropriate. It reduces the risk of exposure to mercury for both man and the environment. Implementation of this restriction will considerably reduce the amount of mercury in measuring devices in professional and industrial uses being introduced on the EU market. The risks associated with alternative measuring devices without mercury are considered to be significantly lower than health and environmental risks posed by mercury in mercury measuring devices.

RAC is of the opinion that the proposed restriction will reduce effectively the amount of mercury being released into environment from mercury measuring devices, contribute to reduction of the level of environmental or occupational exposure to mercury of humans and environmental biota and it will increase a use of alternative measuring devices posing substantially smaller risk to humans and environment than measuring devices containing mercury.

Mercury measuring devices proposed to be restricted are small devices scattered in numerous workplaces of various types, and assuring an appropriate collection and management of wastes is difficult. The currently used risk management measures (RMM) applied on voluntary and mandatory basis were found not sufficiently effective in preventing continuous increase of mercury level in the environment and in the human, animal and plant tissues. Thus, the other risk management measures were not effective in controlling health and environmental risks posed by mercury.

Mercury measuring devices are not a major source of mercury release into the environment; however it has been demonstrated that there are alternative devices, which can replace the

devices containing mercury and the use of which is associated with risks to human health and environment substantially smaller than risks caused by mercury.

Several existing pieces of legislation 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. No other EU legislation which may have the potential of reducing the emissions and risks posed by mercury was identified.

The originally proposed exemption for mercury-in-glass thermometers used by industry to measure temperatures above 200°C is proposed to be deleted. It was originally proposed due to economic reasons – these reasons have been investigated further and SEAC reached a preliminary conclusion that the exemption is no longer necessary. RAC approves this removal of the exemption because the technically feasible alternatives pose substantially lower environmental and human health risks.

RAC would like to highlight the need for other Community-wide measures to improve the collection rate of mercury measuring devices already on the market and to take adequate measures for proper waste handling. An effective collection system for these devices is needed and requires cooperation with the EU authorities for waste legislation.

RAC would also highlight the need to address the production of mercury measuring devices intended for export out of the Community, as exposure will still arise from this production until measures are taken to address production intended for export (like the Regulation (EC) No 1102/2008).

Another issue RAC would highlight is the necessity for addressing the use of mercury in porosimeters. The amount used in is 5-14 t/y is by far the biggest use in measuring equipment and the uncertainties regarding recycling/reuse are large. Consequently, RAC urges the Commission to look into this within a very short period of time and if appropriate propose new legislative measures e.g. a long transitional period to allow users to adapt to a ban.

Effectiveness in reducing the identified risks, proportionality to the risks

The main purpose of the proposed restrictions is to reduce the mercury pool in the society, thus avoiding emissions and exposures causing negative impacts on human health and environment. Because of the well known and recognised properties of mercury, a quantitative exposure assessment or risk characterisation was not carried out. Instead, the total estimated amount of mercury placed on the market in measuring devices containing mercury is used to estimate the maximum potential for mercury *emissions to the environment* that might ultimately occur. The proposed restriction is expected to reduce the amount of mercury placed on the EU market (in devices or to be used in measurements) by 60 tonnes for a 20 year period starting from 2015³. It can be mentioned that this volume reduction would also decrease direct *exposure of workers* in production, use and waste phase -with the exception of exposure related to remaining production for exports. Table 1 summarises the risk reduction

³ Considering the estimates for the amounts of mercury used in products and processes in EU for 2010 (see section B.4 figure 1), the proposed restriction accounts for 1.5 % of the total use. However, the measuring devices account for 4 %, as the suggested restriction does not cover all the mercury measuring devices.

capacity of the proposed restriction for each device. As described above, the amounts of mercury placed on market annually are used to estimate the maximum emissions potential. Both estimates for the representative year (2024) and for the total effect of the 20 years (i.e. 2015-2034) are presented.

