Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

mercury in measuring devices

ECHA/RAC/RES-O-0000001363-81-02/F
ECHA/SEAC/ RES-O-0000001363-81-03/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 8 June 2011) and SEAC's opinion (adopted 15 September 2011)

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8 June 2011
RES-O-0000001363-81-02/F

15 September 2011
RES-O-0000001363-81-03/F

Opinion of the Committee for Risk Assessment
And
Opinion of the Committee for Socio-economic Analysis
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 opinions adopted by RAC and SEAC. 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 Annex XV report 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

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 ***08 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***.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by the SEAC: ***Cees LUTTIKHUIZEN***
Co-rapporteur, appointed by the SEAC: ***Izabela RYDLEWSKA-LISZKOWSKA***

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***15 June 2011.***

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

The draft opinion was published at ***http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp*** on ***17 June 2011.*** Interested parties were invited to submit comments on the draft opinion by ***16 August 2011***.

The opinion of SEAC

The opinion of the SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **15 September 2011.**

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by consensus***.

OPINION

THE 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. 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.

The conditions of the restriction proposed by RAC are:

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

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.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and comments submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on ***Mercury in measuring devices*** is the most appropriate Community-wide measure to address the identified risks considering the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope and conditions are modified.

The conditions of the restriction proposed by SEAC are:

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

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:
   (a) Measuring devices more than 50 years old on 3 October 2007, or
   (b) Measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

The opinion covers restriction proposals for a number of mercury measuring devices[1], 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, meaning the 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[2]. 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

Justification for the opinion of RAC

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.

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

[1] The term "mercury measuring devices" is used throughout this document to cover both, measuring devices containing mercury and measuring devices using mercury.
[2] SEAC specified in its opinion that this relates to public exhibitions.

methylmercury and large numbers among Mediterranean fishing communities and the Arctic population exceed them significantly.

Although the BD 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 compounds[3].

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.

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 76/769EEC 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

[3] http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp

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

Justification for the opinion of RAC

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 for the opinion of SEAC

The proposed Community-wide restrictions are in principle appropriate; comments on the proposal are elaborated below. The mercury measuring devices are produced in as well as imported to the European Union (EU). The proposed restrictions will cut off the supply of these mercury measuring devices to the market in the EU and therefore contribute to the reduction of the available amount of mercury in that market. The proposed restrictions would remove the potentially distorting effect that the current national restrictions may have, leading to a level playing field within the EU for producers and importers. In addition, acting at a Community level could strengthen the possibilities of policymakers to address the adverse impacts of mercury worldwide.

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

Justification for the opinion of RAC

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 the 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 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.

Justification for the opinion of SEAC

In the justification of the most appropriate Community-wide measure below, SEAC considers the proposed restriction from a broad perspective, covering the European waste legislation and the EU mercury export ban Regulation. Following the overall assessment, justifications are given for the restriction proposal in general and for each specific measuring device in particular.

In principle, considering the available information, the suggested restrictions for measuring devices are at the moment the most appropriate Community-wide measures to prevent further emissions from devices, being placed on the market. The suggested restrictions will reduce the total amount of mercury coming from these measuring devices in the long term. The proposed restrictions for the placing on the market, however, only partly address the risks of mercury in measuring devices. Other EU legislation, also with the potential to reduce the identified risks, is not assessed in detail in the BD, because of the scope of the review clause in paragraph 4 of entry 18a ‘mercury’ in Annex XVII of the REACH Regulation. This review clause aims at phasing out of mercury in measuring devices specifically, whenever technically and economically feasible.

The suggested restrictions do not prevent that mercury could be released to the environment when the existing devices enter the waste stage at the end of their life-cycle. The BD gives a rough indication that only 20% of the measuring devices are correctly collected in accordance with the requirements set out in the hazardous waste legislation. This implies that the other 80% of the mercury measuring devices already on the market are most probably not correctly dealt with. This could for example lead to mercury emissions to air by incineration or leaking

to groundwater or soil in case of inadequately protected landfills or other environmental unsound disposal. So outside the scope of REACH there may be a need for other Community-wide measures, and - additional to the proposed restrictions - a proper collection system for these devices may also be necessary to avoid mercury emissions into society from these devices. Collection rates for these devices should therefore improve, though this may require cooperation with the EU authorities for waste legislation. SEAC observes that a number of the electronic alternatives are covered by the RoHS Directive, where the waste impact is regulated through the WEEE Directive. In the present recast of these directives there is a discussion about an obligation for Member States to collect at least 65% of these devices. This demonstrates the need to improve the collection rate of mercury measuring devices already on the market and to take adequate measures for proper waste management.

A consequence of the proposed restriction is that the devices already in use cannot be placed on the market again and at the end of their service-life they have to be disposed of as hazardous waste in accordance with the EC waste legislation. Enforceability at the waste stage is considered appropriate and feasible, because environmentally sound disposal of hazardous waste is a legal obligation for all European Member States.

The proposed restriction does not affect the use of the measuring devices that are already placed on the market. Those devices were bought at a time when there was no restriction and may not yet have reached the end of their service-lives. A premature phase out by restricting their use could easily lead to unjustified capital losses. These losses of the residual value of capital are naturally affected by the potential transitional period after the entry into force of a use ban. In addition to the losses of the residual value of capital, the users affected by such a ban would be facing higher annualised costs for a certain period of time. These impacts have been estimated only for sphygmomanometers. According to the BD, assuming a 5 year transitional period, would lead to a compliance cost of € 8 million (present value for 2011-2024), and affect around 200,000 existing sphygmomanometers (see Annex 3b, Chapter 5). Enforceability of a use ban is more complicated in practice because the devices are used in many different places and users will first have to be made aware of this restriction before they switch to alternative devices.

A possible distorting effect with respect to the aim of the proposed restriction to reduce and eliminate the use of mercury is the allowed production by manufacturers in the EU for exports as long as the EC Regulation 1102/2008 does not limit the export of these devices. Especially in the case of measuring devices where restrictions are proposed without any derogation, SEAC considers an export ban a logical building block to further reduce the amount of mercury in the global community. Assessment of the socio-economic impact of an export ban for these devices falls outside the scope of the restriction proposal and is therefore not elaborated in the BD. An export ban should, however, result in better enforceability of the proposed restriction as manufacturing for both the European market as well as for export would then be prohibited. Article 8(4) of the EC Regulation 1102/2008 requires the Commission to submit a report and possible review of this Regulation by 15 March 2013, with amongst others the need for an extension of the export ban to mercury containing measuring devices.

Nevertheless, SEAC observes that the proposed Community-wide restrictions without derogations for some devices or with limited derogations for other devices are appropriate. Also the general exemptions for devices, older than 50 years or for devices which are to be displayed in public exhibitions for cultural and historical purposes, are appropriate.

The risk management options per device are further elaborated in conjunction with their effectiveness in reducing the risks in the next section.

Effectiveness in reducing the identified risks, proportionality to the risks

Justification for the opinion of RAC

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 2015[4]. 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 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".

[4] 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.

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 thermometers[5].

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 BD the alternatives to mercury used in measuring devices are of lower relative risk compared to mercury measuring devices. This is shown in table 2.

Table 2 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.

Justification for the opinion of SEAC

This section includes a device specific assessment, elaborating the possible options for the proposed restrictions in conjunction with their effectiveness in reducing the risks and the economic feasibility of possible alternatives. In the second part SEAC gives its view on the proportionality to the risks.

[5] 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.

Measuring devices without or with limited derogations:

Barometers
For barometers two other restriction options are identified in Section 4.1.2 of Annex 1 to the BD:

- To restrict also the use of existing mercury containing barometers
- To derogate the placing on the market of new mercury containing barometers for calibration purposes.