Table 1: Estimated amount of mercury not placed on the market as a result of the proposed restriction in 2015-2034 as well as in 2024

Device	2024 per annum kg	2015-2034 cumulative kg
Sphygmomanometers*	1 900	39 000
Thermometers (including hygrometers)*	500	10 000
Barometers**	350	7 000
Manometers (including tensiometers)**	200	4 000
Strain gauges**	14	280
Pycnometers***	~0	~0
Metering devices***	~0	~0
Total	2 964	60 280

Notes: * Number of the mercury containing devices projected to decline by 5% per annum as described in the device specific annexes 3a and 5a
 ** Assuming no change in the trend
 *** There does not seem to be remaining markets for these devices in the EU and thus, the estimated amount of mercury not placed on the market would be close to 0 kg

RAC agrees with the originally proposed restrictions except for:

1. The exemption for mercury-in-glass thermometers used in industry to measure temperatures above 200°C as technically sufficient alternatives with better environmental and human health properties already exist.
2. The wording of “Restriction on the placing on the market of plethysmographs designed to be used with mercury strain gauges”. This should be rephrased as the existing plethysmographs can be used without mercury. So the intention should be to only restrict the mercury containing strain gauges which could be reflected this way: “Restriction on the placing on the market of mercury containing strain gauges”.

According to Annexes 1-10, technically feasible alternatives are available for mercury barometers, hygrometers, manometers, sphygmomanometers, strain gauges, thermometers, pycnometers, and metering devices, with the exception of:

- sphygmomanometers that are used in on-going epidemiological studies or as reference standards in clinical validation studies of mercury-free sphygmomanometers;
- thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers; and
- mercury triple point cells that are used for the calibration of platinum resistance thermometers⁴.

⁴ Triple point cells are not thermometers, but they might fall under the broader wording that is used in the proposed restriction (*‘thermometers and other non-electrical thermometric applications containing mercury’*). For this reason they are discussed as well.

In addition, technical feasibility of alternatives could **not** be established for mercury porosimeters, mercury probes used for capacitance-voltage determinations and devices using mercury electrodes in voltammetry (see section 3.3 of Annex 7, annex 10 and Annex 6 respectively).

As shown in Annex C to the Background Document the alternatives to mercury used in measuring devices are of lower relative risk compared to mercury measuring devices. This is shown in table 3.

Table 3 Semi-quantitative comparison of risks related to mercury containing measuring devices and their alternatives

	Production	Service-life	Waste stage		
			Proper treatment	No proper treatment	
				Incineration	Landfill
Hg	3	3	3	4	4
Hg-free liquid	1-2*	1-2*	1-2**		
EEE	1-2***	1	1	2	2
mechanical	1	1	1****		

Notes 1 - negligible risk potential; 2 - low risk potential; 3 - moderate risk potential; 4 - high risk potential
 Hg - mercury containing measuring devices; Hg-free - measuring devices with mercury-free fillings;
 EEE - electronic measuring devices; mechanical - mechanical measuring devices.
 *Overall risk potential, depending on the properties and share of liquids replacing mercury containing measuring devices.
 ** Overall risk potential, depending on type of treatment (incineration or landfill), and the properties and share of liquids replacing mercury containing measuring devices. Waste not subject to separate collection requirements.
 *** As a rather conservative estimate.
 ****Waste not subject to separate collection requirements

Practicality, incl. enforceability

Bans of other mercury containing measuring equipment for the use of consumers have been in place without problems. Likewise bans on other articles is part of the Annex XVII of the REACH regulation. Enforceability will depend on the final legal text proposed by the Commission, but as other similar bans are in place the enforceability is regarded as easy to reach.

Monitorability

In addition to national reporting of enforcement success, notifications of any violation of the restrictions could be reported and could in that way be used to monitor the results of the implementation of the proposed restriction.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the Opinion.

The main change introduced in restriction(s) as suggested in this opinion compared to the restrictions proposed in the Annex XV restriction dossier submitted by *ECHA* is the deletion of the proposed exemption for mercury in glass thermometers used by industry to measure temperatures above 200°C. The basis for this change is the availability of technically feasible alternatives, which pose substantially lower environmental and human health risks. In addition, based on the information received during the public consultation, RAC suggests that the proposed restriction would not apply to measuring devices which are to be displayed in exhibitions for cultural and historical purposes, replacing the proposed derogation in the Annex XV restriction report for measuring devices that are more than 50 years old on 3 October 2007.