SEAC considers a restriction of the use of existing mercury containing barometers not to be an appropriate Community-wide measure. General arguments not to restrict the uses given in the previous section are also valid for the specific option here not to restrict the use of existing barometers. SEAC considers furthermore that there is no need for a derogation of new mercury containing barometers for calibration purposes because experiences in several Member States show that there is no need for this derogation.

The alternatives are economically feasible as they are available to users in the same price range and electronic barometers are already taking over market shares. Furthermore, the impact of the proposed restriction on the increased production costs of industrial users is estimated to be relatively small.

Manometers and tensiometers
For manometers and tensiometers no other Community-wide measures or restriction options have been identified. There are alternatives for all applications and the available evidence indicates that they are cheaper than mercury manometers and tensiometers, suggesting that the alternatives are both technically and economically feasible. SEAC hence agrees with the proposal for restrictions.

Strain gauges
Only one option was assessed, namely a ban on the placing on the market of plethysmographs designed to be used with mercury strain gauges. As a result of the public consultation, a restriction on the placing on the market of mercury strain gauges (instead of on placing on the market of plethysmographs designed to be used with mercury strain gauges) is preferred because the same plethysmographs can also be used with mercury-free strain gauges.

Considering the high investment cost for the plethysmograph itself (~ € 20,000), the additional annualised cost per gauge (~ € 12) by using the alternative indium-gallium strain gauges to the overall cost of measurements is considered negligible. SEAC concludes that economically feasible alternatives are available and already used to replace mercury strain gauges.

Pycnometers
Only one restriction option was considered, noting that this option will consolidate the current situation. There is evidence that replacement by available alternatives is already taking place. SEAC hence agrees with the proposed restriction.

Mercury metering device for the softening point determination
Only one restriction option was considered, noting that this option will consolidate the current situation. The alternatives, available from the same producer as mercury metering devices, are preferred by users and there is no evidence that economic feasibility is problematic. SEAC agrees with the proposed restriction.

Sphygmomanometers
The BD identifies two options, namely a restriction on the placing on the market (with limited derogations), and a restriction on use. Both options were assessed for their economic feasibility. The BD notes that a use ban provides opportunities for a more effective implementation of national collection campaigns. However, due to practical difficulties (enforceability) and potentially low risk reduction capacity a use ban is not proposed. Furthermore, the general remarks above about not restricting the use of devices are also valid here.

The compliance costs for the first option (restriction on the placing on the market) are calculated to be € 3.2 million per annum (or present value for 2015-2034 € 29 million), which results in an estimated cost-effectiveness of this measure of € 1,300 per kg Hg. Given the uncertainties in the calculations a sensitivity analysis was carried out in Annex 3b of the BD. The high cost scenario resulted in an estimated cost-effectiveness indication of € 3,000 per kg Hg, whereas the low cost scenario resulted in - € 2,400 per kg Hg. A negative cost implies a cost saving or benefit. It is concluded that the proposed restriction on sphygmomanometers is justified.

The second option (restriction on the use) has also been assessed in the BD. The present value compliance costs (for 2011-2024) for this option are estimated to be around € 8 million. Both the compliance costs as the risk reduction capacity are highly dependent on the proposed transitional period.

SEAC notes that the two derogations for use of sphygmomanometers (i) in on-going epidemiological studies and (ii) as reference standard for validation of mercury-free devices are without a time-limit. To SEAC's opinion this seems to be acceptable for the following reasons: (i) the derogation for on-going epidemiological studies is time-limited by nature, as it is covering only studies that are on-going at the entry into force, and (ii) it has not been possible to determine the time needed to develop (and recognise) a mercury-free alternative as a reference standard for clinical validation of existing and future mercury-free blood-pressure measuring devices.

The proposed restriction with limited derogations for sphygmomanometers is the most appropriate Community-wide measure. Also for sphygmomanometers entering the waste stage an effective collection system could contribute to the reduction of mercury releases into the environment.

Thermometers
There are five options assessed in the BD:
1a. Restriction of all laboratory thermometers.
1b. Restriction of laboratory thermometers with a time-limited derogation for some uses.
2a. Restriction of all industrial mercury thermometers.
2b. Restriction of industrial thermometers with a derogation for mercury-in-glass thermometers for temperature measurements above 200°C.
2c. As 2b, including a derogation for mercury dial thermometers.

Table A5a-11 in the BD summarizes the risk reduction capacities and the costs associated with the implementation of the different restriction options. The proposed restriction in the original Annex XV report was a combination of the options 1b and 2b. Taking into account additional advantages of electronic thermometers such as automatic reading and data generation, SEAC concludes that the restriction but without the derogation, that is based on options 1b and 2a, is justified. The public consultation did not bring up any evidence to the contrary.

It is concluded that technically feasible alternatives are available for all applications, with the exception of:

A) thermometers used for testing according to analysis standards that prescribe mercury thermometers, because some time is needed to amend those standards; and
B) mercury triple point cells because mercury is needed as a reference point in the 1990 International Temperature Scale.

The proposed derogations for these applications are justified. For the so-called laboratory thermometers intended to perform tests according to standards, the proposed derogation is time-limited.

All technically feasible alternatives are also economically feasible alternatives. The annualised costs of electronic alternatives for all lab thermometers, industrial dial thermometers, industrial thermometers measuring temperatures below 200°C, and thermometers for measuring ambient temperature and other meteorological measurements are either equal, lower or marginally higher than those for the mercury-containing thermometers. Calculations in the BD demonstrate the economic feasibility of alternatives for industrial thermometers for temperature measurements above 200°C. The annualised cost of alternatives for industry thermometers measuring temperature above 200°C is per device estimated to be around € 13 higher than the annualised cost of a corresponding mercury thermometer, including potential labour time savings (see Table A5b-25 of the BD). The additional annualised costs are estimated to be a relatively small percentage of the industrial users' total costs for purchases of goods and services and are expected to contribute only marginally to the final product cost. Furthermore, the alternatives have additional benefits over the mercury-containing devices which are not considered in the above estimate related to lower spill cleanup costs. In addition, the alternatives have already taken over the market for industrial thermometers and the majority of users are no longer heavy users of mercury-containing devices.

The compliance costs for the proposed restriction for thermometers are calculated to be € 9 million per annum (or present value for 2015-2034 € 97 million), which results in an estimated cost-effectiveness of this measure of € 19,200 per kg Hg. However, there are large uncertainties in these calculations and several one parameter sensitivity analyses are carried out in the Annex 5b of the BD for the different thermometer segments. The results of these sensitivity analyses vary between cost savings and costs of several hundred thousand Euros per kg Hg.

Based on the quantitative and qualitative information on effectiveness (including estimates on compliance costs, cost effectiveness and benefits), practicality and monitorability of the restriction options, it is concluded that the proposed restriction on thermometers is justified.

<u>Measuring devices for which no restriction has been proposed:</u>

Porosimeters

There are four options identified to reduce the risks related to the use of mercury in porosimeters:

1. The 1st option (with 3 sub-options) aims at reducing the amount of mercury used in porosimeters.
2. The 2nd option is the promotion of better waste handling.
3. The 3rd option (including 2 sub-options) is the promotion of appropriate handling of mercury in the use phase.
4. A further assessment of the technical feasibility of alternatives.

Due to the high uncertainty in the technical feasibility of alternatives the placing on the market of porosimeters is proposed not to be restricted. Although porosimeters significantly contribute to the amount of mercury used in devices, action on a Community-wide basis for these devices is at present not justified. SEAC urges the Commission to consider this issue at the short term and, if appropriate, to propose additional legislative measures e.g. a certain transitional period for industry to develop technical alternatives and to allow users to adapt to a ban.

Mercury electrodes used in voltammetry
Only one restriction option was considered: a restriction on the placing on the market of mercury to be used as mercury electrodes in voltammetry. The assessment concluded not to restrict this application; the reason for not restricting is in the evidence that feasible technical alternatives do not exist. SEAC agrees with the proposal.

Mercury probes used for capacitance-voltage determinations
Only one restriction option was considered: a restriction on the placing on the market of mercury probes used for capacitance-voltage determinations. The assessment concluded not to restrict this application; the reason for not restricting is in the evidence that none of the alternatives are both technically and economically feasible. SEAC agrees with the proposal.

Proportionality

The available information about the costs and benefits of the proposed restrictions included in the BD is limited and surrounded by considerable uncertainty. The BD presents the estimated cost-effectiveness of the proposed restrictions in Table 12. The overall cost-effectiveness is estimated to be € 4,100 per kg Hg, but of course there are variations between the different measuring devices.

Appendix 2 of the BD provides a literature review of studies estimating the compliance costs of different policy measures to reduce mercury from different sources, and the human health benefits of reduced mercury emissions, as well as the restoration costs. It includes in Table 1 e.g. cost information of replacing mercury containing items in the US/Minnesota between US$ 20 and 2000 (€ 17 and 1,745) per kg Hg, which comes closest to replacing the existing mercury measuring devices addressed here in the context of REACH.

Table 2 in Appendix 2 is furthermore considering the health benefits from reduced mercury exposure. In this approach uncertainty margins between € 4,926 and 17,683 per kg Hg are found for the avoided damage costs due to reduced mercury exposure, also based on scant empirical evidence from the US. These benefit estimates relate to emissions (to air) and are not directly comparable with the cost-effectiveness of reducing the amount of mercury placed on the market that is estimated in the BD. Furthermore, the values relate to human health impacts, thus omitting the values of impacts that affect the environment as such. Nevertheless, it is illustrative to compare the value ranges for the costs and benefits and to note that the lower end benefit estimate (€ 4,926) is still almost a factor three higher than the higher end cost estimate for replacing mercury items in US/Minnesota (€ 1,745). The lower bound of the benefit estimate refers to the cost of illness for persistent IQ deficits in children, which is scientifically considered most robust and credible. The upper bound refers to the estimated additional health damage costs related to premature male mortality rates due to the cardiovascular effects of eating mercury contaminated fish and is considered much less certain. The estimated benefits exclude however potential environmental benefits. Even if mercury placed on the market in measuring devices is not necessarily released into the environment, at least not immediately, the rate of collection of mercury measuring devices

after their service-life is low and significant amounts may therefore enter the environment in the long term.

Comparing the estimated costs of the proposed restrictions in Table 12 of the BD with the estimated benefits in Table 2 in Appendix 2 of the BD, the weighted average compliance costs of the proposed restrictions for mercury measuring devices (€ 4,100 per kg Hg) are lower than the lower bound of the benefit estimate, justifying an overall restriction. However, the costs vary across measuring devices. The costs of replacing sphygmomanometers can be justified compared to the expected health benefits and are hence considered proportionate to the reduced risk. The costs of replacing strain gauges (€ 9,600 per kg Hg) are almost a factor two higher than the lower bound benefit estimate, but fall well inside the range of € 4,926 and € 17,683 per kg Hg for reduced mercury exposure. The costs of thermometers and hygrometers are a factor two higher than the costs of strain gauges and a little bit higher than the upper bound of the benefit estimate, making it harder to justify the proposed restriction for this category of mercury containing measuring devices.

However, there is evidence of the economic feasibility of substitution of mercury measuring devices such as pycnometers, manometers, sphygmomanometers, tensiometers, hygrometers and thermometers with non-mercury measurement devices in existing markets. Hence, the proposed restriction is further justified for these measurement devices as the mercury measuring devices have to some extent been replaced already or are in the process of being substituted. In the case of mercury barometers, the cost information collected for the BD suggests that cheaper and hence economically feasible alternatives are available, even though the mercury measuring devices have not yet been fully replaced by the non-mercury alternatives. Similar indications are found for laboratory and industrial thermometers, further strengthening the economic proportionality argument, although the evidence of cheaper and more preferred alternatives is not as clear-cut in all cases here. For strain gauges there are indications that alternatives are economically feasible and for mercury pycnometers and mercury metering devices for the softening point determination there does not seem to be a remaining market in the EU.

In summary SEAC notes that the process of replacing mercury measuring devices by mercury free alternatives is already taking place. This trend demonstrates the economic feasibility of the proposed restrictions. Although the costs and benefits are surrounded with uncertainties, SEAC concludes that the proposed restrictions are considered proportionate to the risk.

Practicality, incl. enforceability

Justification for the opinion of RAC

Bans of other mercury containing measuring equipment for the use of consumers have been in place without problems. Likewise bans on other articles are a 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.

Justification for the opinion of SEAC

With the deletion of the derogation for industrial mercury-in-glass thermometers above 200°C, the concern of a potential loophole of the restriction on industrial thermometers has been addressed.

Testing

Various analytical methods for mercury are available and well established. In the measuring devices, mercury is enclosed in a kind of container as the functional and separable part of the article. A specific sampling method is likely not needed. In most cases, a visual inspection as suggested in the BD will be sufficient. Indeed, most mercury measuring devices have a glass column filled with liquid mercury. As explained in section 4.2.1.2 of Annex 5a, also Gallium has a silvery appearance, but the capillary would have a concave instead of convex meniscus as observed with mercury in a glass capillary. The sole exception is mercury dial thermometers that have a mercury filled metal bulb. In this case, a simple identification by a non-destructive analytical method (XRF) can be used. The new entry does not introduce a limit value.

Enforceability

The Forum warned of potential difficulties with the verification of the compliance with some derogations of the proposed entry, e.g. evidence of the use of a sphygmomanometer in epidemiological studies which are on-going at entry into force, or the age of measuring devices being more than 50 years. A consequence of the latter one might be that the market for used devices could be difficult to control. As the proposed restriction is also worded to cover measuring devices placed on the market intended to be filled with mercury, the Forum expressed its reservations with regard to the possibilities to prove the intention to fill empty measuring devices with mercury. The intention to fill empty measuring devices with mercury could probably be based on information in catalogues, order books or operating manuals. To a certain extent this meets the comments from the Forum. The Forum was not consulted on the derogation for devices to be displayed in exhibitions for cultural and historical purposes, as this derogation was introduced to the proposed restriction only after receiving the second Forum advice and it was not found inevitable.

Monitorability

Justification for the opinion of RAC

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.

Justification for the opinion of SEAC

SEAC welcomes the advice from the Forum regarding the monitorability of the proposed restrictions by market surveillance. Order books, financial administrations, operating manuals or catalogues of suppliers enable inspectorates to monitor the placing on the market of restricted measuring devices. The Forum underlines in its advice a preference to close the markets for export outside the EU as well. This is supportive to the opinion of SEAC regarding EC Regulation 1102/2008.

BASIS FOR THE OPINION

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

Basis for the opinion of RAC

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.

Basis for the opinion of SEAC

The main changes compared to the original restriction proposal by ***ECHA*** are that:

i. the restriction on placing on the market of plethysmographs designed to be used with mercury strain gauges was replaced with a restriction on the placing on the market of mercury strain gauges,
ii. the derogation for industrial thermometers for temperature measurements above 200°C was removed, and
iii. a derogation for measuring devices which are to be displayed in public exhibitions for cultural and historical purposes was added.

The basis for these changes is new information submitted through the public consultation.